

An Inclusive Approach Towards Designing Medical Devices for Use in the Home Environment

A thesis submitted for the degree of Doctor of Philosophy

By

Abdusselam Selami Cifter

School of Engineering and Design

Brunel University

February 2011

ABSTRACT

An emerging trend of the healthcare industry is the huge increase in the number of medical devices being used by lay people at home. Home use medical devices range from simple inhalers to very complicated devices such as defibrillators.

This research aimed to assist designers in developing home use medical devices by providing information and suggestions regarding lay users and how to address their needs and expectations.

For this purpose a qualitative and inductive approach was adopted and several studies were carried out, including: (1) a comprehensive literature review to understand the background of the phenomena; (2) observational studies with 40 lay users (i.e. 10 younger lay users, 10 older lay users, 10 users with mobility and sensory disabilities, and 10 users with cognitive disabilities) in order to identify their characteristics when interacting with products; (3) an online questionnaire survey with 53 designers to understand designers' requirements when designing home use medical devices, as well as their expectations for a proposed design support tool; (4) the development of the design support tool; and (5) an evaluation study with 12 professional designers in order to assess the effectiveness of the tool (in a format of a design guidance).

This research adopted an inclusive approach which investigated both lay users' characteristics and designers' perspectives. It has, for the first time, outlined lay user characteristics based on empirical studies with different groups of people. It is also one of few studies focussing on designing home use medical devices; the requirements of professional designers have provided an in-depth insight into the challenges of designing medical devices for use in the home environment. The design guidance, as commended by the designers in the evaluation, was the first comprehensive information source in the UK for the emerging home use medical device field where little support is currently available.

AUTHOR'S DECLARATION

I hereby declare that I am the sole author of this thesis.

I authorise Brunel University to lend this thesis to other institutions or individuals for the purpose of scholarly research.

Signature

Abdusselam Selami Cifter

Date: 07 February, 2011

I further authorise Brunel University to reproduce this thesis by photocopying or by other means, in total or in part, at the request of other institutions or individuals for the purpose of scholarly research.

Signature

Abdusselam Selami Cifter

Date: 07 February, 2011

ACKNOWLEDGEMENTS

There are many people to whom I would like to express my gratitude and thanks for their support during my PhD studies.

In particular, I owe my deepest gratitude to my supervisor Dr. Hua Dong for her invaluable guidance throughout this research, as well as her encouragement and patience. This research would have not been possible without her. I am also grateful to Dr. Julie Barnett for her contributions and guidance during the final stage of my PhD studies and Dr. Sheng Feng Qin for his kind words and assistance throughout the research.

I would like to express my special gratitude and thanks to the late Dr. Huseyin Kurtulus, who sincerely supported and encouraged me all throughout my academic life in the Mimar Sinan Fine Arts University. He was a person whom I always admired and a model of excellence who will continue to be an inspiration for me in my future career. I am very privileged to have known him.

I would like to thank the Inclusive Design Research Group, in particular my colleagues Christopher McGinley and Farnaz Nickpour, who contributed greatly to my research and supported me during these years. I am honoured to have been part of this research group.

I am grateful to my friends: Richard Craig, Ritwik Ritwik, Andrew Fsadni and Ismail Suleyman for kindly helping me to proofread my thesis. I would also like to show my gratitude to many people who took part in this PhD research, to many of the organisations (i.e. Brunel University Disability and Dyslexia Service, Yateley Industries, Mencap, Charles Curran House, The Royal National Institute for Deaf People (RNID), Age Concern Hillingdon and Active Ageing Group Service) which helped me to get in contact with possible participants for the studies, and to the designers who kindly shared their professional insights to this research.

My PhD research was funded by The Council of Higher Education (Turkey). I am grateful to the academic staff of the Industrial Product Design Department in the Mimar Sinan Fine Arts University, in particular Ahmet Cetin Eyup,

Prof. Dr. Suha Erda and Assistant Prof. Dr. Tenguz Unsal who kindly dealt with all the bureaucratic procedures needed to sustain my scholarship and whose advice supported me when writing my research proposal to Brunel University.

My special thanks go to Serhat Ozdiyar who sincerely helped me with the processing of my university acceptance from Brunel University.

Finally I would like to thank to my parents and my brother for always supporting me. Without their invaluable support, I would not have been able to face the challenges of this process.

Thank you very much...

TABLE OF CONTENTS

| | |
|--|------------|
| ABSTRACT | i |
| AUTHOR'S DECLARATION | ii |
| ACKNOWLEDGEMENTS | iii |
| TABLE OF FIGURES | xi |
| LIST OF TABLES | xiv |
| LIST OF APPENDICES | xv |
| CHAPTER 1: INTRODUCTION | 1 |
| 1.1 Overview: Home-Healthcare and Medical Devices | 1 |
| 1.2 Driving Factors for Home Use Medical Devices | 3 |
| 1.3 Examples of Home Use Medical Devices | 6 |
| 1.3.1 Good Examples of Home Use Medical Devices | 6 |
| 1.3.2 Poor Examples of Home Use Medical Devices..... | 9 |
| 1.4 Motivation for Research..... | 12 |
| 1.5 Research Aim, Research Questions and Objectives..... | 14 |
| 1.6 Thesis Structure | 15 |
| CHAPTER 2: LITERATURE REVIEW AND SYNTHESIS | 19 |
| 2.1 Medical Devices for Home Environment..... | 20 |
| 2.1.1 Product Adaptation from Professional Use to Lay Use..... | 20 |
| 2.1.2 Prevalence of Home Use Medical Devices..... | 21 |
| 2.2 Lay Users and Their Characteristics..... | 22 |
| 2.2.1 Definition of a Lay User | 22 |
| 2.2.2 Definition of a Professional User..... | 24 |
| 2.2.3 Professional Users VS. Lay Users | 24 |
| 2.2.4 Types of Lay Users and Their Characteristics..... | 29 |
| 2.2.5 Overall Summary of Lay User and Their Characteristics..... | 33 |
| 2.3 Design Processes of a Home Use Medical Device..... | 33 |
| 2.3.1 Design Process in General Terms | 33 |
| 2.3.2 Design Process for Medical Devices | 36 |
| 2.3.3 Inclusive Design | 40 |
| 2.3.4 The Overall Summary of the Design Process for Home Use Medical Devices..... | 41 |

| | |
|---|-----------|
| 2.4 Challenges for Developing Home Use Medical Devices | 42 |
| 2.5 Medical Devices vs. Home Use Medical Devices: Regulations | 44 |
| 2.5.1 Medical Device Regulations for the European Union | 44 |
| 2.5.2 Regulatory Requirements Regarding the Instruction Manuals of Medical Devices | 48 |
| 2.5.3 Regulatory System for the UK | 49 |
| 2.5.4 Standards for Medical Devices | 50 |
| 2.5.5 Regulations for Home Use Medical Devices | 51 |
| 2.6 Assisting Designers during the Design Process of Home Use Medical Devices | 53 |
| 2.6.1 How to Support Designers | 54 |
| 2.6.2 Designers' Information Usage | 55 |
| 2.7 Summary | 56 |
| CHAPTER 3: RESEARCH METHODOLOGY AND METHODS | 58 |
| 3.1 Type of Research | 58 |
| 3.1.1 Qualitative Research, Quantitative Research and Mixed Method | 58 |
| 3.1.2 Deductive Theory/Inductive Theory | 60 |
| 3.1.3 Characterising This Research | 60 |
| 3.2 Epistemology | 61 |
| 3.3 Design Research Methodology | 63 |
| 3.4 Methods Used in the Descriptive Study 1 | 65 |
| 3.4.1 Understanding Lay Users | 65 |
| 3.4.2 Survey with Designers | 67 |
| 3.5 Methods Used in the Prescriptive Study | 67 |
| 3.6 Methods Used in the Descriptive Study 2 | 68 |
| 3.7 Ethical Approval | 70 |
| 3.8 Validity and Reliability | 70 |
| 3.8.1 Validity | 70 |
| 3.8.2 Reliability and Generalisability | 71 |
| 3.9 Summary | 72 |
| CHAPTER 4: UNDERSTANDING LAY USERS | 74 |
| 4.1 Study Method | 75 |
| 4.1.1 Sampling and Recruitment of the Participants | 75 |
| 4.1.2 Selecting Devices | 77 |

| | |
|--|------------|
| 4.1.3 Preparation of Tasks | 78 |
| 4.1.4 Preparation of the Questionnaires | 81 |
| 4.1.5 Summary of the Methods..... | 84 |
| 4.2 Pilot Study | 86 |
| 4.3 User Study Set up | 86 |
| 4.4 Data Analysis | 88 |
| 4.4.1 Analysis of the Video Recordings | 88 |
| 4.4.2 Analysis of the Post-Questionnaire..... | 92 |
| 4.4.3 Analysis of the Pictures Taken During the Digital Camera Tasks | 92 |
| 4.5 General Results..... | 93 |
| 4.5.1 Possible Systematic Error Due to Level of Education..... | 95 |
| 4.5.2 Results Regarding the Success of the Participants in the Tasks | 97 |
| 4.5.3 Blood Pressure Monitor Tasks..... | 98 |
| 4.5.4 Digital Camera Tasks..... | 99 |
| 4.5.5 Results Regarding the Instruction Manual Usage..... | 103 |
| 4.6 Specific Results for the Younger Participants (YP)..... | 105 |
| 4.7 Specific Results for the Older Participants (OP)..... | 106 |
| 4.8 Specific Results for the Participants with Motor/Sensory Disabilities (M/SDP) | 109 |
| 4.9 Specific Results for the Participants Having Cognitive Disabilities (CDP) | 112 |
| 4.10 The Results for the Post-Questionnaire..... | 114 |
| 4.10.1 The First Two Sections Relevant to the User Trials | 114 |
| 4.10.2 The Third Section of the Post-Questionnaire | 119 |
| 4.11 Discussion | 124 |
| 4.11.1 Methodological Issues | 124 |
| 4.11.2 Characteristics of Users | 127 |
| 4.11.3 Nature of the Interaction Problems | 133 |
| 4.12 Summary | 135 |
| CHAPTER 5: REQUIREMENT CAPTURE: SURVEY WITH DESIGNERS..... | 136 |
| 5.1 Preparation of the Survey | 137 |
| 5.1.1 Sampling of the Designers | 137 |
| 5.1.2 Designing the Questionnaire..... | 137 |

| | |
|---|------------|
| 5.1.3 Analysis of the Data..... | 139 |
| 5.2 Results of the Survey..... | 140 |
| 5.2.1 Do the Respondents Match the Sampling Criteria?..... | 141 |
| 5.2.2 Designers' Points of View Regarding Designing Home Use Medical Devices..... | 141 |
| 5.2.3 Designers' Requirements Regarding Designing Home Use Medical Devices..... | 146 |
| 5.2.4 The Information Sources Used by Designers | 149 |
| 5.2.5 Requirements for the Guidance | 152 |
| 5.2.6 The Content and the Format of the Guidance..... | 153 |
| 5.3 Discussion | 156 |
| 5.3.1 Limitations of the Survey | 156 |
| 5.3.2 Main Findings of the Survey | 157 |
| 5.4 Summary | 163 |
| CHAPTER 6: DEVELOPMENT OF THE GUIDANCE..... | 165 |
| 6.1 Initial Concepts..... | 166 |
| 6.1.1 Guidance for both Designers and Users | 166 |
| 6.1.2 Initial Concept of the Guidance for Designers | 168 |
| 6.1.3 Formulation of the Content..... | 170 |
| 6.2 Preparation of the Detailed Content | 172 |
| 6.2.1 Content of the Home Page | 172 |
| 6.2.2 Content of the 'Home Use Medical Devices' Section..... | 173 |
| 6.2.3 Content of the 'Design Considerations' Section..... | 173 |
| 6.2.4 Content of the 'Regulations' Section..... | 176 |
| 6.2.5 Content of the 'Useful Links' Section | 179 |
| 6.2.6 Content of the 'Documents' Section..... | 179 |
| 6.2.7 Summary of the Content | 180 |
| 6.3 Development of Unique Contents | 181 |
| 6.3.1 Dual Verification Model for Designing Home Use Medical Devices | 181 |
| 6.3.2 Process Model for Designing Instruction Manuals of Home Use Medical Devices in Europe..... | 184 |
| 6.3.3 Guidance Checklist for Developing Instruction Manuals for Home Use Medical Devices for the European Market | 188 |

| | |
|--|------------|
| 6.3.4 Development of ‘Do’s and ‘Don’t’s | 190 |
| 6.4 Design and Development of the Website | 193 |
| 6.5 Summary | 197 |
| CHAPTER 7: EVALUATION WITH DESIGNERS | 199 |
| 7.1 Preparation of the Study | 200 |
| 7.1.1 Sampling of Designers for the Evaluation of the First Draft of the Guidance | 200 |
| 7.1.2 Preparation of the Questionnaire | 201 |
| 7.1.3 Preparation of the Interview Questions | 202 |
| 7.1.4 Study Procedure | 203 |
| 7.2 Analysis of the Data | 205 |
| 7.2.1 Questionnaire Analysis Method..... | 205 |
| 7.2.2 Interview Analysis Method..... | 205 |
| 7.3 Results of the Questionnaire..... | 207 |
| 7.3.1 Content of the Website | 208 |
| 7.3.2 Efficiency of the Website | 209 |
| 7.3.3 Design of the Website..... | 210 |
| 7.4 Results of the Interview..... | 211 |
| 7.4.1 General Observations of the Designers’ Interaction with the Website | 211 |
| 7.4.2 Useful or Not?..... | 212 |
| 7.4.3 Most Useful Features of the Website..... | 213 |
| 7.4.4 Least Successful Features of the Website..... | 215 |
| 7.4.5 Unnecessary or Irrelevant Information | 215 |
| 7.4.6 Missing Information in the Website | 216 |
| 7.4.7 Other Features..... | 217 |
| 7.4.8 Improvements | 218 |
| 7.4.9 Other Information Sources..... | 220 |
| 7.5 Discussion | 220 |
| 7.5.1 Methodological Issues and Limitations | 220 |
| 7.5.2 Main Findings and Their Implications | 221 |
| 7.6 Summary | 226 |
| CHAPTER 8: CONCLUSIONS AND FUTURE WORK | 228 |
| 8.1 Key Conclusions..... | 228 |

| | |
|--|------------|
| 8.1.1 Lay Users and Their Characteristics | 228 |
| 8.1.2 Challenges Designers Face in Developing Home Use Medical Devices | 230 |
| 8.1.3 Supporting the Design of Home Use Medical Devices | 232 |
| 8.1.4 Overall Conclusion | 233 |
| 8.2 Contributions of the Research | 234 |
| 8.2.1 Shedding Light on Lay Users and Their Characteristics | 235 |
| 8.2.2 Identification of the Designers' Requirements when Designing Home Use Medical Devices | 235 |
| 8.2.3 Creation of a Support Tool for Designing Home Use Medical Devices | 235 |
| 8.3 Future Work | 235 |
| 8.3.1 Improvement of the Design Guidance Website..... | 236 |
| 8.3.2 Validation of the Design Guidance Website..... | 236 |
| 8.3.3 Understanding Lay Users' Perspectives on Home Use Medical Devices | 237 |
| 8.3.4 Understanding Professionals' Perspectives on Home Use Medical Devices..... | 238 |
| 8.4 Summary | 239 |
| REFERENCES | 242 |
| APPENDICES | 259 |

TABLE OF FIGURES

| | | |
|--------------------|--|-----|
| Figure 1.1 | The Health Buddy Appliance..... | 7 |
| Figure 1.2 | ClikSTAR reusable insulin injection pen..... | 8 |
| Figure 1.3 | Vicks digital forehead thermometer..... | 9 |
| Figure 1.4 | Optium Glucose Monitoring System..... | 10 |
| Figure 1.5 | Accu-Check Spirit(left) and MiniMed Paradigm Veo (Right) | 11 |
| Figure 1.6 | A common example of a hearing aid..... | 12 |
| Figure 1.7 | Structure of the thesis..... | 18 |
| Figure 2.1 | Different types of end-users..... | 25 |
| Figure 2.2 | Professional and lay users of medical devices..... | 30 |
| Figure 2.3 | Steps in the planning and design process..... | 35 |
| Figure 2.4 | Water Fall Design Process..... | 39 |
| Figure 2.5 | Applications of the three Harmonised Standards..... | 51 |
| Figure 3.1 | Research methodology framework adopted..... | 65 |
| Figure 4.1 | User Pyramid..... | 75 |
| Figure 4.2 | The products used in the user observation study: Sony DSC-S730 and Omron R7..... | 78 |
| Figure 4.3 | Parts of the study..... | 86 |
| Figure 4.4 | The typical setting of the product interaction trials..... | 87 |
| Figure 4.5 | The determination criteria for the task results..... | 89 |
| Figure 4.6 | The transcription table..... | 91 |
| Figure 4.7 | Examples of the good pictures and the bad pictures for Task 5 and Task 6..... | 93 |
| Figure 4.8 | Number of successful completion for each task and the user groups..... | 97 |
| Figure 4.9 | Number of people referred to the instruction manuals during the tasks..... | 103 |
| Figure 4.10 | How to measure blood pressure..... | 104 |
| Figure 4.11 | Confusion due to way of use..... | 108 |
| Figure 4.12 | The buttons of the device and the description of how to delete images..... | 108 |
| Figure 4.13 | The correct position of the blood pressure monitor (left) and the faulty positions performed by the participants (middle and right)..... | 112 |

| | | |
|--------------------|--|-----|
| Figure 4.14 | The participant confused due to the beeping sound given by the blood pressure monitor..... | 113 |
| Figure 4.15 | Results regarding the general preference of the all participants regarding the products that they use daily..... | 119 |
| Figure 4.16 | Results regarding how the participants had found the process of operating the blood pressure monitor and the digital camera..... | 121 |
| Figure 4.17 | Results of ranking the four expected features from a product..... | 122 |
| Figure 5.1 | Data set prepared in SPSS Software..... | 139 |
| Figure 5.2 | The reasons indicated by the respondents for the open-ended Question 4..... | 143 |
| Figure 5.3 | Classification of the categories..... | 146 |
| Figure 5.4 | The mean values for four different types of information..... | 147 |
| Figure 5.5 | Overall results of Question 6..... | 149 |
| Figure 5.6 | Results of Question 6 in relation with the prior experience of the respondents in designing home use medical devices..... | 151 |
| Figure 5.7 | The answers given to the open-ended part of Question 6..... | 152 |
| Figure 5.8 | Previous experience (abscissa), usefulness of the guidance.... | 153 |
| Figure 5.9 | Overall results of Question 8..... | 154 |
| Figure 5.10 | Overall results of Question 9..... | 156 |
| Figure 5.11 | Outline of the format and the content of the guidance..... | 162 |
| Figure 6.1 | Entrance interface for both lay users and designers..... | 166 |
| Figure 6.2 | The interface concept for lay users..... | 167 |
| Figure 6.3 | The guidance website interface for designers..... | 169 |
| Figure 6.4 | Drop-down menus showing the content of the initial concept | 169 |
| Figure 6.5 | Final content of the first draft of the guidance..... | 171 |
| Figure 6.6 | Sections included in the guidance..... | 172 |
| Figure 6.7 | Site map of the guidance website..... | 180 |
| Figure 6.8 | Dual Verification Model for Designing Home Use Medical Devices..... | 182 |
| Figure 6.9 | A Process model suggestion for developing instruction manuals of home use medical devices for the European market..... | 186 |
| Figure 6.10 | Guidance checklist for developing instruction manuals for home use medical devices for the European market..... | 190 |
| Figure 6.11 | A screenshot from Adobe Dreamweaver CS5 during the | |

| | | |
|--------------------|--|-----|
| | development of the website..... | 194 |
| Figure 6.12 | The home page of the first draft of the guidance..... | 195 |
| Figure 6.13 | Different sections of the interface..... | 195 |
| Figure 6.14 | Rollover buttons..... | 196 |
| Figure 7.1 | Three stages of the evaluation study..... | 203 |
| Figure 7.2 | The tools used during the face to face interviews..... | 204 |
| Figure 7.3 | A screenshot from NVivo 8 software to summarise the transcription process..... | 206 |
| Figure 7.4 | A screenshot from NVivo 8 software to summarise the coding process..... | 207 |
| Figure 7.5 | The mean values regarding the content of the website..... | 209 |
| Figure 7.6 | The mean values regarding the efficiency of the website..... | 210 |
| Figure 7.7 | The mean values regarding the usability of the website and the presentation of the information..... | 211 |
| Figure 7.8 | The most useful features of the website..... | 214 |
| Figure 7.9 | Suggested areas for improvements..... | 218 |
| Figure 7.10 | New proposal regarding the content and structure of the guidance..... | 225 |
| Figure 8.1 | (a) Gupta's definition of HUMD, (b) requirements for designing home use medical devices..... | 232 |
| Figure A.1 | Three types of problems and their relation to the interaction problems observed during the blood pressure monitor tasks... | 286 |

LIST OF TABLES

| | | |
|------------------|---|-----|
| Table 2.1 | Research questions and the objectives..... | 19 |
| Table 2.2 | Comparison of professional users and lay users..... | 29 |
| Table 3.1 | Characteristic of the studies carried out in this PhD research. | 73 |
| Table 4.1 | Purpose of the questions in the first two sections of the questionnaire..... | 82 |
| Table 4.2 | Purpose of the questions in the third section of the questionnaire..... | 84 |
| Table 4.3 | Summary of the confirmation methods used for the lay user characteristics..... | 85 |
| Table 4.4 | The general information of the all participants..... | 94 |
| Table 4.5 | Quality of the pictures taken by the participants during Task 6 and Task 7..... | 102 |
| Table 5.1 | Education background of the respondents..... | 141 |
| Table 6.1 | The bullet points used in the guidance website..... | 197 |
| Table 7.1 | Maximum, minimum, average and total time taken of the interviews..... | 206 |

LIST OF APPENDICES

| | | |
|--------------------|---|-----|
| Appendix A1 | Sample of the lay user consent form..... | 259 |
| Appendix A2 | Information sheet for lay users..... | 260 |
| Appendix A3 | Information sheet for designers..... | 263 |
| Appendix B | Details of lay users that participated in the observational studies..... | 265 |
| Appendix C1 | Pre-questionnaire used during the observational studies with lay users..... | 268 |
| Appendix C2 | Task list sheet used during the observational studies with lay users..... | 270 |
| Appendix C3 | Post-questionnaire used during the observational studies with lay users..... | 272 |
| Appendix D1 | Interaction problems observed with the blood pressure monitor..... | 277 |
| Appendix D2 | Interaction problems observed with the digital camera..... | 281 |
| Appendix E | Three types of interaction problems observed during the blood pressure monitor tasks..... | 285 |
| Appendix F | Answers given to the first two sections of the post-questionnaire..... | 287 |
| Appendix G | Summary of lay user characteristics..... | 288 |
| Appendix H | Online questionnaire to obtain the requirements of designers when designing home use medical devices..... | 290 |
| Appendix I | The highlights provided in the guidance checklist for developing instruction manuals of home use medical devices for the European market..... | 293 |
| Appendix J | Summary of the Essential Requirements of the Council Directive 93/42/EEC on Medical Devices..... | 295 |
| Appendix K | Summary of the Essential Requirements of the Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices..... | 296 |
| Appendix L | Summary of the Essential Requirements relevant to instruction manuals of home use medical devices identified in MDD and IVDMD..... | 297 |
| Appendix M | Online-questionnaire for the designers' initial evaluation of the guidance website..... | 299 |
| Appendix N | Interview questions for the designers' evaluation of the guidance website..... | 301 |
| Appendix O | Answers given by the designers to the interview questions during the evaluation study..... | 302 |
| Appendix P | List of publications..... | 306 |

CHAPTER 1: INTRODUCTION

This chapter provides an overview of the background to this research. It gives a definition of a home use medical device, presents a number of good and poor examples of such devices, and explores the driving factors which increase the use of medical devices in the home environment.

It also discusses the motivation for the research, and based on this, identifies the research questions and relevant objectives to be addressed in this PhD thesis. Finally, it provides a summary of the content for each chapter and presents the structure of the thesis.

1.1 Overview: Home-Healthcare and Medical Devices

Home-healthcare was forecast by the FDA's (U.S. Food and Drugs Administration) CDRH (Centre for Devices and Radiological Health) in 1998 as "one of the six major trends of the next decade" (Herman, 2001: p.36). It is expected that the home-healthcare market will grow continuously in the future (Ghandi, 2005). In the UK, the self-diagnostics market has been growing by 6% per year since 2002 from £71 million to £99 million in 2007, and more rapid growth is forecast to 2012 (Intel, 2007).

Susanne Ludgate, Medical Director at the UK Medicines and Healthcare Products Regulatory Agency (MHRA), states that, the number of medical devices being used at home environment increased significantly over the past few years (Ludgate, 2003). Medical devices used outside the clinical environment are often referred to as home use medical devices or home healthcare devices. Gupta (2007), states that most of the home use medical devices were adapted from medical devices for professionals' use and very few of them emerged without going through this adaptation process.

The important question is how do home use medical devices differ from medical devices used by professionals?

In the UK, medical devices are defined in accordance with the European Council Directive 93/42/EEC which was subsequently amended in 2007 by Directive 2007/47/EC. According to the latest revision, medical devices are defined as:

“...any instrument, apparatus, appliance, software, material, or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

And which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.” (EEC, 1993a: p.5-6)

Although the amount of attention focussed on home use medical devices is increasing, there is a lack of formal definition of these devices in the UK. In his PhD thesis, Gupta (2007) recognised this gap and attempted to form his own definition:

“A home-use medical device is a medical device that is or can be used and/or operated by non-professional users, such as patients and their carers, independently in the home environment or other non-clinical environments such as people’s cars, and places of work, etc” (Gupta, 2007: p.25).

On the other hand, in the U.S. a systematic approach has been carried out by FDA (U.S. Food and Drug Administration), with respect to exploring the field of home use medical devices. In 2001, CDRH Home Health Care Committee (HHCC) was formed (FDA, 2010a). According to CDRH HHCC, the definition of a home use medical device is:

“A medical device intended for users in a non-clinical or transitory environment, is managed partly or wholly by the user, requires adequate

labelling for the user, and may require training for the user by a licensed health care provider in order to be used safely and effectively” (FDA, 2010a).

The above two definitions of home use medical devices both emphasise two aspects: users (i.e. lay people or non-professional people), and environments (non-clinical or transitory environments), are major determinants of the nature of home use medical devices.

According to the Medical Device Home Use Initiative (FDA, 2010d) which was issued by CDRH in April 2010, many medical devices are currently being used in the home environment; however, it does not mean that all of them are designed for the use of lay people, or totally outside the clinical environment. Therefore in some special cases a level of training may be necessary. This research focuses on medical devices that are designed for lay people to use outside the clinical environment.

1.2 Driving Factors for Home Use Medical Devices

Three factors are mentioned frequently in the literature as the main driving factors for the prevalence of home use medical devices. These factors are **(1) increased proportion of older people in the adult population** (Nickerson, 1995; Herman, 2001; Gossink & Souquet, 2006; Gupta, 2007; Whelan, 2009; FDA, 2010d), **(2) the trend towards reducing the patient time in hospitals** (Klatzky & Ayoub, 1995; Herman, 2001; Lewis, 2001; Wilcox, 2003; Wiklund & Wilcox, 2005; Gupta, 2007; Lotring, 2009; FDA, 2010d) **(3) and advancements in technology** (Klatzky & Ayoub, 1995; Herman, 2001; Lewis, 2001; Rogers, et al., 2001; Gossink & Souquet, 2006; Gupta, 2007; Hoctor, 2009).

Increased proportion of older people in the adult population

Due to the reduced birth rate and longer life expectancies, the demographics of the developed world are changing (Clarkson, et al., 2007). According to the Office of National Statistics (ONS, 2009a), in the UK the population aged 65 and over has increased by 1.5 million from 1983 to 2008. The fastest population

increase has been with the 'oldest old', for those aged 85 and over (ONS, 2009a), and by 2033 their number is projected to more than double, which will account for 5 percent of the total population by 3.2 million people (ONS, 2009b).

In addition the life expectancy today in the UK has reached its highest level with men expected to live an average 77.2 years and women 81.5 years (ONS, 2009a). However, this does not mean that 'healthy life expectancy' has also been increased. According to the Office of National Statistics, "...life expectancy increased at a faster rate than healthy life expectancy" (ONS, 2009a: p.2). Elderly people are likely to have at least one chronic disease and may need to use home-monitoring devices routinely due to conditions such as heart problems, diabetes, respiratory problems, etc (Lewis, 2001).

The trend towards reducing the patient time in hospitals

There is a trend towards discharging patients earlier from hospital to shorten the length of hospital stays. "Patients are normally discharged from hospital as soon as their acute condition has been stabilised" (Gupta, 2007: p.128). The main reason behind this trend is the increasing cost of healthcare (Klatzky & Ayoub, 1995).

On the other hand, when compared to long-term hospital stays, home care is likely to be a more desirable and affordable option. Home care also provides independence, thus allowing the patients to be more mobile and active in their lives (FDA, 2010d).

Advancements in technology

Advancements in technology give care recipients an opportunity to take an active role in maintaining their own health (Lewis, 2001; Herman, 2001; Rogers, et al., 2001). This leads to a longer life expectancy and allows a better quality of life for those having one or more chronic diseases (Gossink & Souquet, 2006). Particularly the miniaturisation and automation of sophisticated electronics technology enabled greater home care (Hector, 2009).

Today people can buy many over-the-counter medical devices at an affordable price, ranging from simple cold sore treatment devices to very sophisticated home use defibrillators. For example, more than 6000 home use defibrillators

were sold in one year after FDA approved its over-the-counter sale in September 2004 (Schweber, 2005).

Home use medical devices are expected to deliver user friendly and intelligent healthcare in the home environment because they are designed to be 'smart' (Lewis, 2001).

The above three main drivers were mentioned by many researchers. However the most comprehensive study found in this field was Gupta's PhD study (2007) in which he identified 14 driving factors for the prevalence of home use medical devices. These factors were then checked by key stakeholders and ranked regarding their significance: i.e. high, medium and low prominence.

The driving factors for the category of high significance included:

- Increasing proportion of older people in the adult population
- Advancements in healthcare technology
- The increasing prevalence of chronic conditions and diseases across various age groups
- First-world lifestyle syndromes such as obesity

The driving factors that are categorised as being of medium significance included:

- A growing awareness in the general population of health issues and treatment options
- The NHS tendency to treat patients at home due to low healthcare cost at home (Gupta's research focused on the UK market)
- A growing body of knowledge in the general population of health issues and treatment options
- The trend of earlier discharge from hospital
- A greater sense of safety, privacy, autonomy and convenience at home

The driving factors that are categorised as being of low significance included:

- Government initiatives and promotion of self-care
- People's hypochondriac nature (Worried-word syndrome)
- A growing trend towards telehealth and telemedicine

- Emergency situations such as injuries and cardiac arrest in the home
(Gupta, 2007: p.167)

The trend of earlier discharge was regarded as having medium prominence in Gupta's research; however, in the FDA's Medical Device Home Use Initiative (FDA, 2010d), it is treated as one of the two main reasons for the prevalence of home use medical devices. Maybe the reason is that Gupta's research focuses on the UK market whereas FDA regulates the U.S. medical devices market. Gupta treats "the trend of earlier discharge from hospital" and "a greater sense of safety, privacy, autonomy and convenience at home" as two separated factors, however the Medical Device Home Use Initiative (FDA, 2010d) and Klatzky & Ayoub's studies (1995) suggest that these two factors are interrelated.

Alongside these driving factors and the increasing prevalence of home use medical devices, there are specific challenges in designing home use medical devices to be addressed during the design process.

1.3 Examples of Home Use Medical Devices

A number of good and poor examples of home use medical devices were identified in the literature. These examples will be presented in the following sections.

1.3.1 Good Examples of Home Use Medical Devices

The criterion for determining these particular devices as being good examples of home use medical devices was that, they had all received awards for their design.

Designing towards user requirements

According to Gardner-Bonneau (2011), it is important that home use medical devices are designed in a way sensitive to the special requirements of both the user population and the environment of use. Therefore the flexibility of the product is an important factor which should be considered during the design process. The Health Buddy Appliance is a patient monitoring system allowing remote monitoring and educational services for patients receiving care in their homes (Pullin & Bontoft, 2003; Gardner-Bonneau, 2011). It "...was awarded the

silver Medical Device Excellence Award and was selected as one of the Best Products of 2000 by Business Week” (Pullin & Bontoft, 2003).

The appliance (Figure 1.1) is used as part of the Health Buddy System. Depending on the condition (e.g. diabetes and asthma) of the patient, the device asks a number of questions of the patient every day, which allows routine monitoring and assists the patient with managing his/her condition.



Figure 1.1 The Health Buddy Appliance¹

Other home use medical devices also can be connected to the Health Buddy Appliance through the plug-in ports. This way the patient data can be directly transmitted to a website, which can in turn be accessed by healthcare specialists.

During the design process of the Health Buddy Appliance, early prototypes were tested with real users including elderly people. As a result, the device has been developed with their requirements taken into account (Pullin & Bontoft 2003). It has a very simple interface and is large enough to make it easy to press buttons and select functions. This addresses the requirements of those patients with physical or sensory impairments (Pullin & Bontoft, 2003; Gardner-Bonneau, 2011).

Designing for ease of use

Ease of use is an important consideration in medical device design (Kaye & Crowley, 2000). This was the main idea for DCA Design when designing KlikSTAR (Figure 1.2), a winner of the Good Design Award in 2009.

¹ Image source: <http://www.zmescience.com/wp-content/uploads/2008/02/health-buddy.jpg> (last accessed: 20/04/11)



Figure 1.2 ClikSTAR reusable insulin injection pen²

ClikSTAR is a reusable insulin injection pen. In order to make the device easy to use, around 2000 patients and 500 healthcare professionals were involved in the design process of the device (DCA, 2010).

A study was carried out by Penfornis (2011), which involved the testing of four reusable insulin injection pens including ClikSTAR, with the purpose of comparing their ease of use and performance. The study involved 654 users from five different countries (i.e. Canada, France, Germany, United Kingdom and United States). All the participants had type 1 or type 2 diabetes, and some of the participants exhibited visual or dexterity impairments. The ClikSTAR pen was found to be significantly easier to use when compared with other pens, particularly when users were replacing an insulin cartridge, sensing the clicks and setting the dose level to be administered (Penfornis, 2011).

Assisting lay users by design

The users of home use medical devices are frequently untrained people (Fischer, 2001; Lewis, 2001; FDA, 2010d); therefore it should be assumed that they may not have sufficient medical knowledge to effectively perform the task (Backinger & Kingsley, 1997). For example understanding and interpreting the results given by the device may be a problem for some lay users. This problem was identified by Vicks and a proposed solution was embedded in the design of their digital forehead thermometer (Figure 1.3).

² Image source: http://www.bstaendig.at/p3data/PublicFiles/clikstar_silber.jpg (last accessed: 21/04/11)



Figure 1.3 Vicks digital forehead thermometer³

This is a non-invasive thermometer which can take a reading of body temperature in 3 seconds from the forehead. The device helps the user to understand the meaning of the temperature by means of a colour display (i.e. green means a normal temperature where red means a high fever). According to Saunders and Seepersad (2009), the design of the device improves the information flow which in turn decreases the cognitive demands on the user, as they are not required to memorise the appropriate temperature ranges.

Vicks Forehead Thermometer was awarded the gold Medical Device Excellence Award in 2008.

1.3.2 Poor Examples of Home Use Medical Devices

Examples of poor home use medical devices were identified through the product recalls by FDA and MHRA. In order to highlight the emotional factors, a device whose users frequently refused to use it due to a perceived stigma attached to it, is also included.

Confusing display of measurements

Optium Glucose Monitoring System is a blood glucose monitor device manufactured by Abbott Diabetes Care Incorporated. The device was recalled in 2005 by the FDA. Figure 1.4 shows the device.

³ Image source:
http://images.businessweek.com/ss/08/07/0717_idea_winners/image/s_vicks_forehead_therm.jpg
(last accessed: 21/04/11)



Figure 1.4 Optium Glucose Monitoring System⁴

According to the report published by FDA (2005), the device can inadvertently switch the glucose readings from mg/dL (milligrams per decilitre, which is the measurement unit used in the U.S.) to mmol/L (millimoles per litre, as used in the UK) when it is dropped, upon battery replacement or when the time and date settings are changed.

Hoelscher et al. (2011: p.774) confirm that, “recently, several patient injuries and deaths were associated with glucometers that had erroneously changed to different measurement units”.

Insufficient Testing

Errors in use can also be caused by the product itself. According to BS EN ISO 62366:2008 (BSI, 2008c) adverse event reports confirm that many of the user errors are caused by user interface design flaws. In order to overcome this common problem a systematic application of usability engineering design principles is recommended, which should be reinforced by testing of the products through involving their real intended users in the design process (BSI, 2008c).

Figure 1.5 shows two insulin pumps recalled by MHRA in 2009.

⁴ Image source:
<http://www.nationalscrubs.com/ProductImages/Medline009/Optium%20New%20High.jpg> (last accessed 23/04/11)



Figure 1.5 Accu-Check Spirit⁵ (left) and MiniMed ParadigmVeo⁶ (right)

The first device is Accu-Check Spirit manufactured by Roche Diagnostics. The MHRA’s recall report indicated that the device was recalled due to a ‘design fault’. The ‘up’ and ‘down’ arrows which are used to activate the bolus function and change the basal settings (which can be seen on the right edge of the device) are defective and can fail. This may result in the insulin therapy being compromised. (MHRA, 2010a)

The second device, the MiniMed ParadigmVeo insulin pump manufactured by Medtronic, was recalled due to a software defect. Normally the pump device should not display the blood glucose reading more than 12 minutes after the reading has been transmitted from the blood glucose meter. This may result in an incorrect insulin administration, because the patient can become confused as to whether the reading on the display is the old blood glucose measurement or the current one. This fault resulted in the device recall. (MHRA, 2010b)

As can be seen from these two examples, it is important to make home use medical devices highly reliable, because device failures may compromise the health of the users. Therefore sufficient testing of the device is necessary in order to optimise its reliability before launching it on market.

Emotional requirements and stigma

Safety and effective task performance are significant considerations when designing medical devices; however devices should also be pleasing to use (Wiklund & Weinger, 2011). Home use medical devices should be unobtrusive and attractive, as they are frequently used in public or conspicuously within the home (Gardner-Bonneau, 2011). This is a particular problem for assistive

⁵ Image source: http://www.roche.com/de/accu-chek_spirit.jpg (last accessed: 24/04/11)

⁶ Image source: <http://www.presseportal.de/print.htx?nr=1545754> (last accessed: 25/04/11)

technologies, and using such devices is frequently considered stigmatising by users (Parette & Scherer, 2004). According to Newell (2003), in terms of their appearance, assistive devices are often designed in a way more suitable to a hospital environment rather than homes. Hearing aids are one such assistive device; users frequently refuse to use these devices due to the stigma attached (Erler & Garstecki, 2002; Parette & Scherer, 2004; Pullin, 2009). In fact, this can ironically prove to be a dilemma, because refusing to wear a hearing aid may result in social barriers due to communication problems (Prette & Scherer, 2004). Figure 1.6 shows a common example of a hearing aid.



Figure 1.6 A common example of a hearing aid⁷

This problem has been recognised by the National Health Service⁸ (NHS) in the UK, and they announced that a range of new and fashionable hearing aids (including those in different colours) were now available. In this way they are expecting an increase in the number of patients using hearing aids in the UK.

1.4 Motivation for Research

A major motivation for this PhD research is to understand the challenges and provide necessary support for designers to better design medical devices for lay users to utilise at home. Although home healthcare is a fast growing field and home use medical devices are an emerging market, there is surprisingly little information readily available for designers. To date, there is evidence, through the literature review, of only two significant attempts to generate a tool or guide

⁷ Image source: <http://www.dogexpert.com/Images/Hearing%20Aid-2.jpg> (last accessed: 27/04/11)

⁸ Information source: <http://www.nhs.uk/Livewell/hearing-problems/Pages/hearing-aids.aspx> (last accessed: 01/05/11)

specifically for the design and development process of home use medical devices:

- Gupta's design tool to assess home use medical devices during the development process for identifying the issues relevant to the products (Gupta, 2007)
- The FDA's announcement about guidance, specifically for home use medical devices, which is still in the development process

No evidence has been found regarding further actions with respect to improving the design and development process of home use medical devices in the U.K. From 1997 to 2009 the FDA had received 19000 adverse event reports where the incident took place at home environments, and "by clarifying the FDA's expectations, this guidance will establish a more predictable pathway for home use medical devices" (FDA, 2010d: p.7). The FDA have also previously published three documents [i.e. Brochure – Home Healthcare Medical Devices: A Checklist (FDA, 2009a), Home Healthcare Medical Devices: Blood Glucose Meters – Getting the Most Out of Your Meter (FDA, 2009b), and Brochure – Home Healthcare Medical Devices: Infusion Therapy – Getting the Most Out of Your Pump (FDA, 2009c)] for improving the safe use of home use medical devices by lay users.

On the other hand the Medicines and Healthcare products Regulatory Agency (MHRA) reported that they received 9099 adverse incidents in 2009 (MHRA, 2010), and the number of device reports by patients and professionals has risen over the past decade because of the complexity of the devices (MHRA, 2008d); however, they did not mention the percentage of incidents that occurred in the home environment.

User reviews for home use medical devices on popular shopping websites (such as www.amazon.com, www.amazon.co.uk, www.argos.com, etc) and the adverse event reports published in the FDA's MAUDE database suggest that there is a high error rate of the devices as well as widespread dissatisfaction among the users. Some of these comments directly point out design related usability problems of home use medical devices, which suggest the increased awareness of lay users regarding design related problems.

On the other hand designers are often accused of designing for themselves rather than for the actual users (Margolin, 1997; Keates & Clarkson, 2003; Keates & Clarkson, 2004; Wiklund & Wilcox, 2005). As suggested by Persad et al. (2007), during the early stages of the design process, designers require knowledge and data about the target users of the product in order to effectively evaluate its accessibility. Although lay users are frequently mentioned as the users of home use medical devices, it has been found that there is a gap in the literature regarding defining lay users and their characteristics. Therefore helping designers to develop a better understanding of lay users' characteristics is another motivating factor for this research.

1.5 Research Aim, Research Questions and Objectives

This research specifically focuses on the design aspect of home use medical devices. As discussed in the previous section, currently very little information is available for designers' use when designing home use medical devices; therefore it is deemed necessary to provide support for designers, which would also have a direct impact on the satisfaction of lay users when using such products.

The aim of this research is:

To assist designers in developing home use medical devices by providing information and suggestions regarding lay users and how to address their needs and expectations.

With this intention in mind, three research questions and the overall objectives by which these research questions can be addressed have been identified:

RESEARCH QUESTION 1: *Who are lay users and what are their characteristics?*

Home use medical devices are utilised by lay users; therefore in order to address their needs and expectations it is necessary to understand who they are. The objectives are:

- To review existing definitions of lay users
- To identify specific characteristics of lay users
- To identify different types of lay users

RESEARCH QUESTION 2: *What are the challenges faced by designers in developing home use medical devices?*

In order to provide support for designers, firstly it is necessary to understand the design process for home use medical devices and the challenges faced by designers. The objectives are:

- To find out the current design process used for developing home use medical devices
- To identify overall challenges of developing home use medical devices
- To review the regulatory requirements for medical devices for the European market, and identify their relevance to home use medical devices

RESEARCH QUESTION 3: *How to support the design of home use medical devices?*

It is important that the support provided as an outcome of this research addresses the requirements of designers. The objectives are:

- To identify designers' requirements when designing home use medical devices
- To develop and evaluate a suitable prototype method for assisting designers

This PhD thesis proposes to address these three research questions in an effort to achieve the aim of this research. The next section presents the structure of the thesis.

1.6 Thesis Structure

The thesis consists of eight chapters. In this chapter (Chapter 1), a brief overview of the home healthcare market is provided. The definitions of a medical device and a home use medical device are given in order to highlight the differences. A number of good and poor examples of home use medical devices are presented and discussed. The research context and motivations for this research, together with the aim, the research questions and the research objectives are also explained.

In Chapter 2, the research questions are explored through literature review and analysis. (1) The literature review suggests that very limited information is currently available regarding lay users, such as definitions and descriptions of their characteristics. The definitions and characteristics of lay users are discussed in Chapter 2. (2) In order to understand the challenges faced by designers in designing home use medical devices, the design process is investigated. The design process models found in literature for medical devices and for general consumer products are discussed. Due to the fact that home use medical devices are accepted as medical devices, the medical device regulations for the European market are described in relation to home use medical devices. (3) Lastly the ways of supporting designers and the ways in which they use information are discussed.

In Chapter 3, the research methodology and the methods used in each study are justified.

Chapter 4 specifically focuses on the first research question (i.e. who are lay users and what are their characteristics?). An observational study was carried out to verify the lay user characteristics identified from literature. The study involves an observation of 40 lay users from 4 different user groups (i.e. 10 younger participants, 10 older participants, 10 participants with motor and sensory disabilities, and 10 participants with cognitive disabilities) when interacting with two digital devices specifically designed for lay people's use (i.e. a blood pressure monitor and a digital camera). The results of the study is presented and discussed in Chapter 4.

Chapter 5 focuses on the designers' perspectives regarding the design process of a home use medical device and its relevant requirements in an effort to address the second and the third research questions (i.e. 'what are the challenges faced by designers in developing home use medical devices?' and 'how to support the design of home use medical devices?'). For this purpose an online self-administered questionnaire survey was carried out with 53 designers. The results of the survey, which were presented and discussed in Chapter 5, provide first-hand information regarding the support designers require when designing a home use medical device.

Chapter 6 focuses on developing a design support tool. The tool has been developed based on the information derived from the three earlier studies, i.e. the literature review (Chapter 2), the observational studies with lay users (Chapter 4), and the survey with designers (Chapter 5). It is proposed that the tool will be evaluated by professional designers.

Chapter 7 presents the results of the evaluation of the design support tool with professional designers. The evaluation involves an online self-administered questionnaire for the initial evaluation of the tool and semi-structured interviews for an in depth evaluation. A total of 12 professional designers (with or without experience in designing home use medical devices) took part in the interview.

Lastly, in Chapter 8, the overall conclusions of this research, its contributions to knowledge and the proposed future work are discussed.

Figure 1.7 illustrates the structure of the thesis.

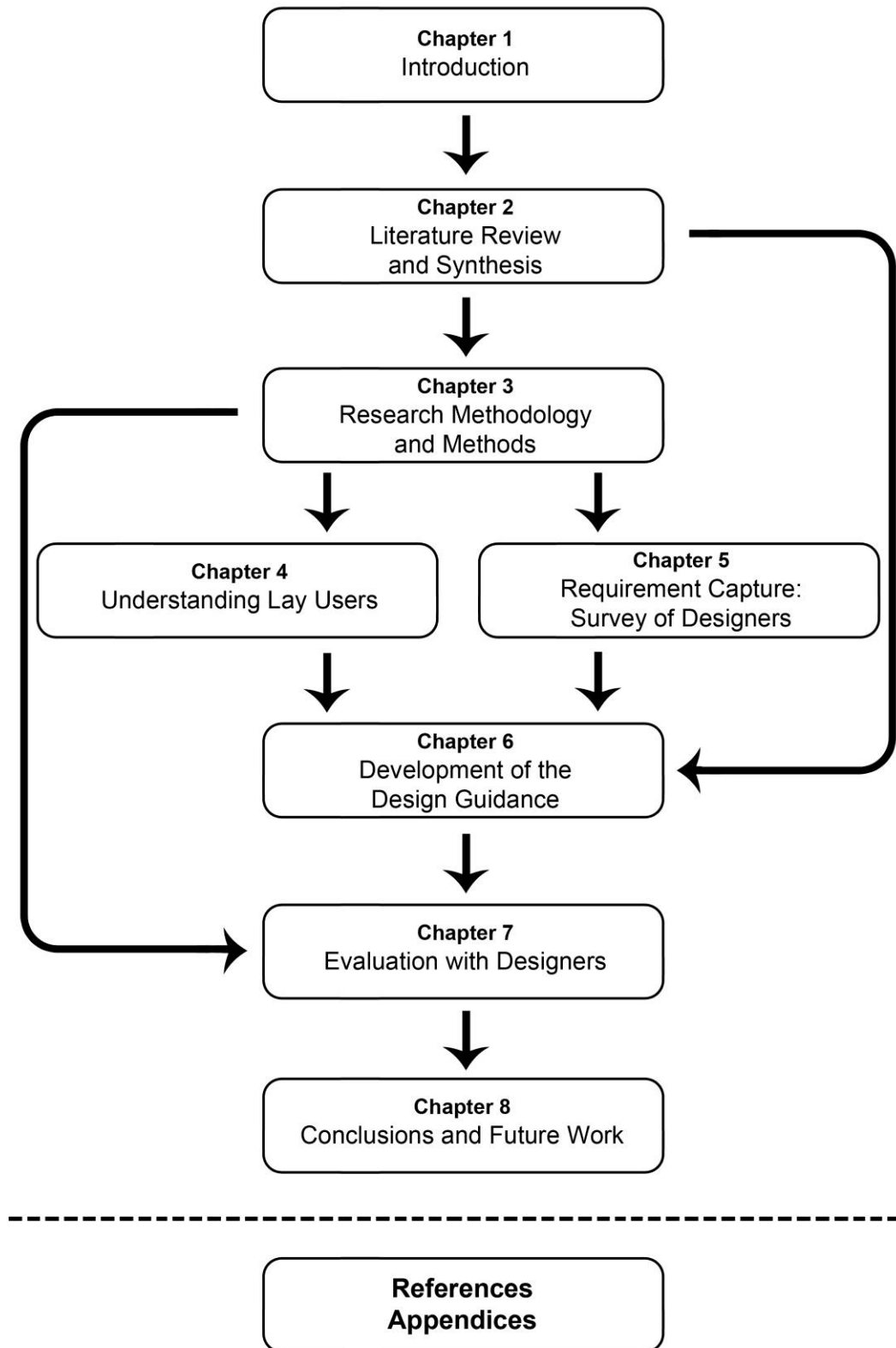


Figure 1.7 Structure of the thesis

CHAPTER 2: LITERATURE REVIEW AND SYNTHESIS

In the previous chapter, a brief overview of the research context was presented, and the aim of the research and three research questions were identified. In this chapter, the factors which increased the use of medical devices in the home environment are to be discussed. This is followed by the exploration of the research questions identified in Section 1.5 through existing literature resources. The objectives for this chapter are summarised in Table 2.1.

Table 2.1 Research questions and the objectives

Who are lay users and what are their characteristics?

Objectives:

- To review the existing definitions of a ‘lay user’
- To identify specific characteristics of lay users
- To identify different types of lay users

What are the challenges faced by designers in developing home use medical devices?

Objectives:

- To find out the current design process of home use medical devices
- To identify the overall challenges of developing home use medical devices
- To review the regulatory requirements for medical devices for the European market, and identify their relevance to home use medical devices

How to support the design of home use medical devices?

Objectives:

- To find out the ways to assist designers during the design process
 - To gain an understanding of designers’ information needs
-

This chapter provides the preliminary answers for the three research questions.

2.1 Medical Devices for Home Environment

The majority of home use medical devices are adapted from professional medical devices (Gupta, 2007). Therefore, it is important to understand the adaptation of products from professional use to lay use.

2.1.1 Product Adaptation from Professional Use to Lay Use

There is an increasing and evolving demand from the end-user market for the adaptation of products originally designed for professional use to the use of lay people. These products were originally designed specifically to meet the needs of professionals, and increasingly many of them become available on the mainstream market for lay people. Such products include hobby products, medical devices, computer accessories, educative products.

According to Heskett (2002), the nature of the objects has been changed during the twentieth century due to the introduction of electronic technology. He also confirms that, “the growth of electronic technology, the manufacture of powerful microchips, and the generation of more sophisticated software at commodity prices mean that products and systems have the potential to be highly flexible in response to specific users’ needs” (Heskett, 2002: p.131). Today designers have the opportunity to design products smaller, smarter, and cheaper than before (Braddock, et al., 2004). Products are becoming smarter, allowing us to carry out complicated tasks through a process of automatic parameter assessment and strictly-regulated action (Norman, 2007). As a result, large and complex scientific instruments are becoming smaller, and entering to our daily lives for communication and entertainment purposes (Whelan, 2009). However, how is technology being transferred from professional people to lay people?

According to Liddle (2007), there are three phases of technology adoption: enthusiast phase (Hobby), professional phase (Work) and consumer phase (Life). The enthusiast phase is the invention phase where people like to exploit the technology without giving consideration to the complexities and difficulties that may inherent within. However, after sometime an enthusiastic user may come up with an idea to implement that technology in a practical way. That is when invention starts to become an innovation. This is the professional phase where

priorities of developers change and they become more focussed on costs and prices. In this phase, the design must be reliable, consistent and above all useful and usable. After the product has built up enough volume through the business phase and technology has become cheaper, the consumer phase starts. In this phase the language of products changes dramatically with respect to the priorities of the consumers. The design must be easy to use, pleasurable and must present its functionality in an aesthetic way. (Liddle, 2007)

Advances in technology have played a major role in the product adaptation process. Home use medical devices which is considered as a growing market, are good examples of this adaptation process. The next section will focus on the home use medical devices market particularly.

2.1.2 Prevalence of Home Use Medical Devices

Today we can see many medical devices used by lay people outside the clinical environment. According to an expert survey carried out in 1998 by the FDA's CDRH (Herman, et al., 1998), home and self-care technologies were identified as one of the six major trends of the medical device technologies for the following decade. This was also confirmed by William Herman (2001), the then Director of the Division of Physical Sciences in the FDA's Centre for Devices and Radiological Health who forecasts that future home use medical devices will provide reliable and cost effective options for health care.

Similarly Gossink & Souquet (2006) argues that, e-health and personal healthcare is one of the major trends in healthcare technology. They also mentioned in their paper that conventional interactions with patients are changing and today patients take more responsibility for their own health. Consequently, patients are now motivated to actively take part in their medical treatment (Klatzky & Ayoub, 1995). However, education of lay users of medical devices is key to safety and performance (WHO, 2003).

Miniaturisation of electronics is one of the key reasons which enabled the technology to move to the location of the patient rather than the patient moves where the technology is (Gossink & Souquet, 2006). This trend will continue in the future and we will see more medical devices in the home environment; "as

medical devices have become more compact and portable, it has become possible to conduct a variety of medical treatments in the home”, and this will provide significant benefits to patients (FDA, 2010d: p.3). Designing smart devices and increased portability are pushing the medical device industry and enable further innovations that benefit patients and professionals (Hocter, 2009).

On the other hand, it is important that the users of home use medical devices should be aware of the associated risks with the devices since they take the responsibility to operate the devices correctly. If the products are able to meet the needs and expectations of the lay people, then home healthcare is a good alternative to provide a better quality of life and a reduction in the cost of care (FDA, 2010d). Therefore designers should be aware of the needs and expectations of lay people during the design process. The next section focuses on lay users and their characteristics.

2.2 Lay Users and Their Characteristics

As mentioned in Chapter 1, users are one of the major determinants for home use medical devices. This section will focus on lay users and their characteristics.

2.2.1 Definition of a Lay User

Although the term of “lay users” is widely used in literature, only a few papers attempt to give a definition. This problem is also highlighted by Hogg & Williamson (2001). In addition, the definitions found in the literature are generally specific to a field (e.g. medical devices) and they do not give a broad description of a lay user.

Other synonyms are also used frequently in various resources such as: layperson, lay people, consumers, amateur users and non-professionals.

The most general definition is found in the Oxford Dictionaries Online⁹ as ‘layperson’: “a person without professional or specialised knowledge in a particular subject.” However, this definition does not elaborate further on what is meant by ‘professional or specialised knowledge’. In the medical field, patients can develop their own specialised knowledge of their specific condition or their

⁹ http://oxforddictionaries.com/view/entry/m_en_us1262529?rskey=yqz7F0&result=2#m_en_us1262529 (last accessed: 18/06/10)

illness through personal experience, or via other information sources such as the Internet, magazines or books.

Entwistle et al. (1998: p.463) addressed this in the definition they created: “people who are neither health care professionals nor health services researchers, but who may have specialised knowledge related to health.” Although this definition recognises that lay people may have specialised knowledge, it does not explain what is meant by ‘professionals’ and it only focuses on the medical device field.

In the Human-Computer Interaction (HCI) field, the term of ‘novice users’ is often used. However, the definitions of a novice user are generally found to be only specific to the HCI field. For example, according to Vatanasombut et al. (2004: p.66), “novice users are those who are not experienced with computers and the Internet; they tend to use the online banking system for simple tasks such as account access.”

Likewise, Fischer (2001: p. 67) argues that: “the original HCI approaches, by being focused on making systems more usable, have often reduced the expressive power of the systems and of interfaces to accommodate novices and casual users who are assumed to be using the system for the first time, for only a few times, and for simple activities.”

It can be seen from the definitions that they attempted to define ‘novice users’ specifically relevant to HCI. Moreover novice users are often defined by their experience, and the term of ‘lay user’ is more about the knowledge gained through an extensive training process regarding a profession. For instance, even though the users of home use medical devices are lay users, they can be novice or experienced users regarding their prior experience with the same or similar products. Therefore a ‘novice user’ may differ from a ‘lay-user’.

The most applicable definition with respect to the purpose of this research was given by Hogg & Williamson (2001: p.3): “lay people are those who have not gone through the training or socialisation into the particular profession (such as medicine, nursing, chiropractic) which we refer to as the index profession.”

This definition is not specific to any field. In addition it evidently indicates that lay people do not have the specific knowledge in the subject field or index profession. Based on this definition, in this study a ‘lay-user’ is defined as:

A user of a product or a system who has not undergone extensive training in the subject field (which enables him/her to be eligible to act as a member of a profession), but uses the system or the product due to his/her special interest or needs.

2.2.2 Definition of a Professional User

Oxford Dictionaries Online¹⁰ defines a professional as: “a person engaged or qualified in a profession”. This definition emphasises the education level and training of the user.

Lundvall (1985: p.5), in his definition, emphasises the role of the user in the economical context: “The professional user - that is a user acting within the formal part of the economy - has a more restricted goal for his activities.” Lundvall also described the goals of lay users in general terms such as, utility maximisation, satisfaction, happiness. He indicates that professional users have restricted goals for their activities.

Cifter and Dong (2009: p.4) define professional users with consideration of the social context in terms of adding value, in addition to the economical context: professional users are “the users who have gone through extensive training to achieve particular knowledge which is valuable in a social or economical context.” This definition also highlights the knowledge of the participant obtained through training in a specific field. This definition of professional users is adopted in this study.

2.2.3 Professional Users VS. Lay Users

Professional users and lay users differ in terms of their knowledge level, where professional users are more knowledgeable regarding the task that they carry out, or with the product they are using (Cifter & Dong, 2009). Lundvall (1985: p.5) argues that “the professional user is expected to be active in his search for new

¹⁰ http://oxforddictionaries.com/view/entry/m_en_us1280978#m_en_us1280978 (last accessed: 18/06/10)

ways to solve his problems. He will also be expected to adapt his behaviour and qualifications when new technical opportunities come forward”.

According to the definitions of a professional user and a lay user, it can be seen that training of the participant has a big effect on determining their classification. By means of training, users obtain knowledge regarding the task or the product. Therefore the knowledge of the participant is the main determinant of this classification, shown in Figure 2.1.

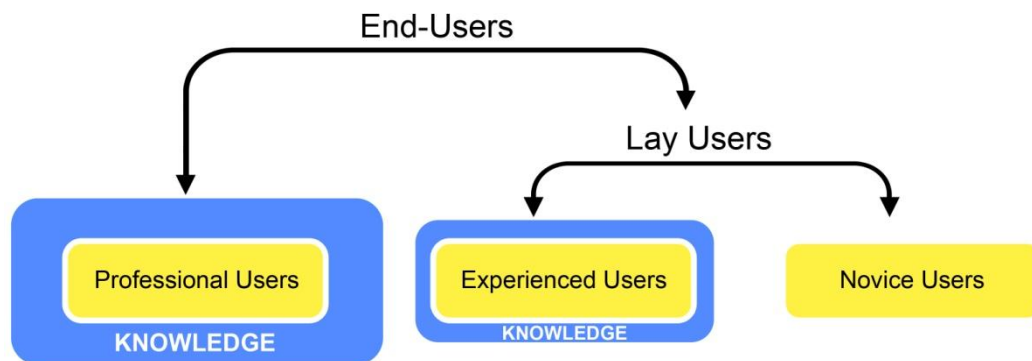


Figure 2.1 Different types of end-users

Although experienced users may acquire knowledge about the product and the task, their knowledge of the task is much limited when compared with professional users. Novice users usually do not have any knowledge about the task and/or the product or it is very limited. This may affect their interaction with the product or their performance in the task (Cifter & Dong, 2009).

Lay users are not homogenous; their needs and expectations differ significantly from professional users (Cifter & Dong, 2009). However, it should now be considered how, and in which context they differ.

The main differences between the professional users and lay users found through literature review are as follows:

- **Capabilities:** Professional users are less likely to suffer from disabilities; however, lay people may have various disabilities, chronic diseases and/or they may suffer from age related capability deterioration (Sawyer, 1996; Kaye & Crowley, 2000; Wilcox, 2003; Wiklund & Wilcox, 2005).
- **Prior experience and intuitive use:** Jordan (2002) argues that, when users interact with a product for the first time, many have expectations about the manner of use. These expectations are frequently based on their

previous experience of performing the task with the previous model of the product or with similar devices (Jordan, 2002). Regarding education and training there can be huge variance between professional users and lay users in terms of their skills in using the devices (Hogg & Williamson, 2001; Ram, et al., 2005; Fries, 2006). Owing to these, lay people are less likely to have prior experience with the products and related tasks. Interaction errors may frustrate users who do not have any previous experience with the product (Lazar & Norcio, 1999).

- **Motivation in using the product:** When lay users are faced with a new device for the first time, there is a lack of confidence; because they might not understand the issues and situations related to their device and their interaction with the device (Gupta, 2007). In addition some of the lay users may be unfamiliar with automated devices, which may discourage them from using such devices (Sawyer, 1996). When faced with a difficulty, lay people are likely to blame themselves, and they are more likely to stop using the device than ask for help because they may feel embarrassed (Rogers, et al., 2001).
- **Ability in using the devices:** Lay users are more likely to make errors (Lazar & Norcio, 1999; Edworthy, et al., 2004). If they inadvertently affect the performance or accuracy of the device, they are less likely to be aware of it (Kaye & Crowley, 2000). Lay users might not be aware of their device giving an improbable result (BSI, 2009a).

Lay users may prefer simple to use products with the necessary functions (Buurman, 1997). According to Buurman (1997) not only the users, but also the products designed for professional use and lay use have considerable differences in terms of usage and usability, because users and their goals are not clearly defined for lay people due to their variation.

- **Ability to overcome device limitations:** Professional users are good at overcoming device limitations (Wilcox, 2003; Wiklund & Wilcox, 2005). They are often much more capable of operating sophisticated devices, and they respond to unexpected or variable situations much better than lay users (Kaye & Crowley, 2000). In contrast when lay users encounter

problems, they are less able to overcome device limitations (Wiklund & Wilcox, 2005). Lay users may require support in many different forms, e.g. maintenance of the product, servicing, repairing and replacements (Gupta, 2007).

- **Context of use:** The context of use for lay people is not clearly defined (Sawyer, 1996; Buurman, 1997; Clarkson, et al., 2004; Gupta, 2007). As mentioned in Section 2.3, using the devices in the home environment brings many challenges for the users and the designers. For example:

“...unlike trained hospital staff, home users may not be equipped to handle medical emergencies in the event of a natural disaster or an electrical outage, particularly in the absence of the back-up power and/or water supply that a healthcare facility may have” (FDA, 2010d: p.4).

In addition home is not the only environment. Users may carry these devices to any kind of non-clinical environment and use them (Gupta, 2007; FDA, 2010a; FDA, 2010d).

- **Information usage:** According to Edworthy et al. (2004), professional users are more likely to follow instruction manuals than lay users. They argue that professional users are subject to regulatory bodies; hence they are more concerned with the legal liability of their actions.

On the other hand lay people may value different type of information resources such as family, friends, local news reports and the public library (Brennan, 2006). Lay users are less likely to be both aware of risks and follow the instructions (Edworthy, et al., 2004). In particular with home use medical devices, the instructions are mainly written for professional people which results in user errors due to the difficulty in understanding the descriptions (Backinger & Kingsley, 1993; Lewis, 2001). Professional users may need more detailed information such as troubleshooting, that lay users often do not need (Backinger & Kingsley, 1993). In addition, lay users may experience difficulty in understanding jargon or technical terms; therefore they should be avoided for lay users (Backinger & Kingsley, 1993; Rogers, et al., 2001).

- **Perception and purchase decision:** According to Crilly et al. (2004), when a user wants to change his/her present product for a new one, prior knowledge may be used to make judgements on attractiveness. Professional users are likely to prefer new products with small changes because of natural psychological tendency to take the tried-and-true path (Wiklund & Wilcox, 2005). For professional users a product with radical change means more time spent on learning the new product and a perceived waste of accumulated experience (Wiklund & Wilcox, 2005). Effectiveness of the product is important for professional users (Buurman, 1997). On the other hand lay people may follow a random, non-systematic search for new products, and they are likely to choose the ones which do not involve extensive training and changes in behaviour (Lundvall, 1985). Lay people can choose whether to use a product or not, therefore pleasure is more important for them during their interaction with the product [Vet (1993) cited in Buurman (1997)]. In addition, the price of the product is an important factor for lay users and may influence their decision at time of purchase (Liddle, 2007). However, 'price' can also be considered as an extrinsic quality signal alongside the other criteria, such as brand name or package (Zeithaml, 1988).

Table 2.2 shows a comparison of the user characteristics of professional users and lay users, in accordance with the information gathered through the literature review.

Table2.2 Comparison of professional users and lay users

| PROFESSIONAL USERS | LAY USERS |
|--|---|
| Usually able-bodied | Vary in age and capability |
| Well-trained | May have little or no training |
| Product function reflects their expertise | Product function reflects their special needs or interest. |
| Knowledgeable regarding the task | May have little or no knowledge regarding the task and/or the product |
| More control of products they use | May have less control of the product they use due to the lack of confidence |
| Good at identifying problems or errors | May be poor at identifying problems or errors |
| Good at overcoming device limitations | May be poor at overcoming device limitations |
| Good at dealing with unexpected situations | May experience difficulty in dealing with unexpected situations |
| Capable of operating sophisticated devices | May prefer easy to use devices with specific functions |
| Contexts of use of the devices is often defined | Contexts of use of the devices may vary significantly |
| More likely to use instructions | May be less likely to follow instructions |
| Understand specific terminology | May have difficulty in understanding specific terminology |
| Follow restricted, experience-based approach when obtaining a device | Generally follow a random, non-systematic approach when obtaining a device |

On the other hand as mentioned before, lay users are not homogenous. Different types of lay user groups may exhibit different characteristics. Therefore it is necessary to identify these different types of lay users.

2.2.4 Types of Lay Users and Their Characteristics

Due to the fact that this research specifically focuses on home use medical devices, the lay user types were identified in accordance with this field. Lay users for home use medical devices are frequently mentioned as patients (Sawyer, 1996; Entwistle, et al., 1998; Rogers, et al., 2001; WHO, 2003;

Wiklund & Wilcox, 2005); however other resources also include carers as lay users (Backinger & Kingsley, 1993; Gupta, 2007; Shah & Robinson, 2008; FDA, 2010d). As mentioned before these people vary significantly in terms of their needs, expectations and capabilities, because they can be healthy people, older people who suffer from chronic diseases, or disabled people. Figure 2.2 summarises the different types of lay users for the market of medical devices.



Figure 2.2 Professional and lay users of medical devices

In this research lay users are investigated in three groups: (1) younger and able bodied users, (2) older users and (3) disabled users.

Younger and Able Bodied Users: Younger and able bodied people are the most advantageous lay user type. According to Dewsbury et al. (2007), we are living in a world oriented towards healthy and younger people. They are quite familiar with the technology; therefore they have good understanding of technological terms (Eisma, et al., 2004). When younger users use products, they are able to perform tasks faster than older users (Langdon, et al., 2007; Lewis, et al., 2008). Maybe the reason is that, as suggested by Backler et al. (2010), there is a correlation between age and intuitive use where younger people are more naturally adept at using products.

In terms of their cognitive abilities, younger people reach their peak in their early twenties, and generally remain stable until their late fifties (Huppert, 2003). During the ageing process *fluid intelligence* is likely to deteriorate, where *crystalline intelligence* remains relatively stable (Czaja & Lee, 2007; Hisham & Edwards, 2007). Fluid intelligence is “the process of reasoning the immediate situation in tasks requiring abstracting, concept formation and attainment, and the perception and education of relations”, whereas crystalline intelligence refers to “...breadth of awareness and subtlety of relations previously perceived, concepts

previously attained, etc., as indicated in tasks requiring recognition of recall of such relations...” (Horn & Cattell, 1966: p.255). This means that older people frequently use their acquired knowledge in order to solve problems, but when they encounter a completely new set of circumstances, they may experience difficulties. Similarly, working memory, which refers to “the ability to keep information active while processing or using it” (Czaja & Lee, 2007), also declines with ageing (Slater, 1988; Czaja & Lee, 2007). Consequently, younger people are more effective in adapting to new set of circumstances and solving problems when they are experiencing them for the first-time.

Older Users: Nowadays we can see more and more older people in the end-user market, particularly in developed countries. “The rapid increase in numbers of individuals who are older is also starting to provide a market ‘pull’ towards more accessible products” (Vanderheiden, 2000: p.33). “Older people may have significantly different needs and wants due to the stage of their lives they have reached.” (Gregor, et al., 2002: p.152).

According to Huppert (2003), we reach our sensory and physical peak around the age of twenties and then we lose our capabilities gradually during the ageing process. Older people can differ from disabled younger people in terms of their overall functionality, because they are likely to suffer from multiple disabilities (Newell & Gregor, 2002). They are likely to have visual impairment, low dexterity, and limited mobility; additionally they can experience a decline in their cognitive capabilities regarding rapid assimilation and analysis of new information (Huppert, 2003).

Older people are likely to spend most of their time at home; therefore they are targets of home-based technologies (Eisma, et al., 2004). However, multi-functionality and the complexity of interfaces alienate older people (Baskinger & Hanington, 2008). Hence they are less likely to use technology when compared with younger people (Eisma, et al., 2004) due to fear of unknown and getting lost in confusion (Hawthorn, 2007). When they are faced with an unexpected situation, they are more likely to be disrupted (Hawthorn, 2003). On the other hand, prior experience has a positive effect when they interact with technology (Hurtienne, et al., 2010).

Home use medical devices are frequently used by older people, because such devices enable them to monitor their own health situation. However, they differ significantly from younger people in terms of their characteristics and capabilities.

Disabled Users: In the UK, particularly after the Disability Discrimination Act in 1995, people have started to give more consideration to the rights of disabled people, and as a result, by means of new regulatory changes in laws, the rights of disabled people have been improved significantly (BSI, 2005). According to the Disability Discrimination Act 1995, disability means a person: "...has a physical or mental impairment which has a substantial and long-term adverse effect on his ability to carry out normal day-to-day activities" (OPSI, 1995).

These people can have congenital disability, or impairment can happen anytime, e.g. stroke or an accident (French, 1994a). Although today the life quality of disabled people is improving day by day, more improvements are necessary. According to Newell & Gregor (1999), improved medical care resulted in longer life expectancy and increasing employment for younger and disabled people, however, this also means that there is an increase in both the severity and diversity of disabilities in the work place. They also argue that even very simple tasks for a younger and able bodied person can turn into a very difficult one to achieve for severely disabled people (Newell & Gregor, 1999).

In addition we can have temporary disabilities through injured or broken limbs. Having or developing a permanent capability loss also brings devastating psychological or social effects, because the needs and expectations of that person changes dramatically (French, 1994a). However, independence is a critical need of these people, because in many ways disabled people live a life dependent on others (French, 1994b).

Designers can learn many things from disabled people, because disabled people have a great capability to develop special skills to cope with products (Newell & Gregor, 1999; Persad, et al., 2007), where these situations only occur in the case of an emergency for able-bodied people (Newell & Gregor, 1999). People having physical, sensory or cognitive disabilities are good information sources because they can show the major problems of the system and suggest improvements to

the overall system, which may result in more effective and efficient designs to operate for everyone (Newell & Gregor, 1999).

2.2.5 Overall Summary of Lay User and Their Characteristics

In this section lay user characteristics, their difference between professional users, and different types of lay users groups are discussed. Although several researchers frequently used the term 'lay people' in their papers, there is no evidence of any comprehensive study about identifying these people and their characteristics. The information discussed regarding lay users in this section is derived from an amalgamation of diverse resources from different fields.

It has been found that the characteristics of lay users were only defined with respect to the way in which they compared with professional users. Therefore the extent to which these characteristics were applicable, when lay users were no longer compared with professional users, was not clear.

Most of the home use medical devices are used by lay people who have limited knowledge regarding the task that they are performing. Therefore their characteristics should be taken into account carefully when designing such devices. The next section will discuss the design process in relation to home use medical devices.

2.3 Design Processes of a Home Use Medical Device

No literature was identified relating to the design process model specifically developed for home use medical devices. Home use medical devices are unique because despite the fact that these devices are used by lay people, they are medical devices which are complex and safety critical. As Gupta (2007) suggests, home use medical devices are everyday products but at the same time they are medical devices. Therefore in this section two different design process approaches were investigated, i.e. the design process in general terms, and the design process for medical devices.

2.3.1 Design Process in General Terms

The development of a new product is a task which requires the balancing of four factors:

1. **Development speed:** It is also known as time-to-market. It means the time between the first instant that work on the product commences and the time the final product meets the end-user.
2. **Product cost:** “The total cost of the product delivered to the customer.”
3. **Product performance:** The justification of whether the product meets its market-based performance specification or not.
4. **Development program expense:** The complete one-time development costs regarding a specific project.

(Magrab, 1997: p.32-33)

A product may require many inputs from different disciplines, and unless all the technological and non-technological components (e.g. man-machine interfaces, shape, form, etc) are in balance, the product may fail in the market place (Pugh, 1991). In addition Pahl et al. (2007) argue that, due to the complexity of the product design process, designers should adopt a procedural plan; otherwise they can be faced with an unmanageable number of possible approaches. “It is therefore necessary for designers to learn about the design process and the application of individual methods, as well as the working and decision making steps proposed in the procedural plans” (Pahl, et al., 2007: p.126).

Design methods can help designers, to improve the quality of their work, and in particular novice designers, to speed up their development and improve the co-operation with essential specialists involved in the design process (French, 1999).

During the literature review, it has been found that there are a number of design process models, such as French’s (1999) block diagram of design process, Cross’s (1996) four-stage design process, Pugh’s total design activity model (1991), Stanton’s (2004) user centred design process model and Wright’s (1998) design process model. All these models are drawn as flow-diagrams. Generally in the design models there are feedback loops, which mean that iterative returns to earlier stages are possible, and in some cases necessary (Cross, 1996). However, Pahl et al. (2007) suggests that, in order to ensure that the design work is effective and efficient, it is important to adopt a systematic approach in an effort to keep the iteration loops to a minimum.

Pahl et al.'s (2007) design process is a well known model which summarises the necessary steps of a design process in general terms. The model is shown in Figure 2.3.

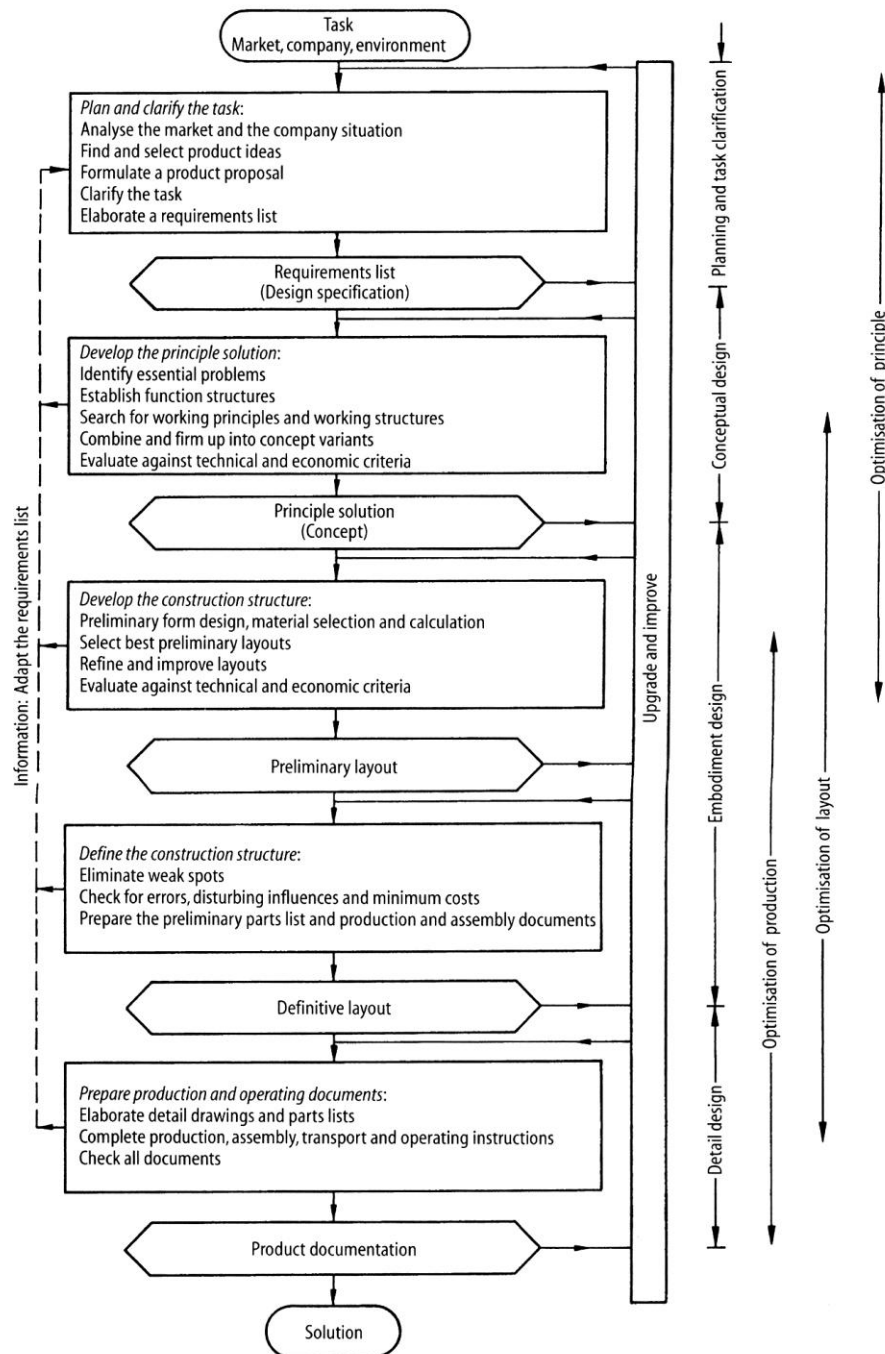


Figure 2.3 Steps in the planning and design process (Pahl, et al., 2007: p.130)

According to the model, the design process has four main phases:

- **Planning and Task clarification:** Product planning is done by a marketing department or a special department that takes responsibility for the product; then the plan is given to the engineers as a task. The

clarification of the task in more detail is necessary before starting the product development. The purpose of task clarification is to gather information about the necessary requirements of a task, as well as about the existing constraints and their importance. This phase results in a requirement list which involves the specification of the design.

- **Conceptual Design:** This phase determines the principle solution (concept) by abstracting the essential problems, establishing function structures, searching for working principles and combining those principles into a working structure. During this phase a number of solution variants are generated and the ones which do not satisfy the requirements are eliminated. The most promising (may be more than one) variants are taken to the next level for the final decision.
- **Embodiment Design:** In this phase one of the promising variants is selected in accordance with the evaluation against technical and economical criteria. As a result of this phase the specification of a layout is identified where the outcome is a definitive layout.
- **Detail Design:** The output of this phase is the production documentation. In this phase “arrangements, forms, dimensions and surface properties of all of the individual parts are finally laid down, the materials specified, production possibilities assessed, cost estimated, and all the drawings and other production documents produced.”

(Pahl, et al., 2007: p.132)

Many other design process models mentioned at the beginning of this section also share a similar core model, although they differ in terms of their approaches regarding specific stages of the design process.

The next section will focus on the design process for medical devices.

2.3.2 Design Process for Medical Devices

Designing medical devices is a strict process. According to Ward et al. (2002), due to the complexity and safety-critical nature of the medical devices, there are a number of engineering and project management challenges in developing medical devices. Medical devices must fulfil the regulatory requirements of the

target market place and prove that they are developed in a way fitting with their purpose (Ward, et al., 2002). The documentation of the verification activities is part of the proof that the device meets the subject requirements (Ward, et al., 2002).

According to Shefelbine et al. (2002: p.33), the “use of the international standards for general products is the most common way to comply with the EU Directives requirements for quality assurance” because it is clearly mentioned in ANNEX II of the Council Directive 93/42/EEC (EEC, 1993a: p.33): “the manufacturer must ensure application of the quality system approved for the design manufacture and final inspection of the products concerned”.

There are two international standards for quality management system, i.e. ISO 9001:2008 (BSI, 2008a) Quality Management System Requirements and ISO 13485:2003 (BSI, 2003) Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes, which are also adopted by British Standards Institute and European Standards. ISO 13485:2003 is based on ISO 9001:2000, but the focus of this standard is only on medical devices. According to EN ISO 13485:2003 (BSI, 2003: p.v), this standard “specifies requirement system that can be used by an organisation for the design and development, production, installation and servicing of medical devices” and “the quality system requirements specified in this international Standard are complementary to technical requirements for products”.

According to EN ISO 13485:2003, **verification** and **validation** are important activities during all stages of the product development process. Due to the fact that this research has been carried out in the UK, the definitions are derived from EN ISO 13485:2003.

- **Verification:** Verification is the activity to be performed “to ensure that the design and development outputs have met the design and development input requirements” (BSI, 2003: p.12). Ward et al. (2002) argue that, verification not only involves testing, but also other activities in order to provide evidence that the necessary requirements are being met. According to Alexander et al. (2001: p.3), verification is the question of “are we building the thing right?”

- **Validation:** Validation is the activity “to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use”, and this activity shall be completed before the product is delivered or implemented (BSI, 2003: p.12). According to Alexander et al. (2001: p.3), validation is the question of “have we built the right thing?”

Verification and validation activities are found to be the most characteristic features of the medical device design process. During the literature review, two design process models were found that were specifically developed for medical device design: (1) Waterfall Design Process Model (FDA, 1997), and (2) Design for Validation (DFV) V-Model (Alexander, et al., 2001; Alexander & Clarkson, 2002).

The Design for Validation (DFV) V-Model (Alexander, et al., 2001; Alexander & Clarkson, 2002) covers the complete device development process, i.e. device design, process design and production development. For the purposes of this section, the Waterfall Design Process Model (Figure 2.4) is presented, which specifically focuses on the design process of medical devices. According to FDA (1997), this design process is based on a traditional waterfall model, where each step proceeds in a logical sequence.

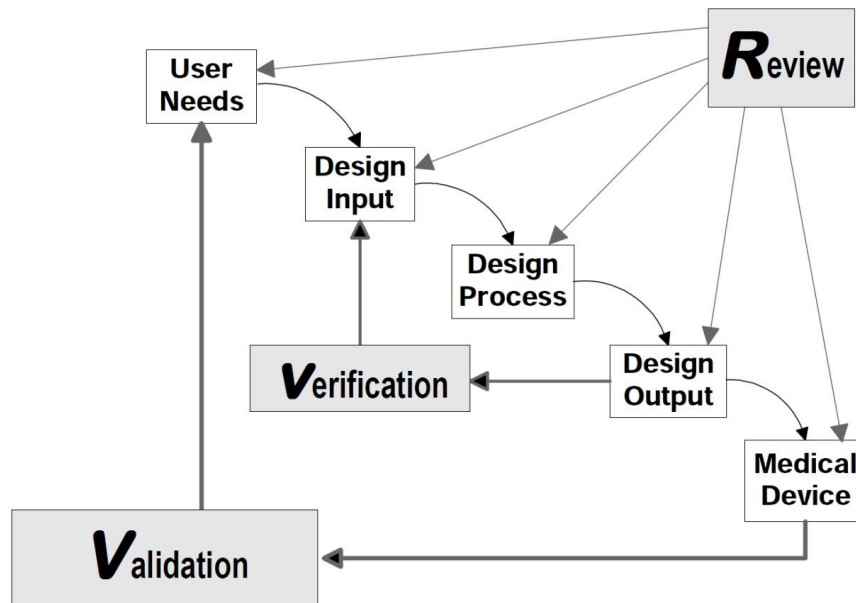


Figure 2.4 Water Fall Design Process¹¹ (FDA, 1997: p.3)

In this model, the design process starts with the development of the requirements, and when these requirements are met with the final design, then the product is transferred to the production. The main difference between this design process model and the design process models in general terms (discussed in 2.3.1.) is that this design process model does not have any feedback loops between previous stages. According to the FDA (1997), this detail is removed from the figure to emphasise the influence of the design controls¹² and their effect on the design process.

Design input is basically the requirements of the device, from which the design outputs are generated. As can be seen from the Figure 2.4, verification is an important phase of the process, which helps designers to see whether the design output meets the design input or not. It helps the designers to answer the critical question: ‘Are we building the right thing?’

Validation is more about the process and also encompasses the verification activities. The main intention is “to address whether devices produced in accordance with the design actually satisfy user needs and intended users” (FDA, 1997: p.4) and answer the question of: ‘Have we built the right thing?’

¹¹ The model is originally developed by Medical Devices Bureau, Health Canada and adopted by the FDA.

¹² Design controls for the Quality System Regulation for the U.S.; however the same procedures are also required for the quality system requirements of the European Market.

Design reviews are also highlighted in the process, and they are conducted at each main steps of the design process. A validation review is conducted before the device is transferred to production. (FDA, 1997)

The verification and validation activities are the main characteristics of the medical device design processes. On the other hand although home use medical devices are accepted as medical devices, according to Wiklund & Wilcox (2005), developing medical devices for lay people requires a different approach from the ones designed for professional users. As more medical devices migrate into patients' homes, an inclusive design strategy becomes more important for making products usable (Wiklund & Wilcox, 2005).

2.3.3 Inclusive Design

According to Dong (2004), universal design, design for all, transgenerational design, life span design, and design for diversity all share similar meanings with inclusive design; however, there is a common belief that inclusive design is a more suitable term for the UK context and value system. The definition of inclusive design is adopted from the British Standards Institution: “design of mainstream products and/or services that are accessible to, and usable by, people with the widest range of abilities within the widest range of situations without the need for special adaptation or design” (BSI, 2005: p.8).

By means of inclusive design products can be designed in a way which can be accessible by people who are likely to be excluded by designers during the design process, i.e. older people and disabled people. However, inclusive design does not mean designing one product which can address the needs of the entire population (BSI, 2005; Clarkson, et al., 2007).

Demographical changes towards ‘ageing’ and recognition of ‘disabled people’ are the two major drivers for inclusive design at the international level (Myerson, 2007). Due to designing for mass production in the second half of the 20th Century, an incorrect understanding was developed by designers towards standardising people to create the ‘universal type’ of user rather than understanding them as individuals (Coleman, et al., 2007). This resulted in shortcomings in terms of user and design compatibility, and inclusive design can

be seen as a response to this situation (Coleman, et al., 2007). Today companies have started to realise the benefits of designing products or systems which aim to include a wider variety of users, rather than designing products or systems focussed on just younger users. In terms of the business case, inclusive design can provide “a better understanding of changing consumer needs, lifestyles, expectations and aspirations which can expand the consumer base, extend product lifecycles and develop brand loyalty” (BSI, 2005: p.3). However, there is still a lack of awareness of inclusive design and its benefits (Dong, 2004).

Today we can find many assistive products on the market aiming to help people with impaired capabilities. These products help older people and people with disabilities to improve their quality of life, and adapt to an often challenging environment which is designed for a younger and able-bodied population. It is, however, recognised that these people frequently refuse to use these assistive products, simply because they act as reminders of their special condition (Wiklund & Wilcox, 2005).

According to Clarkson et al. (2007), inclusive design provides a better design by improving the product quality for a broad range of users. “By determining the capability demand of a product on users, it is possible to identify and quantify those who have difficulty with, or cannot use it” (BSI, 2005: p.2), therefore knowing the needs of users is crucial (Faulkner, 2000).

2.3.4 The Overall Summary of the Design Process for Home Use Medical Devices

No specific design process model for home use medical devices was identified in the literature; these devices share the characteristics of both the design process in general terms and the design process for medical devices. When designing home use medical devices, designers should be both aware of lay user requirements and regulatory the requirements of the target market in relation to medical devices. Therefore designing a home use medical device has its own challenges. These challenges are discussed in the next section.

2.4 Challenges for Developing Home Use Medical Devices

Designing medical devices for home environment brings many challenges; however, very little literature is available. FDA (2010d) identified three unique challenges for developing home use medical devices in their Medical Device Home Use Initiative. These are (1) care giver knowledge (2) device usability, and (3) environmental predictability.

- **Caregiver knowledge:** Medical devices can be too complex for lay people to operate safely and effectively without training (FDA, 2010d). This challenge was also mentioned by other researchers: Backinger & Kingsley (1993), Sawyer (1996), Kaye & Crowley (2000), Lewis (2001), Buckle et al. (2003), Patterson (2004), Fries (2006), Gupta (2007), BS EN ISO:14971 (2009a).
- **Device Usability:** FDA (2010d) divides this challenge into three aspects: (1) labelling and instructions, (2) individual needs of the users such as their capabilities or preferences, and (3) the obtaining of the device.

The information provided to the user with the device is critical (WHO, 2003). However this requirement is often poorly addressed by manufacturers, which results in problems with user-product interaction (Lewis, 2001; Patterson, 2004; Gupta, 2007; FDA, 2010d). It is important to provide efficient labelling and instruction manuals in order to ensure safe use of home use medical devices.

Lay users vary significantly in terms of their needs and capabilities (Sawyer, 1996; Kaye & Crowley, 2000; Fries, 2001; Buckle, et al., 2003; Wilcox, 2003; Wiklund & Wilcox, 2005; Shah & Robinson, 2008). When designing medical devices for lay use, the characteristics of lay users should be taken into account (see Section 2.4). Generally “users appreciate medical devices that are easy to use, if they also know the devices are safe” (Kaye & Crowley, 2000: p.14).

Another important factor is, the way in which users obtain home use medical devices. In some cases these devices may be supplied to the patients by physicians. However, according to FDA (2010d), generally physicians may not control which device is provided to the patient, because an equipment supplier provides these devices. They may prefer

certain brands or models. Today many over-the-counter devices can be purchased via the Internet without the need for a prescription. Although Internet purchasing is advantageous in many ways, such as more control over purchases or lower prices, it still carries associated risks, e.g. the quality and reliability of the product (Meadows, 2005; MHRA, 2008d; FDA, 2010d). According to the MHRA (2008d), one of the biggest disadvantages of purchasing healthcare products via the Internet is the increasing trade in fake or counterfeit medicines and medical devices. Due to the fact that home healthcare provides a lucrative market, Internet purchasers should be wary of illegal products.

- **Environmental Unpredictability:** Home use medical devices are used in uncontrolled environments (Gupta, 2007; FDA, 2010d). If the design of medical devices has problems, lay people can be easily confused during their interaction with the devices in the home environment (Lewis, 2001). Home environment can include risks which may affect the performance of the user or the product as well (Backinger & Kingsley, 1993; Lewis, 2001; FDA, 2010d). Some of the environmental effects that may possibly affect the users are electromagnetic interference, noise levels, and the presence of household pets, etc (FDA, 2010d).

Clarkson et al. (2004) argue that it is important that the designers and manufacturers of medical equipment take into account the various situations in which the products will be used; however, this is sometimes disregarded by designers. It is important to test medical devices in the intended environment of use (BSI, 2008c). Therefore home use devices should be tested in the home environment and possible environmental constraints (e.g. insufficient space) should be simulated as well (Sawyer, 1996).

- **Other Challenges:** There are also other challenges identified by Gupta (2007) in his research. A total of 10 issues are identified (including the three challenges identified by FDA), i.e. business issues, technological issues, design and development issues, regulatory issues, manufacturing issues, point-of-provision issues, use issues, support issues, liability

issues and disposal issues. These challenges cover the full life-cycle of the product from development to disposal.

On the other hand, as mentioned before, designers should be aware of the regulatory requirements for medical devices when designing such a device for home use. The next section will summarise the regulatory requirements of the European market for medical devices and explore the specific regulations for home use medical devices.

2.5 Medical Devices vs. Home Use Medical Devices: Regulations

Although home use medical devices are used by lay people, they are a type of medical device; therefore they must go through medical device regulations for the target market. Different countries may have their own regulations, e.g. Australia, Japan, Canada, China, European Union and United States are some of the important markets with their own regulatory frameworks. This section focuses exclusively on the regulatory framework of the European Union.

2.5.1 Medical Device Regulations for the European Union

Medical devices are regulated differently in the U.S. and in the European Union. The European regulatory system also covers the UK market. Although there have been attempts to harmonise the approval processes and regulations for both the European Union and the US, major differences still exist, and a device must fulfil both the EU and the US regulatory requirements in order to enter both of the markets (Shefelbine, et al., 2002).

The regulatory framework for the EU was harmonised in 1990s (EC, 2010a). According to European Commission (EC, 2010a) medical devices are regulated by three main directives:

- Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD)
- The Council Directive 93/42/EEC on Medical Devices (MDD)
- Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD)

There is also a revision directive, amending Council Directive 90/385/EEC (AIMDD) and the Council Directive 93/42/EEC (MDD):

- Directive 2007/47/EC

According to MHRA (2006a), the AIMDD covers all powered implants or partial implants that are left in the human body such as pace makers, where the MDD covers a wide range of medical devices, e.g. first aid bandages, X-Ray equipment, ECG and heart valves. On the other hand IVDMD:

“...covers any medical device which is a reagent product, calibrator, control material, kit, instruments, apparatus, equipment or system intended for use in-vitro for the examination of specimens, including blood tissue donations, derived from the human body” (MHRA, 2006a: p.2), e.g. pregnancy test kits and Hepatitis B test kits.

It is a core requirement to meet these three directives to be eligible for a CE mark, allowing the device to be sold in the EU. According to these three directives there are essential requirements to meet, divided into two groups. The first one is the ‘*general requirements*’ for all Directives, and the second one is ‘*design and manufacturing requirements*’ for the IVDMD and ‘*requirements regarding design and construction*’ for both AIMDD and MDD. Although the essential requirements are set out separately for each directive, they share similarities regarding the general requirements, and can be summarised as:

- Devices must be designed and manufactured so they will be safe during their intended use, and any risks associated with their intended use must be acceptable when weighed against the benefits to the patient.
- Devices must be manufactured in such a way that is suitable for the intended purpose.
- Devices must not compromise the patient or the user and, where applicable, any third party during the lifetime of the device as indicated by the manufacturer.
- Devices must be designed, manufactured and packed carefully in order to not be adversely affected under storage and transportation conditions.

(EEC, 1990; EEC, 1993a; EC, 1998)

Requirements regarding design and manufacturing/construction differ for each directive due to the type of medical device and they focus on coverage of the products. However, all the three directives highlight the significance of packaging, and providing efficient labelling and instructions. The importance of the ergonomics characteristics of the product is also emphasised in the AIMDD and the MDD.

Classification of medical devices in the EU and conformity assessment

If the device corresponds to the definition of a ‘medical device’ as suggested by the MDD 93/42/EEC, then it is subject to the device classification. However, the classification does not cover active implantable medical devices and in-vitro diagnostic devices because they are the subject of separate directives (EC, 2001).

“The classification rules are based on terms related to duration of contact with patient, degree of invasiveness and the part of the body affected by the use of the device” (EC, 2001: p.6).

There are 18 rules defined in the MDD. The classification is based on the device and the correspondence between these rules. A product can be subject to more than one rule and the classification of the device can differ. The classification is designated in three main groups as (EEC, 1993a):

1. **Class I – Low risk devices:** (e.g. according to the ‘Rule 1’, covers all non-invasive devices unless any other rule applies)
2. **Class II – Medium risk devices:** Medium risk devices are separated into two groups as **Class IIa** (e.g. many invasive devices intended for short-term use and X-ray machines), and **Class IIb** (e.g. many implantable devices and long term surgically invasive devices)
3. **Class III – High risk devices:** (e.g. implantable devices and long term surgically invasive devices which can have a biological effect or to be used in direct contact with the heart)

The device is classified with respect to its relevance with the strictest rules; therefore the characteristics of the device must be taken into account carefully

(EEC, 1993a). The manufacturer can firstly consult a *notified body*¹³ about the classification. However, if there is no consensus between the manufacturer and the Notified Body regarding the classification, then the matter shall be referred to the Competent Authority which designated the Notified Body (EEC, 1993a; EC, 2001; MHRA, 2006d).

After a manufacturer determines the classification of their product, then the product should go through the conformity assessment procedure. The routes for the conformity assessment differ regarding the classification of the product. In this phase a technical documentation of the product must be prepared, which includes documentations such as, a general description of the product, design drawings, planned methods of manufacture, the results of the risk analysis, etc (EEC, 1993a; EC, 1998).

In some cases a manufacturer may be required to apply to a Notified Body for certification (MHRA, 2008a). All Notified Bodies have an identification number and if they have been involved in a conformity assessment, their numbers must be applied below the CE mark (MHRA, 2007). It is not an obligation for manufacturers to apply to a Notified Body in the same national market, since regardless of the Member State in which the Notified Body is established, the certificated product can be freely marketed anywhere in the EU (MHRA, 2006c).

“The CE mark means that a manufacturer is satisfied that his product conforms with the relevant Essential Requirements in the Directives and that it is fit for its intended purpose” (MHRA, 2007: p.2).

However, other products are exempted from the CE mark:

- Custom-made devices¹⁴
- Devices undergoing a clinical investigation
- In vitro diagnostic medical devices for performance evaluation (MHRA, 2007)

¹³ “A Notified Body is a certification organisation which the national authority (the Competent Authority) of a Member State designates to carry out one or more of the conformity assessment procedures described in the annexes of the Directives” (MHRA, 2006c: p.1).

¹⁴ According to MDD (EEC, 1993a: p.6) a ‘custom-made device’ means “...any device specifically made in accordance with a duly qualified medical practitioner’s written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient.

2.5.2 Regulatory Requirements Regarding the Instruction Manuals of Medical Devices

Both of the Medical Devices Directives (i.e. MDD and IVDMD) have specific sections regarding the information provided by manufacturers in the ANNEX 1 ‘Essential Requirements’. The requirements, in particular for preparing instructions for use, are identified in these two Directives: Section 13.6 in the MDD and Section 8.7 for the IVDMD. According to the directives the ‘intended purpose’¹⁵ of the device should be obvious, however if not, then the manufacturer must clearly state in the instruction manuals or on the label (EEC, 1993; EC, 1998). It was also highlighted in the Directives that the information should be easily understood.

The Directives state that, the symbols and colours used in the instruction manuals must comply with the harmonised standards. A number of standards were identified covering particularly the instruction manual development requirements for medical devices for the European market:

- EN ISO 18113-5:2009 – Information supplied by the manufacturer (labelling) – Part 5: In-vitro diagnostic instruments for self testing (BSI, 2010b)
- EN ISO 18113-1:2009 – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements (BSI, 2009b)
- EN 1041:2008 – Information supplied by the manufacturer of medical devices (BSI, 2008b)
- EN 980:2008 – Symbols for use in the labelling of medical devices (BSI, 2008d)
- BS ISO 15223-2:2010 – Symbols to be used with medical device labels, labelling and information to be supplied – Part 2: Symbols development, selection and validation (BSI, 2010c)

These standards aim to help manufacturers to fulfil the Essential Requirements of the Directives regarding the information provided by the manufacturer.

¹⁵ “The use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials” (EEC, 1993; EC, 1998)

2.5.3 Regulatory System for the UK

In the UK, the Medicines and Healthcare Products Regulatory Agency (MHRA) is responsible for regulating medical devices. MHRA "...is a government body which was set up in 2003 to bring together the functions of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA)" (MHRA, 2008d: p.2). The MHRA is the Competent Authority for the UK. According to the MHRA (2008c), the roles of the Agency regarding medical devices can be summarised as:

- Being responsible for ensuring that medical devices work, and are acceptably safe.
- Ensuring that any risk inherent in the product is outweighed by the benefits to patients and the public.
- Taking the necessary action to protect the public promptly, if there is a problem with any devices.
- Aiming to make as much information as possible publicly available.
- Enabling greater access to products, and the timely introduction of innovative treatments and technologies that benefit patients and the public.
- Encouraging the users of the products to inform them about any problems with the devices, that they can investigate and take any necessary action.

(MHRA, 2008c)

The three EC Medical Devices Directives were consolidated and implemented into UK law as Statutory Instruments No. 618 Medical Device Regulations 2002 (MHRA, 2009c). This came into force on the 13th June 2002 (OPSI, 2002). However, there are three other regulations; Statutory Instruments 2003 No. 1697, Medical Devices Regulations 2007 No. 400 for amending the Medical Device Regulations 2002, and Medical Device Regulations No 2936 for transposing Directive 2007/47/EC into UK law which came into force in March 2010 (MHRA, 2009c). MHRA regulates medical devices in accordance with these four regulations. MHRA is also responsible for designating the Notified Bodies and monitoring them through surveillance audits at intervals (MHRA, 2008b).

2.5.4 Standards for Medical Devices

As can be seen from the Directives, they cover a wide range of medical devices, involving many levels and types of technologies. The essential requirements identified in the directives set the overall targets must be met by manufacturers (MHRA, 2006b). According to GHTF, “international consensus standards are a tool for harmonizing regulatory processes to assure safety, quality and performance of medical devices” (GHTF, 2008: p.5). Therefore, European standards organisations have been mandated by the European Commission to prepare European standards, since the standards will assist manufacturer by setting out:

- Objective definitions about the necessary requirements for specific products (MHRA, 2006b)
- Practical means which shows the manufacturers that their products fulfil the Essential Requirements (MHRA, 2006b).

A product can be subject to more than one standard hence the cooperation between the manufacturer and the Notified Body can result in reduction of the risks that the product might not comply with the Essential Requirements (MHRA, 2006b).

There are three types of Harmonised Standards for addressing the Essential Requirements of the device:

1. **Horizontal (Basic) standards:** Cover and applicable to a wide range of medical devices such as standards concerning risk management or the quality management system for the manufacture of medical devices.
2. **Semi-Horizontal (Group/Family) Standards:** Cover the requirements for a similar family of medical device, e.g. standards concerning sterile medical devices.
3. **Vertical (Product) Standards:** Cover requirements for a particular type of medical device, such as for blood glucose meters for self testing.

(MHRA, 2006b; GHTF, 2008)

Figure 2.5 summarises the coverage and application of the three types of Harmonised standards.

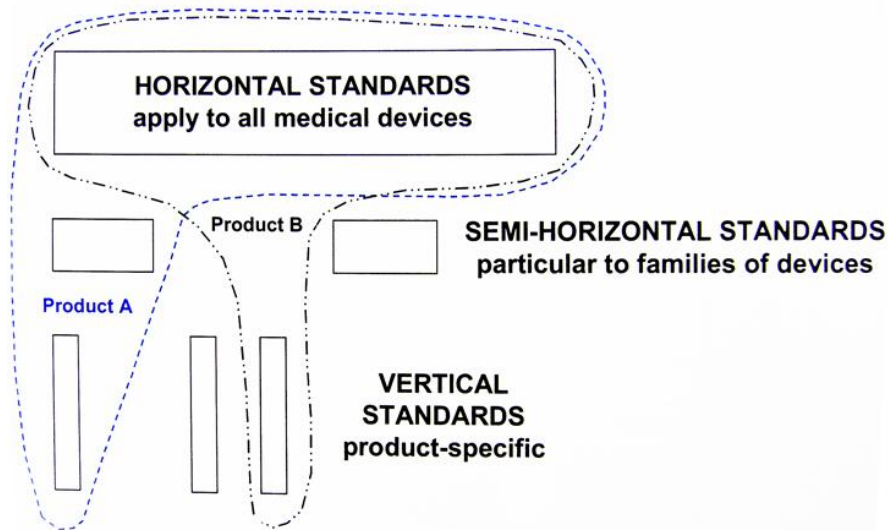


Figure 2.5 Applications of the three Harmonised Standards (Shefelbine, et al., 2002: p.29)

There are three main international standardisation organisations for medical devices, i.e. the International Organisation for Standardisation (ISO), the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU) (WHO, 2003). In addition a country may have voluntary standards bodies, which are normally coordinated and accredited by an official nation organisation (WHO, 2003). The European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) are the European standards organisations, and they are working together with national standard bodies [e.g. the British Standards Institution (BSI)] to set up standards for various products or product groups (MHRA, 2006b).

2.5.5 Regulations for Home Use Medical Devices

Medical device regulations cover all types of medical devices. During the literature review and the background research regarding the regulatory framework for medical devices in the Europe and the U.S., no specific regulations were found specifically for home use medical devices. This finding is consistent with that by Gupta (2007).

However, there is evidence of a developing understanding of home use medical devices, particularly in the U.S. In April 2010 FDA launched the ‘Medical Device Home Use Initiative’. The initiative is a thorough document including descriptive information about the background of such devices and further actions

which will help to address challenges associated with the use of medical devices in the home environment. The further actions are identified as: (1) establishing guidelines for manufacturers of home use devices; (2) developing a home use device labelling repository; (3) partnering with home health accrediting bodies; (4) enhancing postmarket oversight; and (5) increasing public awareness and education (FDA, 2010d).

According to the initiative (FDA, 2010d), the guidance will include recommendations of the actions that manufacturers should take to receive FDA's approval. This will also include recommendations of postmarket surveillance identifying the adverse events that can occur in the home environment.

FDA also has other more specific documents focusing on the use of medical devices in the home environment such as, Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory and Home Use (FDA, 2009d). They announced a workshop entitled 'Medical Device Use in the Home Environment Workshop: Implications for the Safe and Effective Use of Medical Device Technology Migrating into the Home'. The purpose of the workshop was: "to solicit information from primary and secondary healthcare manufacturers, professional societies, patient advocate groups and patients on the challenges surrounding medical device technology in the home environment" (FDA, 2010b).

Although in Europe such activities are less obvious, nevertheless through the amendments it is evident that an understanding of home use medical devices is developing. These devices are the most directly mentioned as, 'device for self testing' in the In Vitro Diagnostic Medical Devices Directive, and defined as "any device intended by the manufacturer to be able to be used by lay persons in a home environment" (EC, 1998: p.7). It can also be seen that the users of the device are stated as 'lay persons'. Moreover in the ANNEX I the 'requirements for self-testing' are identified as a part of the Essential Requirements, which highlights the importance of taking into consideration of the skills and capabilities of the users, as well as the usage environment.

After the launch of the Directive 2007/47/EC (EC, 2007), the Council Directive 93/42/EEC on Medical Devices (EEC, 1993b) has been improved in terms of

taking into consideration of lay users. The Directive 2007/47/EC amended the Council Directive 93/42/EEC which resulted in the change in the Essential Requirements in ANNEX I towards emphasising the diversity of the users, as well as the context of use:

“- reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and
- consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users)”
(EEC, 1993a: p.25).

The awareness of home use medical devices is increasing and its reflection can be seen through the improvements in the regulatory framework of medical devices. According to the approach so far adopted by Europe, it seems as if rather than generating specific regulations for home use medical devices, they are improving particular sections of the existing directives through amendments, in order to cover the regulation of such devices. On the other hand the U.S. has adopted a more focused approach such as forming a committee for home use medical devices and establishing specific guidance.

2.6 Assisting Designers during the Design Process of Home Use Medical Devices

According to Press & Cooper (2003), although the designers do not like to consider themselves as researchers, they nevertheless frequently conduct research. They argue that designers' research involves three main areas, i.e. searching for understanding, ideas and solutions.

Based on the information presented in this chapter, designers may need help in understanding a number of issues when designing home use medical devices:

- **Unique nature of home use medical devices:** although these products are used as everyday consumer products, they are medical devices. Therefore designers should understand their unique nature.

- **Lay users and their characteristics:** home use medical devices are used by lay people whose characteristics differ significantly from professional users.
- **Unique design process:** the design process of home use medical devices shares the characteristics of the processes used for everyday consumer products and medical devices. Also, due to the variety of lay users, home use medical devices should be designed inclusively.
- **Regulatory requirements:** home use medical devices must fulfil the medical device regulations of the target market; therefore designers should be aware of the relevant regulatory requirements during the design process.
- **Environmental problems:** Home use medical devices are used in uncontrolled environments which are often unpredictable.
- **Information provided with the device:** lay users may not have sufficient knowledge to operate their devices correctly, therefore the information provided with the device has a direct effect on the devices' usability. Besides, there are specific regulatory requirements regarding the information provided with medical devices.

These issues highlight different kinds of informational requirements of designers when designing home use medical devices. However it is necessary to understand the appropriate manner in which to support designers regarding these issues.

2.6.1 How to Support Designers

Persad et al. (2007: p.119) argue that, “designers require information and tools that could enable the evaluation of design concepts throughout the design process, from requirements specification and conceptual design through to prototyping and final product development.” They also require a thorough understanding of the context in which they are designing (Press & Cooper, 2003). One of the ways to provide assistance for designers during the design process is providing tools which may support them in the implementation of a new approach to the process; however, these tools should be both informative

and inspiring (Nickpour & Dong, 2010). During the literature review a number of relevant tools were identified, including:

- **The Inclusive Design Toolkit:** www.inclusivedesigntoolkit.com, also available in a book format (Clarkson et al, 2007).
- **Design with Intent:** a toolkit with a card deck of 101 cards which aims to help designers to design products “...that is intended to influence or result in certain user behaviour” (Lockton, 2010). The card deck can be downloaded from a website¹⁶.
- **HADRIAN:** a software-based inclusive design tool which is used with a computer-aided human modelling system SAMMIE (Marshall et al., 2010).
- **The Spidergram Tool for Home Use Medical Devices:** The tool allows the product developer to assess the measure of performance of a medical device against a number of issues identified. This tool is largely aimed at manufacturers (Gupta, 2007).

The review of existing tools suggests that assistance to designers may take a wide range of formats: websites, books, software, physical tools/toolkits. This research also aims to provide assistance for designers, specifically during the design process of a home use medical device. However before selecting the format of the assistance, it is important to understand designers’ preferences for using information.

2.6.2 Designers’ Information Usage

Designers frequently use a variety of information sources in a wide range of formats, including their own experiences and imaginations (Goodman et al., 2007). The previous section listed some examples of design support tools; however, caution needs to be exercised when developing such tools, as Law et al has pointed out that “people creating a design resource can fail to meet the needs of their end-users without careful systematic study of those needs” (Law et al., 2008, p:33).

¹⁶ Derived from: http://www.danlockton.com/dwi/Main_Page#What_is_Design_with_Intent.3F
(Last accessed: 22/04/11)

Mieczakowski et al. (2010) argues that, although designers are aware of some of the tools available, they do not use any of them systematically because they are not able to meet the requirements of designers in a way in which they intend. This problem was also mentioned by Law et al. (2008, and 2010) and Burns et al. (1997). Law et al. (2008) investigated the usability aspect of eight selected universal design resources through a heuristic evaluation study, where they found that the majority of those resources were not developed with the designers' perspectives in mind. Besides, their study suggested that the majority of those tools were found to be inadequately designed in terms of supporting the typical design process and design psychology (Choi et al. 2006; Law et al., 2008). The study carried out by Burns et al. (1997) showed that human factors handbooks are rarely used by designers. They argue that designers often think that the amount of time and effort spent searching for the human factors information in these handbooks is not always worthwhile. Burns et al. (1997) also suggest ways to overcome this barrier: i.e. reducing the cost of time and effort to find the relevant information or tailoring the documents to a single industry or a design problem. When developing support for designers, it is necessary to investigate and identify for which phases of the design process designers require information, what format, and the content of the information (Carthey, 2007).

These aspects are considered in this PhD study when developing design support for designers, especially in terms of understanding designers' requirements (Chapter 5) and selecting a format that would reduce the cost of time and effort to find the relevant information, as well as tailoring the information to a specific industry (i.e. the home user medical device industry).

2.7 Summary

In this chapter a wide range of topics were explored in relation to the aim of this research. The literature review and synthesis have provided preliminary answers to the research questions.

- **Who are lay users and what are their characteristics?**

It was found that, although the term 'lay users' was frequently used by several researchers, very few attempts were made to provide a comprehensive definition of the term. In addition the characteristics of

lay users were only defined in comparison to professional users. Therefore the extent to which these characteristics were applicable, when lay users were no longer compared with professional users, was not clear. It was also found that lay users were very diverse. Through classifying the lay user types into (1) younger and able bodied users, (2) older users and (3) disabled users, typical characteristics of each user type could be identified.

- **What are the challenges designers face in developing home use medical devices?**

The design process of a home use medical device shares the characteristics of both a design process in general terms and the specific design process of medical devices. Home use medical devices require designers to develop knowledge of the diversity of the lay users and sensitivity to the uncontrolled environment in which the devices may be best established for effectiveness of use. Also, because home use medical devices are accepted as medical devices, they should fulfil the regulatory requirements of the target market.

- **How to support the design of home use medical devices?**

As home use medical devices have to conform to medical device regulations and directives, designers and manufacturers must be made aware of existing regulatory frameworks. Specific design process models exist for medical devices, but not for home use medical devices. A design process model incorporating inclusive design strategy may be useful. However, in order to support designers, their needs should be carefully identified. The tools provided for designers' use often fail due to insufficient understanding of designers' needs.

In order to gain an in-depth understanding on the issues identified for each of the research questions, specific studies were carried out. The next chapter will discuss the research methodology and the methods used in this PhD research.

CHAPTER 3: RESEARCH METHODOLOGY AND METHODS

Research is a process of accessible disciplined inquiry and the process is usually shaped by three simple questions: what, why and how (Gray & Malins, 2004). In order to address the first two questions (i.e. what and why), the background of the research subject was investigated in Chapter 1 and the relevant literature was reviewed in Chapter 2. Finding an appropriate research methodology concerns the third question: how. This chapter particularly focuses on this question and proposes to describe the overall research methodology and methods employed during this PhD research. The objectives are:

- Understanding different research approaches
- Identification of the appropriate methodology for this research
- Exploration of the appropriate methods to be employed

Therefore, in this chapter, the research type and its epistemological standpoint are identified, and the research methodology and methods are discussed in detail.

3.1 Type of Research

It is essential for researchers to adopt an appropriate methodology if their research is to be successful. According to Sarantakos (2005), the researcher has direct access to the construction of research design, the definition of purpose and motives, the collection and analysis of the sources of information and the choice of the underlying paradigm and methodology.

As discussed in Chapter 1, three research questions were identified and in order to best address these questions several studies were carried out; hence it was important to understand different types of research methods. In this section such diverse methods were discussed in order to formulate the appropriate methodology in accordance with the research questions which were indicated in Chapter 1.

3.1.1 Qualitative Research, Quantitative Research and Mixed Method

Two types of research strategies are frequently mentioned in the literature, i.e. qualitative research and quantitative research (Vaus, 2001; Brannen, 2004;

Bryman & Teevan, 2005; Creswell, 2009). These research types differ significantly from each other, not only in terms of their nature but also the data collection techniques used during the research.

Qualitative research usually investigates words, rather than quantification in the collection and the analysis of the data (Robson, 2002; Gray 2004; Bryman & Teevan, 2005). “The objective is to take descriptions of people’s behaviour and thoughts to illuminate their social meanings” (Henn, et al., 2006: p.176). Creswell (2009) argues that, qualitative research starts with a research question, not a hypothesis or objectives, because the intent is to explore the central phenomenon. In nature this type of research predominantly involves a theory building rather than a theory testing approach (Bryman & Teevan, 2005; Henn, et al., 2006). Interviews and participant observation are examples of qualitative data collection methods.

On the other hand quantitative research involves numbers and statistics during the collection and the analysis of the data (Bordens & Abbott, 2008). Different to qualitative style, quantitative research starts with ‘quantitative research questions¹⁷, ‘hypothesis’ or ‘objectives’ (Creswell, 2009) and it necessitates a theory testing approach in the research (Bordens & Abbott, 2008) where the researchers adopt the theory-then-research approach (Henn, et al., 2006). The most common quantitative data collection methods are surveys¹⁸ and experiments.

However, it is also argued that this distinction between qualitative research and quantitative research is not useful and even false, because a study may involve both these research strategies at the same time (Bryman & Teevan, 2005). Therefore it was also mentioned in literature that a mixed method approach can be used, including both qualitative and quantitative methods (Brannen, 2004; Creswell, 2009). Creswell (2009) argues that mixed methods research provides the best information for both research questions and hypotheses.

¹⁷ According to Creswell (2009), quantitative research questions “inquire the relationships among variables that the investigator seeks to answer” (Creswell, 2009: p.233)

¹⁸ According to Henn et al (Henn et al., 2006), sample surveys are used by researchers in two circumstances: to provide statistical information on a particular issue or to test the robustness of an existing theory

3.1.2 Deductive Theory/Inductive Theory

A theory has been defined by Kerlinger (1986: p.9) as:

“A set of interrelated constructs (concepts), definitions, and propositions that present a systematic view of phenomena by specifying relations among variables, with the purpose of explaining and predicting phenomena”.

Two types of theory mentioned in literature are ‘deductive theory’ (theory testing) and ‘inductive theory’ (theory building) (Vaus, 2001; Gray, 2004; Bryman & Teevan, 2005; Creswell, 2009). In deductive theory, the hypothesis is formed and tested on the basis of an existing theory (Bryman & Teevan, 2005). Deductive theory is mainly associated with quantitative research methods (Bryman & Teevan, 2005). According to Sim & Wright (2000: p.11), in the deductive approach, “...the researcher draws certain predictions from theoretical propositions contained theory and then collects data to see if they support these predictions”.

On the other hand, according to Sim & Wright (2000), the exploratory research which involves qualitative data collection generally tends to be inductive. Inductive theory starts with observation and attempts to make sense of these observations in order to derive the theory from them (Vaus, 2001). The main purpose is to formulate and introduce a theoretical framework of understanding to an unexplored or poorly formulated area (Sim & Wright, 2000). The inductive theory is mainly associated with a qualitative approach (Bryman & Teevan, 2005).

According to Vaus (2001), although these two types of theories are frequently presented as two separate research modes, they should be part of an ongoing process, and Bryman & Teevan (2005) suggest accepting them as tendencies rather than choosing just one of them.

3.1.3 Characterising This Research

As mentioned earlier this research involves understanding the two critical stakeholders of home use medical devices, i.e. lay users and designers of such devices; and it aims to come up with a practical support for designers, in an effort to improve product quality for lay users.

During the literature review no specific guidance for assisting designers when designing home use medical devices has been identified. In particular the third research question (How to support the design of home use medical devices?) pointed out an unexplored area. The literature review also suggested that characteristics of lay users are frequently inferred or assumed by comparing them with the professional users, which suggests lack of understanding and investigation in this area.

All these facts point to the value of deriving research questions (which were mentioned in Chapter 1, Section 1.5) rather than testing hypotheses, and taking an inductive (theory building) rather than theory testing approach. In addition this research takes a qualitative research approach because the research questions point out an exploratory process. Although the overall research is largely qualitative, some of the studies carried out also involve quantitative methods. The summary of methods used for each study can be found in Section 3.10, Table 3.1. The next section discusses the philosophical standpoint of this research.

3.2 Epistemology

According to Crotty (2004: p.3), epistemology is “the theory of knowledge embedded in the theoretical perspective and thereby in the methodology”. It is important to define the epistemological perspective because the researcher requires knowledge of philosophy to design the research and to clarify the associated issues (Gray, 2004).

There are two main theoretical perspectives discussed frequently in social research; i.e. positivism and interpretivism. Positivism is closely linked to objectivism (Crotty, 2004; Gray, 2004), and for social sciences it means that the research should be carried out with similar methods to those used in natural sciences, e.g. chemistry or biology (Henn, et al., 2006). It argues that the reality can be directly observable and can be perceived through senses (Gray, 2004; Henn, et al., 2006), and there is one single objective reality irrespective of one’s individual values, attitudes or perspectives (Sim & Wright, 2000). A positivist approach is highly associated with quantitative approach, and mainly involves the statistical testing of given theories (Henn, et al., 2006).

On the other hand there are researchers who argue that human beings are complex; they may think through different courses of action and respond differently on the basis of their interpretations and ideas (Henn, et al., 2006). In other words human beings conflict with the world of nature, so the social world requires a different research procedure (Bryman & Teevan, 2005). This is called interpretivism which is a major anti-positivist stance in research. Interpretivism, which is closely linked to constructivism, “asserts that natural reality (and the laws of science) and social reality are different and therefore require different kinds of method” (Gray, 2004: 20). The interpretive approach is highly associated with qualitative research methods and theory building (Henn, et al., 2006).

This research is social research because all the major studies involved investigation of human beings and their attitudes regarding specific aspects of this research. As discussed before, this research mainly involved qualitative studies and was theory building research, because:

- Although the study with lay users involved observation, the data derived from observation was supported by the comments given by the participants during the user trials, where these comments reflected their own perspectives. In addition one of the purposes of the study was to include different types of lay user groups in order to reflect the diversity of lay users rather than accepting them as one single user group.
- Although numerical information was collected during the questionnaire survey with designers, the survey included open-ended questions where the respondents mentioned their own views about home use medical devices.
- During the interviews designers evaluated the first draft of the guidance for designing home use medical devices in accordance with their own perspectives.

As can be seen this research greatly depends on the thoughts and attitudes of human beings; therefore the epistemological standpoint of this research was towards constructivism and an interpretivist theoretical approach was adopted.

3.3 Design Research Methodology

In order to choose the appropriate research methodology for this research, a number of research models have been investigated from both social research and design research, including: The Sequential Model of Research [Howard & Sharp (1983), cited in Gill & Johnson (2010)], The Cyclical Model of Research Process (Frankfort-Nachmias, et al., 1996). Design Research Methodology (Blessing, et al., 1995), the Spiral of Applied Research Methodology (Eckert, et al., 2003).

One of the main purposes of design research is to improve the design process (Blessing, et al., 1995; Eckert, et al., 2003). This research was also focussed on the design process, particularly for home use medical devices. For the purposes of this research Blessing et al.'s (1995) Design Research Methodology (DRM) was found to be the most suitable model. The DRM has been widely accepted and has been directly employed or partly modified and used by several design researchers (Ahmed, 2000; Dong, 2004; Cardoso, 2005; Gupta, 2007). The DRM is composed of four main stages: criteria, descriptive study 1, prescriptive study, and descriptive study 2.

- **Criteria:** DRM starts with the identification of the success criteria, which points out the aim of the research (Blessing, et al., 1995). The aim of this research is to provide guidance for designers particularly for home use medical devices. Therefore the success criteria are: (1) making the process easier for designers by providing them with necessary information, and (2) improving the final product quality which better addresses the need and expectations of lay people. The success criteria formulated the research questions which were described in Chapter 1, Section 1.5.
- **Descriptive Study 1:** According to Blessing et al. (1995), the purpose of the Descriptive Study 1 is to understand the criteria broadly in order to help the researcher to identify the influencing factors on the success (Blessing, et al., 1995). For this research three aspects of home use medical devices were investigated with regards to the success criteria: (1) the currently available information for designers about home use medical devices; (2) lay users and their characteristics; (3) designers' requirements when designing home use medical devices. For this purpose

three separate studies were carried out in order to identify the influencing factors for this research. These studies will be explained and discussed broadly in chapters 2, 4 and 5.

- **Prescriptive Study:** According to the DRM, after understanding the influencing factors on the success criteria, a prescriptive study is carried out to develop a method or a tool to support the problem definition with reference to the results of the ‘descriptive study 1’ (Blessing, et al., 1995). For this research the outcome of the prescriptive study is the first draft of the guidance which was prepared to support designers when designing home use medical devices. The development of the guidance will be explained and discussed in Chapter 6.
- **Descriptive Study 2:** The aim of the ‘descriptive study 2’ is to test whether the support developed in the prescriptive study addresses the identified factors as proposed, as well as to see if it contributes to success (Blessing, et al., 1995). In this research the first draft of the guidance was evaluated by designers in order to assess whether they found the guidance useful, and to identify how it may be further improved. The results of the designers’ evaluation will be explained and discussed in Chapter 7.

Figure 3.1 summarises the studies carried out as a part of this PhD research with reference to Blessing et al.’s DRM.

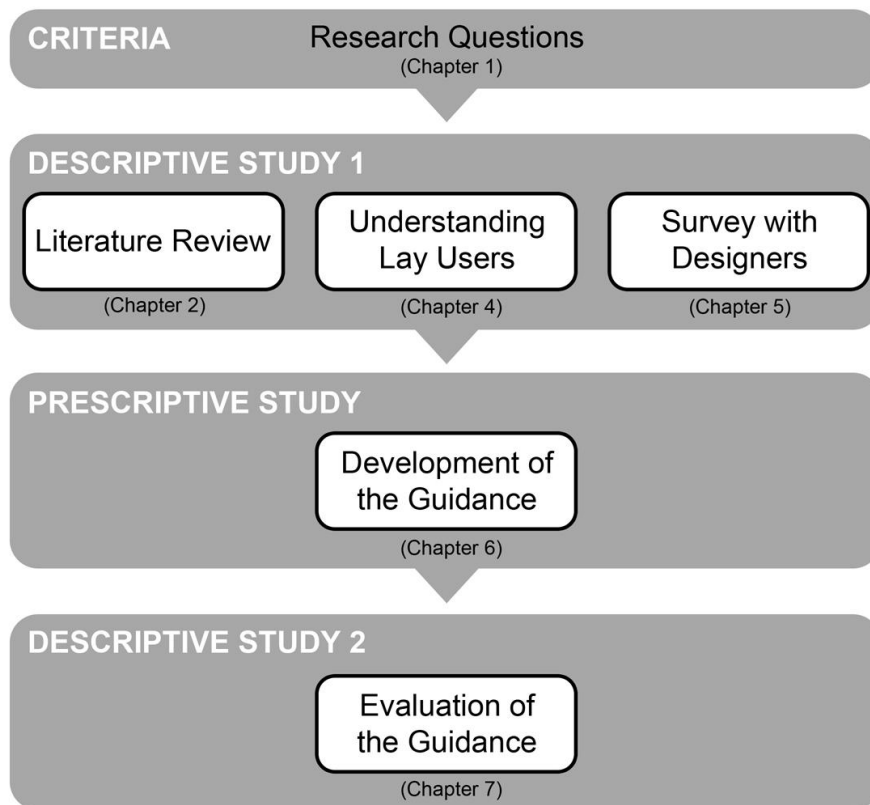


Figure 3.1 Research methodology framework adopted

The methods used at each stage were taken from social sciences, and they will be briefly explained in the following sections. However, detailed information about the study set-ups, sampling of the participants and the analysis of the data can be found in the relevant chapters (refer to Figure 3.1).

3.4 Methods Used in the Descriptive Study 1

Descriptive study 1 consists of three separate studies: ‘Literature Review’, ‘Understanding Lay Users’, and ‘Survey with Designers’.

3.4.1 Understanding Lay Users

This study involves two data collection methods: observation as the main data collection method, and questionnaires as an assistive method.

Observational study

The purpose of this study was to investigate the characteristics of lay users when using products. The study was largely descriptive, so observation was used as a primary method for capturing the outputs of the users (Robson, 2002). Direct observation is a valuable method because it “provides a shared resource to

overcome gaps between what people say they do and what they, in fact, do” (Jordan & Henderson, 1995: p.50). Observational studies enabled the researcher to identify what people actually did during their interaction with the selected devices for the study. This method also reduces the amount of assumptions made by the investigator about the behaviour of real users (Keates & Clarkson, 2003) and it is highly effective where the aim is to identify user difficulties with products (Popovic, 1999; BSI, 2005).

There are different approaches in the observational studies regarding the role of the researcher during the study. For this study mainly¹⁹ the researcher adopted ‘the observer as participant’ role, whereby he stayed with the participants during the study. However, he clarified his role to the participants from the outset, saying that he would only observe and would not actively take part in the study (Robson, 2002; Sapsford & Jupp, 2006).

Observations were captured by a video camera. According to Loizos (2007), where human actions are complex and difficult for a single observer to describe comprehensively, video technology offers a viable method of recording. This method enables the investigator to capture the details which may be unconsciously filtered from our perception (Gray & Malins, 2004). The play and replay features of both sound and vision, even frame by frame, are also other advantages of video recording (Gray & Malins, 2004). Video recording gives the opportunity to capture facial expressions which reflected the feelings of the participants during the study.

Assistive questionnaires

Questionnaires were used as an assistive method for collecting data to support video recordings. As suggested by Gillham (2000), questionnaires are rarely adequate as a research method on their own; using a range of methods gives opportunities to build a more comprehensive picture. Questionnaires were used to collect data where the video recording method was not sufficient to provide specific type of information. Two questionnaires were prepared for the user

¹⁹ For the younger participants ‘the complete observer’ method was used, where the researcher left the participants alone in the room and had no interaction with them during data collection (Sapsford & Jupp, 2006). The study set-up and methodological differences between the user groups will be explained in detail in Chapter 4.

observation study; pre-questionnaire and post-questionnaire. The pre-questionnaire was used to collect general information from the participants and the post-questionnaire was prepared to collect information about their experience during their interaction with the selected products for the study, as well as their thoughts and preferences of the products that they use daily. The preparation of the assistive questionnaires used in this study will be described in more detail in Chapter 4.

3.4.2 Survey with Designers

According to Gray (2004), the main purpose of conducting surveys is to generalise the information for a population group, which involves a systematic data collection. For the purposes of this study, a structured self-administered online questionnaire, where the respondents filled in the questionnaire by themselves was used (Robson, 2002; Gray, et al., 2004; Bryman & Teevan, 2005; Sapsford & Jupp, 2006).

There were two advantages of this method; (1) it enabled the researcher to send the questionnaire to as many designers as possible; (2) it was less time-consuming for the designers, who often have a very busy schedule. It also allowed comparison between the designers who have experience in designing home use medical devices and those who do not.

As discussed by Robson, the complexity of preparing a self-administered questionnaire is to keep the time taken to fill it in to a minimum (Robson, 2002). During the preparation of the questionnaire, a considerable amount of effort was expended on collecting the necessary information by using a minimum number of questions. Another challenge was to identify the best method by which to prepare and send the questionnaire to designers. For this purpose the internet-based survey tool SurveyMonkey was used. The preparation of the questionnaire will be described in more detail in Chapter 5.

3.5 Methods Used in the Prescriptive Study

Prescriptive Study involved the development of the first draft of the guidance in accordance with the information collected during the ‘descriptive study 1’ (refer to Section 3.5). The survey carried out with designers helped the researcher to

identify the overall content and the format of the guidance, and with reference to the preference of the designers the guidance was developed as a website. Adobe Dreamweaver CS5 software was used to prepare a working prototype, and once the development and the pilot study had been finished, the website was put online.

The guidance website was used during the interviews with designers in an effort to observe their interaction with the website and to understand their observations and suggestions about the guidance regarding its efficiency/content, which enabled the researcher to understand which parts require further improvements/changes. The preparation of the first draft of the guidance will be described in Chapter 6.

3.6 Methods Used in the Descriptive Study 2

The Descriptive Study 2 consists of two interlinked studies: (1) a questionnaire for the initial evaluation and (2) interview for the detailed evaluation of the guidance. The results of the ‘Descriptive Study 2’ will be described in Chapter 7 (Evaluation with Designers).

Online questionnaire for the initial evaluation

The first study involves designers’ overall evaluation of the guidance website. For this purpose a self-administered online questionnaire (by using SurveyMonkey tool) was prepared and sent to the possible respondents via email, accompanied by the web link to the website.

The questionnaire helped the researcher to understand the designers’ considerations regarding:

- The content of the first draft of the website
- The efficiency of the first draft of the website (e.g. the relevance of the information to designers)
- The overall design of the first draft of the website (e.g. how easy it was to use)

The questionnaire also ensured that the respondents had looked at the website prior to their participation in the interview exercise, and it also served to shorten the time of the interview session.

However, due to the fact that only closed-questions were used in this questionnaire, it was likely to be of limited use in understanding the factors influencing the choice of the respondents (Oppenheim, 2001; Floyd & Fowler, 2002; Robson, 2002). Therefore, the questionnaire was only used to support the qualitative data gained through the interviews. The preparation and the analysis of the questionnaire will be described at Chapter 7.

Semi-structured interviews

Interviews are the most appropriate method “where quantitative study has been carried out, and qualitative data are required to validate particular measures or to clarify and illustrate the meaning of the findings” (King, 1994).

As mentioned before, although the designers’ evaluation started with a self-administered online questionnaire, this information was not sufficient on its own to understand designers’ feelings and their specific requirements in detail. Therefore a mixed method was used, and as suggested by Hall & Hall (2004), with this strategy the initial questionnaire helps to ‘map the field’, then the semi-structured interviews can be used to explore the issue in detail.

Interviews are a particularly good method when their purpose is to investigate the feelings of people in largely exploratory way (Gray, 2004). The interviews helped the researcher in two ways: they enabled (1) evaluation of the first draft of the guidance in detail in order to understand designers’ consideration regarding the current content and the presentation of the information and (2) exploration of the other requirements of the designers in order to identify any missing information and explore possible means of improvement of the guidance. For this reason semi-structured interviews were carried out. Semi-structured interviews are a flexible method, where the researcher has a list of questions but during the interview their wording and order can be changed; it also allows the respondents to expand their answers where necessary (Robson, 2002; Gray, 2004; Bryman & Teevan, 2005). During the interviews some of the designers answered multiple questions at once.

The interview session was recorded via a voice recorder, with prior consent of the participants obtained. The audio recording was also supplemented by the

note-taking technique. This technique is generally used in social sciences to capture the essence of what was learned for future reference (Henn, et al., 2006).

3.7 Ethical Approval

The research has been approved by the ethics committee of the School of Engineering and Design, Brunel University on 22/01/2009. During the observational study, an information sheet and a consent form were disseminated to the participants prior to their active participation. The participants were informed that they were free to withdraw from the study at any time without giving reasons for their decision. The consent form and the information sheets prepared for lay users and designers can be seen in Appendix A.

3.8 Validity and Reliability

Applying the criteria of validity and reliability is often questioned for qualitative research, because these criteria are derived from quantitative strategies (Potter, 2000; Robson, 2002; Bryman & Teevan, 2005). In this section the validity and the reliability of qualitative research is explored with regard to the purpose of this research.

3.8.1 Validity

According to Henn et al. (2006: p.338) the definition of validity is: “the extent to which the conclusions derived from the research activity approximate the truth, and the degree to which the phenomenon under investigation has therefore been faithfully examined”. However this definition is more appropriate for a quantitative approach, because if it is argued that there is one single ‘truth’, then this means that the research has a positivist standing.

On the other hand, Smith (2000) argues that, the validity of qualitative research should be evaluated differently from quantitative research, since they generally have different epistemological standings. There are three main threats to the validity of qualitative research (Robson, 2002):

- **Reactivity:** The effect of the researcher’s presence in the study setting
- **Respondent biases:** The respondents may try to behave differently to the manner in which they normally would.

- **Researcher biases:** The researcher's assumptions and preconceptions may affect the research setting or data reporting.

However, there are strategies that the researchers can adopt during a qualitative study in order to reduce the effects of these threats, e.g. triangulation, member checking, peer debriefing (Robson, 2002; Creswell, 2009). For this research 'triangulation' was adopted, which means using "...different data sources of information by examining evidence from the sources and using it to build a coherent justification for themes" (Creswell, 2009: p.191).

The analysis criteria were pre-defined in order to prevent researcher biases. However, it should be taken into account that all the data collected during this research was analysed and interpreted by one single researcher, therefore it is impossible to iron out any bias from the findings, although steps have been taken to make the results as objective as possible.

3.8.2 Reliability and Generalisability

Reliability is concerned with the stability of findings (Gray, 2004) and there are two types of reliability assessment strategies (Bryman & Teevan, 2005): internal reliability and external reliability. Internal reliability means that more than one researcher is involved in the research and they agree about the findings, where external reliability is about the replicability of the research. However, replicability is questionable for a qualitative study, because there may be several variables affecting the study setting, the participant or the researcher. However, Perakyla (1998: p.206) argues that if a qualitative research involves recording and transcription, "the key aspect of reliability involves the selection of what is recorded, the technical quality of recordings and the adequacy of transcripts". During this research a considerable amount of effort was expended during the transcription of the data in order to maximise the reliability of the findings.

Generalisability is "the extent to which the findings of research based on a sample can be applied to the wider population" (Henn, et al., 2006: p.332), which is often referred to as external validity (Gray, 2004). In qualitative research the main issue about the generalisation of findings is associated with the small sample size (Gray, 2004; Bryman & Teevan, 2005). However according to

Lincoln & Guba (1985), 'transferability' of the findings is possible, which means that the findings derived from a particular context can be transferred to another context, if these two contexts have been compared and found to be similar in terms of the factors that define them. This is only possible where both contexts are understood thoroughly by the researcher who proposes to make the transfer (Lincoln & Guba, 1985).

Although during the study with lay users the intention was to identify their characteristics from a small sample, the main information was derived from the literature review. During this study the main purpose was to validate these characteristics, which were already generalised for lay users but assumed and/or inferred by comparison with professionals, within the sample. Therefore the term of 'validation' is used within the confines of the limited sample.

Similarly during the studies with designers the main purpose was to see whether the information collected and synthesised during the literature review corresponds to the requirements of designers in order to build a theoretical understanding.

In both studies, a triangulation process was used to improve validity and reliability of the studies carried out (Gray, 2004). In order to allow the transferability of the findings derived from these studies, the study method, the information about the samples, the analysis of the data and the results were presented comprehensively within the relevant chapters or appendices, in an effort to provide a comprehensive understanding of the context in which the studies were carried out.

3.9 Summary

In this chapter, the appropriate research methodology and the methods employed for this PhD research were discussed. Different research approaches were investigated in order to determine the nature of this research and understand its epistemological standpoint. This research requires a theory building (inductive) approach and it is largely qualitative; however, quantitative data was also collected during some of the studies conducted. The epistemological standpoint

of this research is towards interpretivism which is strongly linked to constructivism.

Blessing et al.'s (1995) DRM was employed as the overall research methodology. The research was carried out in four stages. Table 3.1 summarises the studies carried out in this PhD research, with reference to the DRM.

Table 3.1 Characteristic of the studies carried out in this PhD research

| DRM | Studies | Study Type | Study Method |
|---------------------------------|--|--|--|
| DESCRIPTIVE STUDY I | Understanding Lay Users (Chapter 4) | <ul style="list-style-type: none"> Qualitative (Some quantitative data was also collected via the questionnaires) | <ul style="list-style-type: none"> Observation Questionnaire (Assistive) |
| | Survey with Designers (Chapter 5) | <ul style="list-style-type: none"> Mixed Method (Quantitative/Qualitative) | <ul style="list-style-type: none"> Online Questionnaire (Self-Administered) |
| PRESCRIPTIVE STUDY | Development of the Guidance (Chapter 6) | Development of the Guidance Tool for Designing Home Use Medical Devices | |
| DESCRIPTIVE STUDY II | Evaluation with Designers (Chapter 7) | <ul style="list-style-type: none"> Mixed Method (Qualitative/Quantitative) | <ul style="list-style-type: none"> Online Questionnaire (Self-Administered) Semi Structured Interviews |

The sampling methods, the set-ups of the studies and the analysis methods were described in detail in the relevant chapters, starting from Chapter 4, which was carried out as part of 'Descriptive Study 1'. Chapter 4 focuses on the first research question: 'who are lay users and what are their characteristics?'

CHAPTER 4: UNDERSTANDING LAY USERS

Lay users were discussed in Section 2.2, including their definition, their characteristics when using products, and their differences. The literature review suggested that the characteristics of professional users are well documented, whereas due to the lack of investigation in this field lay user characteristics tend to be inferred or assumed. In addition, as discussed in Section 2.2, all the information about lay users was derived from a multitude of different resources from different domains; hence there was some ambiguity regarding the implications of lay user characteristics for design.

This chapter aims to address the first research question: “Who are lay users and what are their characteristics?” The objectives are:

- To confirm the lay user characteristics which were found through the literature review
- To identify different types of lay users in order to understand how they differ in terms of their characteristics
- To identify new lay user characteristics

For this purpose an observational study was carried out. The study involved product interaction trials involving four different types of lay user groups (i.e. 10 younger people, 10 older people, 10 people with cognitive disabilities, 10 people with motor and/or sensory disabilities). The characteristics of the participants were observed during their interaction with two selected devices (i.e. a blood pressure monitor and a digital camera) which were examples of products designed specifically for lay people’s use. Two questionnaires were used as an assistive method of data collection alongside observations.

As shown in Figure 3.1 (Chapter 3), this study was conducted as a part of the ‘Descriptive Study I’ with reference to the DRM (Blessing et al., 1995). The methods used during the study and the results obtained will be described in detail in the following sections.

4.1 Study Method

The study consisted of product interaction trials which involved the completion of given tasks by the volunteer participants through interacting with two selected digital devices. Lay people were identified according to Thiberg's user pyramid (Benktzon, 1993).

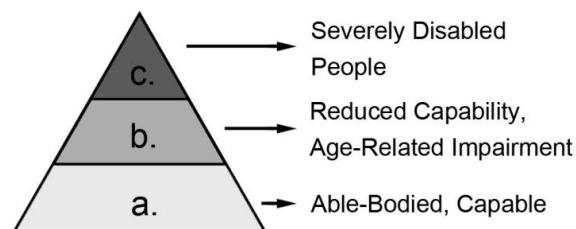


Figure 4.1 User Pyramid (Benktzon, 1993)

In the pyramid (Figure 4.1), able bodied and fully capable people are shown in the lower portion (a). Middle (b) of the pyramid represents people with reduced strength and mobility, caused by disease and more severe age related impairment. The top layer (c) of the pyramid represents the people with severe disabilities, who need help with their daily activities. The figure suggests that if the product is set for the higher portion of the pyramid, the end-users who can benefit from the product can be maximised (Benktzon, 1993).

Based on this pyramid, three kinds of lay user groups were selected for this study:

- Able-bodied young people
- Healthy older people
- People with disabilities

4.1.1 Sampling and Recruitment of the Participants

In the pilot study convenience sampling method (Robson, 2002) was used. The purpose was to test the clarity of the questions and the tasks prepared for the user interaction trials; 8 participants took part in the pilot study, i.e. 4 younger participants, 3 disabled participants and 1 older participant.

Different types of sampling methods were used in the main study:

- **Younger and Able-Bodied Participants:** Younger and able-bodied lay users were identified as, lay users aged from 18 to 64 who do not have any disability or impaired²⁰ capability. Purposive sampling was used as the primary sampling method because the age group of the participants was predefined. The ‘younger and able bodied’ participants were recruited from Brunel University through recruitment advertisements. Snowball sampling was used to find more participants. The study was carried out with 10 younger able-bodied participants.
- **Older Participants:** According to Charness (2008), there is little consensus on how to define older people in the literature; however, general ageing literature considers chronological age bands such as younger old (65-74), middle old (75-84) and old-old (85+) to be most useful. For this study ‘older people’ were defined as people of 65 years and over. In order to recruit older people Age Concern Hillingdon was contacted and they directed the researcher to the Active Ageing Group (AAG) service. The AAG service has groups of older people who meet and socialise every Tuesday and Thursday in the Ruislip Manor Methodist Church. A purposive sampling method was used to recruit 10 older participants.
- **Disabled Participants:** According to the Inclusive Design Toolkit (Clarkson, et al., 2007), when interacting with products three capabilities are critical, i.e. sensory, motor and cognitive capabilities. According to BS 7000-6:2005 (BSI, 2005), motor, sensory and cognitive impairments are the most common reasons for inability to use products, services or facilities. The disabled participants were investigated in three groups in accordance with these three capabilities. Several organisations were contacted to recruit participants with sensory, motor or cognitive disabilities: Brunel University Disability and Dyslexia Service, Yateley Industries, Mencap, Charles Curran House and The Royal National Institute for Deaf People (RNID). Purposive sampling was adapted as the primary sampling method together with snowball sampling method. A total of 20 disabled participants were recruited, i.e. 10 people with

²⁰The participants wearing spectacles due to minor sight loss were accepted as able bodied.

cognitive disabilities and 10 people with motor/sensory disabilities (5 with motor disabilities and 5 with sensory disabilities).

4.1.2 Selecting Devices

For this study, it was decided to involve two different types of products; home use medical devices and general consumer products, in order to enable the comparison of lay users' approaches in using these two product categories. A number of criteria were considered in selecting the devices used in the study. The devices were intended to be:

- Designed for lay users
- Commonly used by lay people
- With a digital interface
- Light weight and easy to carry
- Safe to use

Most home use medical devices are considered 'invasive' (such as digital ear thermometers, blood sugar monitors and etc.), and therefore they were not suitable for this study. A blood pressure monitor was selected as the home use medical device, because such devices are one of the most commonly used home use medical devices and their operation is wholly non-invasive. A wrist-fitted blood pressure monitor was selected because these devices were relatively new on the market, and they were more compact when compared with the upper arm models. The Omron R7 Digital Automatic Blood Pressure Monitor was selected.

It was assumed that the older participants would possibly be more familiar with blood pressure monitors when compared with the younger participants. Therefore, a digital camera was selected as the general consumer product, as conversely the younger participants would possibly be more experienced in using digital cameras compared to the older participants. This allowed the researcher to make a more fair comparison between the groups by taking into account the possible effects of familiarity with similar products in their interaction. A Sony DSC-S730 digital camera was selected for this purpose.

The selected devices are shown in Figure 4.2.



Figure 4.2 The products used in the user observation study: Sony DSC-S730 and Omron R7

4.1.3 Preparation of Tasks

One of the purposes of this study was to validate²¹ the lay user characteristics gathered through the literature review; therefore the tasks were prepared in accordance with the characteristics gathered in Section 2.2.

During the preparation of the tasks considerable attention was given to prepare realistic tasks in accordance with the functions of the products; unreasonable tasks were avoided. Three tasks were prepared for the blood pressure monitor testing, and five tasks were prepared for the digital camera testing, including a hidden task.

In the task list sheet, the participants were informed that if they encountered any difficulty during the tasks, they were free to move on to the next task, and were also free to use the instruction manuals of the devices. A 14 point font was used in the task list sheet, as it is the recommended size to be used for older people or visually impaired people (Backinger & Kingsley, 1993; Smith, 2003).

The final design of the task list sheet can be seen in Appendix C2. The instructions for the blood pressure monitor tasks were:

- **Task 1- Please prepare the device to be used:** The participants were expected to open the protective case and take the monitor out. They were then expected to take the batteries out of the box and insert them into the device and switch it on. During this task the participants' behaviour and comments were recorded as a reflection of their motivation and confidence in using the device. The influences of prior experience of the

²¹ As mentioned in Section 3.8, in this chapter the term 'validation' is used within the confines of the limited sample.

task, and effects of the participants' motor and sensory capability levels were observed during this task.

- **Task 2- Measure your blood pressure and write down the score:** The participants were expected to attach the device to their wrist in the correct position as specified in the instruction manual. They were supposed to use their elbow as a 'turning point' and take the device to their heart height until hearing the beeping sound, indicating the correct height has been reached and a measurement has started. During the measurement they were expected to obtain the correct posture and sustain their position until the device deflated. The task finished when the participants wrote their scores on the task list sheet.

In this task the participants were expected to interact with the blood pressure monitor device's digital interface. Several lay user characteristics were observed during this task: specifically their knowledge level and its influences on their performance, their confidence, their capability in identifying errors and problems, and their understanding of the specific terminology. Inferences about the participants' knowledge levels were drawn from the answers given to the questionnaire after the user trials.

- **Task 3- Switch off the device as if it will not be used for a long time:** The participants were expected to turn off the device and take the batteries out. The task finished when they successfully put the device back into the protective case. In the 'Maintenance and Storage' section of the instruction manual, it was mentioned that the batteries of the device should be taken out if it is not to be used for a long time. In this task it was specifically intended to observe participants' propensity towards using the instruction manual of the device, and the effects of the participants' motor and sensory capability levels.

The tasks for the digital camera part:

- **Task 4- Please prepare the device to be used:** The participants were expected to insert the batteries and the memory stick, and then switch on the device. The purpose of this task was similar to Task 1: the participants were expected to interact with the device physically and give feedback

reflecting their motivation and confidence in using the device. The influences of prior experience on their performance, and the effects of the participants' motor and sensory capability levels were observed during this task.

- **Hidden Task:** The memory stick used for the study was left full hence the participants were expected to create space in the memory stick by erasing the pictures or formatting the card to be able to continue the tasks. The purpose of this task was to enable the observation of the response of the participants when they encounter an unexpected situation. (On the basis of the results of the pilot study, this task was removed from the study for the older people's group, as they were experiencing great difficulties in understanding and coping with the situation, resulting in frustration and even withdrawal from the study)
- **Task 5- Take your own picture reflected in the mirror provided. Please try to take at least one good picture:** The participants were expected to direct the camera to the mirror and then take a picture of their own reflection. Flash was left on to motivate the participants to interact with the buttons and the digital interface. Due to the fact that the glare from the flash will spoil the picture, the participants were specifically asked to try to take at least one good picture. The participants' reactions when faced with an unexpected situation, and their means of overcoming the device limitations through using more functions, were observed. The participants were free to pass to the next task when they were satisfied with the picture.
- **Task 6- Take a picture of the toy car provided. Please try to take at least one good picture:** The participants were asked to take a picture of the small toy car provided. Similar to Task 5, the participants were expected to interact with more functions of the device, allowing the researcher to observe how they overcome the device limitations. Due to the fact that a small object was selected for this task (i.e. a tiny toy car), the participants were expected to use different functions such as, Macro function, zoom or other photo capture modes. In order to take a good picture the participants should also focus and frame well. However, they

were free to pass to the next task when they were satisfied with the picture.

- **Task 7- Erase the unwanted pictures and switch off the device:** This task required interaction with the digital interface of the device. The participants were asked to leave two pictures in the memory card: one from Task 5 and the other from Task 6. If they had taken more than one picture during any task, they were asked to erase unnecessary pictures. This task was designed to enable the researcher to see the influence of the familiarity of the participants with the specific terminology and the symbols used on the device and in the instruction manual. The effects of prior experience and the knowledge of the participants regarding the product or the task were also observed. The confidence and motivation of the participants in using the digital interface were reflected by their behaviour and their comments during this task.

The preference of the participants in using instruction manuals for both of the devices and the effects of any cognitive, sensory and/or motor capability impairment(s) were investigated during all the tasks.

4.1.4 Preparation of the Questionnaires

Questionnaires were used as an assistive method for collecting data to support video recordings and to support situations where video recording method was not sufficient to provide specific type of information. Two questionnaires were prepared for the user observation study.

Pre-questionnaire about general information of the participants

The main purpose of this questionnaire was to collect general information (i.e. age range, gender, education level, ethnicity, occupation and, if applicable, the disability or impaired capability) of the participants. The prior consent form (Appendix A1) was also attached to this questionnaire. The questionnaire was composed of mainly closed questions; however, to collect more information about the participants' disability or impaired capability, open-ended questions were also included.

Post-questionnaire regarding the experience of the participants during the study and their general preferences

This questionnaire was designed to support the visual data recorded during the observation of the study, as well as to understand the general preferences of the participants regarding the products that they use daily. The layout of the questionnaire was similar to the pre-questionnaire and the task list sheet. The questions were grouped into relevant topics in order to ensure a logical order, which, as suggested by Hauge (1993), helps respondents to flow through on questions in a sensible and orderly way. Three topics were identified and the questionnaire was divided into three sections, with a headline leading to each relevant group of questions. These sections were:

1. Use of a blood pressure monitor
2. Use of a digital camera
3. General questions

In the first two sections, the participants were frequently asked to recall the details from their interaction with the devices during the study. The data about their prior experience with the same or similar devices was also gathered. In addition the participants were asked whether they felt confident that they had completed the tasks correctly. This helped the researcher to compare their actual performance (from the video recordings) to the participants' views on their own performance (from the post-questionnaire). Table 4.1 summarises the intention of the questions asked in the first two sections of the post-questionnaire. The questions can be seen in Appendix C3.

Table 4.1 Purpose of the questions in the first two sections of the questionnaire

| PURPOSES OF THE QUESTIONS (FIRST TWO SECTIONS) | Blood Pressure Monitor | Digital Camera |
|---|-----------------------------------|---------------------------|
| Does the participant have any prior experience with the same device or similar devices, and familiarity with the task? | Question 1 | Question 9 |
| | Question 2 | Question 10 |
| | Question 3 | |
| What difficulties does the participant think that he/she experienced during his/her interaction with the device? | Question 4 | Question 11 |
| | Question 5 | Question 12 |
| | Question 6 | |
| Was the participant confident that he/she completed the tasks for each of the devices correctly? | Question 7 | Question 13 |
| | Question 8 | |

The participants were asked to answer the questions in sequence. The types of the questions were mainly behavioural and attitudinal, and many of them were closed questions of selected responses; however, some of the questions were routed with an open-ended part due to the variety of possible answers, e.g.:

Have you ever used a similar device to a blood pressure monitor?

(Please circle the appropriate answer)

YES / NO

If 'Yes' please indicate what devices:

Although the majority of the questions were 'Yes' or 'No' questions, some of the questions were offering the 'Not Sure' option. According to Oppenheim (2001), in some situations the third possibility, where the respondent is not clearly sure about the answer, also can be very important, e.g.:

Are you confident about the output of the device?

(Please circle the appropriate answer)

YES / NO / NOT SURE

Please indicate why:

According to this question, there is a possibility that the participant is not clear about the output of the device; this can be the reason behind the participant's inadequate knowledge regarding the output or mistrust in the device. The 'Not Sure' option was followed by an open-ended question in order to allow the participant to explain the reasons.

The third section of the questionnaire was mainly about the preferences of the participants regarding the products that they use daily. In this section different types of questions were used: three selected response questions, a ranked response question and a five-point (which allows a neutral response designated as '3') scaled response question. The intention of these questions were summarised in Table 4.2. The questions can be seen in Appendix C3.

Table 4.2 Purpose of the questions in the third section of the questionnaire

| PURPOSES OF THE QUESTIONS (THIRD SECTION) | Common |
|---|---------------|
| What are the general preferences of the participants regarding the products that they use daily? | Question 14 |
| | Question 15 |
| | Question 18 |
| Did the participants employ a different approach to using the devices during the user trials? | Question 16 |
| | Question 17 |

At the very end of the questionnaire the participants were asked whether they wished to participate in a further study.

Wording of the questionnaires

During the development of the questionnaires attention was given to the wording. As suggested by Oppenheim (2001), jargon, technical terms, acronyms and abbreviations were avoided. Leading questions, double negatives, proverbs and loaded verbs were not used and double barrelled questions were kept minimum (Oppenheim, 2001). To check the clarity of the wording, these two questionnaires were tested with other research students and revised several times. In addition the wording of the questionnaire was also tested during the pilot study.

4.1.5 Summary of the Methods

Table 4.3 maps the lay user characteristic with validation methods. These lay user characteristics were derived from the literature review in comparison with professional users' characteristics which were explained in 2.2. However, this observational study did not intend to make comparisons between lay users and professional users.

Table 4.3 Summary of the confirmation methods used for the lay user characteristics

| LAY USERS CHARACTERISTICS | VALIDATION METHOD |
|--|---|
| Personal and/or demographic variation | All the tasks, Pre-Questionnaire |
| May have little or no training | Pre-Questionnaire and Post-Questionnaire |
| May have little or no knowledge regarding the task and/or the product | Task 2, Hidden Task, Task 7 |
| May have limited control of the product they use due to the lack of confidence | Task 1, Task 2, Task 4, Task 7 |
| May be poor at identifying problems or errors | Task 2, Task 3, Hidden Task, Task 5, Task 6 |
| May be poor at overcoming device limitations | Task 5, Task 6 |
| May experience difficulty in dealing with unexpected situations | Task 2, Hidden Task, Task 5 |
| May prefer easy to use devices with specific functions | Post-Questionnaire |
| Unlikely to refer instructions | All the tasks |
| May have difficulty in understanding specific terminology | All the tasks |

Two of the lay user characteristics identified during the literature review were not included in this study. These lay user characteristics were:

- **May use the products in various environments:** One way to validate this lay user characteristic was to recruit and interview only the participants who have prior experience in using the devices used in the study. However, in this study the participants were recruited regardless of their prior experience in order to provide a realistic sample.
- **Generally follow a random, non-systematic approach when obtaining a device:** Although this is an important lay user characteristic, it is not in the main focus of this research which specifically focussed on the design process.

4.2 Pilot Study

The participants were recruited from the students or the staff of the Brunel University. During the pilot study they were asked to evaluate the questionnaires and the task list sheet in terms of the clarity of their layouts and their wording. The questionnaires and the task list sheet were modified several times in accordance with the feedback of the participants. The participants who attended the pilot study were not included in the main observation study.

4.3 User Study Set up

A total of 40 participants voluntarily participated in the study:

- 10 Younger and able bodied people (YP)
- 10 Older people (OP)
- 10 People with cognitive disabilities (CDP)
- 10 people with motor/sensory disabilities (M/SDP)

The product interaction trials were conducted in a quiet room with one participant each time. The study takes a maximum of one hour for each participant, and consists of three parts. Figure 4.3 summarises these parts.

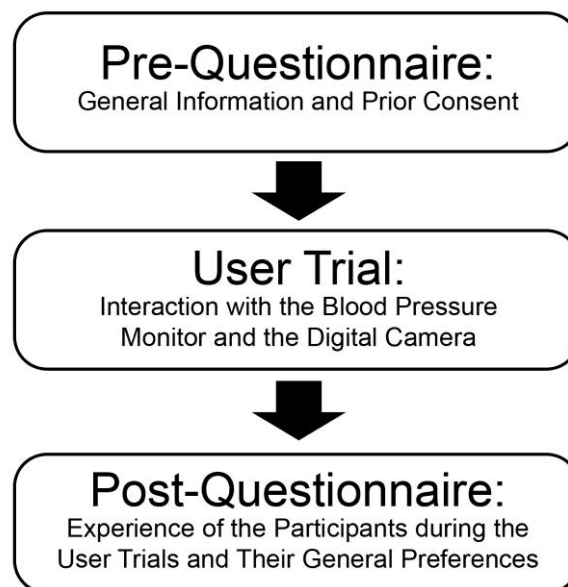


Figure 4.3 Parts of the study

The first part: An information sheet (Appendix A2) which describes the main purpose of the study was given to the participants; and they were encouraged to ask questions about the research if they would like to do so. After they read the

information sheet and agreed to participate in the study, the pre-questionnaire about the general information of the participants were given to them. A 'Consent Form' (Appendix A1) was also given to the participants, asking for their prior consent before their participation.

The second part: After participants filled out the pre-questionnaire they were given the task list sheet and asked to complete the tasks by using the devices. Figure 4.4 shows the typical setting of the product interaction trials.



Figure 4.4 The typical setting of the product interaction trials

The instruction manuals of the devices were also provided and the participants were informed that they were free to use them if they would like to do so. The participants were encouraged to give verbal feedback during their interaction. This session was recorded by a video camera to capture their behaviour and facial expressions, as well as to enable in-depth analysis afterwards. Refreshments were also provided during the trials to make the participants feel comfortable and relaxed.

The third part: Once the participants had completed the tasks, they completed the post-questionnaire. This part was also recorded by a video camera, because during the pilot study it was observed that the participants were more motivated to give verbal feedback about their experience (e.g. thoughts, feelings about the tasks, products and their expectations) rather than writing them down. Therefore they were encouraged to give any verbal comments during the study.

After the participants completed the third part of the study, they were thanked for their participation, and if necessary, they were asked if they could identify any

other people who were likely to take part in the study in order to recruit more participants.

4.4 Data Analysis

Three different types of interrelated data sources were identified; i.e. the video recordings, the answers given to the questionnaires, and pictures taken during the digital camera tasks.

4.4.1 Analysis of the Video Recordings

According to Vermeeren et al. (2002), there is no standard procedure for running user tests or for analysing the data from the user tests. During the literature review a number of methods were investigated, and it was found that there were software tools developed particularly for the analysis of videos. These methods and tools provide a systematic way to transcribe the captured data, in order to enable a structured analysis. The methods investigated during the literature review included:

- Structured Usability Problem Extraction (SUPEX) (Cockton & Lavery, 1999)
- Detailed Video Analysis (DEVAN) (Vermeeren, et al., 2002)
- Interaction Analysis (Jordan & Henderson, 1995)
- Co-Discovery Exploration (Kemp & Gelderen, 1996)

These methods are based around the usability evaluation of the selected products or the investigation of user performances; however, the focus of this study was the identification of the characteristics of the different types of lay user groups through the observation of the difficulties experienced during their interaction with the products. Therefore an analytic frame was designed specifically for the purpose of the research.

Analysis criteria

This study aimed to observe the user characteristics when they interact with the two selected devices. In order to capture the user characteristics of different types of lay user groups, the **interaction problems** and the related **responses** of the participants were observed during their performance in the Tasks. According to Cockton & Lavery (1999: p.345), “a problem may refer to both a cause or a

difficulty and it is important to pay attention to the context in which difficulties arise.” Due to the fact that this research does not focus on the usability evaluation of the products, the cause was determined as the mistakes the users made during the tasks.

The definition of difficulty is adopted from Oxford Dictionaries Online²²: “a thing that is hard to accomplish, deal with, or understand”. This definition suggests that either motivational or cognitive effects may result in a difficulty. Prior to the analysis of the data a number of criteria, which are summarised in Figure 4.5, were determined in order to identify when the participants were having a difficulty.

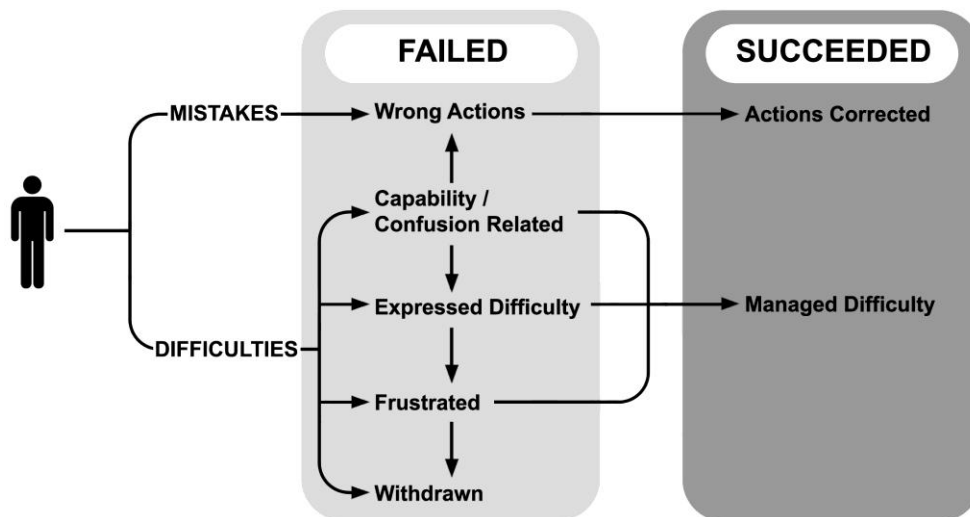


Figure 4.5 The determination criteria for the task results

As can be seen from Figure 4.5, if the participants (1) found it hard to perform the task or could not complete it due to sensory and/or motor capability loss; (2) looked confused; (3) made repetitive mistakes; (4) expressed frustration; (5) decided to withdraw; or (6) mentioned that they were having difficulty, then it was regarded as a ‘difficulty’.

Norman (2002) argues that there are two fundamental categories for errors, i.e. slips and mistakes. Slips result from automatic behaviour whereas mistakes result from conscious deliberations. During the observational studies it was quite difficult to identify the subconscious behaviour (slips) of the participants; therefore all the errors are accepted as mistakes. According to Norman (2002),

²² http://oxforddictionaries.com/view/entry/m_en_gb0225270#m_en_gb0225270 (last accessed: 22/08/2010)

inappropriate goals due to poor decision, misclassification of a situation, or failing to take all relevant factors into account result in mistakes. In this study if (1) the participants performed irrelevant actions, or (2) the performed action was not consistent with the descriptions given in the manual, then it was regarded as a 'mistake'. If the participants did not correct their mistakes and completed the Task, then it was regarded as a 'failure' in that task (Figure 4.5).

As mentioned in 4.1.3, there were seven tasks to be completed by the participants during the study. The participants who completed the task correctly as described in the manual were deemed to have been successful in that task. However, if they did/could not carry out the actions correctly due to experienced difficulties or mistakes during a task, then they were accepted as failing that task.

Transcription table

The starting point of the analysis was the transcription of the video material (Jordan & Henderson, 1995; Cockton & Lavery, 1999; Faulkner, 2000; Vermeeren, et al., 2002). According to Rose (2007), the purpose of this activity is to generate a data set enabling a careful analysis and coding. The captured video recordings were transcribed using a transcription table which is shown in Figure 4.6. Initially the data captured from able bodied younger participants and older participants were transcribed and analysed manually, then for the disabled participants QSR NVivo²³ 8 software was used.

During the transcription of the video recordings it was found that although the overall effect was similar for analysing the data manually or by means of a computer aided software, QSR NVivo 8 made the analysis process easier because (1) watching the video and transcription can be managed in the same context; (2) the transcribed segment can be directly linked to the video, therefore it is much easier to go back and watch a specific instance; (3) the software allows coding of the segments of the video recordings, which enables the researcher to see all the relevant transcription segments within a model. A similar transcription table was prepared for NVivo 8.

²³ A qualitative analysis software for use with unstructured information, such as documents, videos, pictures or audio recordings. The Software is developed by QSR International. [http://www.qsrinternational.com/products_nvivo.aspx (Last accessed: 29/04/11)]

| PARTICIPANT CODE: PO10 | | TOTAL TIME: 31.54 | | | |
|------------------------|---|---|--|-----------------------|------------|
| TIME: | PROBLEM & LOGGING: | COMMENTS: | MANUAL: | T. NO.: | SUC: |
| 11.47 | DIFFICULTY IN SEEING THE BATTERY DIRECTION INDICATORS -Checking for an indicator showing the battery direction P. "I do not know which way the batteries going" -Checking the instruction manual to understand the directions. | *Participant could not see the battery indicator due to its size. Comments of the researcher | Manual used for understanding the battery direction Instruction manual usage record | Task 4 Task number | SUCCESSFUL |

Figure 4.6 The transcription table

Due to the confidentiality, all the participants were given anonymity by an assigned code shown on the very top of each paper. The total time of completion of all the tasks was also mentioned near the participant's code.

The first column shows the time of the interaction event happened. Including a time column enabled the researcher to easily return to a particular segment of the video and watch it again.

The second column shows the interaction problems experienced by the participant and the logging of his/her interaction events. The problem (difficulty or mistake) was briefly described in capital letters as the heading of the cell. This helped the researcher to go back and find a specific type of problem easily, particularly when matching the similar or the same type of difficulties experienced by other participants. The logging of the interaction events and the comments of the participants were transcribed in the same cell.

The third column represents the comments of the researcher regarding the interaction problem. Due to the fact that the researcher accompanied most of the participants, some of the interaction problems were explained here more in detail where these details were hardly visible due to the limitations of the camera angle.

The fourth column represents the instruction manual usage preference of the participants, and the fifth column shows the task number in which the interaction

event took place. Lastly, the sixth column gives information regarding the participants' degree of success with the given task.

Identification of the interaction problems

The interaction problems were identified in accordance with the pre-determined analysis criteria. Once all the transcriptions of the video recordings of a specific type of participant group (e.g. all the older participants, or all the participants with cognitive disabilities) had been completed, the similar or same interaction problems observed more than one participant within the same group were coded.

4.4.2 Analysis of the Post-Questionnaire

The aim of the post-questionnaire was to collect data which was not possible to collect through user trials. The information derived from the first two sections (i.e. use of the two devices) of the questionnaire was compared with the participant's performance during the analysis of the video recordings.

The third section of the questionnaire is more about understanding the general preferences of the participants. SPSS 15.0.1.1 statistical analysis software was used to analyse the data collected for these questions, and descriptive statistic methods and non-parametric tests (i.e. Kruskal-Wallis and Mann-Whitney U tests) were used because of small sample sizes.

4.4.3 Analysis of the Pictures Taken During the Digital Camera Tasks

As mentioned in 4.1.3, two of the digital camera tasks involved taking pictures, i.e. Task 5 and Task 6. During these tasks the participants were told that they could take as many pictures as they like, but they were asked to provide a 'good' picture for each task.

In Task 7 the participants (if they had taken more than one picture for each task) were asked to leave the best picture for each task and delete all the other unwanted ones, and eventually they provided two pictures during the digital camera tasks.

During the analysis of the pictures a number of criteria were defined and a checklist was prepared to evaluate the quality of the pictures. If the picture was

blurred, out of focus, dark due to insufficient lighting or badly framed or spoiled due to flash mode, then it was accepted as a bad picture. Figure 4.7 shows the examples of good and bad pictures.



Figure 4.7 Examples of the good pictures and the bad pictures for Task 5 and Task 6

4.5 General Results

In this section the general results of the tasks are presented: firstly an overview of the participants' characteristics, and secondly the overall success of the participants for each task, including an explanation of the common interaction problems.

As mentioned before, the participants' general information was collected via the pre-questionnaire, and Table 4.4 summarises the data collected. As can be seen from the Table, despite the fact that all the participants were lay users, they varied significantly in terms of their age, education level, occupation and capabilities. This was in line with the previous characterisation of lay users.

In addition observational studies showed that the participants also presented different characteristics in terms of their preference of and approach in using the instruction manuals, and the results are also presented in this section. The specific results for the each participant group are discussed in the sections 4.6, 4.7, 4.8 and 4.9.

Table 4.4 The general information of the all participants

| | G. | Age | | Education | | Ethnicity | Occupation | Disability |
|------------------------|------|--------------|----|------------------------------|---|-------------------------|--|---|
| YOUNGER | Male | -18 | - | Less than High School | 1 | British: 3 | <ul style="list-style-type: none"> • Student (Most of the participants) • Personal Assistant | - |
| | 6 | 18-24 | 5 | High School | 2 | Irish: 1 | | |
| | | 25-34 | 3 | College | 1 | Romanian: 1 | | |
| | Fem. | 35-49 | 1 | University Graduate | 6 | Turkish: 3 | | |
| | 4 | 50-64 | 1 | Post Graduate | - | Spanish: 1 | | |
| | | 65+ | - | | | Russian: 1 | | |
| OLDER | Male | -18 | - | Less than High School | 4 | British: 10 | <ul style="list-style-type: none"> • Housewife • Retired (Most of the participants) | <ul style="list-style-type: none"> • Impaired sight • Impaired hearing • Arthritis • Heart problems, blood pressure • Diabetes |
| | 2 | 18-24 | - | High School | 5 | | | |
| | | 25-34 | - | College | 1 | | | |
| | Fem. | 35-49 | - | University Graduate | - | | | |
| | 8 | 50-64 | - | Post Graduate | - | | | |
| | | 65+ | 10 | | | | | |
| MOTOR / SENSORY | Male | -18 | - | Less than High School | - | British: 8 Indian: 2 | <ul style="list-style-type: none"> • Charity Worker • Shop Assistant / Receptionist • Student • Packer / Counter • Charge Hand • Researcher • BSL Presenter • Computer Science • Housewife | <ul style="list-style-type: none"> • Right side hemiplegic and a stutter • Spina bifida, Hydrocephalus • Spinal Muscular Atrophy Type II – Neuromuscular • Cerebral Palsy • Tetraplegic • Deafness • Keratoconus • Cortical visual impairments • Deafness and Usher Syndrome |
| | 3 | 18-24 | 1 | High School | - | | | |
| | | 25-34 | 4 | College | 7 | | | |
| | Fem. | 35-49 | 3 | University Graduate | 2 | | | |
| | 7 | 50-64 | 2 | Post Graduate | 1 | | | |
| | | 65+ | - | | | | | |
| COGNITIVE | Male | -18 | - | Less than High School | 2 | British: 10 | <ul style="list-style-type: none"> • HR Admin Assistant • Handy Person • Fundraising Admin Assistant • Campaign Representative • Unemployed • Reception Assistant • Campaign Assistant • Admin Assistant | <ul style="list-style-type: none"> • Learning Disability • Down Syndrome • Speech impediment, hearing loss, heart murmur, high blood pressure • Communication difficulty • Hard of hearing, diabetic |
| | 5 | 18-24 | - | High School | 1 | | | |
| | | 25-34 | 2 | College | 7 | | | |
| | Fem. | 35-49 | 7 | University Graduate | - | | | |
| | 5 | 50-64 | 1 | Post Graduate | - | | | |
| | | 65+ | - | | | | | |

4.5.1 Possible Systematic Error Due to Level of Education

As can be seen in Table 4.4, the participant groups had been educated to different levels, with the older participants and the participants having cognitive disabilities seeming less educated than the other groups. This may have had an effect on the results of the observational studies. Therefore the level of education was assessed to identify any statistically significant differences between participant groups.

The *hypothesis* was that ‘there might be a difference between the participant groups in terms of their level of education’, thus the *null hypothesis* was that ‘the level of education was similar for all the participant groups’. Due to the fact that the sample sizes were very small and the data was not normally distributed, a non-parametric test was used to test the hypothesis (Kinnear & Gray 2004; Field, 2005). For this purpose the Kruskal-Wallis test was employed, which is used to “compare the scores on a variable of more than two independent groups” (Foster, 2002: p.225). The results of the Kruskal-Wallis test suggested that in terms of the level of education there was a significant difference between these user groups, where the *p value* (*Exact*²⁴) was less than 0.0005: $\chi^2(3, N=40) = 16.388, p < .05$.

Although the results of the Kruskal-Wallis test showed the overall level of significance, it was not clear which participant group(s) was/were significantly different than the others. The mean rank scores for each group were:

- Younger participants: 26.35
- Older participants: **9.70**
- Participants having cognitive disabilities: **18.40**
- Participants having motor/sensory disabilities: 27.55

The mean ranks suggest that the older participants and the participants with cognitive disabilities were less educated when compared with the other two groups. The mean rank of the younger participants was slightly lower than the participants having motor/sensory disabilities. Therefore statistically significant differences were assessed between: (1) older participants vs. younger participants; (2) participants with cognitive disabilities vs. younger participants

²⁴ Exact significance test is selected due to small sample sizes.

and, (3) older participants vs. participants with cognitive disabilities. It was assumed that, if the results would be significant for the younger participants, it would also be significant for the participants having motor/sensory disabilities since they have a higher mean rank; therefore the results were not tested with this participant group separately. The Mann-Whitney U test [compares the “scores on a specific variable of two independent groups” (Foster, 2002: p.224)], was used to test the hypotheses. However using multiple Mann-Whitney U tests for testing a hypothesis may result in a *Type I error*²⁵; therefore a *bonferroni correction*, where the critical value for significance (.05) is divided by the number of tests carried out, was applied in order to avoid a Type I error (Field, 2005). Although the bonferroni correction can be too conservative if too many tests are to be conducted, it is an effective means of correction for a Type I error (Field, 2005). Due to the fact that 3 tests were planned, the critical value of .05 was divided by 3; and therefore the critical value was accepted as 0.017 for these tests. The results can be seen below. The *null hypothesis* for all these tests were: ‘the two groups compared were similar in terms of their level of education’.

- **Hypothesis 1:** *The older participants were significantly less educated than the younger participants.*

The result confirms the hypothesis, where the p value (Exact) was 0.003: (U=15.500, N₁=10, N₂=10, p < .017, one tailed).

- **Hypothesis 2:** *The participants having cognitive disabilities were significantly less educated than the younger participants.*

The result does not allow the researcher to reject the null hypothesis, where the p value (Exact) was 0.042. (U=27.500, N₁=10, N₂=10, p > .017, one tailed).

- **Hypothesis 3:** *The older participants were significantly less educated than the participants having cognitive disabilities.*

The result confirms the hypothesis, where the p value (Exact) was 0.011: (U=23.000, N₁=10, N₂=10, p < .017, one tailed).

As can be seen from the results, the level of education might have an effect on the results of the study where the older participants were significantly less educated than the other participant groups. Care should therefore be taken in

²⁵ “Type I error occurs when we reject a null hypothesis when it is true...” (Foster, 2002)

attributing results to age *per se* without considering the co-occurrence of older people and lower educational levels. However, as discussed by Savage et al. (1973, cited in Woods & Britton, 1988), the educational level of the older generation should be considered in view of their childhood circumstances. They argue that, some of them were required to cut their education short due to war or economic depression. Similarly Meyer et al. (1992) argues that, the expansion of mass education systems had a sharp increase after World War II in the World. This suggests that today's younger people have better educational opportunities. Nevertheless the effect of the level of education should be considered when interpreting the results presented in this chapter.

4.5.2 Results Regarding the Success of the Participants in the Tasks

As can be seen from Figure 4.8, the results differ for each lay user group. The most critical results were observed during Task 2 for the blood pressure monitor tasks, and Hidden Task and Task 7 for the digital camera tasks.

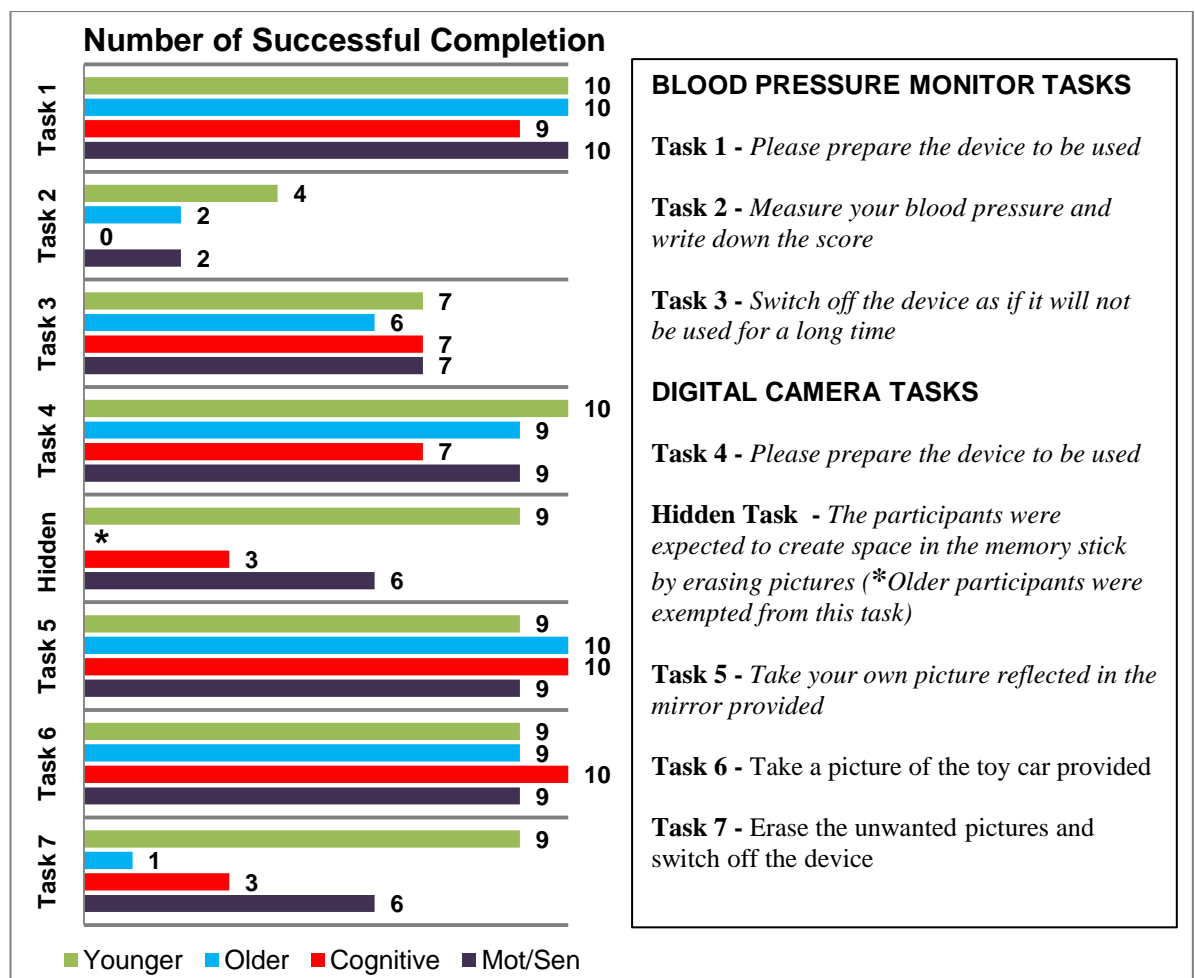


Figure 4.8 Number of successful completion for each task and the user groups

4.5.3 Blood Pressure Monitor Tasks

The complete list of the interaction problems observed during the blood pressure monitor tasks are summarised in Appendix D1.

Task 1 - Please prepare the device to be used

All the participants except one who had a cognitive disability were able to complete the Task successfully. A common difficulty observed during this task was that 8 out of 40 participants [i.e. 2 older participants (OP), 3 participants having motor or sensory disabilities (M/SDP), and 3 participants having cognitive disabilities (CDP)] experienced **difficulty in opening the protective case of the device** due to impaired dexterity.

Task 2 - Measure your blood pressure and write down the score

Task 2 was the least successful task of all the blood pressure monitor tasks, and participants experienced several difficulties during their performance in this task. CDP were the least successful among all the user groups. None of the CDP completed Task 2 successfully.

The nature of the errors made was similar across all those who had difficulty with the task. The most common interaction problem observed was that 30 out of 40 the participants (i.e. 7 YP, 8 OP, 5 M/SDP, and all the CDP) **attached the device to their wrist in an incorrect position**. Some of the participants corrected their mistake during the task; however, 11 participants did not identify their mistake and failed the task due to this interaction problem.

Most of the participants experienced difficulty in understanding how to use the device. Normally the device works only when it has been taken to the heart level; however, 25 out of the 40 participants (i.e. 4 YP, 8 OP, 6 M/SDP, and 7 CDP) had **an incorrect expectation of the device's manner of usage**, as they expected the device to work automatically when turned on.

18 out of the 40 participants (i.e. 6 YP, 3 OP, 4 M/SDP, and 5 CDP) **adopted wrong postures** which were inconsistent with the descriptions given in the instruction manual.

21 out of the 40 participants (i.e. 2 YP, 6 OP, 6 M/SDP, and 7 CDP) adopted a **trial and error approach** during their interaction with the product. The observational studies showed that surprisingly, younger participants very rarely adopted the trial and error approach, and they frequently referred to the instruction manual when it was deemed necessary.

10 out of the 40 participants (i.e. 3 YP, 3 M/SDP, and 4 CDP) **initially attached the device to their right hand**, where in the default mode the device measures the blood pressure from the left hand. However, during the task all these participants recognised their mistake and corrected it.

Task 3 - Switch off the device as if it will not be used for a long time

During Task 3 the participants were expected to turn off the device, take the batteries out and put it back into the protective case. However, 16 out of the 40 participants (i.e. 3 YP, 5 OP, 4 M/SDP, and 4 CDP) **left the batteries inside the device**, therefore they were deemed to have failed the task.

10 out of the 40 participants (4 YP, 4 M/SDP, and 2 CDP) experienced **difficulty in putting the device back into its protective case**. The reason behind this problem was the undefined shape of the protective case, which only allows the users to put the device back inside one way. Surprisingly, older participants did not experience this interaction problem.

5 out of the 40 participants (i.e. 2 OP and 3 CDP) experienced difficulty in **taking the batteries out**, but they eventually managed it.

4.5.4 Digital Camera Tasks

The complete list of the interaction problems observed during the digital camera tasks are summarised in Appendix D2.

Task 4 - Please prepare the device to be used

Most of the participants successfully completed this task. However, a few participants from different lay user groups failed. The observation suggested it was due to their impaired capabilities or unfamiliarity with digital cameras.

The CDP returned the least successful results, as 3 participants were not able to complete the task: (1) one could not find the battery lid and refused to use the instruction manual; (2) one could not figure out the correct direction in which to insert the batteries; (3) and one could not comprehend the correct way in which to insert the memory card.

Hidden Task – Specific Results for Hidden Task

The purpose of this task was to observe the participants' reaction to an unexpected situation: the memory card was full, and in order to save new pictures they were required to delete the existing ones. As mentioned before, older participants were exempted from the hidden task therefore the results only applied to the younger participants and the disabled participants.

The CDP experienced difficulties in understanding and managing unexpected situations. As a result they performed the least successfully, with only three successful completions. Additionally, all these three participants had had prior experience with a digital camera.

19 out of the 29 participants (i.e. 5 YP, 7 M/SDP, and 7 CDP) either **did not notice or ignored the flashing message on the screen** which indicated that the memory card was full, and tried to take a picture.

15 out of the 29 participants (7 YP, 4 M/SDP, and 5 CDP) **read the flashing message superficially and checked for personal mistakes**, as if they inserted the memory card wrongly. After they realised that it was not about their mistake, they read the message again carefully and understood the nature of the problem.

The following three reactions were commonly observed across all user groups: (1) participants first ignored the feedback from the device and tried to use it as if everything was normal, then (if the first attempt did not work) (2) they read the feedback message superficially to understand what it was telling them and tried to correct their personal mistakes, (3) they finally returned and read the message again more carefully, and tried to understand the main cause of the problem.

Task 5 and Task 6 – Take your own picture reflected in the mirror provided. Please try to take at least one good picture / Take a picture of the toy car provided. Please try to take at least one good picture

Most of the participants were able to take at least one picture during these tasks. Two participants (one YP and one M/SDP) did not take part in these two tasks due to their withdrawal from the study during the Hidden Task.

Due to the fact that the participants were asked to provide one good picture for each of these two tasks, the quality of the pictures was also investigated. The reason behind asking for a good picture was to observe their motivation to cope with the embedded potential barriers (which were explained in 4.1.3) and encourage them to interact with the digital interface. Table 4.5 shows the results for each group.

During Task 5 it was observed that the YP were more motivated to interact with the different functions of the device, and the majority of the participants turned the flash off easily. On the other hand, although 6 older participants took bad pictures due to the reflection of the flash, they were unmotivated to attempt to turn off the flash and eventually did not even try.

Some of the M/SDP experienced difficulties due to their capability loss, which are discussed separately in 4.8.

CDP took the least number of good pictures. It was observed that they were also unmotivated to try to turn the flash off: only 2 participants tried this.

A number of the participants were **confused about how to use a digital camera**. As an automated behaviour, 7 out of the 40 participants (i.e. one YP, 4 OP and 2 CDP) held the digital camera up to an eye as if they were trying to look through the viewfinder (there was no viewfinder on the device) rather than using the LCD screen.

Table 4.5 Quality of the pictures taken by the participants during Task 6 and Task 7

| | TASK 5 | | TASK 6 | | Summary: |
|---------------|--------|-----|--------|-----|---|
| | Good | Bad | Good | Bad | |
| Younger | 8 | 1 | 5 | 4 | A total of 13 good pictures were taken by 9 participants during these two tasks. During Task 5, eight participants turned off the flash function and one participant intentionally turned on the flash to take a good picture. |
| Older | 4 | 6 | 6 | 3 | A total of 10 good pictures were taken by 10 participants during these two tasks. During Task 5, four participants managed to turn off the flash and had taken good pictures. |
| Motor/Sensory | 3 | 6 | 5 | 4 | A total of 8 good pictures were taken by 9 participants during these two tasks. During Task 5, three participants managed to turn the flash off; however, one of these participants blurred the image and provided a bad picture. One participant preferred to take the picture with the flash on and he had taken a good picture. |
| Cognitive | 4 | 6 | 3 | 7 | A total of 7 good pictures were taken by 10 participants during these two tasks. During Task 5, two participants turned the flash function off; however, one of the participants blurred the image and provided a bad picture. One participant preferred to take the picture with the flash on and she took a good picture. 2 participants did not turn the flash off; however, due to the lighting of the room the flash was not reflected back from the mirror, and despite the flash they took good pictures. |

Task 7 - Erase the unwanted pictures and switch off the device

The results of this task were very diverse for each participant group. YP proved to have the most successful results among all the user groups, where OP returned the poorest results. The majority of the CDP failed this task, and it was observed that insufficient reading skills frequently hindered them.

21 out of the 40 participants (i.e. 6 OP, 6 M/SDP, 9 CDP) adopted a **trial and error approach** during this task in order to see the pictures or to figure out how to delete the unwanted pictures. The observational studies showed that all the 9 YP who had taken part in this task were able to perform this task easily and did not require adopting the trial and error approach.

10 out of the 40 participants (i.e. one YP, 4 OP, 3 M/SDP, and 2 CDP) were **confused by the multiple function buttons**. Similarly **confusion due to the variety of the buttons** often resulted in interaction problems, such as with participants iteratively pressing the wrong buttons or having difficulty in understanding the relevant buttons for the required functions. 23 out of the 40 participants (i.e. all the OP, 5 M/SDP, and 8 CDP) experienced this problem and frequently complained about it. Such confusion was not observed during the observational studies with the YP.

4.5.5 Results Regarding the Instruction Manual Usage

The preference of instruction manual usage of the participants was also investigated during the observational studies, and the results are shown in Figure 4.9.

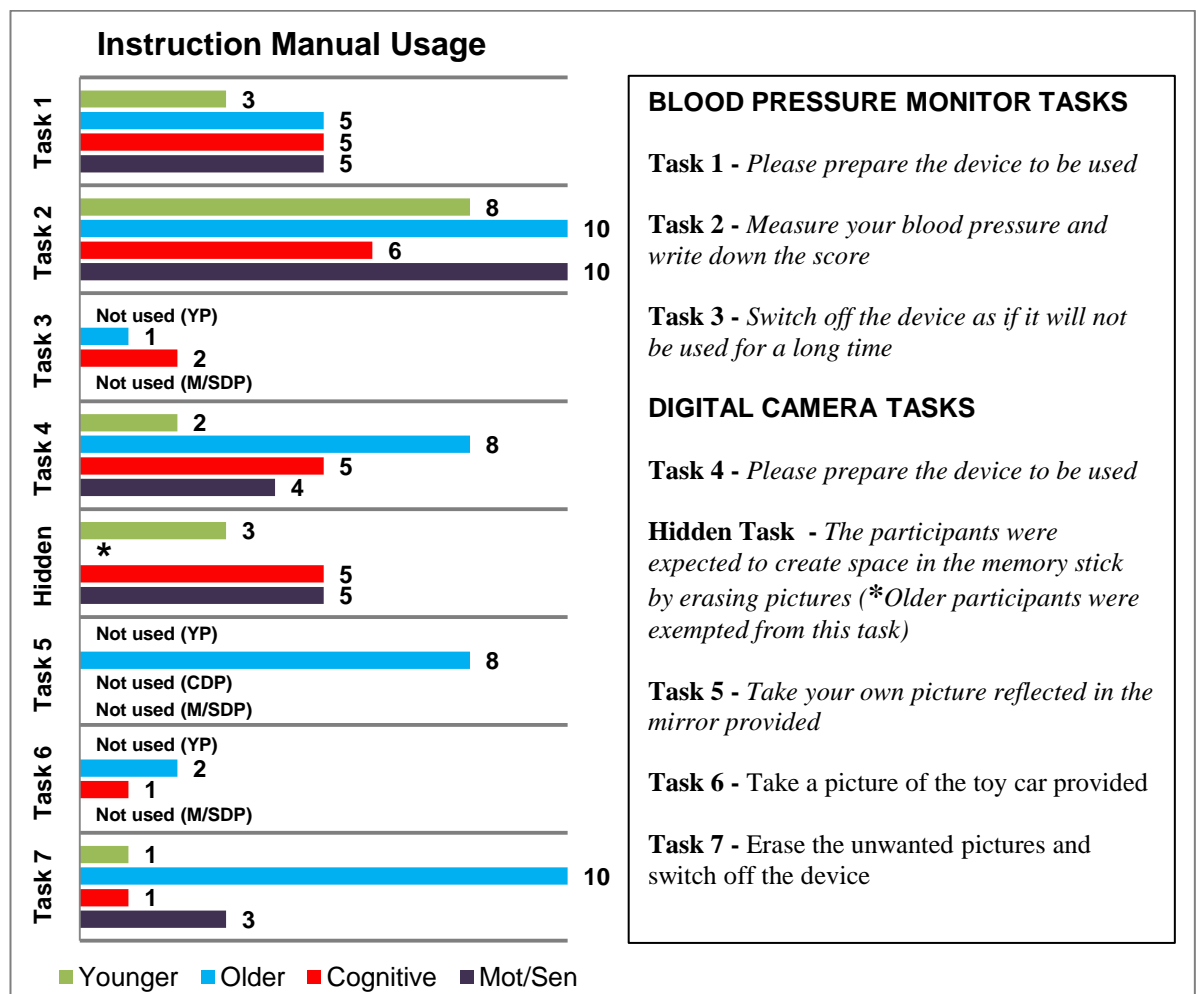


Figure 4.9 Number of people referred to the instruction manuals during the tasks

It was found that the preference of use and the way that users interacted with the instruction manuals differed for different types of lay user groups. The Figure also suggests that use by the same group varies considerably between tasks. During Task 2 the majority of the participants from all the participant groups referred to the instruction manual.

The observation showed that most of the YP preferred not to use the instruction manual during the digital camera tasks and overall performed the most successfully with the camera out of all the user groups. However, most of the YP preferred to use the instruction manual during the blood pressure monitor tasks, in particular Task 2, where they performed the least successfully.

Overall OP used the instruction manuals more than all the other user groups. Particularly during Task 2 and Task 7, all of the OP used the instructions, even though these were their two least successful tasks, in particular Task 7. During Task 5 a total of 8 OP used the instruction manual, where only one of the participants from the other user groups did so.

Half of the CDP did not use the instruction manuals for most of the tasks, although they could not complete them. They mainly preferred to use the instruction manual during Task 2, where none of them could complete the Task successfully. Similarly, most of the CDP preferred not to use the manual throughout the digital camera tasks, even though most of them could not achieve successful results.

Two interaction problems were observed during the observational studies, which were directly relevant to the instruction manuals. The first one is that **some of the descriptions in the instruction manuals led to confusion**. Figure 4.10 shows an example where several participants misinterpreted this description.

• Adjust the height of your wrist by using your elbow as a fulcrum. When the (◀ ▶) will reach the (♥) sign you will hear a beeping sound indicating that your blood pressure monitor is at the correct height (heart height). The (♥) sign will change in the (🩺) sign and the measurement will start.

Figure 4.10 How to measure blood pressure (Omron: p.10)

By this the participants were supposed to switch on the device and bring it to the heart level by lifting their hand using their elbow joint. During this process the

arrow sign on the screen moves towards the heart symbol and the device gives a beeping sound. After participants heard the beeping sound, they were supposed to maintain their position and to not move until the measurement was taken. However, 3 out of the 8 YP, 5 out of the 10 OP, 6 out of the 10 M/SDP, 4 out of the 6 CDP (some of the YP and CDP did not use the instruction manual during this task) believed the arrows mentioned in the manual referred to the ‘arrow buttons’ on the product. They pressed these arrows buttons and waited for some time for the device to work without holding the device at their heart level.

The second problem was caused due to terminology used in the instruction manual of the blood pressure monitor. As Figure 4.10 shows, the description is to “adjust the height of your wrist by using your elbow as a fulcrum”. With this description, most of the participants (the majority of the participants’ first language was English) admitted that they did not know the meaning of the word ‘**fulcrum**’. In total 29 out of the 40 participants (6 YP, 6 OP, 7 M/SDP and 10 CDP) said that they did not know the meaning of the word ‘fulcrum’. Ten participants did not mention anything about this word. Only one participant was able to tell the meaning of this word from her knowledge of physics. All of the OP’s, all of CDP’s, and all of the M/SDP’s first language were English.

4.6 Specific Results for the Younger Participants (YP)

The observation showed that, the majority of the YP were confident in interacting with both the devices, in particular with the digital camera. They rarely adopted a trial and error approach when compared with the other user groups.

Most of the specific characteristics of YP observed during the user trials related to their approach to using the instruction manuals of the devices. Rather than reading the manual beforehand, most of them preferred to use it when it was deemed necessary. They were skilled in finding the relevant parts of the instruction manual. Where necessary they referred to the ‘table of contents’; which was observed as affecting their interaction positively.

During the digital camera tasks most of YP used their prior experience with other digital cameras. However, during Task 2, prior experience had a negative effect

for some of the YP, where if the participants had used a similar device before, they were less likely to refer to the instruction manuals. As a result, 5 participants mentioned in the post-questionnaire (which was given after the user trial part), that they had prior experience in using a blood pressure monitor before, and three of them misused the device due to wrongly attaching the device to their wrist. Two of these participants did not use the instruction manual at all and they mentioned that they did not need to, because they were familiar in using blood pressure monitors. The observational studies suggested that prior experience and high-confidence in using sophisticated devices may mislead the younger users.

The majority of the YP did not experience any difficulty when using the digital camera, except the ones discussed in Section 4.5. They experienced more interaction problems (discussed in 4.5) with the blood pressure monitor.

4.7 Specific Results for the Older Participants (OP)

The observation suggested that OP had tendency to blame themselves about the experienced difficulties. During the digital camera tasks, 6 out of the 10 participants blamed themselves for their experienced interaction problems.

- *“I cannot even use the television. There is so many buttons to press and everything is like that. I just like to press one button and that is it...I am hopeless, I cannot do that.” (O1)*
- *“I am afraid it is beyond me.” (O3)*
- *“That is why I never had a camera, I did not know anything about them. I made a little bit mess of it, didn't I?” (O4)*

During the digital camera tasks 6 out of the 10 OP presented the evidence of losing motivation in using the device.

- *“I found the blood pressure monitor is easier, because I know precisely what that is doing.” (O3)*
- *“I do not think older people would buy digital cameras! I do not think so. Personally myself.” (O10)*

They also blamed themselves for the difficulties experienced in using the instruction manuals.

- *“It is not about that this (showing the manual) not being good. I think it is just me! It does not matter what the product is, I have to read the instructions then I cannot find the bit I am looking for.” (O2)*
- *“It is a shame really, because it is all there (showing the manual), isn’t it?” (O10)*

Due to the small font size, OP experienced difficulty in reading the instruction manuals. Generally 14-point type is recommended to be used in instruction manuals for older people or visually impaired people (Backinger & Kingsley, 1993; Smith, 2003). However, 7 out of the 10 older participants experienced difficulty in reading the instruction manual of the blood pressure monitor (6 point type font size is used) and 4 of them also experienced the same problem with the digital camera’s instruction manual (7-point type font size is used).

- *“I did find this (the instruction manual of the blood pressure monitor) a bit difficult to read with my eye sight. You know a bigger print will help. Because, well you see I have got glasses but still I cannot see small print very well.” (O4)*
- *“I found it is difficult to follow the instruction manuals and, I also think the print is too small. It should be much larger, perhaps sort of this size (showing the questionnaire where 14 point type was used).” (O3)*

Impaired dexterity was another problem that the OP had when interaction with the devices, in particular with the digital camera. For example, 4 out of the 10 participants experienced difficulty in pressing the buttons of the digital camera.

- *“The buttons are even too small for the people’s hands. When you get older...See (showing her hand)... you get arthritis. Look my fingers have gone fuggy. So I think it is because of getting older. People’s hands are not able to use these.” (O4)*

The observational studies showed that, OP were not only unfamiliar with the devices, but were also not familiar with the symbols, interface metaphors used on the device and within the instruction manuals, and moreover even guessing the manner of use. Figure 4.11 presents an example of the unfamiliarity with the concept of taking digital pictures, where the participant approached the device to

look through the “viewfinder”, where there was no window for this purpose on the device. In addition she did not switch on the device and held it in a reversed position.



Figure 4.11 Confusion due to way of use

None of the OP could guess the way to see the pictures in the memory card by the symbols on the buttons. The instruction manual also led them to confusion, because the figure which indicates the button that functions the ‘zoom’ is displayed as, “⊕ (playback zoom) button”. As a result four of the OP were confused by this and pressed the zoom button to go into playback mode. It was also observed that they experienced difficulty in understanding the descriptions which includes symbols and text together, for example only one OP could carry out the action shown in Figure 4.12b. Four OP could not understand which button was the ‘round’ button because there are five round shaped buttons on the product; however, none of them have a round symbol (refer to Figure 4.12a).

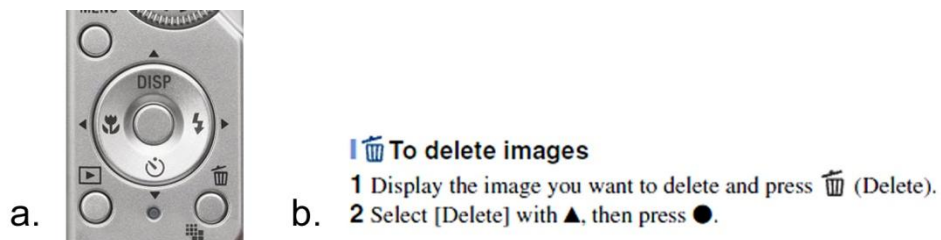


Figure 4.12 The buttons of the device and the description of how to delete images

When the participants were asked to delete some pictures, 8 out of the 10 OP experienced difficulty in understanding the relationship between the buttons and the interface. Most of the participants believed that they had managed to delete

pictures by only pressing the delete button, even without selecting pictures, and they did not give any attention to the LCD screen when they pressed a button.

When the participants were asked to switch the digital camera off, 4 out of the 10 participants could not remember where the power button was. Some of those participants referred to the instruction manual, and the others found it again by trial and error.

4.8 Specific Results for the Participants with Motor/Sensory Disabilities (M/SDP)

The motivation and the capability level of the M/SDP were quite diverse. It was observed that prior experience in using the devices had a big effect on the performance of the M/SDP during the tasks. The participants who have prior experience with the digital camera often did not refer to the instruction manual, but most of them were able to complete all the digital camera tasks correctly.

M/SDP participants frequently experienced difficulties due to their impaired capabilities. It was observed that some of the participants were using assistive devices, i.e. wheelchairs, magnifiers and special contact lenses, in order to offset their capability loss. Some of the participants were found to be more adaptive by using their own ways of coping with the experienced difficulties, which were often different than the normally expected methods. For example one participant was not able to use her right hand and she also had limited capability of using her left hand. As a result she required holding the camera upside-down in order to press the shutter button and she complained about it.

- *“I have to turn it around to see if I have done it right. I wish they had left-handed ones would be better... they will be upside down though.”*
(DP5)

Another participant who had very limited eye-sight was not able to understand whether he could take a picture after pressing the shutter button. However, he found out that the camera holds the picture on the screen for a few seconds, and he adopted his own way of rapidly moving the camera after taking a picture in order to understand if he had taken a picture.

The participants having motor disabilities or sensory disabilities experienced different difficulties depending on their capability loss.

Motor difficulties:

Participants who were having motor disabilities experienced difficulties regarding their motor capability loss. 5 participants having motor disabilities took part in the study. A summary of the experienced difficulties:

- One of the participants experienced difficulty in opening the battery lid of the both devices; however, eventually she managed to do it.
- 2 out of the 5 participants experienced difficulty in inserting the batteries of the blood pressure monitor; however, eventually they succeeded. These participants did not experience the same difficulty during the digital camera tasks, because in order to insert the batteries of the digital camera, it is not required to exert pressure using the fingers.
- 2 out of the 5 participants experienced difficulty in performing the actions which require using both hands for both devices.
- 3 out of the 5 participants experienced difficulty in attaching the blood pressure monitor to their wrist, and one of them who had a very severe motor disability could not perform the action at all and asked for help.
- One of the participants experienced difficulty in pressing the buttons of the blood pressure monitor due to limited dexterity. Two participants (one of the participants was the same) also experienced the same difficulty with the digital camera used in the user trials.
- 2 out of the 4 participants (only 4 participants were using a wheelchair) experienced difficulty in obtaining a correct posture due to their sitting position in the wheelchair. One of these participants failed the task due to this problem.
- 2 out of the 5 participants (during the digital camera tasks) experienced difficulty in pushing the memory card into its space due to impaired dexterity.
- 2 out of the 5 participants dropped the digital camera when they were trying to press the buttons. There are no textures on the surface of the camera which might make it easier to grab.

Sensory difficulties:

5 participants (i.e. 2 deaf participants, 2 participants with impaired eyesight and 1 deaf participant having also impaired eyesight) having sensory disabilities took part in the study. Below is a summary of the difficulties they experienced:

- All three deaf participants could not hear the beeping sound given by the device when it was taken to the heart level. The observation showed that one of these participants failed Task 2 because she could not find the correct height which was indicated by two means, i.e. the beeping sound and the changing symbols on the screen.
- All the three deaf participants could not understand when the measurement had been finished and waited for a few more seconds and sustained their position. The observation suggested that when the device completed the measurement the cuff deflated which made a very short sound of deflating air. However, all the deaf participants could not hear that sound, which worked as a means of feedback for all the other user groups, and this might be the reason why they could not understand clearly when the measurement had been completed.
- The two participants having impaired sight experienced difficulty in seeing the buttons of the digital camera. The reason of this problem might be the very small size of the buttons and/or the low contrast in terms of colour with the device itself.
- All the three participants having impaired sight experienced difficulty in reading the text based descriptions within the instruction manuals of the both devices.

Most of the M/SDP experienced several difficulties during their interaction with the instruction manuals of the devices and frequently complained about them.

- *“So much rubbish in the books....Too much information in it, not easy to read!” (DP2)*
- *“It is extremely small! (About the text size of the instruction manual of the blood pressure monitor) I mean even with this (a magnifying glass) it is a bit difficult.” (DS4)*

- *“I want to know what is 61 on the screen. There is no explanation there. I am looking for explanation in the manual..... No I could not find it! No clear explanation.” (DS1)*
- *“Okay there are actually 2 different kinds of blood pressure here. I do not actually know the difference between systolic and diastolic. I want to look those up in a dictionary but I have not got one here! (Laughs)” (DS4)*

4.9 Specific Results for the Participants Having Cognitive Disabilities (CDP)

CDP were found to be the most critical lay user group, because they not only experienced difficulties during their interaction with the devices, but also frequently failed to use the instruction manuals. It was observed that CDP may have problems due to their reading skills, comprehension, impatience and short attention spans. They frequently experienced difficulties in understanding the actions described within the manuals and adopted a trial and error approach.

The observation suggested that, trial and error approaches frequently caused trouble for the participants. For example 4 participants during the blood pressure monitor tasks and 3 participants during the digital camera tasks could not insert the batteries in the correct direction, despite attempting to do so several times. Similarly 4 participants experienced the same problem when replacing the battery lid of the blood pressure monitor.

CDP also experienced difficulties in understanding the figures. For example 4 of the participants wrapped the device around their wrist in wrong positions and failed Task 2. Even though they checked the figure (shown in Figure 4.13), they were still not able to perform this routine correctly.



Figure 4.13 The correct position of the blood pressure monitor (left) and the faulty positions performed by the participants (middle and right)

Finding the correct section within the instruction manual was another difficulty for them, although only two participants used the ‘table of contents’ of the instruction manual during the tasks.

5 out of the 10 CDP were confused by the beeping sound. Figure 4.14 shows an example, where one of the participants wanted to scratch his head and the device started to give beeping sound and the participant could not figure out what was happening. Similarly 4 out of the 10 participants (where 2 of these participants were same) ignored the beeping sound. Due to these interaction problems, only three of the CDP coincidentally made the device work and the remaining participants could not manage to get a reading from the device at all.



Figure 4.14 The participant confused due to the beeping sound given by the blood pressure monitor

CDP were more likely to ask for help or give up. 5 participants during the blood pressure monitor tasks and 3 participants during the digital camera tasks asked for help. Particularly during the blood pressure monitor tasks 4 participants exhibited evidence of lack self-confidence, and 3 of these participants blamed themselves about the experienced difficulties.

Like the older participants, it was observed that most of the CDP were not familiar with digital devices. For example, 7 of the 10 participants experienced difficulty in understanding the symbols on the digital camera and within the instruction manual. Most of these participants confused the playback button symbol with the right arrow on the navigation button. In addition, as observed with older participants, 2 CDP were confused about the way of use of the digital camera and took the device to their eyes to look through the viewfinder, although there was no window on the device for this purpose.

CDP were found to be poor at understanding or dealing with unexpected situations. During the hidden task, 7 out of the 10 participants could not understand that the memory card was full; some of the participants could not read the flashing message on the screen at all due to their reading skills; and some of the participants thought that the indicator concerned the batteries, due to the similarity of the flashing symbol (indicating the memory stick was full) to the battery indicator.

4.10 The Results for the Post-Questionnaire

The post-questionnaire was used as an assistive method in addition to video recordings. The results of the post-questionnaire are presented in this section.

4.10.1 The First Two Sections Relevant to the User Trials

The first two sections of the post-questionnaire contained questions relevant to the user trials. Therefore, the results were frequently compared to the participants' performance during the user trials. The full list of the questions and the answer given by all the user groups can be seen in Appendix F.

Results for the blood pressure monitor section:

Prior experience and success with the blood pressure monitor: Except one participant from the CDP group, all the other participants from all the user groups had seen a blood pressure monitor being used prior to the study (Question 2), which means that they have an idea about the product and its function. Although 14 out of the 39 participants (one participant from M/SDP did not take part in the post-questionnaire) had personally used a blood pressure monitor before (Question 1), the observation showed that only 3 of them were able to use the device correctly.

Association with other products: When the participants were asked whether they have used a similar device to a blood pressure monitor (Question 3), surprisingly the majority of the YP did not associate the blood pressure monitor with other products that they used in their daily lives. Other groups mentioned a number of products: alarm clocks, manual blood pressure monitors, blood sugar monitors, different model/brand of blood pressure monitors, ECG monitors and digital cameras.

Participants' thoughts about difficulties experienced: The participants were asked if they experienced any difficulty during the blood pressure monitor tasks (Question 5). The majority of the YP and OP indicated not, although OP experienced several difficulties during their interaction with the blood pressure monitor. One YP could not manage to obtain a reading and responded that he experienced difficulties. However, he blamed himself about that in the open-ended part of the question:

- *“Seemed straightforward to operate and yet was not able to activate reading.” (Y9)*

Another YP who completed all the blood pressure monitor tasks correctly mentioned the manner of use of the device as a difficulty. One OP also indicated a similar reason.

- *“The device does not work till the arm is in the correct position.” (Y8)*
- *“Yes I think I had some difficulties about where to put my hand and the way the machine supposed to be on the wrist.” (O9)*

Disabled participants were more aware of the difficulties experienced during their interaction with the device and in particular all the M/SDP indicated that they experienced difficulties. Some of the comments of the disabled participants were as follows:

- *“Inserting the batteries, setting monitor up using buttons. I find it difficult to manage which button is which.” (DP2)*
- *“Cannot use right hand to put it on my left arm.” (DP5)*
- *“Could not read the instructions. Messages on the screen were not very clear. Instruction book is very thick and small, also the font size is very small.” (DS4)*
- *“Oh yes, just putting it away! I think because it is not same shape. If it was designed same shape you can easily put in.” (CDP5)*

Ease of use of the blood pressure monitor: The participants were asked if they thought it was easy to use the blood pressure monitor (Question 6). Although all the YP, half of the older participants and the majority of the CDP mentioned that it was easy to use, the observation suggested that most of these participants could

not use the device correctly. In particular none of the CDP was able to complete Task 2 correctly.

Only for the M/SDP, the majority of them responded to this question as ‘no’ or ‘not sure’. However, three M/SDP responded ‘yes’ to this question, even if they failed Task 2. Some of the comments of the participants given to the open-ended part of the question:

- *“Not sure, it was easy to set up, but to understand how it works is complex.” (DS1)*
- *“I was looking for a button to say ‘start’, but I could not find it, and only started it accidentally.” (DS3)*

Output of the device: The participants were asked if they were confident that they had completed the blood pressure monitor tasks correctly (Question 7). Except for the M/SDP, the majority of the participants from all the other user groups indicated that they were. The participants frequently mentioned that the reason for their confidence was because the reading seems correct:

- *“Yes, because the reading it gave me was not too unlike my past reading with the doctor.” (Y1)*
- *“Well, I think it was quite normal blood pressure for a woman at my age.” (O9)*
- *“I think I am, because it looks like it is right when compared with the doctors. It went tight on my wrist and the things like that the doctors did.” (DP5)*

The five participants from the M/SDP who responded ‘no’ or ‘not sure’ to this question mentioned two reasons for their suspicions: (1) unclear description about the output in the instruction manual, or (2) mistrust regarding the accuracy of home use blood pressure monitors.

Confidence in completion of the blood pressure monitor tasks: The participants were asked if they were confident that they had completed the blood pressure monitor tasks correctly (Question 8). All the other participants except four, indicated that they were. However, as discussed in Section 4.5.3, the majority of the participants failed Task 2. The participants expressed different

reasons for their confidence, because: (1) they were able to obtain a reading; (2) they felt like they completed the task successfully; (3) the reading seemed to be okay for them; and (4) they trusted their prior experience and understanding of blood pressure monitors.

Results for the digital camera section:

Prior experience and success with the digital camera: The results of the questionnaire (Question 9) suggested that differently to all the other user groups, the majority of the OP did not have any prior experience in using a digital camera prior to the study, and the observation showed that overall they performed the least successfully during the user trials (refer to 4.5.2). Although four older participants had prior experience in using a digital camera before, none of them were able to complete Task 7 successfully; surprisingly the only OP who succeeded all the digital camera tasks indicated in the questionnaire that she did not have any prior experience.

The majority of the YP, M/SDP and CDP had prior experience in using a digital camera before and the observation showed that during digital camera tasks prior experience had a positive effect in particular for YP and M/SDP during their interaction with the device.

Association with other products: The participants were asked if they used a similar device to the digital camera before (Question 10). Except for the OP, all the other participant groups associated the digital camera with other devices more than they did with the blood pressure monitor. This may suggest that there is a relation with the association and the familiarity of the users with a particular technology. The products that the users associated with the digital camera are: camcorders, webcams, MP3 players, blood sugar monitors, mobile phones, old fashioned cameras, Polaroid cameras, photocopiers and other digital cameras.

Ease of use of the digital camera: The participants were asked if they thought it was easy to use and find the functions of the product (Question 12), and except for the older participants, the majority of all the other user groups found it easy. Indeed the YP did not experience so much trouble when using the digital camera and most of them completed all the digital camera tasks easily. On the other

hand, with the exception of three OP, all the others responded to Question 12 as ‘no’ or ‘not sure’. The reasons as they indicated in the open-ended section were summarised as being due to too many buttons, the instruction manual, lack of prior experience, impaired dexterity and impaired sight. The observation suggested that, all the three OP who answered as ‘Yes’ experienced several interaction problems and failed Task 7.

Three M/SDP mentioned that they were either not sure about or did not find easy to use and find the functions of the digital camera although two of these participants were found to be successful during the user trials. One M/SDP who found it easy and answered ‘yes’ to this question failed the task. Some of the comments given by the M/SDP:

- *“Some of the functions were not, because the two circles were in different places. I got mixed up with the two buttons. Both black... (She was talking about the round button, refer to Figure 4.12b)” (DP5)*
- *“I am not too sure actually, because they were a bit small to see, as you physically see. Some of the buttons were too small to see.” (DP3)*

The majority of the CDP failed the Hidden Task and Task 7; however, most of them mentioned that they found it easy, where only 3 of these participants were able to complete the digital camera tasks correctly. The other participants who responded ‘not sure’ mentioned that it was (1) not easy to understand which one was the delete button on the device, (2) the instruction manual was hard to use, and (3) it was not clearly shown on the device in which way batteries should be inserted.

Confidence in completion of the digital camera tasks: The participants were asked if they were confident that they have completed all the digital camera tasks correctly (Question 13). The majority of the respondents from all the user groups mentioned that they were. This was surprising particularly for the OP and CDP, because only one OP and three CDP were able to complete all the digital camera tasks correctly. Participants frequently mentioned that they were confident because they were able to take the required pictures.

4.10.2 The Third Section of the Post-Questionnaire

The third section of the post questionnaire contains questions to understand: (1) the preferences of the participants regarding the products that they use daily, and (2) whether the participants employed a different approach to using the two devices during the user trials.

General preference regarding everyday consumer products

According to Buurman (1997), lay users prefer simple to use devices with necessary functions, and this was consistent with the results of the survey. In order to explore this statement, the participants were asked about their general preferences about the products that they daily use (Question 14 and Question 15). 57% of the participants mentioned that they generally prefer using only the relevant functions rather than trying to learn all the functions of a product (refer to Figure 4.15a).

In addition, 65% of the participants mentioned that they prefer simple products with specific functions (refer to Figure 4.15b). All the older participants mentioned that they prefer simple to use devices.

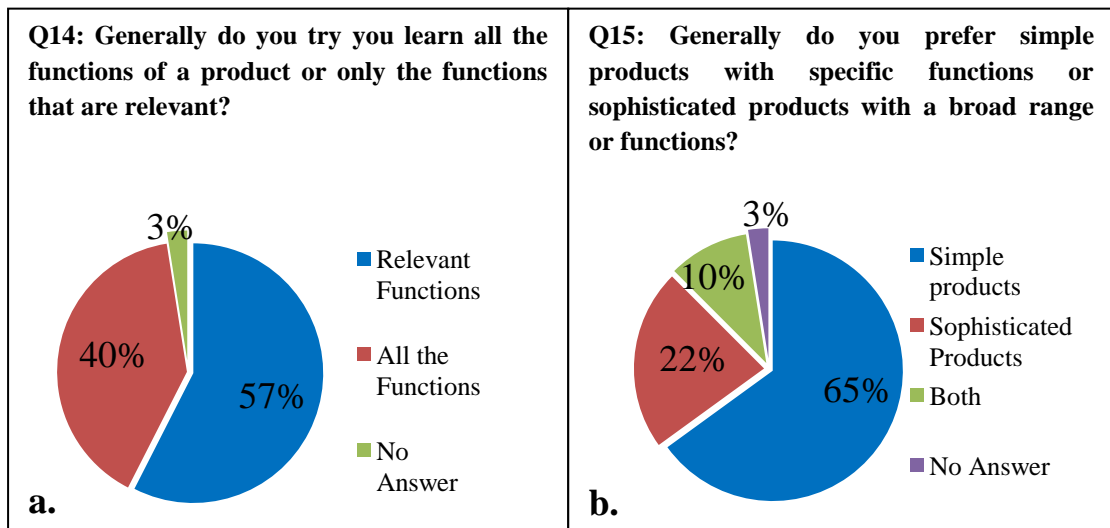


Figure 4.15 Results regarding the general preference of all participants regarding the products that they use daily

In order to identify an association between these two suggestions a Pearson Chi-Square test was applied by using SPSS statistical analysis software. The *hypothesis* was that ‘there would be a statistically significant association between the participants’ preference in using either simple or complex products and their

preference in learning only the relevant functions or all the functions of a product in general'. The *null hypothesis* was that 'there is no association between these two variables'. Four respondents who selected both options in Question 15 were exempted from this statistical test. Due to the fact that one cell had an expected value of less than 5, the results of the *Fisher's Exact Test* were taken into account. The results suggested that there is no statistically significant association between these two variables, where the p value was 0.237: ($\chi^2 = 1.222$; $p > 0.05$). This result does not allow the researcher to reject the null hypothesis.

Difference regarding the approach of the participants in using the devices

The participants were asked to indicate why they chose to use the instruction manuals for the both products or not (Question 16). The results showed that prior experience was the main determinant in the participants' decision. A few participants who used the instruction manual of the blood pressure monitor only mentioned that they used it because of the safety-critical nature of the device compared to the digital camera. This suggests that lay people may approach the use of home use medical devices differently.

- *"I used the manual for the blood pressure monitor because I never used that particular one (wrist) before. **I thought that improper use might influence the result.** I did not read the camera instructions, because I have used digital cameras before, although not Sony ones. In comparison to the blood pressure monitor, it is easier to determine if camera output is not correct. That is why I was not bothered much with its instructions."* (Y4)
- *"With the pressure monitor, **I was afraid that if I did something wrong, I could harm myself in some way, so it was better to make sure I use it right.** Digital cameras are –from experience- easy to use and understand. I did not feel like I need instructions."* (Y6)
- *"Used a camera before. Not so important if used incorrectly. But I think it is better if you use the manual for the blood pressure monitor because **you won't want to get it wrong.**"* (DP4)

The participants were asked to rate (on a scale of 1 to 5) how similar they found the operation of both the blood pressure monitor and the digital camera used in the study (Question 17), where 1 was totally different and 5 was very similar. 66.7% of the participants returned a rating of 1 or 2, meaning that a majority of respondents found the process of operating of these two devices very different.

The results of this question are presented in Figure 4.16.

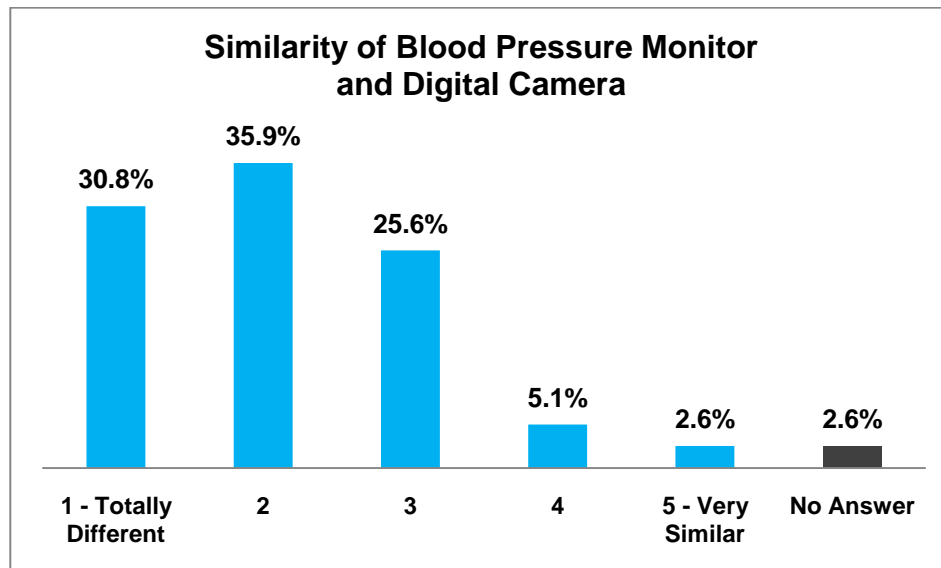


Figure 4.16 Results regarding how the participants had found the process of operating the blood pressure monitor and the digital camera

Expected features from a product

According to Vet [Vet, (1993) cited in Buurman, (1997)], lay users often seem to prefer to use products that are less efficient but more pleasing to operate: effectiveness and efficiency are less important for them. Buurman (1997) argues that pleasure and early success are important because they motivate lay users to seek further interaction. In order to test these statements, the participants were asked to rank four features of the products, i.e. simplicity, efficiency, pleasure, and ease of learning, and they were asked to use 1-4 for each parameter. As can be seen in the Figure 4.17, the results suggested that different types of users may have different expectations. However, overall ‘easy to learn’ and ‘simplicity’ got the highest ranking where pleasure was the least ranked feature. However, some of the participants with cognitive disabilities experienced difficulty in understanding this question, and seemed to have given random responses. The results suggested that ‘early success’ was definitely important for lay users;

however, overall ‘pleasure’ was less important than ‘efficiency’ when using the products.

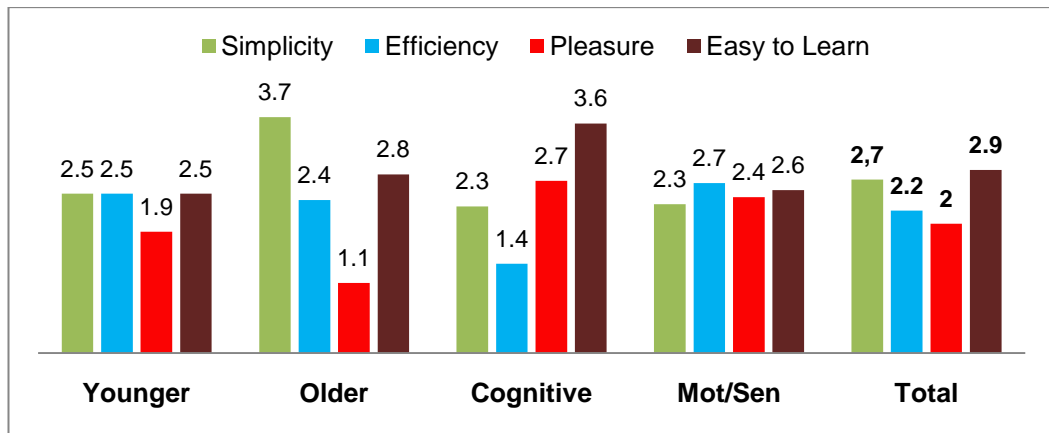


Figure 4.17 Results of ranking the four expected features from a product

The results were also tested in order to identify any statistically significant differences between the participant groups. The Kruskal-Wallis test was used due to the small sample size of each of the participant groups (refer to 4.5.1). It was *hypothesised* that “there would be a statistically significant difference between the participant groups in terms of their ranking of these four features”, where the *null hypothesis* was that “the participant groups responded in a similar manner when ranking these product features”. A *bonferroni correction* was applied in order to avoid a Type I error, therefore the critical value of .05 was divided by 4. The level of significance was .013 for these tests.

Simplicity: According to the results of the Kruskal-Wallis test, there was a statistically significant difference between participant groups, where the p value (Exact) was 0.005: $\chi^2(3, N=39) = 11.882, p < .013$. The mean rank values of the groups were: YP = 18.05, OP = **30.20**, M/SDP = 15.94, CDP = 15.40. As can be seen, there is a big difference between the OP and the other groups in terms of the mean ranks. Therefore a Mann-Whitney U test was used to identify any statistical significance between the OP and the YP. If these two groups are different, then this means that the result would be the same for the other participant groups, since the YP had the second highest mean rank value. The *hypothesis* was that ‘simplicity was a more important feature of a product for the OP when compared with the YP’, where the *null hypothesis* was that ‘both participant groups considered it to be equally important’. The results confirmed

the hypothesis, where the p value (Exact) was 0.013: (U=22.000, N₁=10, N₂=10, p < .05, one tailed). Simplicity was significantly more important for the OP when compared to the other participant groups.

Efficiency: According to the results of the Kruskal-Wallis test, there was a statistically significant difference between the participant groups, where the p value (Exact) was 0.006: $\chi^2(3, N=39) = 11.397, p < .013$. The mean rank values of the groups were: YP = 22.35, OP = 23.00, M/SDP = 24.94, CDP = **10.20**. As can be seen, there is a big difference between the CDP and the other participant groups in terms of the mean ranks. Therefore a Mann-Whitney U test was used to identify any statistical significance between the CDP and the YP. If these two groups were different this means that the result would be the same for the other participant groups, because the YP had the second lowest mean rank value. The *hypothesis* was that ‘efficiency was a less important feature of a product for the CDP when compared with the YP’, where the *null hypothesis* was that ‘both groups thought it was similarly important’. The results suggested that, confirmed the hypothesis, where the p value (Exact) is 0.018: (U=22.000, N₁=10, N₂=10, p < .05, one tailed). Efficiency was a significantly less important factor for the CDP when compared with the other participant groups.

Pleasure: According to the results of the Kruskal-Wallis test, there was a statistically significant difference between the four participant groups, where the p value (Exact) was 0.004: $\chi^2(3, N=39) = 11.397, p < .013$. The mean rank values of the groups were: YP = 19.40, OP = **10.75**, M/SDP = 23.83, CDP = 26.40. As can be seen, there was a big difference between the OP and the other participant groups in terms of the mean ranks and some difference between the YP and the CDP. Therefore a Mann-Whitney U test was used to identify any statistical significance, firstly between the YP and the OP, and then between the YP and the CDP. A *bonferroni correction* method was applied; therefore the critical value of significance (.05) was divided by 2. The level of significance is .025 for these tests.

The first *hypothesis* was that ‘pleasure was significantly less important for the OP when using a product when compared with the YP’, where the *null hypothesis* was that ‘both participant groups considered it to be equally

important'. The results confirmed the hypothesis, where the p value (Exact) was 0.017: (U=23.500, N₁=10, N₂=10, p < .025, one tailed). Pleasure was a significantly less important factor for the OP when compared with the other participant groups.

The second *hypothesis* was that 'pleasure was significantly less important for the YP when using a product when compared with the CDP', where the *null hypothesis* was that 'both participant groups thought it was similarly important'. The results did not allow the researcher to reject the null hypothesis, as the p value (Exact) was 0.74: (U=29.500, N₁=10, N₂=10, p < .025, one tailed).

The overall results suggested that 'pleasure' was significantly less important for the OP when using a product than the other participant groups.

Easy to learn: According to the results of the Kruskal-Wallis test, there was no statistically significant difference between these four user groups, where the p value (Exact) was 0.79: $\chi^2(3, N=39) = 6,672$, p < .013. This does not therefore allow the researcher to reject the null hypothesis: there were no significant differences between the participant groups in their responses to this feature.

4.11 Discussion

In this section, the methodological issues encountered during the observational studies and the overall results are discussed.

4.11.1 Methodological Issues

This study was intended to involve a diverse range of lay users who differ in terms of demographics or capabilities. Although this diversity was achieved and four different types of lay users took part in the study, it was also identified that the participant groups not only varied in terms of their age and/or capabilities but also in terms of their level of education, gender balance or ethnicity. Regarding their level of education especially, the difference between the participant groups might have an influence on the results of the study, therefore this was tested in order to identify any statistical significance. The results suggested that older participants were significantly less educated when compared to the other user groups. However this might be expected due to the increased educational opportunities available with the onset of time, in particular after the World War

II [Savage et al., 1973 (cited in Woods & Britton, 1988); Meyer et al, 1992]. On the other hand the possible effect of gender balance within the groups could not be tested due to very small sample sizes, however, the gender criteria was not considered to have a significant influence on this study. Nevertheless, the level of education should be considered when interpreting the results, where the older participants were less educated than the other user groups.

Although the participants were told to behave as realistically as possible, it is argued that people may behave differently in real life than in the observational studies (Faulkner, 2000). According to Keates & Clarkson (2004), user observation study is generally supplemented by a 'think aloud protocol'. This procedure "involves a participant speaking about what they are doing and thinking when using an interface" (Jordan, 2002: p.57). However, this method was frequently criticised by researchers, because when users are forced to speak during their performance, they are likely to behave differently than usual (Jordan, 2002; Rosson & Carroll, 2002; Nemeth, 2004). 'Think aloud' has limitations in terms of timing, because talking aloud may lead to longer task performance times, and it is labour-intensive due to the difficulty in summarisation of the complex behaviour (Nemeth, 2004). In addition it requires a certain degree of skill of verbalisation and concentration; for example participants who have cognitive disabilities or who are deaf might find it difficult to verbalise their actions concurrently during their interaction with the products. Therefore a think aloud protocol was not adopted in this study.

A retrospective think aloud protocol, where the participants verbally explain their actions after the task on the basis of a video recording of their performance (Haak et al., 2003), might prove useful; however this technique would dramatically increase the duration of the participant session (Haak et al., 2003) and was not adopted. Instead, the participants were encouraged to give any kind of verbal comments during the user trials. Besides, their considerations of their performance during the user trials were investigated in the post-questionnaire where they were asked questions to share their feelings and observations about the interaction problems experienced.

Jordon (2002) suggests that, filming the participants with a hidden video camera under the consent of the participants is one of the most effective ways in order to reduce the negative effects of the observation. However, this was not possible for this study, because most of the time the observational studies were conducted at the place of the organisations that helped to recruit the participants, and none of these organisations have the facilities suitable to hide the video camera.

One of the disadvantages of the observation was that the analysis of the video data was very time-consuming (Robson, 2002; Nemeth, 2004), where in some cases the analysis of the data for one participant had taken up to 6-7 hours for 1 hour of video recording. The analysis of the data gathered from participants having cognitive disabilities was particularly difficult, because some of the participants also had speech impediments which made their speech very difficult to transcribe. Similarly the study room (provided by the organisation), in which the study with the older participants was carried out, was very noisy, which also made it difficult to transcribe and most of the time iterative listening was required.

There was a methodological difference between the younger participants and the other participant groups. It is suggested in the literature that when conducting an observational study, the effect of the researchers' presence should be kept to a minimum in order to ensure the interaction of the participant is natural (Faulkner, 2000; Jordan, 2002; Robson, 2002; Keates & Clarkson, 2003; Nemeth, 2004). Owing to this, the younger participants were left alone during their interaction with the device, and this worked well. However, during the study with all the other participants, the PhD researcher was asked (by the organisations that helped recruit the participants) to accompany the participants during the study. Although the PhD researcher tried his best not to influence the user's interaction with the device, his presence might have had some effect on the users.

On the other hand the presence of the researcher during the study had a positive effect, because it was observed that participants were happy to share their insights and give more details about their prior experiences with similar or different products they use in their daily lives.

After the pilot study it was decided to remove the ‘hidden task’ from the study with older participants, because during the pilot study the PhD researcher was advised to do so. In fact, with the exception of one participant, none of the older participants could complete Task 7 which also involved deleting pictures from the memory card, and all these participants withdrew from the study during Task 7. This means that in some cases the study was adapted to the specific characteristics of the older participants. This was also suggested by Hawthorn (2007) for conducting usability tests, because older people have unique characteristics and require an appropriate methodology to suit them.

4.11.2 Characteristics of Users

The observational studies suggested that, all the participants experienced interaction problems during the user trials. Particularly during Task 2, 30 out of the 40 participants failed to use the device correctly. However, it was observed that different types of lay user groups experienced different interaction problems, or the same interaction problems due to different causes. They also reflected different user characteristics during their interaction with the products.

It was observed that there was a difference in terms of the participants’ approach in using these two devices. During the blood pressure monitor tasks, most of the participants from all the user groups referred to the instruction manual in order to use the device correctly and obtain accurate readings. On the other hand during the digital camera tasks participants frequently adopted a trial and error approach to explore means of using the device.

All the user characteristics found through the literature review (refer to Table 4.3) were confirmed through the observational studies. However, some of these characteristics were found to be more relevant to specific user groups rather than to lay users in general. The complete list of lay user characteristics observed during the study is summarised in Appendix G.

- **Personal and/or demographic variation:** Four different user groups were identified, and the observational studies showed that the majority of the participants had an idea of how to use the products, and some of them had even personally used similar devices prior to the study. This suggests that all these user groups are potential users of these products and they

vary significantly regarding their personal and/or demographic characteristics.

- **Little or no training:** The results of the questionnaires suggested that although some of the participants had prior experience with similar devices used in the study, none of them were professional users and they did not receive any training.

- **Little or no knowledge regarding the task and/or the product:** Participants frequently required information to perform the tasks or confirm their actions. Although in many cases they referred to the instruction manuals, they frequently complained about them.

Similar observations were also made during the digital camera tasks, in particular for OP and CDP. Some of the participants had prior experience of a digital camera and hence they had an idea about the basic functions of such a device. However, in some situations they required more information to perform the tasks, so as a result they referred to the instruction manual or tried to solve the problems with their own limited understanding.

- **Limited control over the product they use due to lack of confidence:** As is discussed by Langdon et al. (2007), it was observed that prior experience generally has a positive effect for all the participant groups. However, the study suggested **that in some cases prior experience might mislead the users**, in particular the younger able bodied users, because they may have high-confidence in using sophisticated devices and they frequently rely on their prior experience rather than the information provided by the manufacturer.

On the other hand according to Gupta (2007), lay users lack confidence, and the results of the observational studies were consistent in particular with the older participants, the participants with cognitive disabilities, and some of the participants having motor/sensory disabilities. Although it is confirmed that, some of the lay user groups may lack confidence, highly motivated users may exhibit over-confidence which mislead them during their interaction with sophisticated products.

- **Poor at identifying problems or errors:** During the blood pressure monitor tasks most of the participants misused the device but they were not aware of the interaction problems experienced or the errors that they made. Surprisingly most of the participants from all the user groups thought, via the questionnaire, that they were confident that they had completed the tasks correctly, although the observation demonstrated contradictory results, where (in particular during the blood pressure monitor tasks) the participants often made mistakes which might inadvertently affect the accuracy of the device. This suggests that lay users are poor at identifying problems or errors (Kaye & Crowley, 2000).
- **Poor at overcoming device limitations:** This was observed during the digital camera tasks (Task 5 and Task 6), where the participants were asked to take a good picture. The tasks were prepared to include some potential barrier which would make it harder to take a good picture by only using the basic functions of the device. In particular OP, CDP and some of the M/SDP were unmotivated to try using other functions of the device and stuck to the basic functions where the device provides a limited range of functionality options. As a result several participants provided bad pictures during these tasks. However, it was also observed that YP and some of the M/SDP were more likely to use other photo capture modes or functions of the digital camera in order to provide good pictures.
- **May experience difficulty in dealing with unexpected situations:** During Task 2, Hidden Task and Task 5 this characteristic was frequently observed for all the participant groups. A common reaction was to ignore the unexpected feedback given by the device, or if possible ignore the problem itself and hope for the best. This might be the result of the bad pictures provided by the participants during Task 5 where they frequently did not even attempt to turn the flash off in order to avoid reflection back from the mirror (refer to 4.5.4).
Although very rarely this characteristic was also observed with YP, they were found to be the most successful group in dealing with unexpected situations. This may be the result of their familiarity with technology.

- **Prefer easy to use devices with specific functions:** The results of the post-questionnaire suggested that lay people prefer simple products and they frequently use only the relevant functions rather than trying to learn all the functions (Figure 4.15). As can be seen in Figure 4.17, the overall results showed that when using products, lay users expect the products to be easy to learn. The results also suggested that the simplicity of a product is particularly important for older people, whereas experiencing pleasure when using products is less important for them when they are compared with the other user groups. Similarly, efficiency of a product is less important for cognitively disabled people when compared with other features.
- **Unlikely to follow instructions:** The observational studies suggested that there are three aspects to this characteristic; (1) user preference of not referring to the manual, (2) design and development related problems in the manuals, and (3) not being able to use due to impaired capabilities. On the other hand, although overall the older participants used the instruction manuals more than all the other user groups, they experienced several difficulties due to their impaired capabilities, and this was consistent with the studies carried out by Horen et al. (2001; 2005). In terms of approach to using the instruction manuals of the devices, it was observed that the most successful user group was the YP, because where they referred to the instruction manuals, they used them effectively. OP and some of the M/SDP experienced design related difficulties when interacting with the manuals, such as not being able to read the text due to very small font size. CDP frequently complained about the instruction manuals of the devices. Most of the CDP participants who used instruction manuals experienced difficulties due to their reading skills (Gardill & Jitendra, 2001), and reading comprehension deficiency was prominent (Gardill & Jitendra, 2001; Gestern, et al., 2001). This was demonstrated through their understanding of the text descriptions and occasionally they had difficulty in understanding the figures. Attention deficits were also frequently observed as suggested by McKinney (McKinney, 1984), especially when

they were trying to find the correct sections within the manuals, which turned into a challenge for CDP.

- **Have difficulty in understanding specific terminology:** Majority of the participants experienced difficulty in understanding the descriptions given in the instruction manuals and often complained about the complexity of the information. Particularly during the blood pressure monitor tasks, participants experienced difficulty in understanding the specific terminology used in the descriptions such as the word of ‘fulcrum’. Some of the medical terms also lead to confusion, e.g. systolic or diastolic blood pressure.

There were also other user characteristics observed during the study. As suggested by Jordan (2002), the observation and the feedback given by the participants during the post-questionnaire showed that, lay users frequently had **expectations regarding the way that products should be used.**

During their interaction with the products, some of the M/SDP **developed their own strategies to cope with the barriers they encountered** (Newell & Gregor, 1999; Marshall, et al., 2010). Both of the products required the use of both hands in order to perform some actions, therefore the products used in the study were found to be high-capability-demanding for some of the severely disabled participants. The M/SDP who had prior experience with similar devices performed better than the others.

OP and CDP were found to be unfamiliar with digital devices. This was consistent with Eisma et al.’s (2004) study, where they argue that older people are **less familiar with the concepts, visual language and the interface metaphors of digital devices.** According to Wright (2000), older people are likely to experience difficulties with three aspects of cognitive change, i.e. memory, attention and comprehension. The effects of decreased memory were obvious where they were asked to recall a previous action. They had a **tendency to give up and as a result blame themselves** for failing to complete the tasks; and this was consistent with the findings that Hawthorn (2007) discussed in his paper. It was also observed that older people had tendency to **try to perform the**

given actions in the instruction manual, instead of trying to understand the logic behind these.

CDP experienced more difficulties than all the other user groups. This may be the result of, as discussed by Keates et al. (2007), society still lacking recognition of people with cognitive and learning difficulties when compared with motor or sensory disabilities, and a subsequent lack of consideration of their needs and requirements. The observation showed that CDP frequently experienced interaction problems due to their reading skill, comprehension, impatience and attention issues, which hinder them in using the devices, as well as the instruction manuals. According to Valett (1969), repeated failure can have negative motivational effects on people with learning disabilities. This may be the reason why CDP were unmotivated in using the devices, and as well as the accompanying instruction manuals.

As suggested by Gillham (2000), questionnaires were used in the study to complement the observations made and to provide a more comprehensive picture about what was observed. The results of the post-questionnaire showed that, **participants' perceptions about their performance did not tally with what was observed during the study.** Although during the user trials many participants experienced several difficulties, most of them were not aware of these difficulties or they did not recognise them as a difficulty.

The results of the questionnaire suggested that although both the devices were digital, most of the participants found that the operating processes for both were different. However due to the fact that this study only involved testing of two devices from two different markets (i.e. one home use medical device and one general consumer product), it does not provide sufficient evidence to identify any issues relevant to the field of home use medical devices. The results cannot be generalised for neither wrist-fitted blood pressure monitors nor digital cameras overall. As mentioned before, this study particularly focussed on the identification of lay user characteristics, and the characteristics identified (the full list can be seen in Appendix G) do not point towards a specific product or field.

4.11.3 Nature of the Interaction Problems

The analysis of the video recordings and the feedback given by the participants suggested that the interaction problems experienced by the participants are classified in three categories, i.e. (1) user - product: usage related problems, (2) user capability - product: matching problems, and (3) user - designer: understanding problems.

User – Product: usage related problems are the avoidable mistakes given the design of the product. Although the solution is provided by the designers in the design of the product itself, with labels on the product or within the instruction manual, users may make mistakes due to not referring to or ignoring the information provided by the manufacturer or the feedback given by the device.

“Some people are especially prone to making errors. Similarly the design of some device seems to invite errors in their use” (Wiklund & Wilcox, 2005: p.169). According to Smith (2003), users frequently behave in a way that is inconsistent with what the manufacturers intended; and they may not prefer to use instruction manuals and might try to work out how to use the device themselves using their own intuition. It is important to investigate foreseeable errors in use during the design process and provide solutions to keep these errors to minimum.

User Capability – Product: matching problems emerge when the product requires higher capability than the actual capability of the user. In fact, they are a design fault given the user characteristics, because these problems are caused when the designers have a lack of understanding about the capabilities of the target users. Older people and disabled people are frequently faced with this problem. However, by setting the capability demand of a product during the design process this problem can be solved. This will result in an increased number of people who can use the device, as well as increased satisfaction of users (Clarkson, et al., 2007).

User – Designer: understanding problems are the most critical ones, and these problems emerge if the solutions developed by designers in the design process do

not match target users' mental model which results in confusion when using the products. Therefore *designing for compatibility*²⁶ is crucial (Jordan, 2002).

Norman (2002) identifies three different aspects of mental models, i.e. the design model, the user's model, and the system image. He argues that, the design model (the conceptualisation that the designer has in mind) and the user's model (the users' interpretation on the operation of the system) communicate only through the system itself. Therefore the designers must ensure that the product clearly exemplifies the operation of the proper conceptual model, which should be consistent with the users' model. The system image also includes the instruction manuals and other documentation.

These three types of problems are interrelated to each other, and one type of problem may lead the user to another. For example during the blood pressure monitor tasks, some of the participants attached the device to their hand in the wrong position, although the correct position was described in the instruction manual. In this case, the interaction problem was identified by the designer during the design process and in order to prevent this problem the solution was given in the instruction manual. Therefore this is an example of a 'user – product: usage related problem'.

On the other hand although the solution of the possible interaction problem was provided by the designers, the method of use was not intuitive (the way of use is unexpected for the users) which led to confusion of the users and misuse of the device. This is a 'user – designer: understanding problem' which leads to a 'user/product usage related problem'.

A diagram can be seen in Appendix E, exemplifying these three types of interaction problems by giving examples from those observed with the blood pressure monitor during the user trials.

²⁶ According to Jordan (2002: p.26) designing for compatibility is "the way the product works first in with users' expectations based on their knowledge of the 'outside world'".

4.12 Summary

This chapter provided a comprehensive picture of lay users and their characteristics. It particularly focussed on addressing the first research question: “who are lay users, and what are their characteristics?” This study was carried out as a part of the ‘Descriptive Study I’ with reference to the DRM (Blessing et al., 1995). Three objectives were achieved:

- **Confirmation of the characteristics of lay users determined by the literature review:** All the lay user characteristics found through the literature review were confirmed by means of the observational studies.
- **Identification of different types of lay users in order to understand how they differ in terms of their characteristics:** Different types of lay users who differ in terms of their demographics and capabilities were identified. The results of the observational studies suggested that some of the characteristics were specifically relevant to some of the lay user groups, but not applicable to all.
- **Identification of new lay user characteristics:** A number of new lay user characteristics were identified. Most of these lay user characteristics were specific to specific lay user groups. In total 20 new lay user characteristics were identified in this research. The characteristics of lay users are summarised in Appendix G.

The observational studies suggested that lay users’ diversity makes it impossible to consider them as one single user group. Different types of lay users are likely to exhibit specific user characteristics in accordance with their personal/demographic state and capabilities. This information may be useful for designers when designing products for lay users, such as home use medical devices.

The next chapter will discuss the designers’ point of view regarding home use medical devices and their requirements during the design process, in an effort to address the second research question (what are the challenges faced by designers in developing home use medical devices?). It will also provide the preliminary answers to the third research question (how to support the design of home use medical devices?).

CHAPTER 5: REQUIREMENT CAPTURE: SURVEY WITH DESIGNERS

As discussed in 1.4, it was considered necessary to provide guidance for designers during the design process of home use medical devices, which will help them to better address the needs and expectations of lay users. A similar approach has been initiated by the FDA with respect to providing guidance for manufacturers in order to ensure the safe use of medical devices in the home environment. Their focus, however, was on the requirements of the U.S. market (FDA, 2010d). This research focuses on the requirements of designers, and in particular, for the European market.

In Chapter 2, the design process of home use medical devices was investigated and a number of challenges faced when designing home use medical devices were identified in literature. In addition, it was found that home use medical devices must also fulfil the regulatory requirements of medical devices. However the information found in literature was very limited; and although Chapter 2 provided an idea of the issues relevant to designing home use medical devices, it was necessary to understand designers' point of view in order to address their requirements when undertaking the design of home use medical devices.

This chapter aims to provide first hand information from designers for the second and (partly) third research questions: 'what are the challenges faced by designers in developing home use medical devices?' and 'how to support the design of home use medical devices?' With this intention in mind, a questionnaire survey was conducted with professional designers. The objectives are to identify:

- Designers' perspectives on the design process of home use medical devices
- Designers' requirements when designing home use medical devices
- Designers' expectations regarding a suitable method for assisting them

This study involved both qualitative and quantitative data collection methods: i.e., designers' insight through open-ended questions and numeric data by means of closed questions.

As shown in Figure 3.1 (Chapter 3), this study was carried out as part of the ‘Descriptive Studies I’ (Blessing et al., 1995). The results of this study lead to the development of the first version of the support tool.

5.1 Preparation of the Survey

A survey was considered to be the most suitable method to collect the necessary information, where the reasons were discussed in Section 3.4.2 (Chapter 3).

5.1.1 Sampling of the Designers

The sampling methods used for this study differ from those used for the pilot study and main survey.

The purpose of the pilot study was to identify any mistakes in the questionnaire which might result in misunderstanding of the respondents’ answer. Therefore convenience sampling was utilised (Robson, 2002). All the participants were recruited from within the ranks of lecturers and other research students in the Brunel University, and colleagues. 12 participants took part in the pilot study.

On the other hand, in order to recruit the participants for the actual study, purposive sampling (Robson, 2002) was utilised. The researcher wanted all the participants to be professional designers having a BA or BSc from a design related subject involving the design of products, and having at least 2 years of experience in the field. In order to approach possible respondents, personal contacts, Brunel University alumni, and other designers located in the UK were found through ‘www.designdirectory.co.uk’ and contacted. The questionnaire was sent to 400 designers and 53 of them responded.

5.1.2 Designing the Questionnaire

The questionnaire was prepared by means of the SurveyMonkey tool. After the completion of the first draft, several changes were made in accordance to the feedback given by the respondents during the pilot study.

The title of the questionnaire was highly indicative of its content (Gillham, 2000). During the pilot study it was observed that the respondents were often inclined to mention their lack of confidence in responding to the questionnaire, because they did not have any prior experience in designing any kind of medical

devices. Therefore, the term ‘medical device’ was not included in the title, and ‘lay users’ and ‘design’ terms were used instead.

Similarly, in order to elicit appropriate responses, it was important to make the respondents understand the aims of the survey (Gillham, 2000). Therefore a small introductory section was included at the beginning of the questionnaire. This included information about the purpose of the research and the importance of the respondents’ contribution.

10 questions were included in the questionnaire. Although it was not separated into sections, relevant questions within it were grouped into four sections in order to provide a logical flow. (1) The first section was prepared in order to collect general information about the participants, to see whether they matched the sampling criteria; (2) the second section focuses on understanding the designers’ point of view in designing home use medical devices and their requirements regarding the design process, (3) the third section was about understanding the designers’ requirements and preferences about the guidance (4) and the last section was included to ask for designers’ participation in the further study in order to evaluate the first draft of the guidance.

Most of the questions in the questionnaire were selected response questions. Some of these questions were routed to an open-ended part in order to collect more information about the reasons given for the respondents’ answers. In addition, a number of multiple choice questions were used in the questionnaire, and all these questions included an ‘other’ option to allow the respondents to mention other choices which were not offered in the relevant question.

The questionnaire includes four interrelated scale response questions, where all these questions were grouped and presented as a single question in order to emphasise their relationship to each other. In this question the participants were asked to rank four different types of information according to their importance in the design process. A popular five-point (Hague, 1993; Gillham, 2000) scale was used (‘1’:‘Not important’; ‘5’:‘Very important’). The consideration that some designers may wish to express neutrality for these questions, therefore, ‘3’ was deemed appropriate to express this view.

The final version of the questionnaire can be seen in Appendix H.

5.1.3 Analysis of the Data

Two different methods were utilised when analysing the data, one for analysing answers to closed questions, and the other for answers to open-ended questions.

All the data was entered and analysed by means of SPSS statistical analysis software (see example in Figure 5.1).

| | Question1 | Question2 | Question3 | Question4 | Question5a | Question5b | Question5c | Question5d | Question6a | Question6b | Question6c | Question6d | Qu |
|----|-----------|-----------|-----------|-----------|-------------|-------------|-------------|-------------|------------|------------|------------|------------|----|
| 1 | 7,5 | ID | Yes | Yes | High Import | Average Im | High Import | Extremely I | 1 | . | . | . | . |
| 2 | 5,0 | IDT | No | No | High Import | High Import | High Import | Extremely I | 1 | 1 | 1 | 1 | . |
| 3 | 6,0 | PD | No | Yes | High Import | Extremely I | Extremely I | Extremely I | 1 | 1 | 1 | . | . |
| 4 | 6,0 | PD | No | No | Average Im | Extremely I | High Import | High Import | 1 | 1 | 1 | . | . |
| 5 | 7,0 | PD | No | Yes | Extremely I | Extremely I | Extremely I | Extremely I | 1 | . | . | . | . |
| 6 | 6,0 | ID | No | Yes | Extremely I | Extremely I | Extremely I | Extremely I | 1 | 1 | 1 | 1 | . |
| 7 | 6,0 | PD | Yes | Yes | Average Im | Extremely I | High Import | Extremely I | 1 | . | . | . | . |
| 8 | 6,0 | PD | No | No | Extremely I | Extremely I | Extremely I | Extremely I | 1 | 1 | . | . | . |
| 9 | 3,0 | ID | Yes | Yes | High Import | Extremely I | Extremely I | Average Im | . | . | . | . | . |
| 10 | 4,0 | ID | Yes | No | Average Im | High Import | Extremely I | Extremely I | 1 | 1 | 1 | . | . |
| 11 | 5,0 | PD | No | Yes | Extremely I | High Import | Extremely I | High Import | 1 | . | . | 1 | . |
| 12 | 6,0 | PD | No | Yes | Extremely I | Extremely I | Extremely I | Extremely I | 1 | 1 | . | . | . |
| 13 | 7,0 | ID | No | Yes | High Import | High Import | Average Im | Extremely I | 1 | . | . | . | . |
| 14 | 7,0 | IDT | No | Yes | High Import | Average Im | Extremely I | Extremely I | 1 | 1 | 1 | 1 | . |
| 15 | 3,0 | IDT | No | Yes | Extremely I | Extremely I | Extremely I | Extremely I | 1 | 1 | . | . | 1 |
| 16 | 7,0 | PD | No | Yes | Average Im | Extremely I | Extremely I | Extremely I | 1 | 1 | . | . | . |
| 17 | 10,0 | PD | Yes | Yes | Extremely I | Average Im | High Import | Extremely I | 1 | . | . | . | . |
| 18 | 6,0 | PD | No | Yes | Average Im | Extremely I | Extremely I | Extremely I | . | . | . | . | . |
| 19 | 5,0 | IDE | No | No | Extremely I | Extremely I | Extremely I | Extremely I | 1 | 1 | . | . | . |
| 20 | 4,0 | IDE | No | Yes | Extremely I | Extremely I | Extremely I | Extremely I | 1 | . | . | . | . |
| 21 | 4,5 | PD | No | Yes | Extremely I | Extremely I | Extremely I | Extremely I | 1 | 1 | 1 | . | . |
| 22 | 5,0 | IDT | Yes | Yes | Average Im | Extremely I | Extremely I | Extremely I | 1 | 1 | . | 1 | . |
| 23 | 6,0 | IDT | No | Yes | Extremely I | Extremely I | Extremely I | Average Im | 1 | 1 | 1 | 1 | . |
| 24 | 3,0 | PD | No | Yes | High Import | Average Im | High Import | Extremely I | 1 | . | . | . | . |
| 25 | 4,0 | ID | No | Yes | High Import | Extremely I | Extremely I | High Import | . | 1 | . | 1 | . |
| 26 | 4,0 | PD | No | Yes | Extremely I | Extremely I | Extremely I | Extremely I | 1 | 1 | 1 | . | . |
| 27 | 4,0 | ID | No | Yes | High Import | Extremely I | Extremely I | High Import | . | . | . | . | . |
| 28 | 6,0 | PD | Yes | Yes | Extremely I | Extremely I | Extremely I | Extremely I | 1 | 1 | 1 | . | . |

Figure 5.1 Data set prepared in SPSS Software

Coding was used to analyse the data collected via the open-ended questions. According to Robson (2002: p.257), the main purpose of coding is “to simplify many individual responses by classifying them into a smaller number of groups, each including that are similar in content.” An example of coding is illustrated here by Question 4 (Comparing ‘home use medical devices’ and ‘everyday consumer products’, do you think there are any differences in terms of the design approach?) where all the participants were asked to briefly indicate the reasons behind their choice. During the analysis of the data, all reasons mentioned by the respondents were derived from the text and summarised. Each summarised reason was written in a MS Word file as a separate row, which includes the code

of the respondent at the beginning of the sentence. The word document was printed out and each reason was cut as a separate card.

After this exercise all the reasons were reviewed in order to prepare a coding frame. Coding frames, also known as codes, include the entire classification scheme which enables the researcher to create a sensible categorisation (Oppenheim, 2001; Floyd & Fowler, 2002). The coding method was utilised for Questions 4, 5, 6, 8, 9. Following the suggestion by Oppenheim (2001), a separate coding scheme was developed for each of these questions. The biggest challenge was to keep the number of categories as minimal as possible, as in the literature generally around twelve categories are suggested for each coding frame (Oppenheim, 2001; Robson, 2002). After the first categorisation attempt, the categories used by only one respondent were combined as a separate ‘other’ category (Oppenheim, 2001; Floyd & Fowler, 2002). With the exception of the ‘Other’ category, if the same participant mentioned two or more similar reasons which fell into the same category then only one of them was included.

5.2 Results of the Survey

The survey was sent to 400 designers and 53 responded; a response rate of 13.25%. As mentioned in 5.1.2, the questionnaire was designed to collect information to answer four questions and these are addressed in the sections below.

- Do the respondents match the sampling criteria?
- What are the designers’ points of view on designing home use medical devices and what are their requirements during the design process?
- Do they require guidance, and if so, what information is required?
- Would the respondents like to take part in the further study where they will be asked to evaluate the first draft of the guidance?

This section presents the results of the survey in order to address the first three questions.

5.2.1 Do the Respondents Match the Sampling Criteria?

All the respondents had two or more years of design experience. 71.7% of the participants had 4 to 6 years of experience. 20.8% of the participants had more than 6 years of experience. The mean value is 5.6 years of experience.

All the respondents hold a degree of a product design related subject. Table 5.1 summarises the subject of the degrees of the respondents and presents the percentages within the whole sample group. 34% of the respondents were product designers.

The respondents were also asked whether they have any prior experience in designing home use medical devices, and 18 respondents (34% of all) indicated that they have prior experience.

Table 5.1 Education background of the respondents

| Subject of Degree | Frequency | Percent |
|-----------------------------------|------------------|----------------|
| Industrial Design | 12 | 22.6% |
| Product Design | 18 | 34% |
| Industrial Design and Technology | 12 | 22.6% |
| Design Engineering | 6 | 11.3% |
| Mechanical Engineering and Design | 3 | 5.7% |
| Ergonomics | 1 | 1.9% |
| Engineering Design | 1 | 1.9% |
| Total | 53 | 100% |

The results suggested that all the respondents matched the sampling criteria.

5.2.2 Designers' Points of View Regarding Designing Home Use Medical Devices

In Question 4, the participants were asked if there was any difference in terms of the approach to the design of 'home use medical devices' when compared with 'everyday consumer products'. The results suggested that 76% of the participants think there is a difference.

It was *hypothesised* that 'there would be a statistically significant association between prior experience in designing home use medical devices and the

designers' thoughts on whether there was any difference in terms of the approach to designing home use medical devices when compared with everyday consumer products'. The *null hypothesis* was that 'there was no association between these two variables'. This was tested using a Pearson Chi-Square test.

The Pearson Chi-Square test, basically, cross tabulates and compares the observed values to the expected values for each of the cells in the table; therefore the test can be used for unequal sample sizes and for non-normally distributed data as well (Field, 2005). On the other hand it requires all the cells to have an expected count of more than 5 (Field, 2005). For this test one of the cells had an expected count of 4.42; therefore Fisher's Exact Test (used for 2×2 tables if the sample size is small), was used (Foster, 2002; Kinnear & Gray, 2004).

According to the results no statistical significance was identified between the respondents with prior experience and the others with no prior experience, where the p value was 0.470: (χ^2 (1) = 0.155; $p > 0.05$). This does not allow the researcher to reject the null hypothesis.

The respondents were asked to indicate why they thought that there was a difference. In total, 87 reasons were given by the respondents. All these reasons were coded under 14 categories, including an "other" category. Figure 5.2 summarises the results.

The differences indicated by the participants regarding the approach to designing home use medical devices

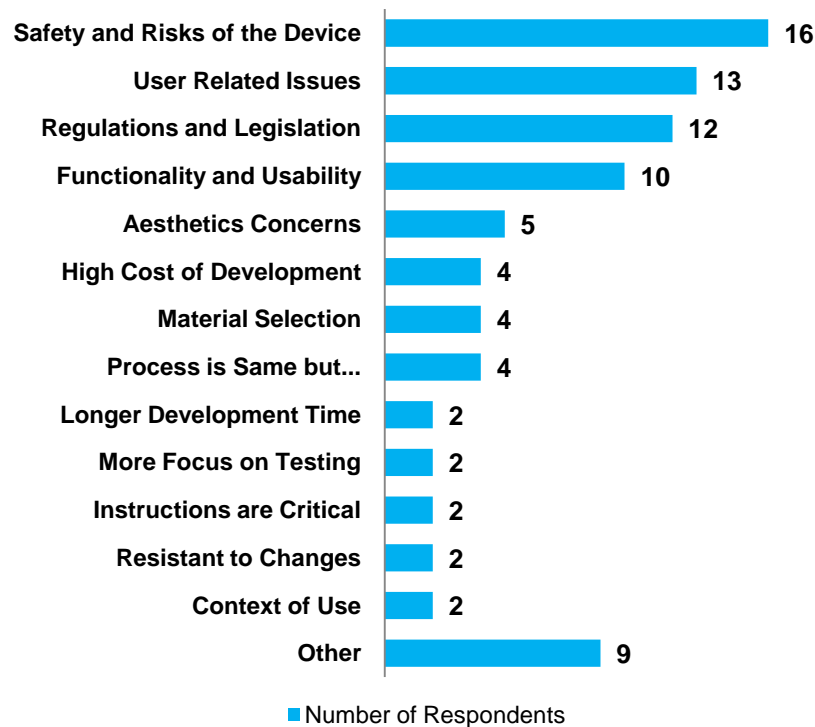


Figure 5.2 The reasons indicated by the respondents for the open-ended Question 4

- Safety and risk of home use medical devices:** As can be seen from Figure 5.2, ‘Safety and the possible risks of the device to the user’ was the most mentioned category; it was mentioned by 16 designers. The respondents frequently mentioned that reliability of the product is a significant consideration with home use medical devices and incorrect action may pose a threat to the wellbeing of the user. These devices require extra attention so that they work accurately. It is also important that the devices do not lead to misuse.
- User related issues:** ‘User related issues’ were mentioned by 13 designers. The respondents mentioned that the diversity of the users and their capabilities should be taken into account during the design process of home use medical devices. Although the respondents frequently mentioned some of the lay user characteristics (e.g. the knowledge level of the participants, their capabilities or emotional needs) during this question, only one of these respondents used the term ‘lay users’.
- Regulations and Legislation:** ‘Regulations and legislation’ was the third factor, mentioned by 12 respondents. They mentioned that the regulations

are stricter for home use medical devices and due to the fact that these devices are accepted as medical devices, different types of standards are required. One of the respondents also mentioned that designers are concerned about their legal protection due to the possible risks to the users of the device.

- **Functionality and Usability:** 10 respondents mentioned that there is more emphasis on the functionality and/or usability aspects of home use medical devices. In addition two respondents mentioned that functionality and usability were weighted more heavily in the design process than aesthetics.
- **Aesthetics Concerns:** 5 respondents mentioned that home use medical devices require more attention to aesthetical considerations, as many existing medical devices feature a lack of any such styling. One participant mentioned that home use medical devices are special in that they have their own aesthetics which are associated with both clinical and consumer products.
- **Higher Cost of Development:** 4 designers mentioned that home use medical devices often have higher cost of development, and consumers frequently find these devices expensive. In addition, higher costs of development sometimes affect the material selection or the manufacturing selection of the devices.
- **Material Selection:** 4 respondents indicated that extra care should be given to material selection for home use medical devices, for example choosing body-safe materials.
- **Process is same but...:** 4 respondents indicated that they think the process is similar but there are subtle differences in detail. They mentioned that the priority of the considerations and the requirements are different.
- **Longer Development Time:** 2 respondents mentioned that home use medical devices have longer development time. One of these participants mentioned that this is the result of longer testing time for medical devices.
- **More Focus on Testing:** 2 respondents mentioned that during the design and development process of home use medical devices there is more

focus on user testing and product testing when compared with everyday consumer products, in order to make the medical device more robust.

- **Instructions are Critical:** 2 respondents indicated that instruction manuals are critical for home use medical devices because usability of these devices frequently depends on the information provided in the manuals. Therefore the accompanying instructions should be easy to understand and easy to use.
- **Resistance to Changes:** 2 respondents indicated that designers generally came up with the obvious solutions, because manufacturers are quite resistant to changes unless their advantages are justifiable. Manufacturers frequently look for high traceability.
- **Context of Use:** 2 respondents mentioned that understanding the context of use is significant when designing home use medical devices.
- **Other:** 7 respondents mentioned 9 more factors; all these factors are only mentioned once. Examples are as follows:
 - Different research methods are required for designing home use medical devices.
 - Design approach also varies depending on the type of home use medical device.
 - Home use medical devices are only indicators, and outputs must be verified by a medical professional.
 - Home use medical devices are medical devices, not every day products.

All the categories discussed above were grouped into three in accordance with their level of importance. The more frequently a group was mentioned, the more importance it was given. The first four categories were grouped together and named as the ‘unique aspects of home use medical devices’. The last 5 categories (including ‘other’) which were only mentioned by two or one respondents were grouped as ‘minor differences of home use medical devices’. The other categories, in the middle (mentioned by four or five respondents), were deemed major differences of home use medical devices. Figure 5.3 summarises the grouping.

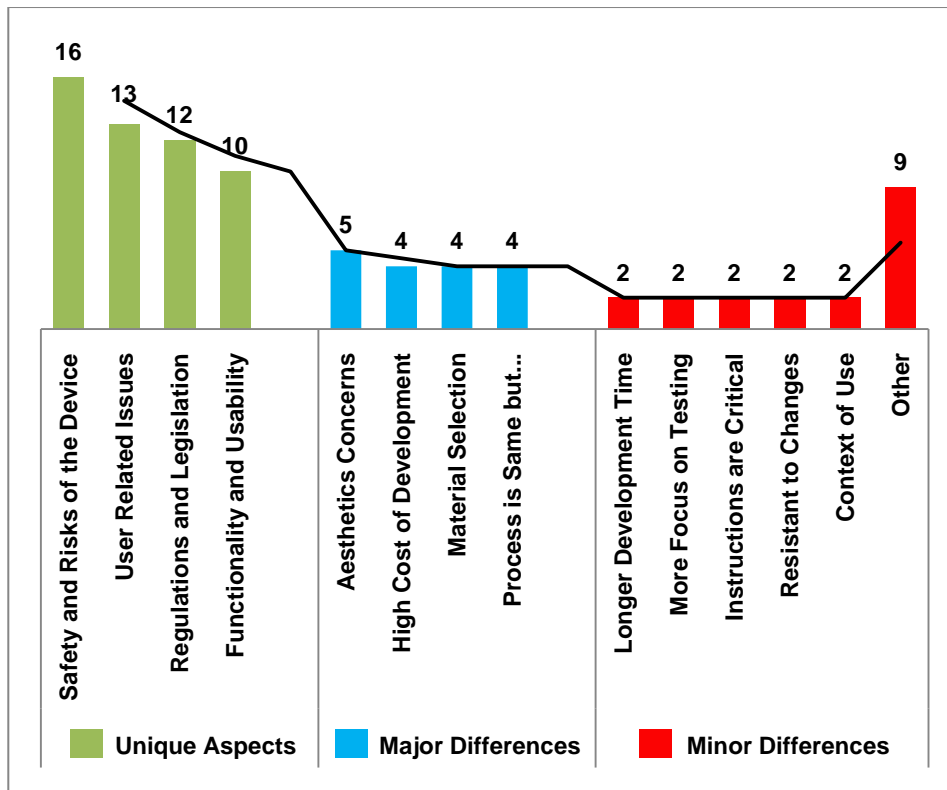


Figure 5.3 Classification of the categories

5.2.3 Designers' Requirements Regarding Designing Home Use Medical Devices

One of the aims of the survey was to identify the designers' requirements during the design process of home use medical devices. The designers were asked to scale four different types of information in terms of their importance throughout the design process of home use medical devices (Question 5). These four information types were:

- Medical knowledge relevant to the design process
- User information
- Context of use of the product
- Regulations and legislation

A five-point scale was used in Question 5 ('1': 'Not important'; '5': 'Very important'). An 'other' option was also provided. The overall results of the question can be seen in Figure 5.4 where the mean values are presented for each information type.

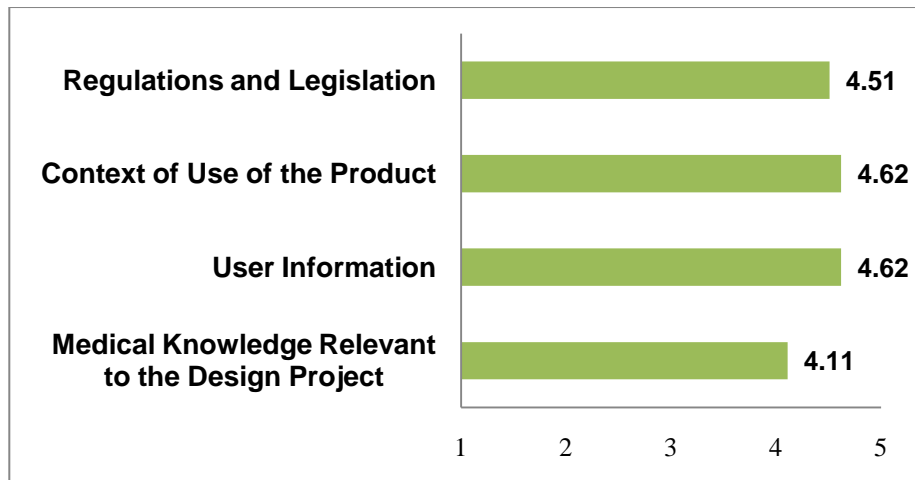


Figure 5.4 The mean values for four different types of information

The overall score suggests that all of the four types of information are necessary during the design process of home use medical devices. The results suggest that the ‘context of use of the product’ and ‘user information’ have the highest importance (both with a mean value of 4.62).

In order to understand whether prior experience in designing home use medical devices had an effect on the designers’ perspective, the results were assessed in order to identify any statistical significance. A non-parametric test was used due to small sample sizes (Foster, 2002; Kinnear & Gray, 2004; Field, 2005). *Mann-Whitney U test* was found to be the most suitable test for the purposes of this analysis, because: (1) it is a non-parametric test, (2) it can be used for unequal sample sizes, and (3) it is used for comparing two independent samples (Field, 2005). A *bonferroni correction* was also applied to avoid the possibility of a type I error; therefore the critical value of .05 was divided by 4. The significance value for these tests was thus .013.

The *hypothesis* was that ‘the designers having experience might respond differently when ranking these four information types when compared to the others with no experience’. However the hypothesis was non-directional, as there was no clear rationale to suggest that designers who have experience in designing home use medical devices would consider each of the information types to be more or less important than designers with no experience in this field; therefore a two-tailed test was used. The *null hypothesis* was that ‘there would be no difference between the designer groups (with or without experience) to each of these information types’. The results can be seen below.

- **Regulations and Legislation:** No significant difference was identified between the two groups, where the p value (Exact) was 0.513: (U=282.500, N₁=35, N₂=18, p > .013, two tailed). This does not allow the researcher to reject the null hypothesis.
- **Context of Use:** No significant difference was identified between the two groups, where the p value (Exact) was 0.788: (U=303.000, N₁=35, N₂=18, p > .013, two tailed). This does not allow the researcher to reject the null hypothesis.
- **User Information:** No significant difference was identified between the two groups, where the p value (Exact) was 0.235: (U=263.500, N₁=35, N₂=18, p > .013, two tailed). This does not allow the researcher to reject the null hypothesis.
- **Medical Knowledge Relevant to the Design Project:** No significant difference was identified between the two groups, where the p value (Exact) was 0.035: (U=211.000, N₁=35, N₂=18, p > .013, two tailed). This does not allow the researcher to reject the null hypothesis.

The respondents were also asked to specify any other type of information requirement during the design process, and 8 designers responded, identifying 9 information types. These information types were further grouped into two categories:

- **Current market information:** 5 respondents mentioned that they require specific information about the current market, such as the information about similar products in the market, or the information about the current healthcare systems and any associated restrictions such as those on over-the-counter/prescriptive devices.
One respondent also mentioned that market specific regulatory information would be useful, such as variation of regulations from region to region, or the recency of regulations for a specific market.
- **Information from other stakeholders:** 3 designers mentioned that they require direct information from other stakeholders involved in the process from the conception to production, such as medical doctors, nurses, patients, pharmacists, marketing organisations, manufacturers, regulatory bodies, etc.

5.2.4 The Information Sources Used by Designers

In order to understand what types of information sources are frequently used by designers during the design process, a multiple response question was prepared. In Question 6, a number of different types of information sources were given in order for the respondents to select the ones that they use regularly when designing products. In case respondents wished to identify other information sources that they use, an ‘other’ option was also provided.

The overall results of all the respondents were presented in Figure 5.5. According to the results, 90.6% of the respondents selected ‘consulting a specialist’, which suggests that it is the most used information source for all the designers. The second information source is ‘observation’ (selected by 88.7% of the respondents), and the third one is ‘the internet’ (selected by 81% of the respondents). On the other hand ‘a toolkit’ is the information source least used by designers. In fact, 3.8% of the respondents selected this option.

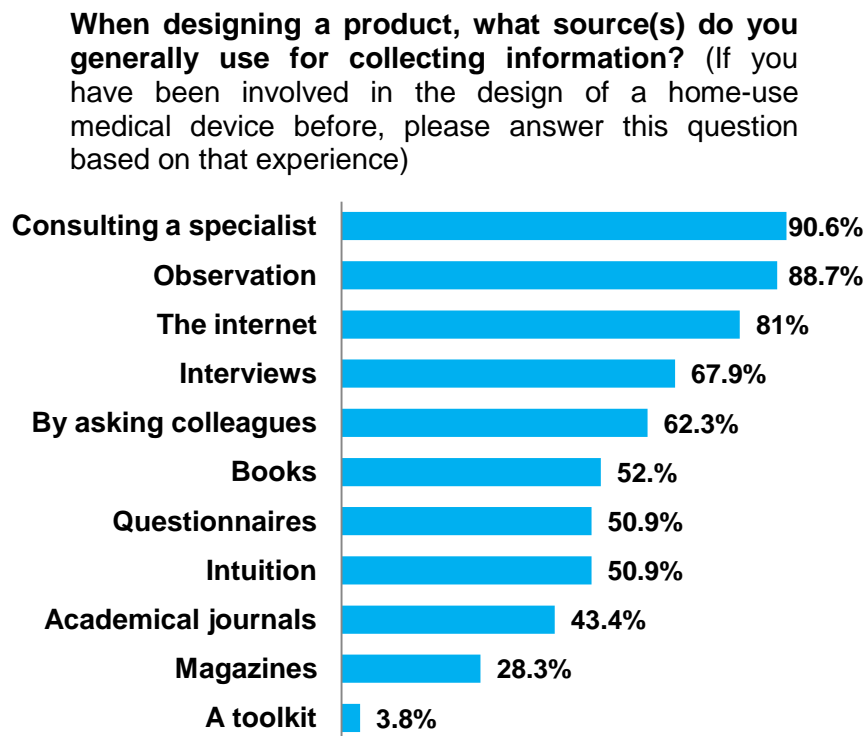


Figure 5.5 Overall results of Question 6

Designers previously involved in home use medical device design were asked to respond to the question regarding their experience. It was *hypothesised that* ‘designers use different types of information sources when designing a home use

medical device'. Therefore the *null hypothesis* was that 'there is no difference between designing a home use medical device or any other product in terms of the types of informational resources used'. For this purpose each of the information sources were tested separately by using a Pearson Chi-Square test. Due to the small sample sizes the 'Exact' significance value was considered. In order to avoid a Type I error, a *bonferroni correction* was applied, therefore the critical value of .05 was divided by 11. The critical value of significance was .005 for these tests.

The results suggested no statistical significance for all the information sources, which does not allow the researcher to reject the null hypothesis.

The overall percentage of responses for each informational resource was also investigated for both designer groups. These information sources were gathered under two main categories, i.e. 'available information' and 'customised information'. Available information sources include: the internet, books, intuition, academic journals, magazines and toolkits, where the information is often readily available. On the other hand customised information sources are derived from stakeholders where designers play an active role in the data collection or require interpreting the raw data in order to turn it into a design input; i.e. consulting a specialist, observation, interviews, by asking colleagues and conducting surveys. In this case designers require bespoke information for their specific project which is not readily available.

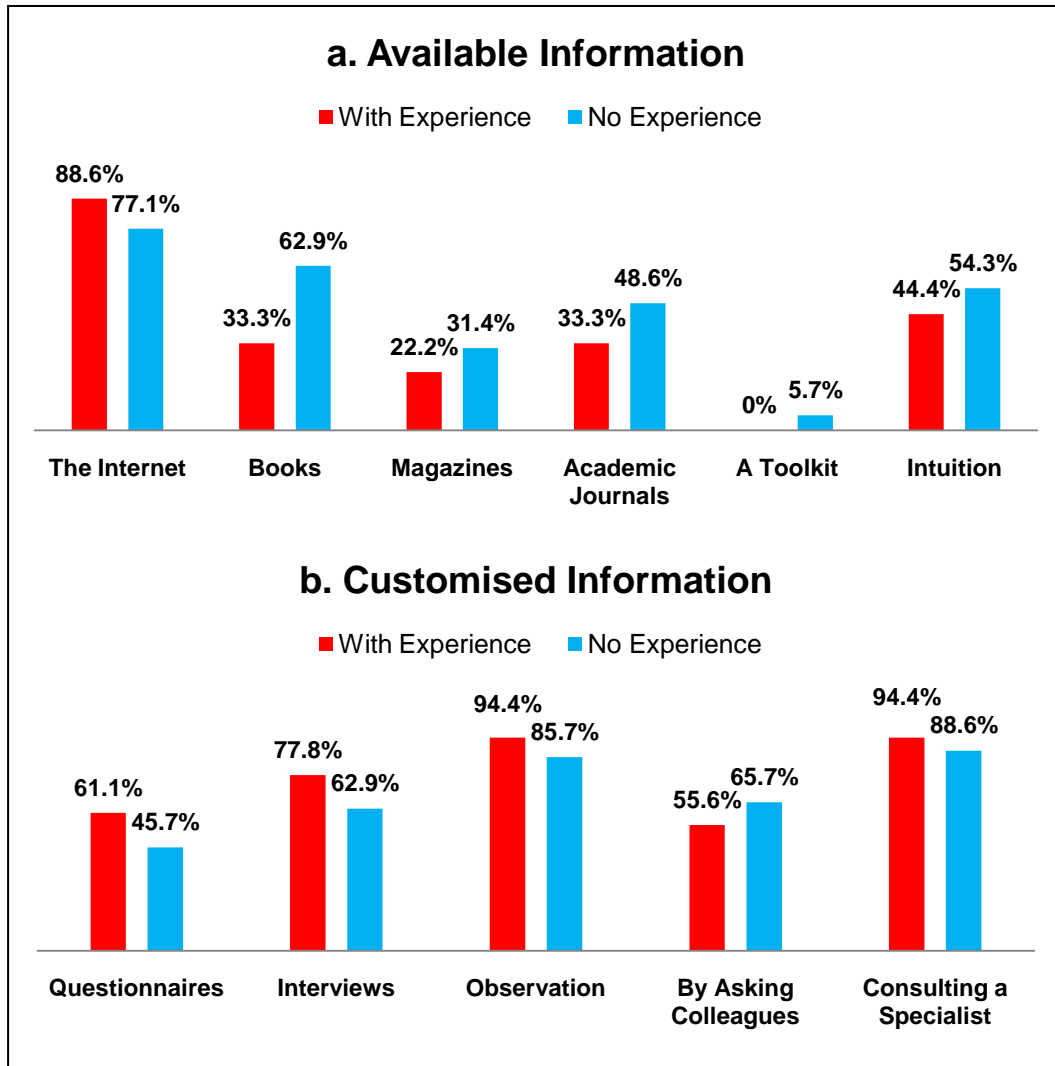


Figure 5.6 Results of Question 6 in relation with the prior experience of the respondents in designing home use medical devices

The percentages suggested that except for ‘the internet’ (refer to Figure 5.6a), designers are less likely to use ‘available information’ sources (particularly ‘**books**’) when designing home use medical devices; and they are frequently more likely to use ‘customised information’.

10 designers also responded to the open-ended part of the question and identified 17 other information sources which were coded into 6 categories. Figure 5.7 shows these categories. The ‘other’ category includes all the other information sources which were mentioned by a single respondent.

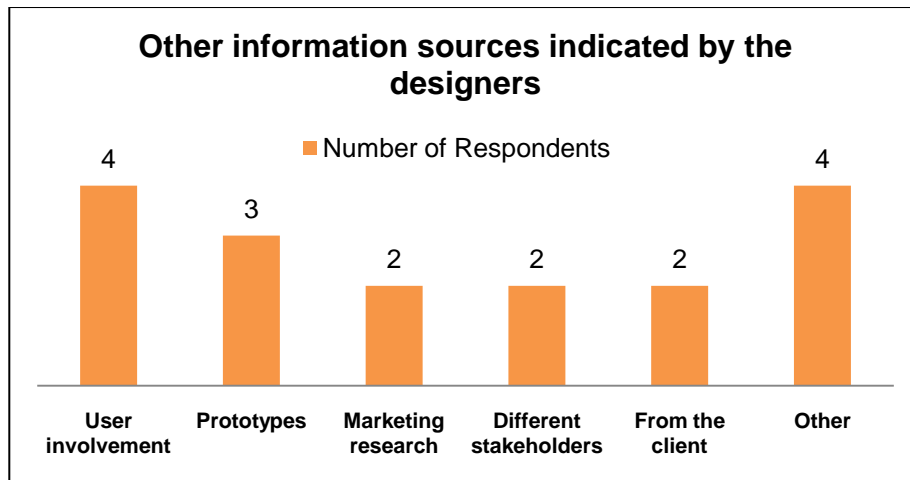


Figure 5.7 The answers given to the open-ended part of Question 6

The results suggested that ‘user involvement’ in the design process was the most frequently mentioned information source (mentioned by 4 designers). 3 designers mentioned ‘making prototypes’ as another type of information source which provides valuable information. ‘Marketing research’, ‘involving different stakeholders in the design process’ (e.g. hospital staff, clinicians, specialists, etc), and ‘the client’ are also mentioned as information sources, (each mentioned by 2 respondents). The ‘other’ category includes 4 different types of information sources, i.e. ‘conferences’, ‘newspaper’, ‘academic research departments’, and ‘working as a diverse team’.

5.2.5 Requirements for the Guidance

In Question 7, a ‘yes or no’ question, the respondents were asked about the potential usefulness of guidance for designing home use medical devices if such help was available. Questions 8 and 9 asked additional information about how the design guidance should be prepared, i.e. the content and the format of the guidance. Therefore the participants who responded ‘no’ were asked to skip Questions 8 and 9. Overall 30 out of the 53 respondents (56.6%) mentioned that guidance would be useful for them.

The percentages of the answers given to this question for both participants with experience and no experience are shown in Figure 5.8. The percentages suggested that, the participants having prior experience in designing home use medical devices were likely to find available guidance more useful than the others.

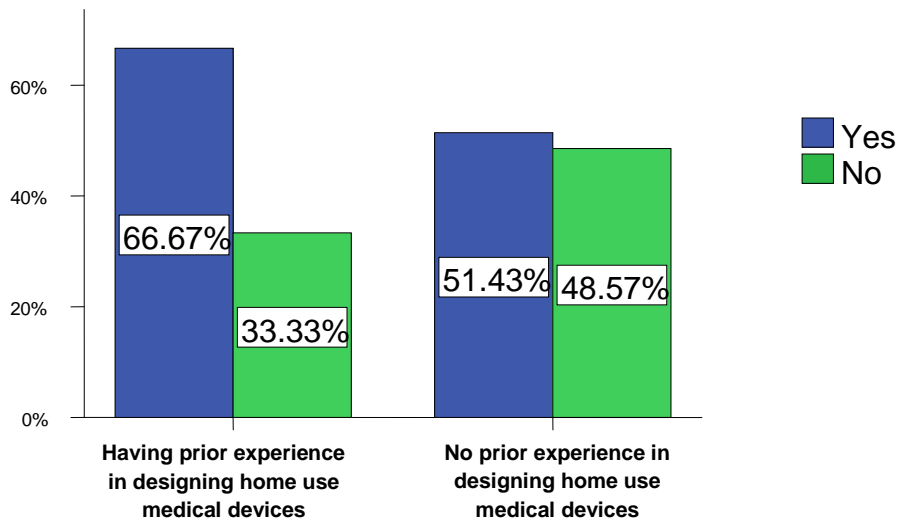


Figure 5.8 Previous experience (abscissa), usefulness of the guidance

Therefore it was *hypothesised* that ‘there would be an association between having prior experience in designing home use medical devices and the designers’ assessment of the usefulness of the guidance’. The *null hypothesis* was that ‘there is no statistically significant association between these two variables’. A Pearson Chi-Square test was performed to test the hypothesis. However, no statistically significant association was identified, where the p value was 0.222: ($\chi^2 (1) = 1.124$; $p > 0.05$). This does not allow the researcher to reject the null hypothesis.

5.2.6 The Content and the Format of the Guidance

The respondents who indicated that the guidance would be useful to them were asked about their preference for the content (Question 8) and the format of the guidance (Question 9). In Question 8, the multiple choices were based on literature review and the information gathered through the other stages of the PhD research. An ‘other’ option was also included in the question for the designers to suggest any ideas to be included in the guidance.

30 out of the 53 participants (12 with prior experience and 18 with no prior experience of designing home use medical devices) responded to this question, which the remaining 23 designers skipped because they indicated that the guidance would not be useful for them. A summary of the overall results are presented in Figure 5.9.

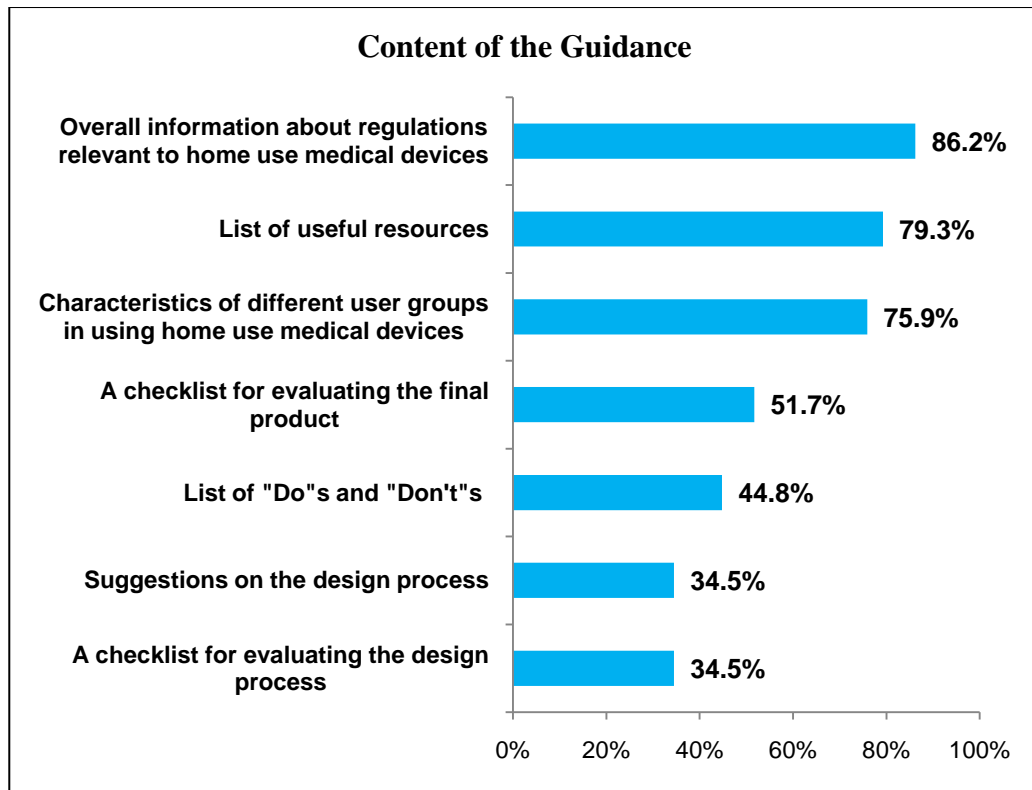


Figure 5.9 Overall results of Question 8

The most useful information for designers included:

1. Overall information about regulations relevant to home use medical devices (86% of the respondents)
2. List of useful resources (79% of the respondents)
3. Characteristics of different home use medical devices user groups (76% of the respondents)

Therefore it was necessary for these three types of information to be included in the guidance.

The percentages of ‘a checklist for evaluating the final product’ and ‘list of “Do”s and “Don’t”s’ were close to each other and around half of the respondents found them useful. Although these ideas were found to have only average importance, it was still deemed useful for them to be included in the guidance.

The last two information types were considered to be less important when compared with the other five mentioned in the previous paragraphs.

Each of these types of information was also tested in order to identify any statistical significance and whether prior experience in designing home use

medical devices had an effect on respondents' choices. The *hypothesis* was that 'prior experience in designing home use medical devices might have an effect on participants' choice for each of the content ideas'. The *null hypothesis* was that 'there was no statistically significant association between these two variables'. The hypothesis was tested by a Pearson Chi-Square test, and the Exact Significance value was used due to small sample sizes. A *bonferroni correction* was applied due to conducting multiple tests; therefore the critical value of .05 was divided by the number of tests performed. The critical value for these tests was thus 0.008.

The results suggested that there was no statistically significant association between having prior experience of designing home use medical devices and designers' preferences for each of the content ideas. Therefore the test results do not allow the researcher to reject the null hypothesis.

Six designers also responded to the open-ended part of the question and suggested further content, i.e. information about applicable standards, useful hints in an informative way, contacts for specialists, contacts for real users, and contract requirements.

In Question 9, the designers were asked about their preferred format for the guidance. Four options were given in the question (i.e. web based, booklet, software, a physical toolkit) and an 'other' option was also provided. This was a multiple response question; so the designers were allowed to select more than one option. According to the results, the 80.6% of the respondents who answered this question preferred a web-based guidance. The other preferences are shown in Figure 5.10.

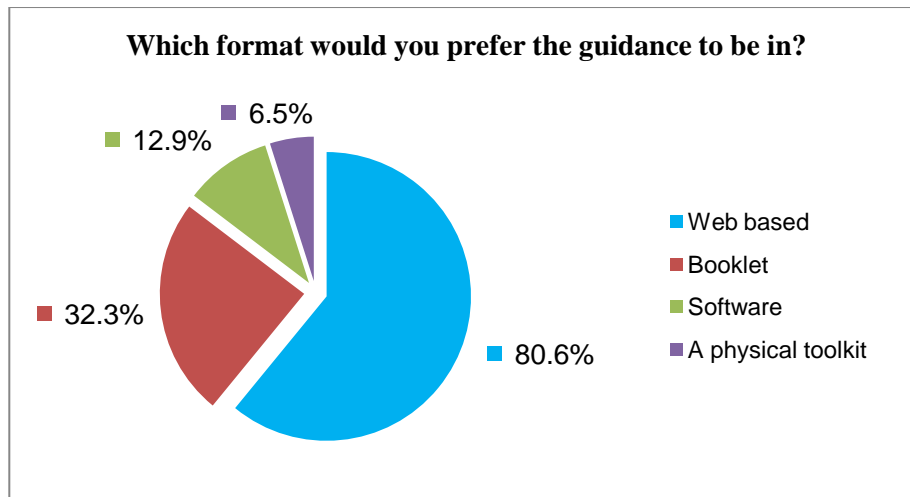


Figure 5.10 Overall results of Question 9

Other formats suggested by the respondents included: PDF documents, video lectures, and real world examples.

5.3 Discussion

In this section, the limitations of the method used and the main findings of the study will be discussed.

5.3.1 Limitations of the Survey

There are a number of disadvantages of conducting a questionnaire survey. Self-administered questionnaires are frequently criticised because of low response rates (Robson, 2002; Sapsford & Jupp, 2006). The response rate for this survey was 13.25%; however, it targeted a very specific field of expertise therefore this relatively low response rate was expected.

The questionnaire was sent to 400 designers who were deemed to match the sampling criteria (refer to 5.1.1). Their participation, however, was totally voluntary. In total 53 participants responded to the survey. According to Dörnyei & Taguchi (2010), in such cases volunteers may demonstrate characteristic differences compared to non-volunteers, and as a result the sample may not be representative of the population. This is called the ‘problem of participant self-selection’. However they also argue that this problem is inevitable to some extent when carrying out self-administered surveys, because in many cases questionnaires cannot be made compulsory (Dörnyei & Taguchi, 2010). For this research, this was indeed inevitable, as the designers who responded to the

survey may differ from the non-respondents in terms of their level of motivation or their interest in the subject.

When conducting self-administered questionnaires the researcher cannot guarantee that all the respondents understand the questions clearly (Gillham, 2000; Bryman & Teevan, 2005). In addition, it is hard to identify which participants may have misunderstood the questions when analysing the results (Robson, 2002). During the analysis, especially for the open-ended parts of the questions, it was found that a few of the responses were not directly relevant to what was being asked, which might be the result of misunderstandings; however, most of the time the questions worked well.

As suggested by Robson (2002), it is hard to identify if the respondents treat the questionnaire seriously; however, from the answers given to the questions (in particular to the open-ended parts) it was concluded that most of the respondents sincerely tried to share their insights.

Two groups of designers were frequently compared during the analysis of the questions: (1) the designers who had prior experience (n=18), and (2) the designers with no experience (n=35). However, the numbers of the respondents were not equally distributed for the two groups. Also, because of small sample sizes, the data was not normally distributed. Owing to these, a non-parametric testing method, i.e. Mann-Whitney U tests, were employed to undertake the statistical analysis. Similarly when performing a Chi-Square test, the Exact significance value was considered due to small sample sizes. Although the necessary methods were employed to reduce the effect of small and unequal sample sizes on the results, these factors should be borne in mind when interpreting the results, especially the statistical test results.

5.3.2 Main Findings of the Survey

In this section the main findings of the survey is discussed.

Designing home use medical devices requires a different approach

The results of the survey showed that the majority of the designers who took part in the survey think that there is a difference in terms of the approach to the design of home use medical devices (HUMD) when compared with everyday

consumer products. The results also suggested that both the designers who had prior experience and the others having no experience responded similarly: both groups indicated that there should be a difference in terms of the approach. This contradicted the results of the study carried out by Gupta (2007). In his research the majority of the product developers argued that designing either a consumer product or a professional device is achieved by basically the same process as designing a home use medical device.

However during this survey a number of reasons regarding the difference of the approach in designing a home use medical device were mentioned by the respondents. All the reasons were coded, and 14 categories were identified and grouped into three (i.e. unique aspects of HUMD, major differences of HUMD and minor differences of HUMD). As a result four unique differences of home use medical devices were identified:

- **Safety and risks of HUMD:** When designing HUMD, extra attention must be given to the safety of the device, because use errors may result in a risk to the health of users. The reliability and the accuracy of the device are significant and the design must help the user to use the device correctly.
- **User related issues:** The users of HUMD vary significantly. During the design process, the characteristics of this diverse population must be taken into account. Users of HUMD may not have any training on how to use the device, and their knowledge level regarding their task might be very limited. In addition not only their physical requirements, but also emotional requirements must be addressed.
- **Regulations and legislation for HUMD:** Regulations are strict for HUMD and different types of standards are required. When designing home use medical devices, designers must be aware of the regulatory framework of medical devices of the target market.
- **Functionality and usability of HUMD:** Some of the respondents mentioned that functionality is more important when compared with aesthetics for HUMD. When designing products designers should be more aware of the function of the device, and optimum usability must be ensured during the design process in order to prevent use errors.

It was also observed from the comments of the respondents that some of the reasons were associated with each other. For example:

The (1) manufacturers are resistant to changes because (2) the development costs of home use medical devices are high and a new (3) product development process is very long. This also affects the final price of the devices and as a result (4) frequently lay people find these devices expensive.

As can be seen from the above example where four different reasons mentioned by designers were interrelated, each of these factors form part of the process and one factor may link to another.

Information requirement of designers

The survey showed that designers require different types of information when designing home use medical devices. Four different types of information (i.e. ‘context of use’, ‘user information’, ‘regulations and legislation’ and ‘medical knowledge relevant to the design project’) were given for the designers to rate. The results suggested that all these four information types are important during the design process; however, ‘context of use’ and ‘user information’ were rated as the most important ones. The respondents also suggested other information types, which were coded into two categories as ‘current market information’ and ‘information from stakeholders’. Overall the study identified 6 types of designers’ information requirements when designing home use medical devices.

Different types of information sources were also investigated according to their frequency of use by designers, and the results showed that designers use a variety of information sources. Overall the most used information sources included: (1) consulting a specialist, (2) observation and (3) the internet. The least used information source was ‘a toolkit’; however the term ‘a toolkit’ can cover different informational formats. For example the Inclusive Design Toolkit (Clarkson et al., 2007) takes two different formats, i.e. a book and a website, while the Design with Intent Toolkit (Lockton, 2010) was a physical toolkit which consisted of a deck of cards. Due to the fact that in the question (Question 6) ‘books’ and ‘the internet’ were given as separate options, the term ‘a toolkit’

was deemed to mean a physical toolkit. However it was not clear whether the designers considered other types of toolkits other than a physical toolkit for this option.

Designers were less likely to use available information (e.g. books, magazines, academic journals, etc) when designing HUMD and they frequently use customised information (such as, interviews, observation, etc) where they actively took part in the collection of the necessary information. Designers are less likely to use books when designing HUMD. This may be because of the lack of comprehensive books for designers to use during the design process of HUMD. They tend to adopt a more active approach in order to collect the necessary information. This suggests that there is a gap in this area, and providing information for designers for the design process of HUMD is necessary.

Similarly the results suggested that designers are less likely to seek information from their colleagues when designing home use medical devices. The reason may be that these devices are relatively new to the market and in essence they are medical devices. Therefore designers might prefer to collect the information personally from the stakeholders.

How should the guidance be prepared?

According to the results of the survey, 56.6% of the designers indicated that an available guidance source would be useful for them. The results suggested that the designers who have prior experience were more likely to find the guidance useful for them. However, the respondents were not asked about the reasons for their decision. This was one of the disadvantages of asking closed-questions in the survey, where researchers may not be able to understand the factors influencing the choice of the respondents (Oppenheim, 2001; Floyd & Fowler, 2002; Robson, 2002).

The preferred contents of the guidance included: *'overall information about regulations relevant to HUMD'*, *'list of useful resources'* and *'characteristics of different user groups in using HUMD'* (mentioned by the majority of designers,

very important); *'a checklist for evaluating the final product'* and *'a list of "Do"s and "Don't"s'* (mentioned by many designers, average importance).

In addition some of the respondents identified other contents, i.e. applicable standards, useful hints, contacts for specialist and real users, and contract requirements.

The majority of the respondents wanted the guidance to be web-based. This was also consistent with the result of another 'Question 6' where the designers were asked to indicate the information sources that they frequently use when designing products, and the internet received the highest number of responses from the designers within the 'available information sources'.

Figure 5.11 summarises the result of the survey regarding the format and the content of the guidance. In order to prepare this figure the results of the sections 5.2.3 and 5.2.6 were used and three main areas were identified where the designers require assistance when designing home use medical devices: (1) regulatory information, (2) specific information regarding the design process of home use medical devices and (3) other sources where designers may find information relevant to the design project. The black text shows the primary content, where the grey text presents the secondary content to be included in the guidance depending on the designers' preferences.

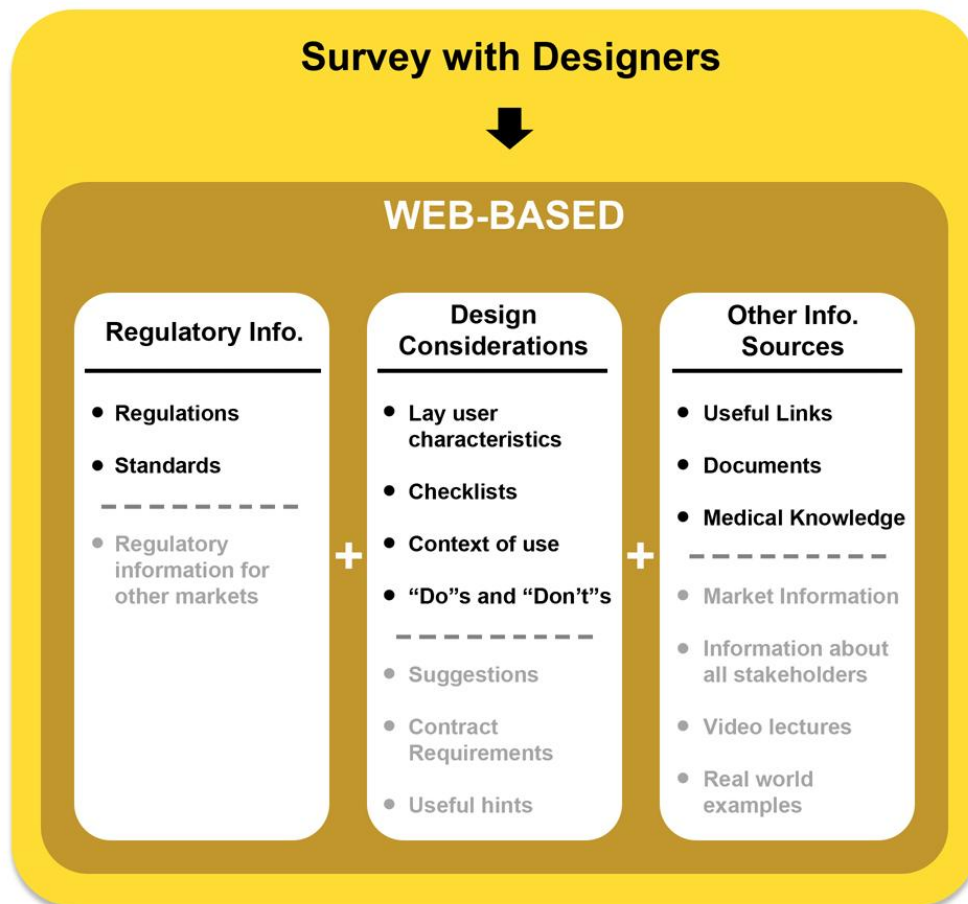


Figure 5.11 Outline of the format and the content of the guidance

A Guidance Website

With reference to the results of the survey, a guidance website was proposed in order to provide support for designers in designing home use medical devices. This was consistent with the findings of Goodman et al. (2007), who also suggested ‘the Internet’ as one of the most commonly used informational sources for designers.

As mentioned in 2.6.1, both the studies carried out by Burns et al (1997), Law et al. (2008) and Choi et al (2006) suggest that, unless the information resources are prepared with designers’ perspectives in mind, they are likely to fail in their purposes. Law et al. (2010) recommends that both the target users of the information resource and their needs should be explicitly defined, and those needs should be addressed systematically during the development process of the guidance. Therefore this study started with the investigation of the requirements and preferences of designers.

When designing home use medical devices, designers require a diverse range of information. The guidance website was intended to be an information resource to put all the necessary information on designing home use medical devices in one place. Therefore, as suggested by Burns et al. (1997), the website proposes to reduce the cost of time and effort to find the relevant information. In addition it will focus on the requirements of a very specific industry, also suggested by Burns et al. (1997) for developing support for designers. The next chapter will focus on the development of the website.

Other Ways of Assisting Designers

Although the Internet was identified as one of the preferred information resource when designing HUMD, designers may need to undertake intensive searching and evaluation to effectively use the Internet as an information source. In addition, the reliability and trustworthiness of the information should be assessed by designers before using it as a reference. One way to assess the reliability and trustworthiness of a website is to get approval from the relevant legal authorities or reputable organisations, such as the MHRA or GHTF (Global Harmonisation Task Force) for home use medical devices. This was not deemed necessary for this PhD research, since the focus was on the development of the support for designers.

On the other hand, some designers preferred other formats, such as a booklet. After the development of the content of the website, the same content can also be prepared in different formats such as a PDF document or a booklet so as to reach more designers.

5.4 Summary

This Chapter was specifically focussed on the second and third research questions. In order to address these research questions a questionnaire survey was carried out with professional designers with and without prior experience in designing a home use medical device. The main findings are summarised as follows:

- **What are the challenges faced by designers in developing home use medical devices?**

The results of the study suggested that designers consider that designing a home use medical device requires a different approach from designing an everyday consumer product. The designers identified 13 different aspects of designing a home use medical device. The most frequently mentioned issues were: (1) safety and risks of home use medical devices, (2) user related issues, (3) regulations and legislation for home use medical devices, (4) functionality and usability of home use medical devices. These issues were accepted as the unique challenges of designing home use medical devices.

It was also found that designers required different types of information when designing home use medical devices; however they frequently took part in the data collection process. This was considered to be due to the lack of available information for designers' use in this field.

- **How to support the design of home use medical devices?**

Based on the designers' requirements and expectations, a web-based guidance on home use medical devices was outlined (Figure 5.11). Three main areas were identified where the designers may require assistance when designing home use medical devices: (1) regulatory information, (2) specific information regarding the design process of home use medical devices and (3) other sources where designers may find information relevant to the design project.

This study was carried out as part of the 'Descriptive Studies I' (Blessing et al., 1995). With reference to the information collected in this study, the first draft of the guidance tool was developed. The next chapter (Chapter 6) will describe its development.

CHAPTER 6: DEVELOPMENT OF THE GUIDANCE

In the previous chapter, designers' points of view on designing home use medical devices and their requirements regarding the design process of such devices were investigated by means of a survey. The results of the survey showed that the majority of the designers preferred web-based guidance.

This chapter outlines the development process of the first draft of the guidance which was developed as a website. It was proposed that the website be evaluated by professional designers (Chapter 7), in order to:

- Clarify the needs
- Collect specific information on designers' requirements when designing home use medical devices
- Assess what information is critical or irrelevant for designers
- Identify how the guidance can be improved in order to address their needs and expectations effectively

For this purpose a working prototype was to be developed, as it was considered that, this would ensure a focussed discussion and stimulate the thoughts of the designers during the evaluation (Chapter 7). The development process mainly involved the formulation of the content, in accordance with the designers' preferences outlined in Chapter 5. The information presented in the website was based on the findings of the 'Descriptive Study 1' (i.e. Chapters 2, 4 and 5). This research also made a number of contributions (e.g. a design process model specifically for home use medical devices) in the content of the guidance. The development process of the guidance is presented in detail in this chapter.

This study was carried out as the 'Prescriptive Study' of this research, with reference to the DRM (Blessing et al., 1995). The outcome of this study was used during the 'Descriptive Study 2' (i.e. evaluation of the guidance), which will be described in Chapter 7.

6.1 Initial Concepts

This section describes some of the initial concepts considered before starting the development of the guidance website.

6.1.1 Guidance for both Designers and Users

As mentioned in Chapter 1 (Section 1.4), it was found that FDA has published a number of documents in particular for supporting users of home use medical devices (FDA, 2009a; FDA, 2009b; FDA, 2009c). During the study with lay users as described and discussed in Chapter 4, it was observed that lay users sometimes could not follow the instructions provided by the manufacturer and as a result misused the device without being aware of it. Home use medical devices are in essence medical devices which require extra care to ensure that users operate these devices correctly and safely. The PhD researcher's initial concept was to develop the guidance for both users and designers. Figures 6.1 and 6.2 show two early interfaces prepared by using the Adobe Photoshop graphical editing program.

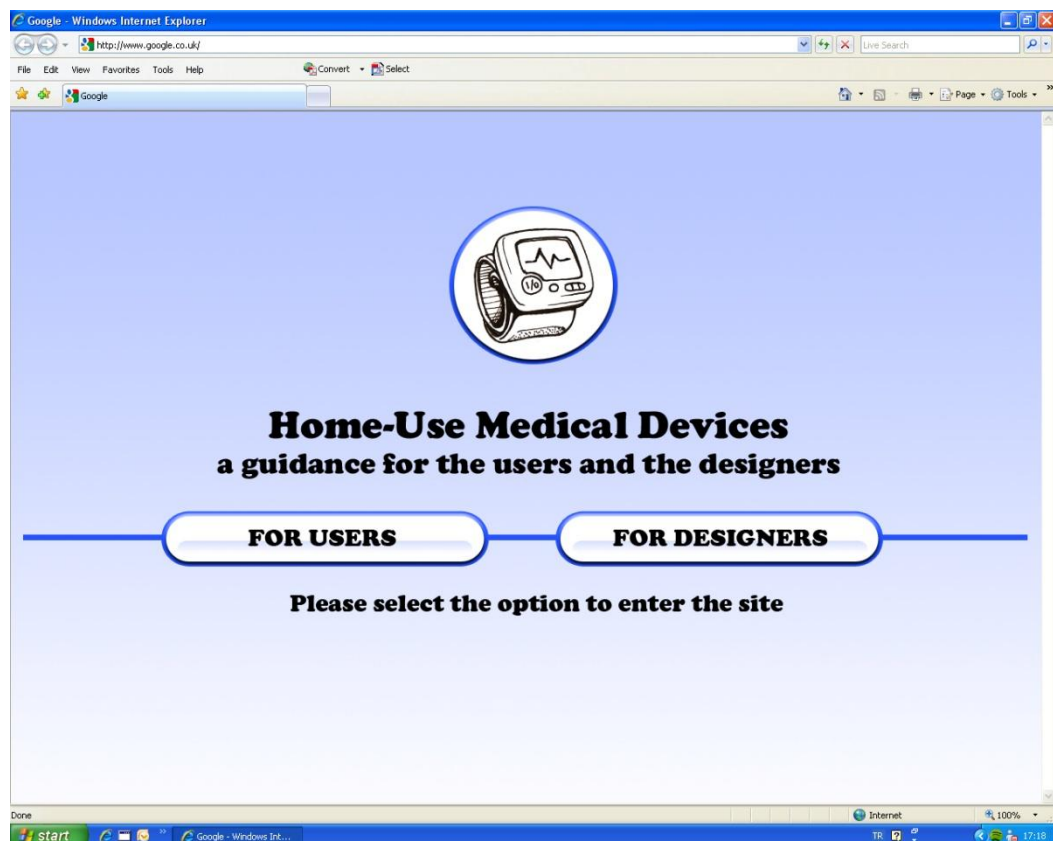


Figure 6.1 Entrance interface for both lay users and designers

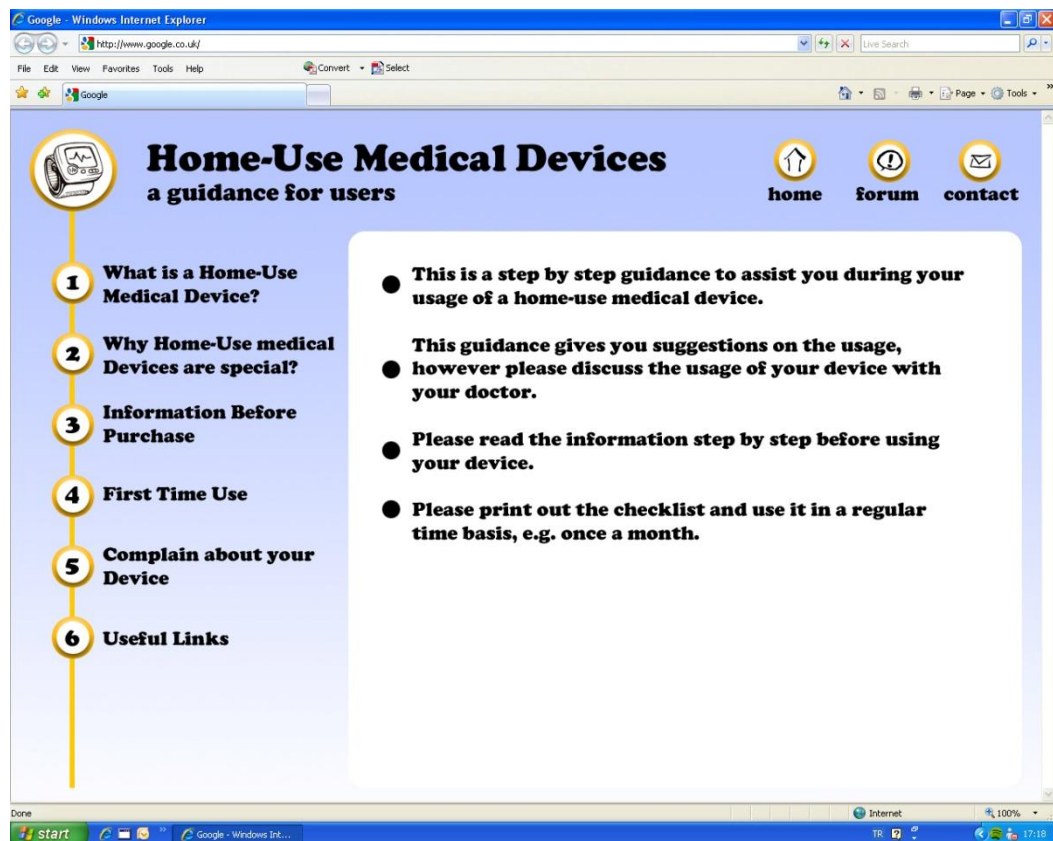


Figure 6.2 The interface concept for lay users

The idea was to support lay users and instruct them about the various aspects of home use medical devices. As can be seen from Figure 6.2 a step by step guidance was to be developed. In order to make the website accessible for a wide range of lay users, the general outlook was designed as simply as possible and the font size was kept sufficiently large to accommodate people with sight impairment. The ‘Forum’ section was considered to be a shared area for both the users and the designers of home use medical devices, where lay users can share their feelings and thoughts about the devices that they use and designers can directly contact the real users and collect first hand information.

However, these images illustrate the initial idea which was mainly based on assumptions of the researcher and the literature review. In order to develop the content of each section shown in Figure 6.2, a comprehensive study was necessary to understand the requirements of lay users, in particular those who frequently use home use medical devices. This was not directly in the scope of this PhD study, therefore it was decided that the specific guidance section for lay users was to be exempted and not included in the guidance.

6.1.2 Initial Concept of the Guidance for Designers

During the survey carried out with designers, after a number of responses had arrived, it was considered useful to start developing the initial concept of the guidance for designers in order to speed up the actual development process. The images shown in Figures 6.3 and 6.4 illustrate the interfaces for designers prepared by using the Adobe Photoshop software.

It was the intention to make the website as simple as possible. An initial idea was to use only a top bar for the main information, hiding all the subsections in drop-down menus which can be opened when the visitor moves the cursor over the buttons in the top bar (Figure 6.4). There were five main sections included in this initial concept, i.e. (1) ‘what is a home use medical device?’, (2) ‘lay-users’, (3) ‘design considerations’, (4) ‘regulations for home use medical devices’, and (5) ‘useful links’. The subsection which can be seen in Figure 6.4 was prepared in accordance with the first few responses, and the content was revised after the completion and analysis of the survey (Chapter 5).

The documents (which can be seen as the checklist in Figure 6.3) were to be included in the main page of the website in order to make them easy to find and access. The ‘forum’ was also included in this concept; however, it was only developed for designers to use, a place where they can share their experiences or search for very specific information by opening discussion topics.

Although the contents of the guidance had been revised several times during and after the survey with designers, its outlook remained a simple interface similar to those shown in Figure 6.3 and 6.4.



Figure 6.3 The guidance website interface for designers

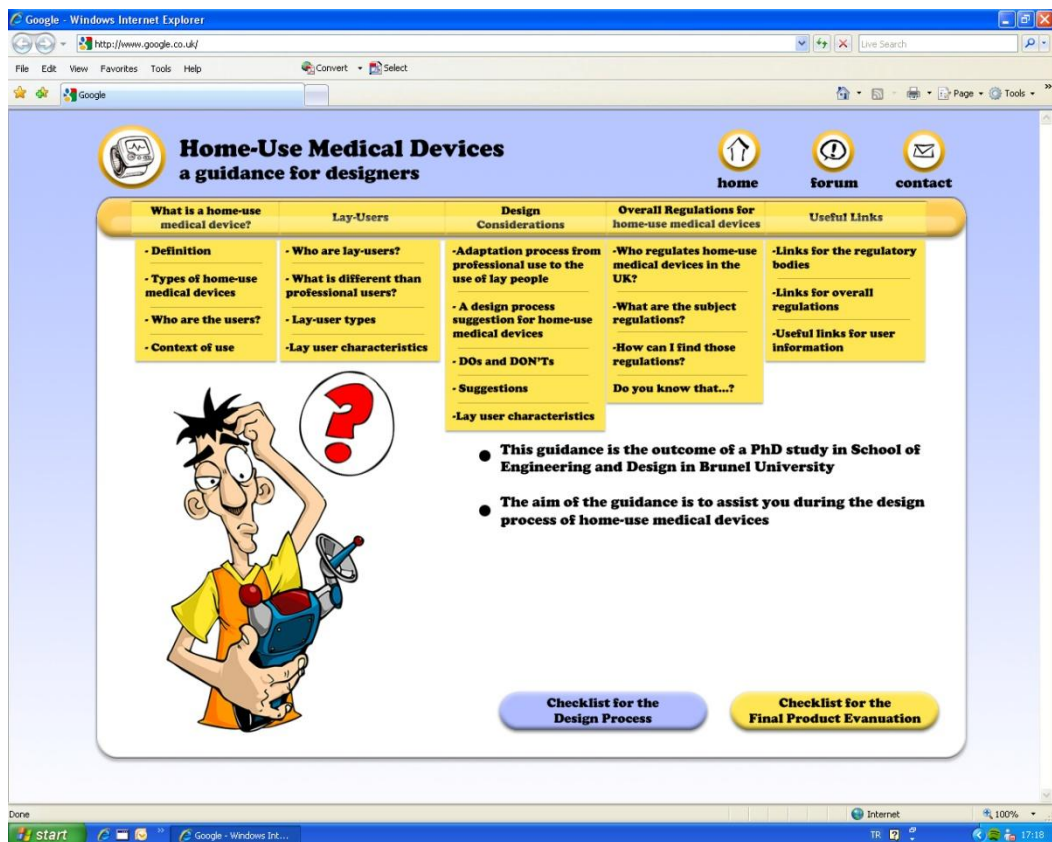


Figure 6.4 Drop-down menus showing the content of the initial concept

6.1.3 Formulation of the Content

The overall content of the guidance was formed in accordance with the results of the survey with designers. The results regarding the format and the content of the guidance were discussed and illustrated in Figure 5.11, Section 5.3.2. However, that Figure is only based on the findings of the study carried out with designers, and does not include the inputs from the literature review (Chapter 2) or the study carried out with lay users (Chapter 4). Figure 6.5 has incorporated the literature review and the user studies and outlines the final content of the guidance. As can be seen from Figure 6.5 the ‘medical knowledge’ in the ‘other information sources’ group was filtered, because this information is very product specific, and it is not in the scope of this PhD research.

It was considered that some of the information collected during the literature review might be helpful for novice designers to understand the nature of such devices, particularly if they have never been involved in a home use medical device design project. Therefore it was decided to include this basic information in the website (such as giving the definition of a home use medical device) as well as relevant examples.

During the study with lay users it was found that these people cannot be categorised as a single user group, and their characteristics vary significantly depending on their personal or demographic variation. Therefore it was deemed necessary to include specific characteristics of these user groups which were gathered through the literature review and the observational study with lay users (Chapter 4).

In addition, the observational study revealed that preparing good instruction manuals was important, as poorly designed instructions may mislead the user. Particularly for home use medical devices, the users may require very detailed and comprehensive information to use the device safely. There are also specific regulations and standards for preparing instruction manuals for medical devices, therefore it was decided that such information should be included in the guidance.

The detailed content of the guidance will be described in the following section.

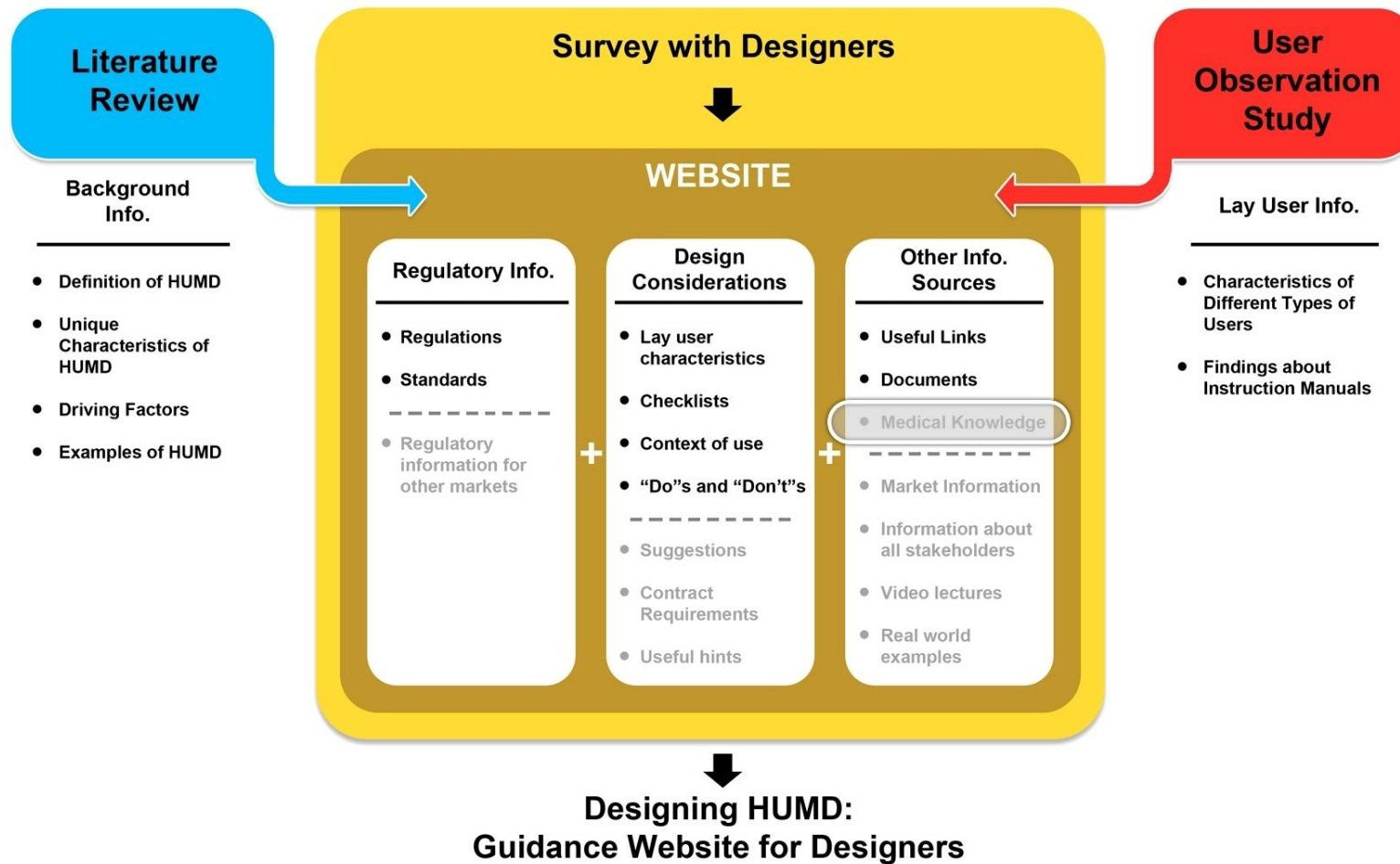


Figure 6.5 Final content of the first draft of the guidance

6.2 Preparation of the Detailed Content

With reference to the results of the survey, five main topics were identified and earmarked to be included in the website; i.e. (1) background information of HUMD, (2) design considerations for HUMD, (3) regulations relevant to HUMD, (4) useful links relevant to HUMD, (5) documents that designers might find useful when designing HUMD.

A short distinctive name was given to these five sections and they were put in a logical order to provide a sequence for designers who do not have any experience in the area. Figure 6.6 illustrates this sequence.

As mentioned in 6.1.2, an initial plan was to have a main section about ‘lay users’; however, during the preparation of the content of the guidance, it was decided to embed it inside the ‘design considerations’ section as the information about lay users is one of the specific requirements of the design process of home use medical devices. The documents section was designed as a separate section in order to make it easy to find and access.

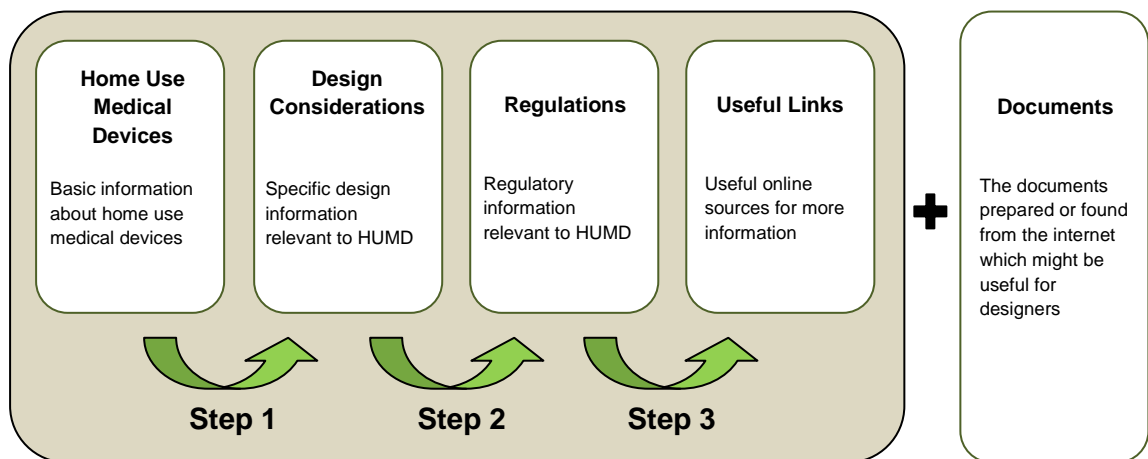


Figure 6.6 Sections included in the guidance

6.2.1 Content of the Home Page

The home page is the first page that the designers see when they enter the website. In order to make the intention of the website clear for designers, it was necessary to consider the following questions:

- What is the overall purpose of the website?
- Who are the users of this website?

- What information does the website include?

A short introduction was included in the home page and it was emphasised that this website was developed specifically for the requirements of the European market.

A summary of how to use the website was offered, and the questionnaire which was prepared for designers' evaluation of the guidance was also linked to the home page to make it accessible for designers. The designers' evaluation of the guidance will be described and discussed in Chapter 7.

6.2.2 Content of the 'Home Use Medical Devices' Section

This section was prepared for novice designers who are new to designing home use medical devices. It includes five subsections where designers can find basic background information about HUMD, i.e.:

- Definition of a home use medical device
- The unique factors of HUMD that differentiate them from everyday consumer products and the medical devices used in the clinical environment
- Key driving factors which increased the prevalence of HUMD
- Examples of home use medical devices

All the information presented in the website is based on the literature review carried out for this research. A short section about the results of the survey conducted with designers (refer to Chapter 5) was also included in this section in order to explain how the content and the format of the guidance were determined.

6.2.3 Content of the 'Design Considerations' Section

The purpose of the 'design considerations' section is to highlight specific issues about the design process of home use medical devices. As discussed in the literature review, home use medical devices are medical devices which are complex in nature but are used by lay people. In addition according to the results of the survey (Chapter 5), designing home use medical devices requires a different approach during the design process when compared with everyday consumer products. Therefore some of the specific characteristics of designing

home use medical devices are demonstrated in this section. A specific subsection is also included for designing and developing instruction manuals for home use medical devices.

The design considerations section consists of six subsections.

Design process

There are a number of specific characteristics of the design process of home use medical devices, which were identified both during the literature review and the survey carried out with designers. These characteristics are emphasised in this subsection, i.e.:

- HUMD must fulfil the regulatory requirements
- Validation and verification activities are the part of the process
- HUMD are used by lay people and the context of use is often not clearly defined

A design process model, called the ‘Dual Verification Model’ was developed and included in this subsection. The model and its development process will be described in detail in 6.3.1.

Inclusive design

As discussed by Wiklund & Wilcox (2005), designing home use medical devices requires adopting an inclusive design approach during the design process; therefore a basic explanation of inclusive design is given in this subsection. Designers can also find the ‘Waterfall Model of Inclusive Design’ (Clarkson, et al., 2007: p.2-5) via a hyperlink.

Some links to the other external sources are also included in this subsection where designers can find more information about inclusive design.

Lay users

The information presented in this subsection was based on the findings of the observational studies (Chapter 4) and literature review (Chapter 2). Three types of information were presented regarding lay users, including:

- General information about lay users, such as general definition of lay users and who the lay users of HUMD are

- Different types of lay users based on Thiberg's user pyramid (Explained in Benktzon's (1993) paper)
- Characteristics of lay users, based on literature review (Chapter 2) and the results of the observational study carried out with lay users (Chapter 4)

The characteristics of lay users are presented in four separate sections, i.e. (1) general characteristics of lay users, (2) characteristics of able bodied lay users, (3) characteristics of older lay users, and (4) characteristics of disabled lay users.

Context of use

There are a number of environmental challenges that the devices may encounter in daily use, and they should be taken into account by designers when designing HUMD. There is a possibility that some of the reasonably foreseeable environmental conditions may affect the intended performance of the device, therefore the associated risks should be minimised (EEC, 1993a; EC, 1998). In this part those environmental challenges are emphasised.

When designers look for more information, they are directed to FDA's (2010c) 'Unique Considerations in the Home' webpage via a hyperlink where some of the environmental challenges are described. In addition two European Standards are mentioned [i.e. EN ISO 14971: 2009 (BSI, 2009a) and EN 60601-1-11:2010 (BSI, 2010a)] where the designers can find more information about the environmental factors that can affect the performance of HUMD.

Instruction manuals

There were two reasons for including a specific subsection on designing and developing instruction manuals: (1) the results of the observational study carried out with lay users suggested that instruction manuals should be carefully prepared for HUMD; (2) there are specific European market regulatory requirements directly addressing the instruction manuals of HUMD, which can be found in the Essential Requirements of the Directives (EEC, 1993a; EC, 1998).

Therefore, in this subsection designers are assisted during the design and development process of instruction manuals for home use medical devices. For this purpose some of the important characteristics of the process are emphasised.

A specific model for developing instruction manuals for home use medical devices was also developed and included in this subsection. The development of the model will be described in detail in 6.3.2.

In addition a checklist was developed in the PDF format which aims to assist designers during the design and development process of instruction manuals of HUMD for the European market. The development of the checklist will be described in detail in Section 6.3.3.

'Do's and Don't's

In this subsection some useful hints and suggestions about designing HUMD are given. These suggestions were based on the findings of the 'Descriptive Study 1' (i.e. Chapters 2, 4 and 5). The development of the information presented in this subsection will be described in detail in 6.3.4.

6.2.4 Content of the 'Regulations' Section

The purpose of the 'Regulations' section is to present the overall regulatory framework of the European market for designing HUMD. Therefore this section mainly covers:

- The general information about the regulatory framework in Europe
- The specific requirements of the relevant Directives relevant to HUMD
- The general information about the Standards and their relevance to HUMD

A specific section on the regulatory requirements for preparing instruction manuals of HUMD is also included. This section consists of five subsections, and the detailed descriptions of the content of these subsections are given below.

In Europe

This subsection gives the basic information about how medical devices are regulated in Europe, and the relevance of this information for HUMD. It describes which Medical Device Directives are relevant to designing HUMD.

In the UK

Due to the fact that this research was carried out in the UK, in this subsection it was briefly described how the Medical Devices Directives were consolidated and implemented into UK law.

For devices

As discussed in the literature review, there are two European Medical Devices Directives relevant to HUMD. In this subsection the requirements of these Directives are explained separately.

Regarding the Council Directive 93/42/EEC on Medical Devices (MDD) (EEC, 1993a):

- A PDF document was prepared and included in the subsection which summarises the Essential Requirements of the Directive. The prepared document can be found in Appendix J
- The basic information about the classification of medical devices
- In order to give information about the conformity assessment procedure, designers are directed to one of the MHRA guidance documents (MHRA, 2008a) where they can find detailed information
- The basic information about the CE marking of conformity is given

Regarding the Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD) (EC, 1998):

- It was emphasised that the designers should check both the definitions of a ‘medical device’ and an ‘in vitro diagnostic medical device’ due to the fact that they are interrelated
- A PDF document was prepared which summarises the Essential Requirements of the Directive and was included in the subsection. The prepared document can be seen in Appendix K
- In order to give information about the conformity assessment procedures for in vitro diagnostic medical devices, designers are directed to one of the MHRA guidance documents (MHRA, 2006e) where they can find the detailed information

- Basic information about the ‘Common Technical Specifications’ are given and the designers are directed to the European Commission’s website (EC, 2010b) where they can find the specific document

For instruction manuals

This subsection mainly emphasises that the regulatory requirements regarding the instruction manuals must be fulfilled. In order to provide guidance for designers regarding this issue:

- The similarities of the two Directives are presented
- A PDF document was prepared and included in this section, which compares the specific requirements of the both Directives relevant to developing instruction manuals for HUMD. To see the document refer to Appendix L
- A list of Harmonised Standards covering instruction manuals for medical devices is given. A total of 6 Standards and their brief explanation are presented which are directly relevant to HUMD

Standards

As discussed in the literature review (Section 2.5.4), standards are one of the important components of the regulatory framework. During the literature review a number of European Standards were identified which were directly relevant to HUMD. Therefore a specific subsection is included in the website within the Regulations section about Standards. In this section designers can find:

- The overall information about Standards, such as definition of Harmonised Standards
- The brief description of different types of Harmonised Standards
- The hyperlinks to the European Commission’s website where designers can find reference lists of Harmonised Standards for both medical devices and in vitro diagnostic medical devices
- A list of some of the European Standards directly relevant to HUMD. A total of 14 standards are presented and their contents are briefly described

6.2.5 Content of the ‘Useful Links’ Section

A number of online resources which the designers might find useful were identified during the literature review study. Some of the information was derived from these online sources and used during the development of the content of the website. However, it was considered that some designers might look for more information about the subjects covered in the website. Therefore a number of online sources were selected and grouped into three categories, as: (1) the sources relevant to the general information on HUMD, (2) the sources relevant to the design process of HUMD, and (3) the other sources which are relevant to the Medical Device Regulations. These categories are presented as the subsections of the Useful Links section and the links to these online sources are given in these subsections to direct visitors.

6.2.6 Content of the ‘Documents’ Section

It was decided to prepare a separate section for documents that are mentioned within the website. Although these documents can be found via hyperlinks in the relevant sections of the website, it was considered that it is better to put them in one place to make them easier to find when required.

First of all it was necessary to include the links to the actual Medical Devices Directives. During the literature review it was found that MHRA and FDA published a few online guidance documents regarding medical devices. Although none of these documents directly focuses on the requirements of designers, they might be useful for them to check during the design process. In addition a number of documents were prepared as a part of this research. All these documents were included as hyperlinks within this section.

The documents were grouped under two subsections, such as internal documents which are the ones prepared as a part of this research, and external documents which are the other online documents prepared by other organisations or researchers. Most of the documents included in this section are in the PDF format.

6.2.7 Summary of the Content

Different levels of information were included in the Guidance website by using subsections. For this purpose many hyperlinks are used which lead the designers to pop-up windows, other websites, or documents. Figure 6.7 shows the content of the website as a site map. Some of the information was specifically developed as part of this research, as highlighted in Figure 6.7.

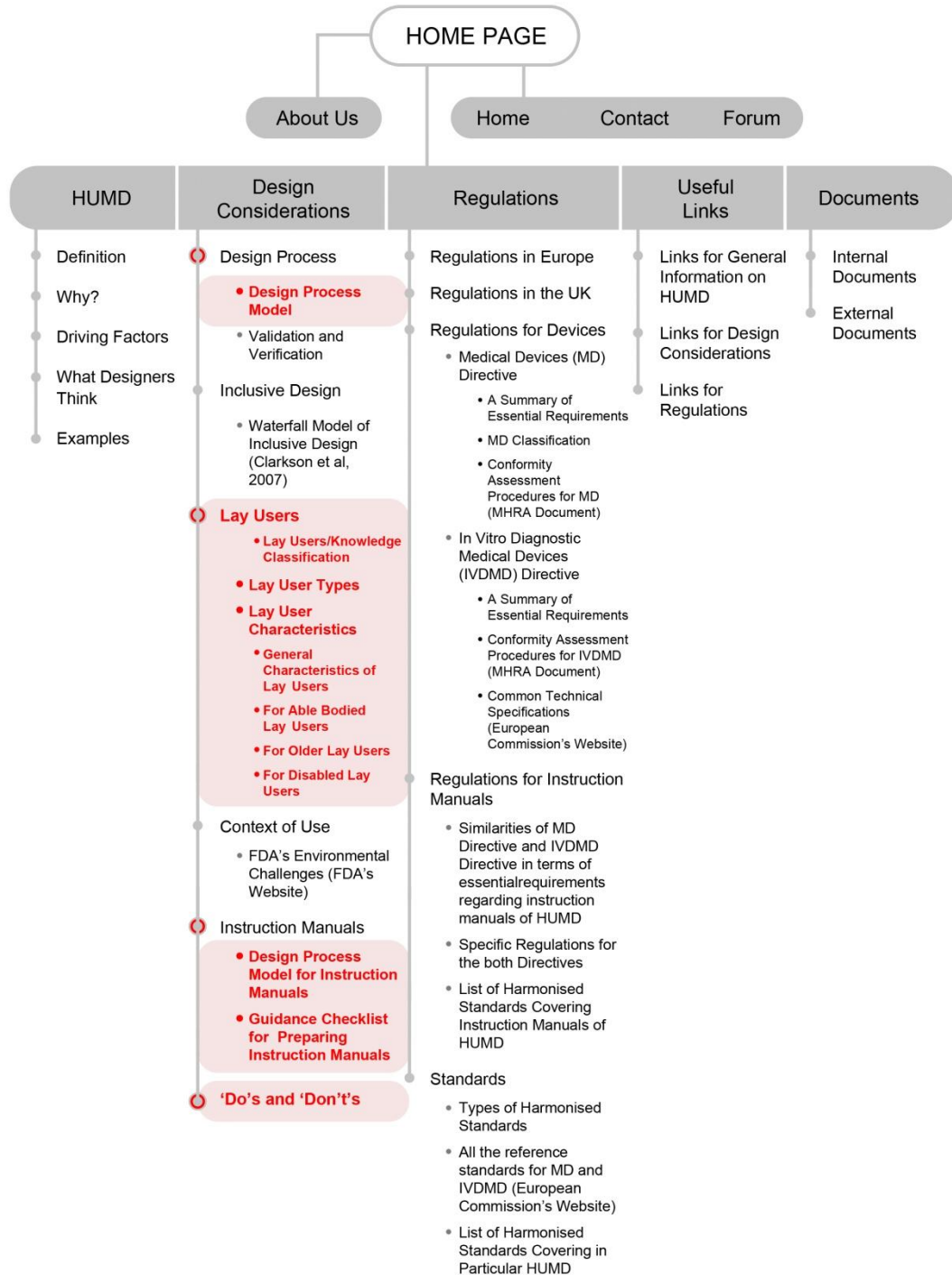


Figure 6.7 Site map of the guidance website

6.3 Development of Unique Contents

This research made particular contributions to the content of the website, with those sections highlighted in Figure 6.7. In this section, the development of the information presented in those sections will be discussed. The ‘lay users’ section, shown in Figure 6.7, includes a summary of the information presented in Chapter 4; therefore this information will not be presented here again.

6.3.1 Dual Verification Model for Designing Home Use Medical Devices

As discussed in Chapter 2, home use medical devices inherit the characteristics of both the design processes of everyday consumer products and medical devices (Gupta, 2007; Gardner-Bonneau, 2011). However, Wiklund & Wilcox (2005) suggest that these devices require a different approach than medical devices designed for professional use, because lay users differ significantly from professionals in terms of their needs and capabilities (Wiklund & Wilcox, 2005).

The results of the survey with designers also suggested that designing home use medical devices required a different approach during the design process, due to the inherently unique nature of the field. In Section 5.2.2, the designers identified 13 features that make the design process of a home use medical device different from that of an everyday consumer product.

In order to support designers during the design process, in particular those with no prior experience in designing home use medical devices, it was considered to be useful to outline the overall process and its associated requirements. However, as indicated in 2.3.4. (Chapter 2), no literature was identified relating to the specific design process model for home use medical devices. On the other hand, a number of other models for both the design process in general terms and the design process for medical devices were identified and some of them were presented in Chapter 2. On the basis of these models [in particular the Pahl et al’s (2007) design process model, the waterfall model of an inclusive design process (Clarkson et al, 2007) and Waterfall Design Process Model (FDA, 1997)], a design process model was developed specifically for designers of home use medical devices, i.e. the ‘Dual Verification Model for Designing Home Use Medical Devices’ (Figure 6.8).

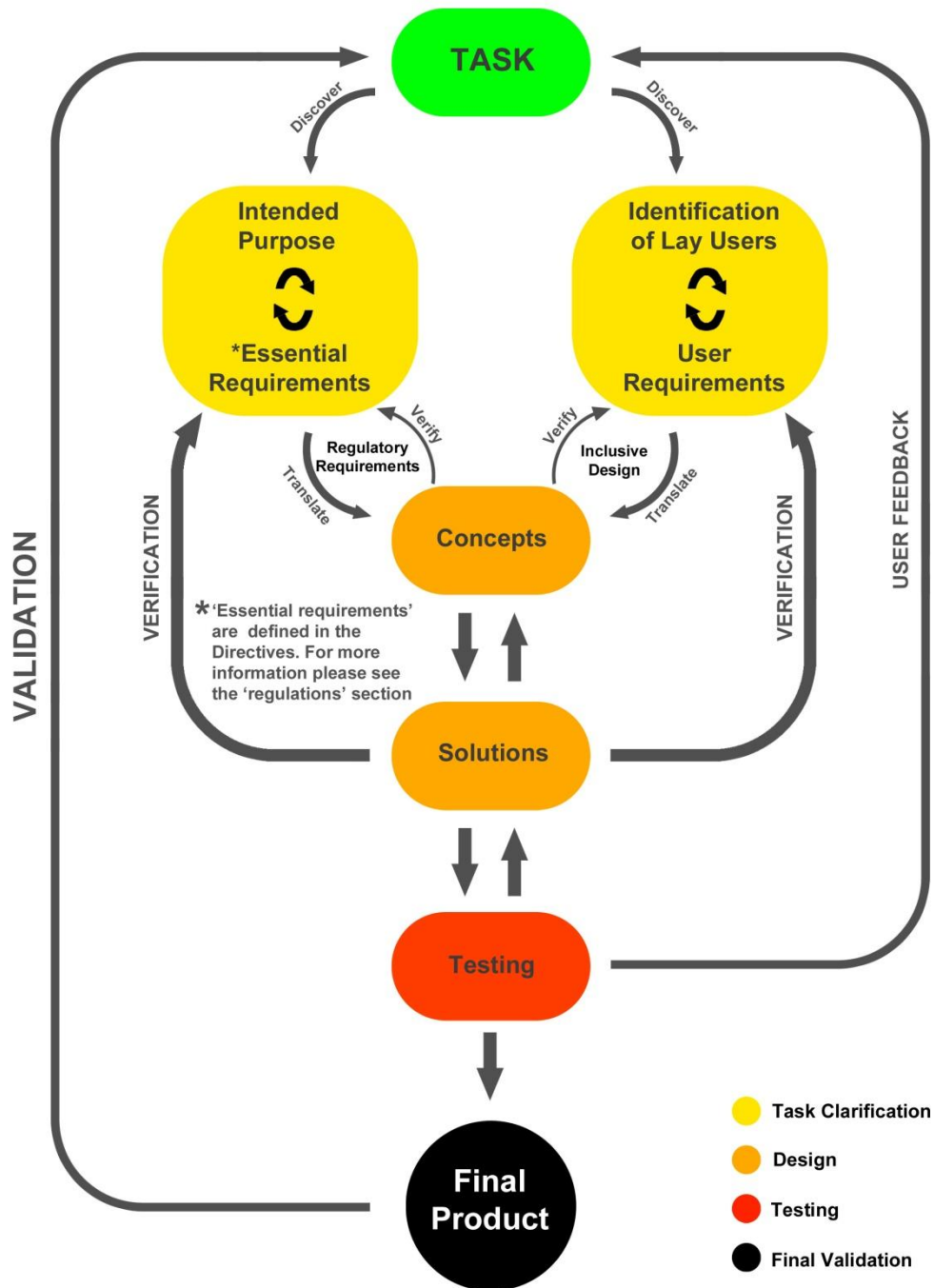


Figure 6.8 Dual Verification Model for Designing Home Use Medical Devices

The unique aspect of this model is that it highlights the understanding of both the regulatory requirements (derived from the MDD and IVDMD) for developing home use medical devices and lay user requirements (derived from literature review and observational studies) and presents them as parallel tasks. In addition it also emphasises the validation and verification activities which are the important characteristics of the design process of medical devices.

As can be seen in Figure 6.8, the model involves five main stages, i.e. discovering the needs, task clarification, design, testing and final validation. These stages are described below.

Discovering the Task

The process starts with a task and the desired outcomes of the task should be identified. Due to the fact that the design subject is a medical device which is used by lay users, two questions need to be answered: ‘Who are the target lay users of the device?’ and ‘What is the intended purpose of the device?’ According to the Directives, the ‘intended purpose’ of the device means “the use for which the device is intended...” (EEC, 1993a; EC, 1998).

Task Clarification

In this stage the requirements of the task should be specified precisely in order to be used in the design stage. This stage involves two unique tasks which need to be carried out simultaneously as parallel tasks:

- The needs identified regarding the intended purpose of the device must be investigated through the ‘Essential Requirements’ of the relevant Directive (MDD or IVDMD) in order to prepare the documentation of the regulatory requirements.
- The requirements of the users should be investigated in accordance with the target lay users. This stage involves an intensive investigation of the user requirements which will result in the necessary documentation to ensure that the final product is designed inclusively and the capabilities of all the target lay users are taken into account. Emotional requirements of the users also should be considered during this activity.

Design

The design stage consists of two parts. In the first part requirements identified in the task clarification stage are translated into initial concepts. All the initial concepts should be verified with regard to the requirements.

In the second stage of the design process the best solution(s) is/are selected from within the concepts. It is important to verify that ‘you are doing the thing right’. If the solution(s) selected is/are found to be unsuccessful, there is always an

iteration loop to the prior design stage. The verification activity should be carried out during this stage and the necessary documentation (for the Quality Systems requirements) should be prepared as the outcome of this activity (BSI, 2003). As a result, the best solution is selected and the prototype of the solution will be prepared for testing.

Testing

This stage involves the testing of the solution with real lay users. It is strongly recommended to test the prototype with different types of lay users and in the actual context in which the device will be used. There is an iteration loop to the design stage to improve the design. There is also a user feedback loop to the very beginning of the design process in order to check the requirements regarding the users and the intended purpose of the device if necessary. After all the improvements are made, the testing stage finishes.

In this stage, it should also be noted that a ‘clinical evaluation’²⁷ of the device might be required for the demonstration of the conformity with the relevant Directive. This may necessitate conducting clinical trials with ethical considerations in mind, in accordance with the mandatory Helsinki Declaration (EEC, 1993a).

Final Validation

As a final stage of the process, the validation activity is carried out prior to the production of the device in order to see whether the device meets the user needs; which helps to answer the question, ‘have you built the right thing?’ This activity must be documented to meet the Quality Systems requirements (BSI, 2003).

6.3.2 Process Model for Designing Instruction Manuals of Home Use Medical Devices in Europe

Designing instruction manuals for home use medical devices is a critical task due to the unique nature of these devices: despite the fact that these devices are used

²⁷ Clinical evaluation is described in the Annex X of the MDD. Basically it can be carried out in three ways: (1) through the relevant scientific literature by showing the data of the equivalence of the device, or adequate demonstration of the data compliance with the relevant essential requirements; (2) through the critical evaluation of the results derived from the clinical investigations carried out; or (3) the data combined both the relevant scientific literature and clinical investigations (EEC, 1993a).

by lay people, they are medical devices which are complex by nature and demand safety-conscious operation. According to Backinger & Kingsley (1993), due to the fact that lay users experience difficulty in understanding instruction manuals provided with the devices, errors in use have become a growing problem. It is also argued that the instruction manuals for home use medical devices are mainly written for professional people, and therefore lay people struggle with some of the terminology within (Backinger & Kingsley, 1993; Lewis, 2001). It should be ensured that medical device documentation provides clear, accurate and easy to follow instructions (Gwynne & Kobus, 2011). If the users experience difficulties in understanding the instruction manuals, then instruction manuals may also cause errors in use when using medical devices in the home environment (Backinger & Kingsley, 1993).

There are specific regulatory requirements for developing instruction manuals (refer to 2.5.2), as well as standards prepared specifically to help the developers of medical devices instruction manuals in order to fulfil the 'Essential Requirements' of the target Directive. EN ISO 18113-5: 2009, particularly, covers several medical devices used in the home environment, because this Standard focuses on self-testing in-vitro diagnostic instruments. No other Standards were identified as particularly focusing on the requirements regarding the information provided by manufacturers for home use medical devices. The literature review also suggested that, currently, very limited information is available regarding developing instruction manuals for home use medical devices for the European market. Therefore a design and development process model (Figure 6.9) was developed for the European market.

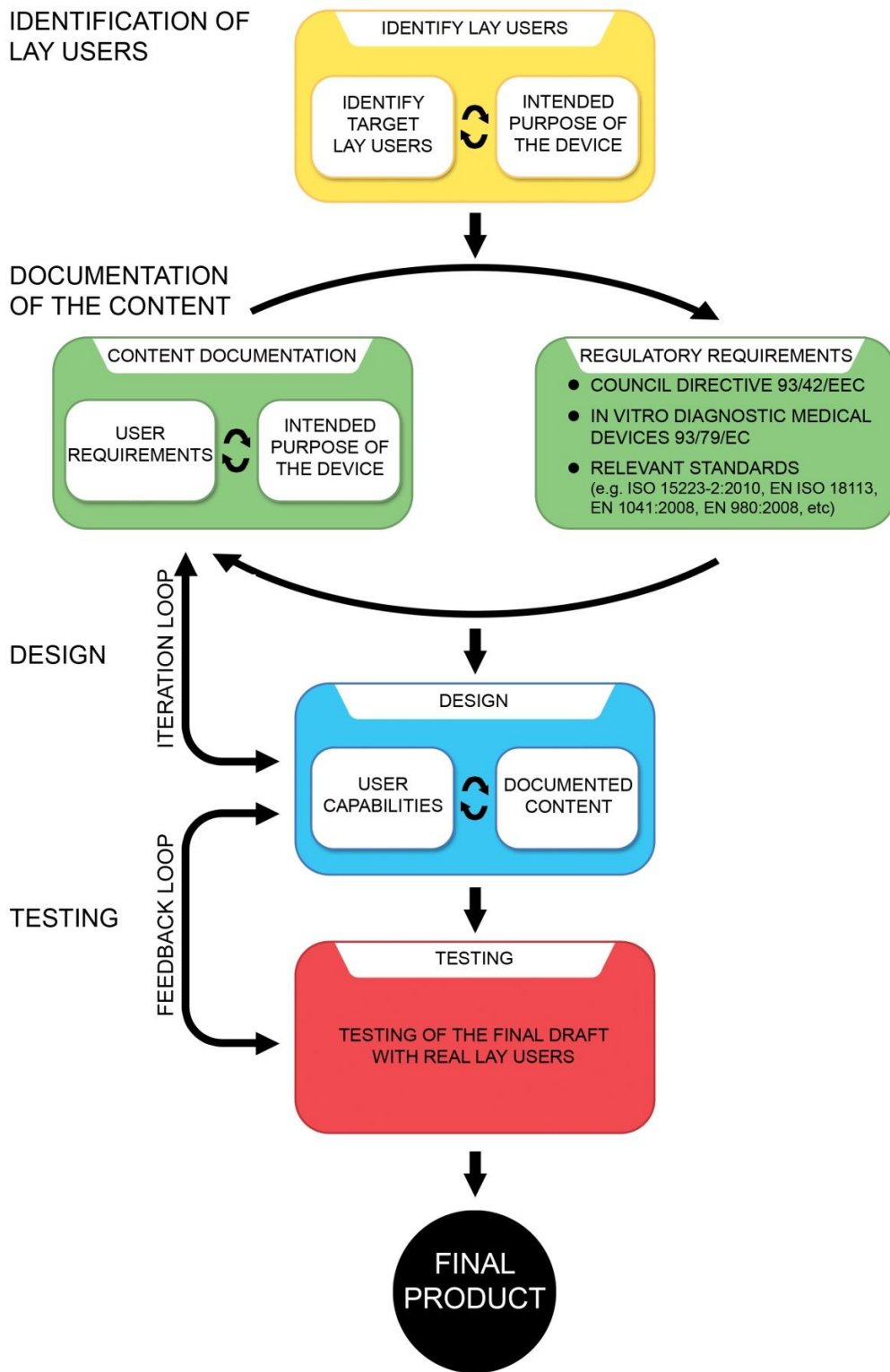


Figure 6.9 A process model suggestion for developing instruction manuals of home use medical devices for the European market

The model will help designers to understand the overall process and necessary requirements when developing instruction manuals for home use medical devices. The model is based on:

- The literature review on instruction manuals [in particular DTI, (1989); Backinger & Kingsley (1993); Wright, (2000); Horen (2001, 2005); Smith, (2003)]
- Regulatory requirements relevant to developing instruction manuals of medical devices for the European market (EEC, 1993a; EC, 1998)]
- The results of the observational studies carried out with lay users (Chapter 4)

A checklist was also prepared by using the same model to present the requirements of the different stages of the process. The development of the checklist will be described in 6.3.3.

According to the model, the design process is separated into four stages, i.e. identification of lay users, documentation of the content, design and testing.

Identification of Lay Users

The design and development process starts with identification of the target lay users: the users of the device. The target lay users are identified in accordance with the intended purpose of the device.

Documentation of the Content

After the target lay users are identified, a new stage involving the development of the content begins. For this purpose, user requirements should be identified and the intended purpose of the device should be documented in accordance with these requirements. The developer of the instruction manual must be aware of and take into account the regulatory requirements of the device, because the content of the instruction manual must fulfil the requirements of the relevant Directive and, where necessary, the requirements of the Harmonised Standards. As an outcome of this stage the documented content will be ready for the design stage of the instruction manual.

Design

During the design stage, the diverse capabilities of potential users should be taken into account. These will affect the final design of the manual in terms of, e.g., the text size, size of the graphical explanations, design of the cover, design

of the page layout, format of the page. The context in which the product will be used should also be taken into account. Factors such as this may influence the nature of the final product, affecting such aspects as the paper selection or the cover of the instruction manual.

In this stage there is an iteration loop to the previous stage (Documentation of the Content) to improve or modify the content regarding the user capabilities or requirements, and to verify the regulatory requirements as well.

Testing

When the design of the product has been finalised, the product is ready for testing. It is important to test it with real lay users and in the real-life settings in which the device will be used. There is a feedback loop to the design stage to enable the improvements regarding the design of the instruction manual. It is recommended that different types of lay users are included and consulted during the testing stage. Once it has been decided that the final product has succeeded in meeting the needs and the requirements of the target lay users, the design and development stage is completed.

6.3.3 Guidance Checklist for Developing Instruction Manuals for Home Use Medical Devices for the European Market

As can be seen in the model illustrated in Figure 6.9, the design and development stage is divided into four main stages. All these stages have different requirements to be considered. Although the figure shows the complete flow of the process, it does not specify the requirements for each individual stage. Therefore a checklist was developed in order to help the developers to evaluate their design and development process of instruction manuals for home use medical devices specifically for the European market.

The checklist developed by the FDA (Backinger & Kingsley, 1993) was used as a starting point. However this checklist was developed for the U.S. market. In addition the FDA's checklist covers the whole process, and does not specify the requirements for each distinct stage. The checklist developed as a part of this research specifically focuses on the requirements of the European market, and it

offers recommendations for different stages of design and development process.

These recommendations were based on:

- Literature review [in particular Rude (1988), DTI (1989), Backinger & Kingsley (1993), Wright (2000), Lewis (2001), Horen et al. (2001, 2005), Smith (2003), BS EN 1041:2008 (BSI, 2008b), BS EN 980:2008 (BSI, 2008d), BS EN ISO 14971:2009 (BSI, 2009a), BS EN ISO 18113-5:2009 (BSI, 2010b), FDA (2010d)]
- The observational studies which were presented in Chapter 4
- The requirements of the two Directives [i.e. MDD (EEC, 1993a) and IVDMD (EC, 1998)] regarding the instructions for use

Due to the fact that the regulatory requirements may change regarding the type of the home use medical device, the checklist mainly covers the general terms. However, some of the highlights provided in the checklist may still not be relevant to all types of home use medical devices, such as some of the Class I devices. The highlights provided in the checklist are listed in Appendix I.

In order to highlight the requirements of different stages of the process, the checklist was incorporated into the model. Colour coding was used to link the relevant parts of the model with the checklist. Figure 6.10 shows the final design version. The checklist has been developed in A3 paper size.

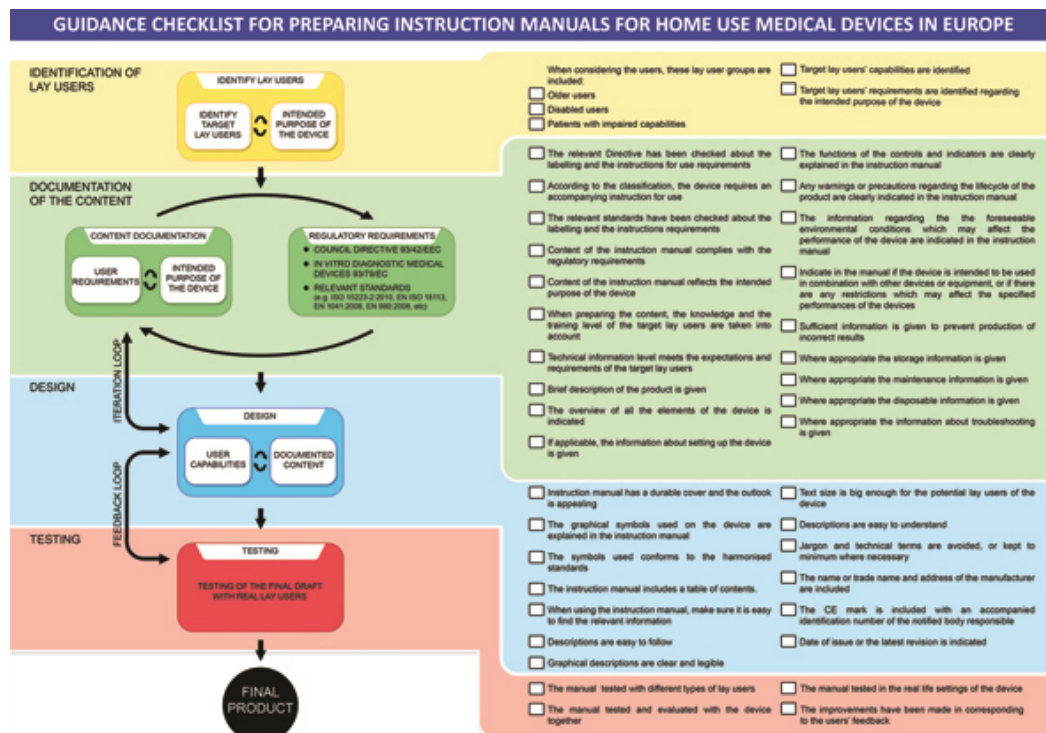


Figure 6.10 Guidance checklist for developing instruction manuals for home use medical devices for the European market

6.3.4 Development of 'Do's and 'Don't's

Based on the results derived from the descriptive studies (i.e. the literature review, observational studies with lay users and survey with designers), a number of suggestions, which might be useful when designing home use medical devices, were made for designers. These suggestions were grouped under two categories: i.e. 'do's and 'don't's. This section intends to describe how these suggestions were formulated.

'Do's

These are the suggestions for what designers should do when designing home use medical devices.

- **Be aware of the lay user requirements:** The literature review and the results of the observational studies showed that lay users differ from professionals in terms of their capabilities and characteristics. Therefore in order to address their requirements, designers should be aware of lay user requirements.
- **Consider the knowledge level of lay users:** As suggested by Backinger & Kingsley (1993), lay users may not have sufficient medical knowledge

to operate home use medical devices correctly. This was also consistent with the observational studies carried out as a part of this research.

- **Be aware of the regulatory requirements of the target market, because they may differ in different countries or regions:** This research specifically focuses on the European market. However, as mentioned in Chapter 2, the regulatory requirements may differ in different countries or regions (WHO, 2003).
- **Try to make the final product easy to use and as intuitive as you can:** Ease of use is an important factor for the usability of the device, particularly for lay users (BSI, 2008c). Besides, as discussed in Chapter 2, lay users may not always follow instruction manuals; therefore intuitiveness of home use medical devices in order to ensure lay users' safety.
- **Always keep the intended purpose of the device in your mind:** The device must fulfil the regulatory requirements of the relevant Directive. The 'Essential Requirements' are based on the intended purpose of the device (EEC, 1993a; EC, 1998).
- **Be aware of the environmental challenges. Using medical devices in the home environment may present additional risks to the user:** As highlighted in Chapter 2 home use medical devices are frequently used in non-clinical and/or transitory environments. This may bring additional challenges for designers (FDA, 2010d).
- **Design the device inclusively:** As suggested by Wiklund & Wilcox (2005), home use medical devices should be designed inclusively due to diversity of their users.
- **Test the device with real users and also in the real environment in which the device will be used:** It is important to test a home use medical device in the home environment or in a simulated environment. This may help designers to assess the problems associated with the device's intended usage environment (Sawyer, 1996, Kaye & Crowley, 2000, BSI, 2008c). It is also recommended that testing the device with its intended users takes place (Sawyer, 1996, Kaye & Crowley, 2000).

- **Be aware of the users' thoughts and feelings about similar products currently available on the market:** User reviews on home use medical devices on the popular shopping websites have proven to be a good information source for designers. Also FDA's adverse event reporting system or MHRA's product recall reports can be checked for an in depth analysis of device failures or any interaction problems experienced by lay users with similar devices.

'Don't's

These are the suggestions for what designers should NOT do when designing home use medical devices.

- **Do not design home use medical devices by only considering the needs and expectations of younger and able-bodied people:** Home use medical devices are frequently used by older people or people with impaired capabilities (Lewis, 2001; Wiklund & Wilcox, 2005). This suggestion also highlights the importance of designing home use medical devices inclusively (refer to the 'Do's).
- **Do not assume that all the users will read the instruction manual thoroughly before using the device:** As discussed in Chapter 2, lay users may not or sometimes cannot use the instruction manual provided with the device. The observational studies also suggested similar results.
- **Do not underestimate the environmental risks which may occur in the home environment or any other environment that the device is likely to be used in:** Presence of children or, pets or noise levels are some of the examples of those environmental challenges (FDA, 2010d).
- **Do not omit the emotional needs of lay users when designing home use medical devices:** This issue was highlighted by designers during the survey. This problem is particularly prevalent in the case of assistive devices, where users frequently refuse to use such devices (Parette & Scherer, 2004; Wiklund & Wilcox; 2005).
- **Do not expect the users to have medical knowledge to perform the task or be able to interpret the results correctly when using the device:** This point also focuses on the knowledge level of lay users (refer to 'Do's), however it also highlights their information requirements.

- **Do not compromise aesthetics when designing home use medical devices:** This issue was highlighted by designers during the survey, and it is directly relevant to the emotional needs of lay users (refer to ‘Do’s). Home use medical devices should be aesthetically pleasing and unobtrusive (Gardner-Bonneau, 2011).
- **Do not compromise functionality when designing home use medical devices:** This issue was highlighted by designers during the survey, where they suggested that the functionality of the device and aesthetics should be balanced carefully. It was also highlighted in the Directives that the device must function in accordance with its intended purpose (EEC, 1993a; EC, 1998).

6.4 Design and Development of the Website

Designing websites is a different field of expertise and there are several different ways to build a website. It is not only the content, but also the presentation of the information that is very important to make the website accessible to the target audience. The PhD researchers’ skills and knowledge were very limited when it came to website design, which resulted in the design and development of the first draft of the guidance frequently being limited by the researchers’ abilities in this area.

Adobe Dreamweaver CS5 software was used during the development of the website. Figure 6.11 shows a screenshot from the development process.

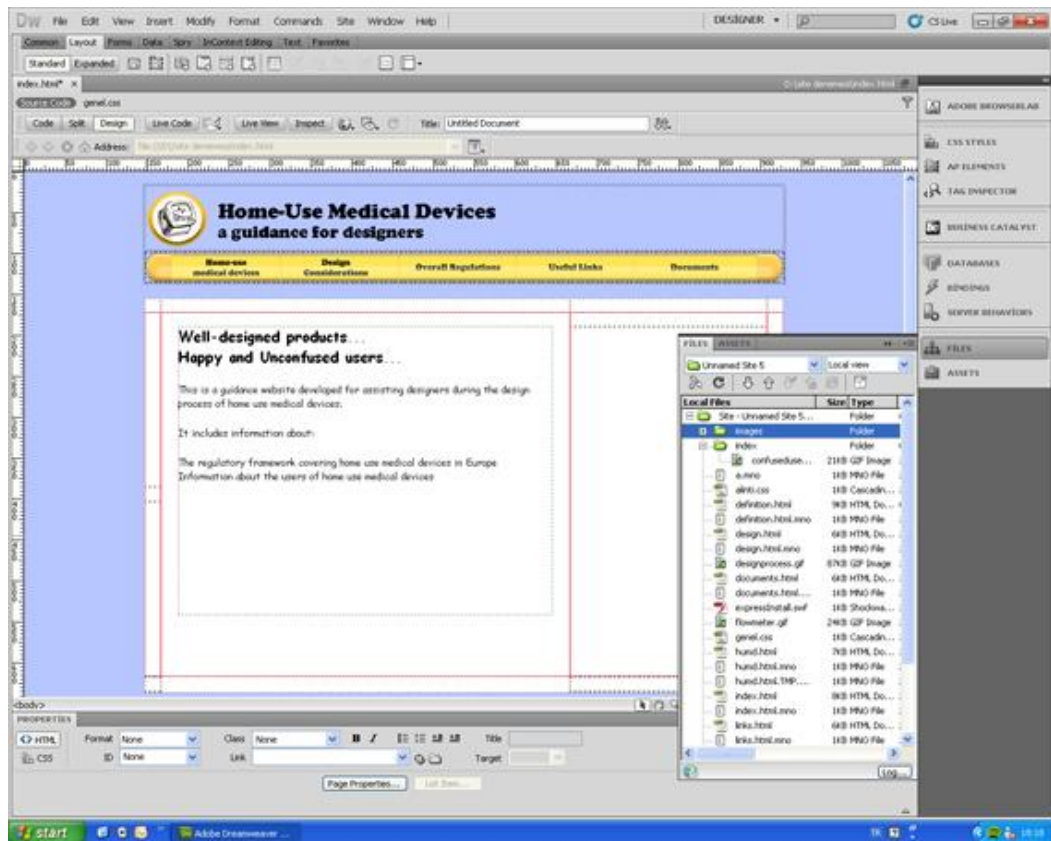


Figure 6.11 A screenshot from Adobe Dreamweaver CS5 during the development of the website

Outlook of the website

The general outlook of the website is based on the initial concept shown in Figure 6.3 with minor modifications. The final design can be seen in Figure 6.12, where the home page of the website is shown. Also the different sections of the interface are presented in Figure 6.13.

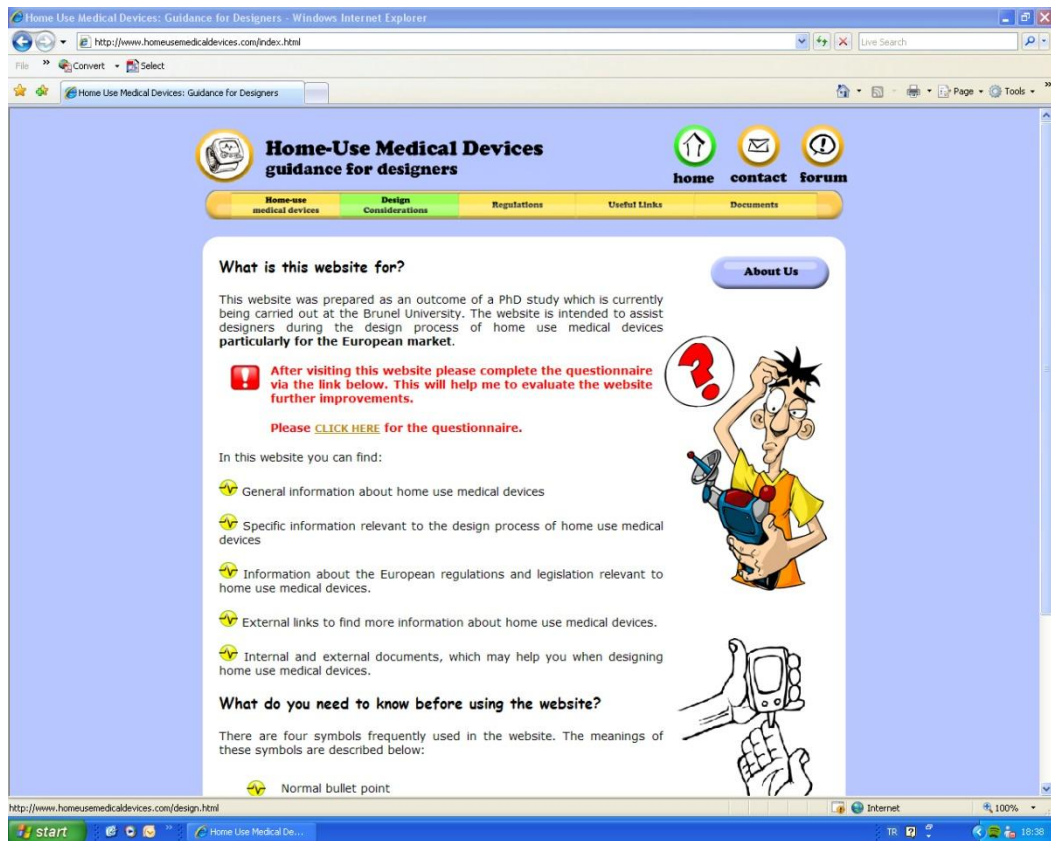


Figure 6.12 The home page of the first draft of the guidance

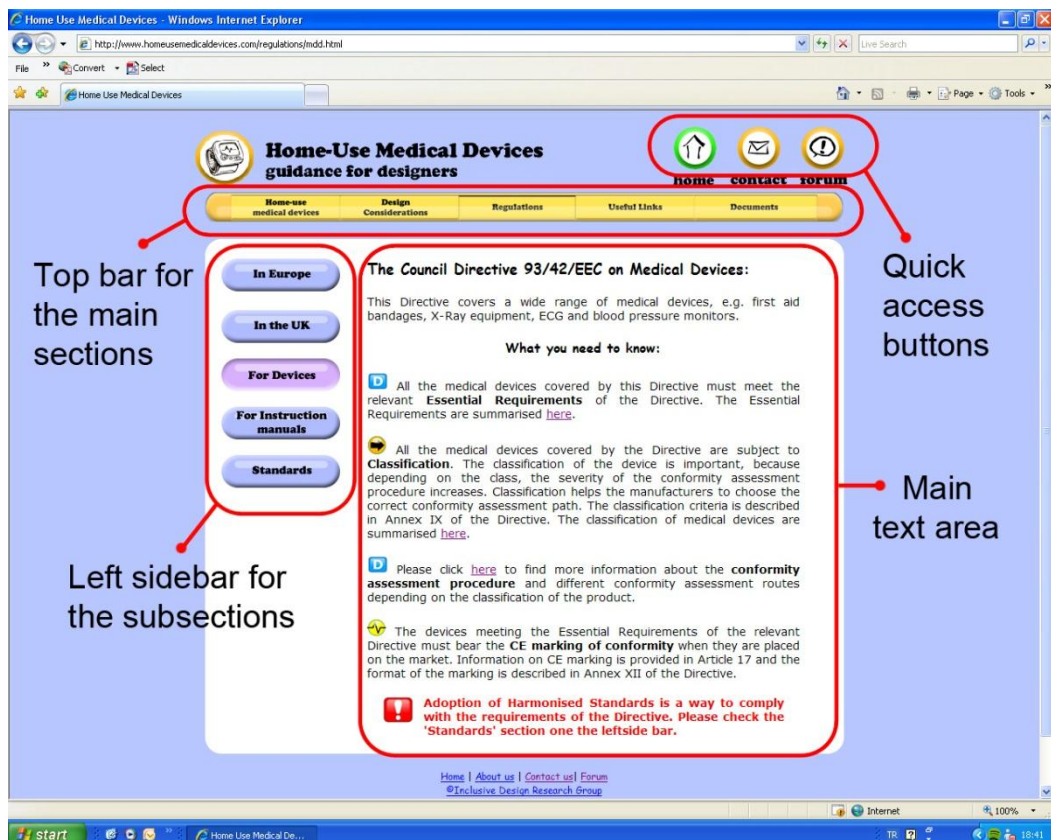


Figure 6.13 Different sections of the interface

Although the survey with designers provided valuable information about the content of the guidance and helped the researcher to adopt a website as the format of the guidance, the survey did not provide any information about how the website should look like. To illustrate lay users and home use medical devices cartoons were designed by the PhD researcher and used in the website in order to attract the attention of the visitors and give the website a more memorable style.

Different shapes and colour codes are used to highlight the different groupings of the buttons. The main information can be accessed from the top bar, therefore a bright colour was used to attract visitors' attention. As previously shown in Figure 6.4, drop-down menus were initially planned for the subsections; however, a left sidebar was used in the final design. The purpose of this change was to make it obvious to visitors which section of the website they are browsing.

In order to provide interactivity between the visitors and the website, rollover buttons were created, which means that the state of the button changes if the user moves the cursor over the button or clicks the button. By this way the website also provides feedback to the user about which section is currently selected. This is demonstrated in Figure 6.14.

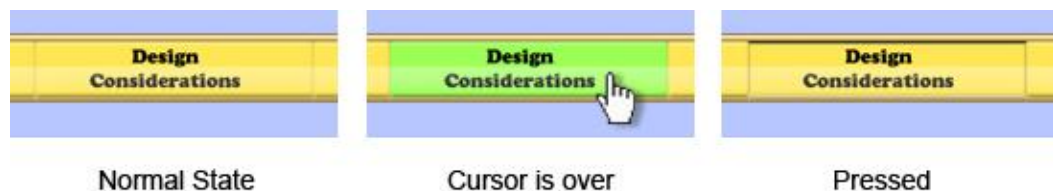






Figure 6.14 Rollover buttons

It was proposed that step by step information should be provided in the main text area, therefore bullet points are used. Important information is highlighted in bold typeface (refer to Figure 6.13).

Different bullet points were designed and used to present different types of information. Table 6.1 defines these bullet points. These definitions can be accessed via the home page.

Table 6.1 The bullet points used in the guidance website

| The Bullet Points and Their Meanings | |
|---|---|
|  | Normal bullet point |
|  | This bullet point indicates that, if clicked, a pop up window will be opened to give detailed information. This also applies to anchor text following this symbol |
|  | This bullet point indicates that a PDF document will be opened if clicked. Also applies to anchor text following this symbol. |
|  | This symbol means that important information is given in the following (red coloured) text. |

The ‘Forum’ section which was mentioned in Section 6.1.2, is also included in this first draft of the guidance. However, with the current skills of the researcher it was not possible to develop a functioning forum with interactive features, therefore only a short introductory message was included in this section which briefly described the purpose of the forum and indicated that it was currently not available.

Domain name of the website

Selecting a domain name was not an easy task because it should be:

- Distinctive
- Easy to remember
- Self evident about the content
- Available

After some investigation, the following domain name of the website was selected as <http://www.homeusemedicaldevices.com> which satisfied all the criteria above.

6.5 Summary

In this chapter the development process of the first draft of the guidance was described. The development process was undertaken as the ‘Prescriptive Study’ with reference to DRM (Blessing et al., 1995). The content of the guidance was based on the findings of the ‘Descriptive Study 1’ which includes the literature

review (Chapter 2), understanding lay users (Chapter 4), and the survey with the designers (Chapter 5).

This chapter mainly focused on the formulation of the content of the guidance. Five main sections were identified (i.e. home use medical devices, design considerations, regulations, useful links and documents) in order to provide guidance for designers. When preparing the contents of these sections, in addition to the information derived from the available literature, this research made a number of specific contributions to the content of the website:

- Design process model specific to home use medical devices (Dual Verification Model)
- Design process model for developing instruction manuals of home use medical devices for the European market
- Guidance checklist for developing instruction manuals for home use medical devices for the European market
- A list of useful suggestions referred to as *'Do's and Don't's* which was presented as a specific section on the website

The development of this information was presented and discussed in this chapter.

In terms of the presentation of the information, it was necessary to provide a logical order; so the sections and subsections were grouped and sequenced hierarchically. A working prototype was developed using Adobe Dreamweaver CS5 software. It was proposed that the website would be used during an evaluation study; therefore it was uploaded to the Internet to make it easy for designers to access. A distinctive and self-exploratory domain name was selected. The website is accessible via <http://www.homeusemedicaldevices.com>.

The next chapter (Chapter 7) will focus on the evaluation, by professional designers, of the guidance website.

CHAPTER 7: EVALUATION WITH DESIGNERS

The development of the website which aims to provide guidance on designing home use medical devices was described in Chapter 6. To assess whether the guidance was effective in meeting designers' needs, an evaluation study was conducted with professional designers.

According to Robson (2002: p.202), "the purpose of an evaluation is to assess the effects and effectiveness of something, typically some innovation, intervention, policy, practice or service" where researchers should be clearly aware of what they are doing and why. He also argues that the purpose of an evaluation study is not only to assess the value but also to seek the ways in which what is being evaluated can be improved (Robson, 2002). However, the challenge of evaluation is that there are no set rules on how to carry it out, and it depends on the researcher's purpose (Gray, 2004).

There are different types of evaluation approaches (e.g. experimental, system, illuminative, goal-based, etc) and they differ in terms of what is being evaluated (Gray, 2004). The main purpose of this study was to assess whether the guidance developed corresponds to the aim of the overall research, which was to assist designers in developing home use medical devices by providing information and suggestions regarding lay users and how to address their needs and expectations. Therefore the 'goal-based evaluation' approach was adopted, which focuses on the achievement of pragmatic outcomes in order to understand whether the planned goals meet the actual goals (Gray, 2004).

This chapter will also provide additional understanding regarding the third research question: "how to support the design of home use medical devices?"

The objectives are:

- To evaluate designers' perspectives on whether the guidance is effective in meeting their needs
- To identify ways in which the guidance could be improved, so as to better meet the needs of designers when designing home use medical devices

For this purpose two methods were used: (1) an online questionnaire for the initial evaluation and (2) semi-structured interviews for the detailed evaluation. A total of 12 professional designers (with/without experience in designing home use medical devices) took part in this study.

The results of the evaluation will be presented and discussed in detail in this chapter. The study was undertaken as the 'Descriptive Studies II' of this research (refer to Figure 3.1, Chapter 3) with reference to the DRM (Blessing et al., 1995).

7.1 Preparation of the Study

As mentioned in 3.6, this study involved two stages: the initial evaluation by an online questionnaire, and the detailed evaluation through semi-structured interviews.

7.1.1 Sampling of Designers for the Evaluation of the First Draft of the Guidance

During the pilot study convenience sampling (Robson, 2002) was used where all the participants were recruited from within the staff or other research students of Brunel University. Four people took part in the pilot study, and all these participants had a major degree in a product design related subject. Before putting the website online, the root-folder of the website was given to them, enabling them to view and use the website as if it was online, and they were asked to identify design related problems (such as broken links). The participants were also asked to identify any obvious missing information which could be included in the content.

All the participants were asked to complete the questionnaire, and two of them were also interviewed. The questionnaire questions and the interview questions were revised several times based on the feedback received at the pilot study. For example, no exemplars of home use medical devices in the initial design of the website were provided. This was suggested by three participants of the pilot study and the examples of home use medical devices section was added to the website before the main study.

For the main study, purposive sampling (Robson, 2002) was the main sampling method, because: (1) only the designers who have a major degree in a product design related subject, and (2) who have at least 2 years of experience as a professional designer were contacted. In addition the researcher aimed to include both designers having prior experience in designing a home use medical device and others who do not. During the pilot study it was also suggested to the researcher that designers who are new to designing home use medical devices and thus requiring information regarding the overall design process, should also be included. Therefore this group of designers having ‘very little experience’ was included in the main study.

The designers who took part in the ‘Survey with Designers’ study and indicated that they would like to take part in the evaluation of the guidance were contacted. A number of designers mentioned that they were still available for the interview; however, others mentioned that they were busy or away from the UK at the time. Therefore, additional designers were contacted through www.designdirectory.co.uk, and www.linkedin.co.uk. The snowball sampling method was also utilised, where the designers who agreed to take part in the study were asked to identify other possible participants matching the sampling criteria.

The message calling for participation for the evaluation study was sent to 80 designers and 18 of them responded. However, although six of those participants completed the online questionnaire, they could not participate in the interview due to their very busy schedule. Therefore their results were exempted from the analysis below. As a result 12 designers took part both in the questionnaire and semi-structured interviews.

7.1.2 Preparation of the Questionnaire

SurveyMonkey, a popular online survey tool, was used to prepare the online self-administered questionnaire. The questionnaire was used as an assistive method to the interviews, in order to provide data and method triangulation to improve the reliability of the results.

This questionnaire was designed to collect information about:

- Designers' considerations regarding the content of the website
- The efficiency of the first draft of the website, and whether it would be useful for designers
- The overall design of the first draft of the website

The logo of the website was used in the questionnaire in order to emphasise their relationship to each other, and a short introduction was included in the very beginning of the questionnaire explaining the purpose of the study. In the questionnaire, except for one open-ended question where the name of the respondents was requested, only closed-questions were used.

In order to identify the designers having experience in designing home use medical devices and those having no prior experience in this field, a question was included in the questionnaire asking the respondents about their experience levels.

The survey questionnaire adopted 5-point scale questions where the respondents were asked to rank specific aspects of the website.

The final version of the questionnaire used during the study can be seen in the Appendix M.

7.1.3 Preparation of the Interview Questions

The participants who completed the questionnaire were expected to participate in the interview exercise as well. Semi-structured interviews were carried out with designers in order to collect detailed information regarding their thoughts about the first draft of the guidance website.

Robson (2002) suggests a sequence of questions which includes 5 steps: i.e. introduction, warm-up, main body of interview, cool-off, and closure. During the preparation of the questions this sequence was considered. In addition, all the questions were kept as short as possible; double-barrelled questions were avoided; language was kept simple, and jargon and leading questions were avoided in the interview questions (Robson, 2002).

The main objectives of this interview evaluation were:

- To observe how designers interact with the website
- To understand the reasons behind their answer to the evaluation questionnaire
- To identify information needs (the most and the least useful parts of the guidance, the unnecessary or irrelevant parts of the guidance and any missing information)
- To find ways to improve the guidance

The aim was to keep the interview session to less than 30 minutes. Therefore only 9 questions were included. The participants were also asked to identify other useful information sources to assist designers when designing home use medical devices.

The questions were prepared as an ‘interview questions sheet’ which includes sufficient space between each of the questions to allow note-taking during the session.

The interview questions can be seen in Appendix N.

7.1.4 Study Procedure

The designers who fulfilled the sampling criteria (refer to 7.1.1) were contacted via email or internal messages through www.linkedin.com. The designers were asked to reply to the message if they would be interested in taking part and contributing to the research. It was also clearly indicated in the message that the interview session would not last more than 30 minutes. Figure 7.1 summarises the procedure of the evaluation study.

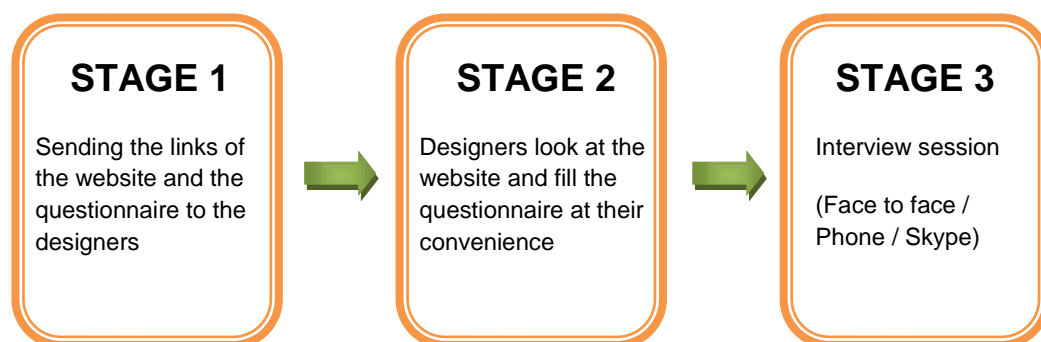


Figure 7.1 Three stages of the evaluation study

At the first stage, the links to the website and the questionnaire were sent to those designers who wanted to take part in the study. The designers were also asked to indicate their preferred date, time and venue for the interview session.

At the second stage, the designers were given sufficient time to look through the guidance website before the interview and complete the online questionnaire on their own. In particular they were asked to check the content of the five main sections of the website: (1) home use medical devices, (2) design considerations, (3) regulations, (4) useful links, and (5) documents.

At the third stage, the designers were interviewed on their preferred date, time and venue. If the designers mentioned that they would prefer the interview to be conducted via phone or Skype, their preferred format was adopted. Eventually the interviews were carried out by using three different methods: face to face, via phone, or Skype.

A number of tools were used to facilitate the interviews, and they are presented in Figure 7.2.

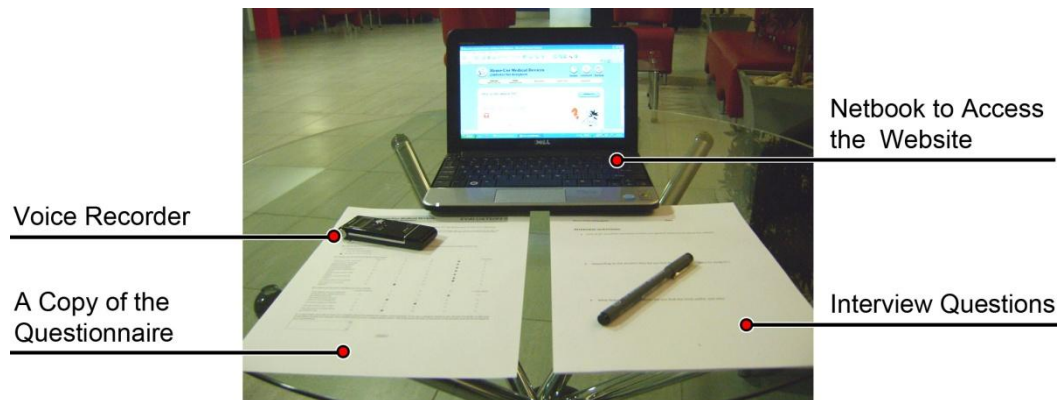


Figure 7.2 The tools used during the face to face interviews

The sessions were recorded by means of a voice recorder if the permission of the participants was given. Note-taking (e.g. short notes) was also utilised during the interviews (Figure 7.2).

A copy of each participant's answers to the questionnaire was also brought to the interview for reference in order to understand the reasoning behind their answers in the questionnaire. During the face to face interviews a netbook was used to access the website. This proved useful because the researcher had the opportunity

to observe the designers when they interacted with the website. However, this was not possible during phone or Skype interviews.

After the completion of the interview, the researcher thanked all the participants for their participation and contribution to the research, and the participants were asked whether they would like to be notified about the further development of the website.

7.2 Analysis of the Data

Different methods of analysis were used for the data collected via the questionnaire and during the interviews with designers. In this section, the analysis methods used will be discussed.

7.2.1 Questionnaire Analysis Method

The online questionnaire helped the researcher to collect numerical data, e.g. ranking based on a 5-point scale. The SPSS 15.0.1.1 statistical analysis software was used to analyse the questionnaire data, and the descriptive statistics 'Frequency' tool was used to calculate the mean values and the overall percentages of the choices of the respondents. During the analysis of the questionnaire '3' was accepted as the neutral value, while a score over '3' was accepted as a 'positive' response and a score below '3' was accepted as 'negative'.

Although this study involved three types of designers with different level of experiences, it was not investigated whether there were any statistically significant differences between these groups due to the relative small sample size. The results of the questionnaire will be presented in Section 7.3.

7.2.2 Interview Analysis Method

The interview time varied for each of the participant; some of the designers had very limited time and some wanted to share their perspectives after the 30 minutes. Table 7.1 summarises the information about the time taken during the interviews.

Table 7.1 Maximum, minimum, average and total time taken of the interviews

| Time Taken During the Interviews | |
|----------------------------------|--|
| Minimum | 10 minutes 23 seconds |
| Maximum | 1 hour 1 minute 33 seconds |
| Average | 28 minutes 10 seconds |
| Total time | 5 hours 40 minutes 15 seconds (12 Designers) |

As mentioned in 7.1.4 note-taking and voice recording techniques were utilised during the interviews. All the interview records were transcribed using the QSR NVivo 8 software, and the notes taken helped the researcher to find the important parts of the recordings. Figure 7.3 shows a screenshot from the transcription process, and describes the interface features of the software.

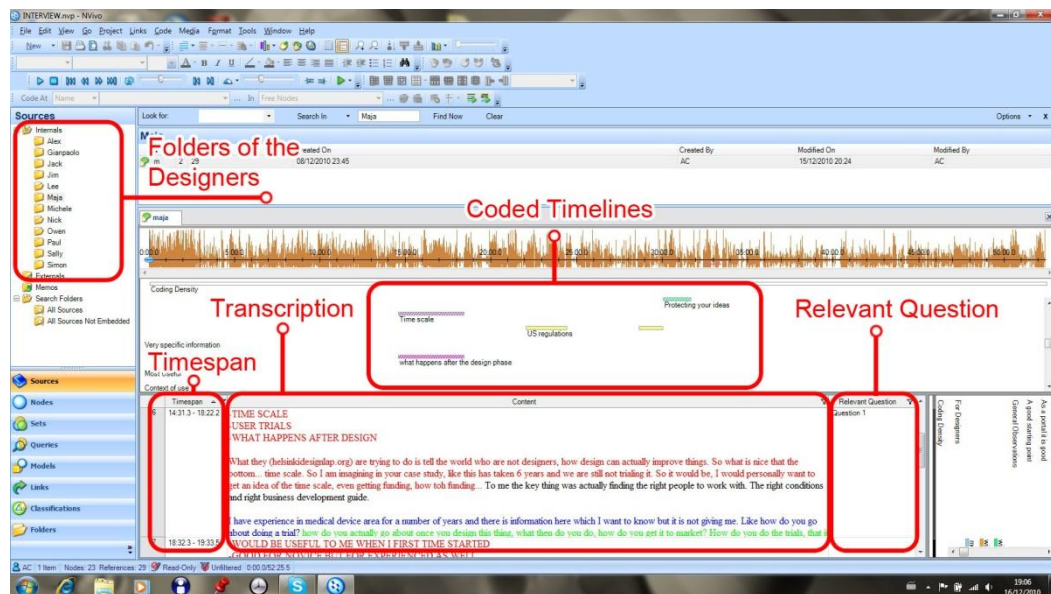


Figure 7.3 A screenshot from NVivo 8 software to summarise the transcription process

The NVivo software made the transcription process easier. The timespan feature enabled the researcher to return or find a particular part of the transcription when it was deemed necessary. As can be seen from Figure 7.3, colour coding was used during the transcription process in order to distinguish different statements. Short headings were given to each of the transcription cells to summarise their content.

Some of the participants partly answered a few questions in one question, and this was indicated in the 'relevant question' section of the transcription table.

All the different statements were coded by using the ‘tree nodes’ function which allowed the researcher to build a hierarchical structure during the coding process. Figure 7.4 shows a screenshot from the NVivo’s interface in order to demonstrate the coding process by using the tree nodes function.

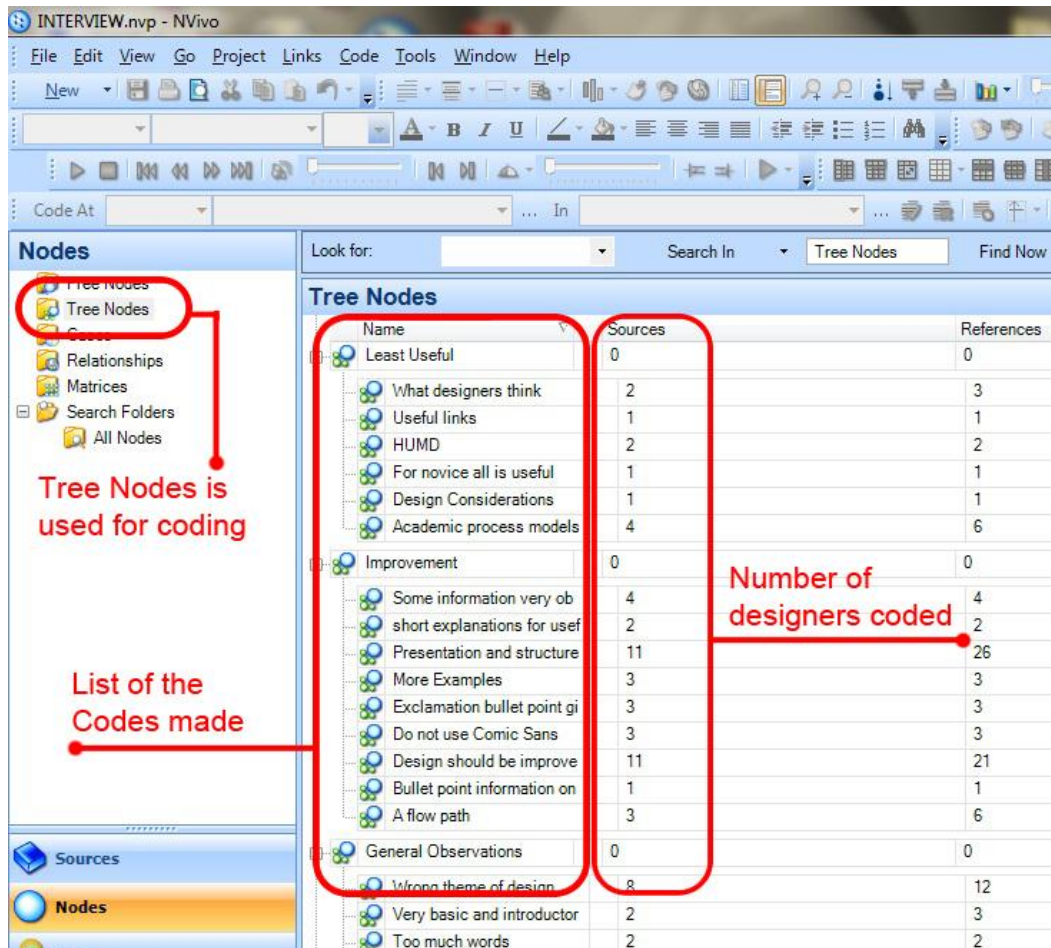


Figure 7.4 A screenshot from NVivo 8 software to summarise the coding process

As can be seen from Figure 7.4, each of the interview questions were accepted as a main category and the subcategories were identified according to the answers the designers gave to those questions. The software also shows how many sources were used and how many references were made for a specific node. The results of the interviews will be presented in Section 7.4.

7.3 Results of the Questionnaire

Overall, 12 designers took part in both the questionnaire and the interview. The designers indicated their level of experiences in designing home use medical devices in the questionnaire:

- 3 Designers had experience
- 5 Designers had very little experience
- 4 Designers had no experience

As can be seen 8 designers had some level of experience in designing home use medical devices, which suggests that they were likely to be aware of the issues relevant to designing such products. Four of the designers were complete novices in the field; however, they helped the researcher to understand novice designers' points of view regarding the guidance as this research also aimed to cover those with no prior experience in designing home use medical devices.

The questionnaire asked for specific comments on the content, efficiency and design of the guidance website. The results regarding the three aspects are as follows.

7.3.1 Content of the Website

In order to understand the designers' considerations about the content of the website, 5-points scale response questions (1 = 'Very poor', 5 = 'Excellent') were used, and the designers were asked to scale the following features of the website:

- Relevance of the information
- Content of the 'Home Use Medical Devices' section
- Content of the 'Design Considerations' section
- Content of the 'Regulations' section
- Content of the 'Useful Links' section
- Content of the 'Documents' section
- Overall content of the website

Figure 7.5 presents the mean values for each of the features indicated above.

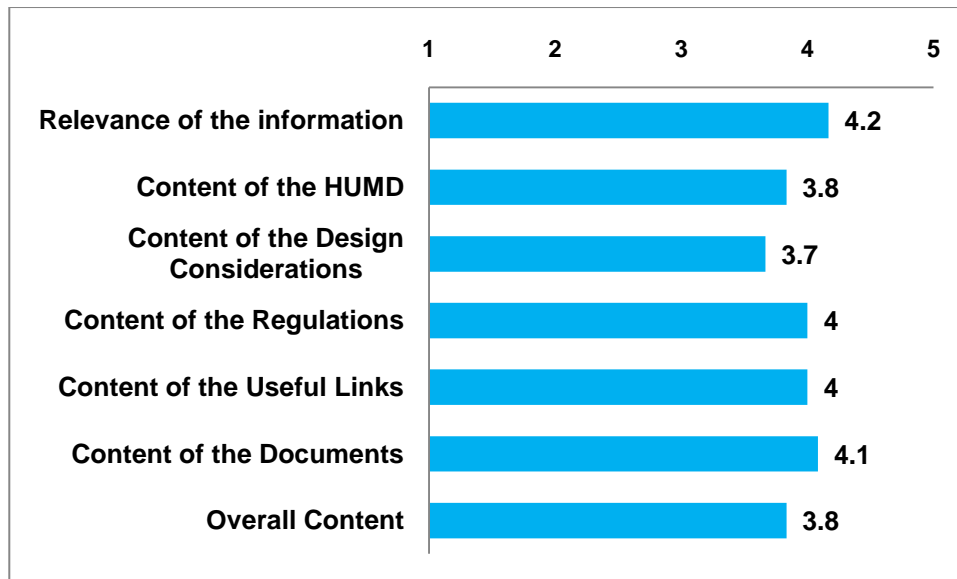


Figure 7.5 The mean values regarding the content of the website

As can be seen from Figure 7.5, in terms of the content (although the website is only the first draft), all the results have a mean value over 3.5. According to the results, the designers found the information presented in the website relevant to them. The Documents, Regulations and Useful Links sections received the highest ranks from the designers. Although the Design Considerations section has the lowest mean value (i.e. 3.7), 67% of the designers ranked the content of this section 4 or 5, (25% of them ranked as: ‘5’=‘Excellent’). The overall results suggested that most of the designers that participated in the study were satisfied with the content of this first draft of the guidance website.

7.3.2 Efficiency of the Website

In order to understand the efficiency of the website the designers were asked to rate four aspects of the website, i.e.:

- Whether the website would be useful for designers when designing HUMD
- Whether the website would only be useful for novice designers
- Whether the level of detail of the information presented is sufficient
- Whether the information is up to date

5-points scale response questions were used. Figure 7.6 demonstrates the mean values for each of the characteristics mentioned above (1: ‘Totally disagree’; 5: ‘Totally agree’).

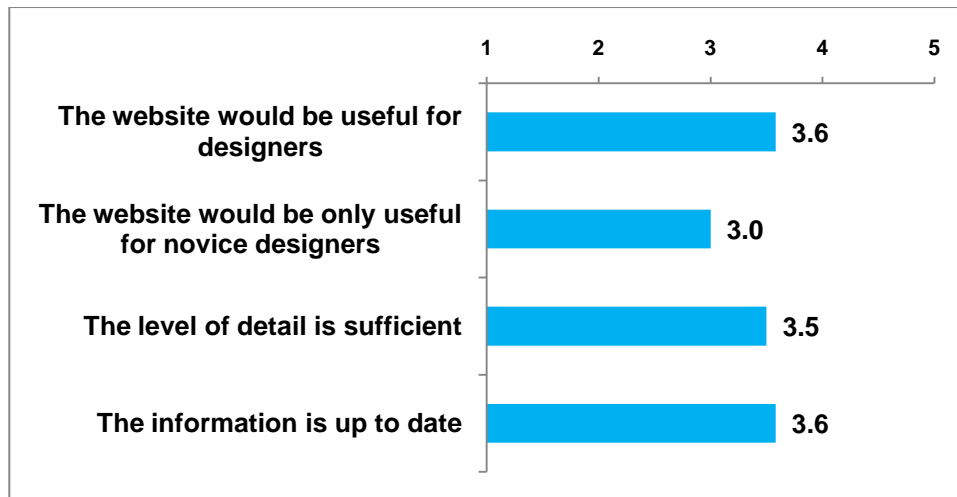


Figure 7.6 The mean values regarding the efficiency of the website

As Figure 7.6 shows, overall most of the respondents found the website useful for designers when designing home use medical devices. On the other hand the results also showed that some of the designers thought the website would only be useful for novice designers. Due to the fact that this was a closed question, it was not possible to understand the reasoning behind the respondents' choices, however, the reasons were investigated during the follow-up interview session, with reference to the designers' answers given in the questionnaire.

Overall the designers found the level of detail of the information presented in the guidance was sufficient, as demonstrated by a mean value of 3.5. In addition most of the designers found the information presented was up to date, which accounts for the 92% of the respondents who rated this question 3 and over.

7.3.3 Design of the Website

The designers were asked whether they found the website easy to use and whether the information was presented in an effective way. The first question received the average mean value 3 (42% of the designers ranked 3), and the second question the average mean value 2.8 (50% of the designers ranked less than '3'). This suggests that the usability and the presentation of the website have great scope for improvement.

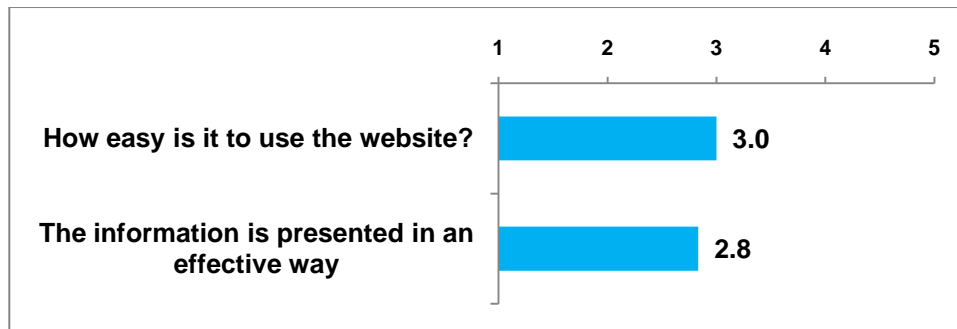


Figure 7.7 The mean values regarding the usability of the website and the presentation of the information

7.4 Results of the Interview

During the interviews 9 questions were asked and the responses from the designers were coded in 77 categories by using NVivo 8 software. During the coding process, a total of 320 references were made from 12 sources. The complete list of the categories can be seen in Appendix O.

7.4.1 General Observations of the Designers' Interaction with the Website

11 out of the 12 designers taking part in the interview had very positive comments on the website. Some of the examples of the comments are:

- *"I think it is a very good concept! It would be welcomed by designers who perhaps avoid medical devices, because they are unsure of what requirements there are to get involved in designing such devices." (D1)*
- *"I was thinking going back a few years to when I first started designing home use medical devices. It (the guidance) would be probably useful to actually have. It is a good overview to help me get started and to give me an idea of what the process is." (D6)*
- *"I just think it is a great resource of information. What you managed to get in there is absolutely fantastic!" (D12)*

One designer who had experience in designing home use medical devices had overall negative comments on the website, mentioning that some of the information presented in the website was very simple and introductory. On the other hand some other designers who did not have prior experience or had very little experience found the introductory information useful.

Four designers mentioned that the website was a good starting point for those involved in a HUMD project. On the other hand two designers argued that, in fact the client generally provided the necessary information in the design brief. However, they also mentioned that nonetheless they found the website useful because it could act as an additional information source or a reference point.

On the other hand, 8 out of the 12 designers mentioned that an inappropriate visual style was selected for the design of the website. Due to the fact that the information pertains to the field of medical devices, the overall design should be accordingly reverential and more serious. The designers frequently mentioned that the cartoons, colourful buttons and menus, and the Comic Sans font used in the website, did not provide the feeling of an informative medical website. As a result, it was harder for them to take the information seriously.

- *“In terms of the general tone, the illustrations that populate the website, I think they gave the wrong impression. They made me not take the material as seriously.” (D4)*
- *“I do not think the cartoon background is appropriate for the environment. I think the visual interface dilutes it. So in branding terms, it is the wrong brand.” (D8)*

On the other hand in terms of the content most of the designers found the website successful; because they found it comprehensive, informative and interesting. However, a few designers mentioned that there is too much text on the website and it includes too much information which can sometimes serve to confuse the reader.

7.4.2 Useful or Not?

The respondents were asked why they found the website useful (or not) for designers, or why they found it more useful for novice designers with reference to the answers given in the questionnaire. There was a consensus between all the designers that the website would be useful for designers when designing home use medical devices:

- *“I think it is useful for designers because it gathers most of the information you might need when you are doing this sort of project in one*

single place. It is like a touch point, I guess it is like a hub of information. So that is good.” (D2)

- *“It has got all the basic steps that you need to follow in a design process and also has external links that you can use to find out what the process should be and how to expand it.” (D7)*
- *“Designers, particularly, may not know what regulations there are. And even if they know there are regulations, they do not know where to find them. So it is nice to have them all in one place.” (D11)*

Eight designers mentioned that the current version of the guidance might be more useful for novice designers, arguing that experienced designers might develop their own understanding of the process and may already be aware of most of the information presented in the website.

However, 5 designers also mentioned that the website would be useful for expert designers. They particularly found the regulations section and the forum useful for experienced designers.

The results of the interviews suggested that the type and the level of the information required by designers differ according to their level of experience. As mentioned in 7.1.1, three types of designers were identified before the study. However, during this question the possible existence of one more group of designers was raised: the designers having great experience in the field of medical device design, who spontaneously find themselves with a home use medical device project. The difference of this group is that, although they are familiar with the medical device regulations, they are confused about what makes home use medical devices different and how the regulations affect the priority of the decisions to be taken into account during the design process. The requirements of this designer group will be investigated in future work (refer to Section 8.3.2)

7.4.3 Most Useful Features of the Website

Thirteen features of the websites were identified as the most useful. To see the full list refer to Appendix O. Seven of those features were indicated by more than

one designer. These features are presented in Figure 7.8. The numbers in Figure 7.8 show how many designers indicated the usefulness of each feature.

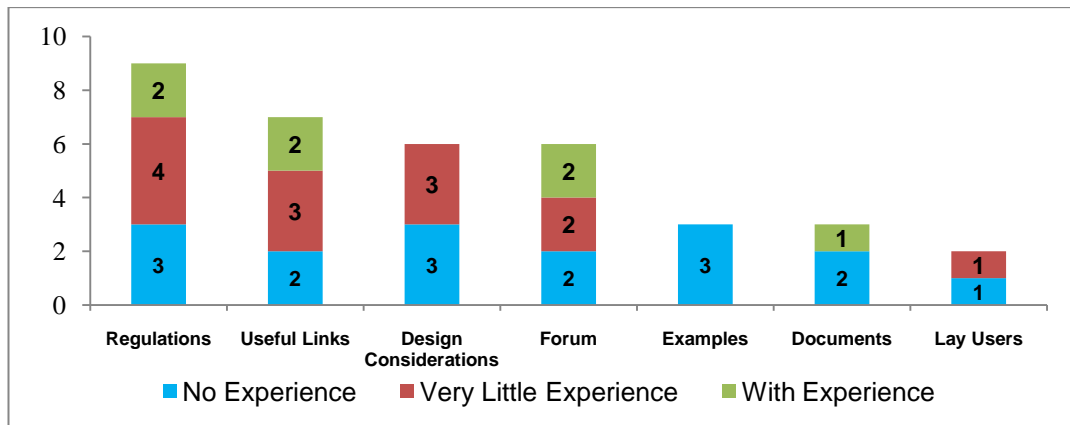


Figure 7.8 The most useful features of the website

‘Regulations’ was regarded as the most useful feature. The designers indicated that it is useful to have all the regulatory information in one place. They also mentioned that some designers try to avoid the field of medical devices because it is a highly regulated sector.

‘Useful Links’ were the second most useful feature of the website, followed by the ‘Design Considerations’ and the ‘Forum’ features. A few designers also indicated some of the specific **subsections** as the most useful, such as ‘examples’ and ‘lay users’.

The ‘Regulations’, ‘Useful links’, and ‘Forum’ sections were found to be particularly useful for the participants with prior experience. Those designers mentioned that the references made in the ‘Regulations’ section were especially useful and would help them to find specific information when required. In addition, it was deemed useful that a number of MHRA documents were hyperlinked in the Regulations section, which makes them easy to find and access. These designers also mentioned that they found some of the links given in the ‘Useful links’ section interesting; however they suggested that this section should be regularly updated and expanded. The ‘Forum’ section was also mentioned as a useful feature, because it provides an environment for designers to discuss specific issues relevant to a particular design project.

On the other hand, the ‘Design considerations’ and ‘Home use medical devices’ (including ‘Examples’) sections were found to be more useful by designers

without experience when designing home use medical devices. They indicated that the ‘Design considerations’ section summarises the overall process and highlights the specific issues relevant to designing a home use medical device, and they think it was useful. Similarly, the ‘Home use medical devices’ section was found to be a useful resource as an overview of the market. The designers without experience found the ‘Examples’ section particularly useful. It works as a product categorisation for different types of home use medical devices.

7.4.4 Least Successful Features of the Website

Five features of the website were indicated as the least useful, and three of those were mentioned by more than one designer. According to the results the least useful feature of the website was **the design process models** given in some of the subsections. Four designers mentioned that although these design process models looked useful from an academic perspective, they were not that useful in practice unless they were supported by other features such as checklists, case studies or action plans. Some of the designers also mentioned that experienced designers often had their own process models in their heads and would rarely refer to other models. Some designers mentioned that these models were likely to be useful for novice designers in order to understand the overview of the process.

‘What Designers Think’ subsection and ‘Home Use Medical Devices’ section were also considered to be the least successful features, each by two designers. The ‘What Designers Think’ subsection was found to be more relevant to the PhD researcher than the designers, although two of the designers did not think that section should be taken out. Two other designers argued that, the ‘Home Use Medical Devices’ section looked very useful at the very beginning. However, as it only provides the background information, once the information is referred to, it is no longer considered informative. Additionally a reader with prior experience in designing home use medical devices, since the section only gave overall background information, may not glean much of use.

7.4.5 Unnecessary or Irrelevant Information

Half of the designers mentioned that they found all the information presented in the website relevant and necessary. The other half of the designers identified

seven things which were unnecessary or irrelevant in the website. However, all the others were mentioned only once during the interviews, with one exception.

Four of the designers mentioned that using different types of bullet points in the website was unnecessary; considering them to actually add more complexity.

- *“Like on the bottom of the home page you have the logos, the bullet points... it is nice but maybe not necessary.” (D3)*
- *“... The bullet points. So if you go to home page, you clearly defined these, but I am not sure if this is over-complicating it.” (D5)*

The remaining unnecessary or irrelevant points which were only mentioned once during the interviews can be seen in Appendix O.

7.4.6 Missing Information in the Website

The designers were asked to identify any missing information that they would like to see in the website. Two designers did not mention anything due to their lack of experience in designing home use medical devices. The other designers identified eight types of information missing from the website.

Five designers mentioned that they would like to see very specific information regarding product categories and their specifications, capabilities of different types of users and different types of medical conditions which caused patients to use home use medical devices. The designers mentioned that these types of very specific information would be very useful, in particular, for experienced designers.

Another three types of missing information, indicated twice during the interviews, were:

- U.S. Regulations for entering the U.S. market
- The attitudes of users towards a specific medical condition, such as how emotional factors affect the ability of the patients to manage their condition
- Information about how to carry out clinical trials

Four more types of additional missing information were also identified by designers. However, each of them was only mentioned once: information about

the protection of ideas, the overall time scale for a home use medical device design project, other methodologies, and further information to demonstrate what happens after the design stage.

7.4.7 Other Features

During the interview the designers were asked to identify other features which might be useful to be included in the website, and 15 features were identified. Seven of these features were mentioned more than once during the interviews. Some examples are listed below, and the full list can be seen in Appendix O.

- **Case studies:** 6 out of the 12 designers mentioned that they would like to see case studies of successful products in the website. They argued that case studies would help designers to put the information presented in the website into context.
- **Checklists to check the process:** As mentioned in 7.4.4., some of the designers did not find the design process models presented in the website useful, finding them too academic. However, two of those designers indicated that checklists could be included in the website in order to increase the practicality of the design process models. One of the designers mentioned that the guidance checklist (Section 6.3.3) which was prepared for developing instruction manuals was exactly what he meant, but he wanted to have a similar checklist for the design process of home use medical devices.
- **Search bar:** Two designers wanted a search bar to be included in the website, to facilitate designers in their search for information.
- **Classification calculator:** As mentioned in 2.5.1., all medical devices are subject to medical device classification. However, two designers with experience in designing home use medical devices indicated that Medical Device Regulations were not product specific but classification specific, with designers finding it very complicated to discover to which class their product belongs. Therefore they wanted a ‘classification calculator’ on the website, which by asking visitors a few questions, will suggest the correct classification for the product.
- **Existing products:** Two designers indicated that it would be useful to have a section which provides links to existing products on the market.

- **Others' contribution:** Two designers mentioned that allowing others' contribution would be very useful for expanding the content of the website.

Some of the other features mentioned included: a section about materials, videos, interviews, newsletters and a site content map.

7.4.8 Improvements

One of the main purposes of this evaluation study was to understand the ways in which the guidance website could be improved. Therefore, during the interviews, the designers were asked to share their thoughts about what could be improved upon. As a result 10 aspects of the website were identified as requiring improvement, with eight of those mentioned by more than one designer. Figure 7.9 shows those eight aspects. The numbers show how many designers mentioned each of them.

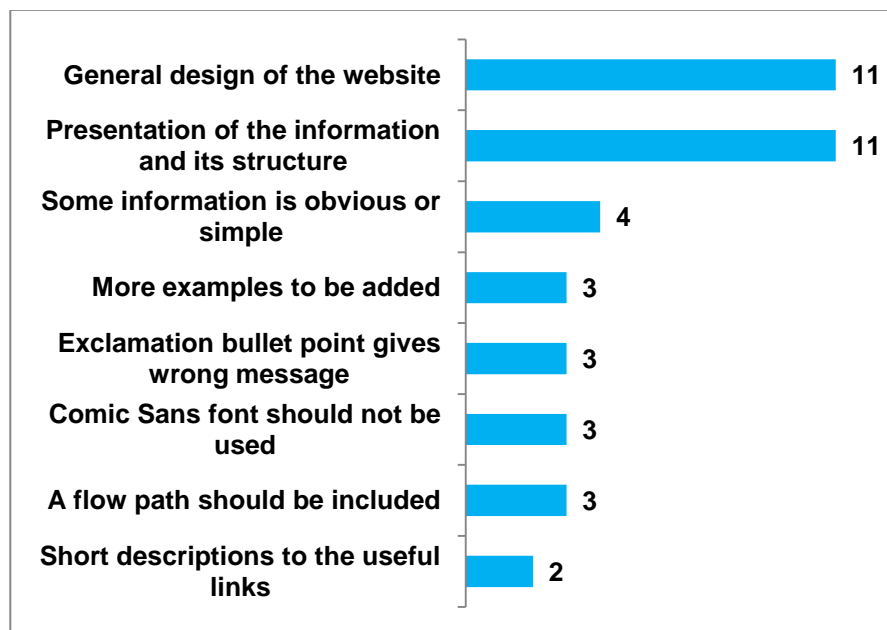


Figure 7.9 Suggested areas for improvements

- **General design of the website:** There was a consensus among the majority of the designers that the general graphic design of the website should be completely changed and turned into something more relevant and appropriate to medical devices.
- **Presentation of the information and its structure:** 11 out of the 12 designers mentioned that the presentation of the information and the way

it was structured should be improved, because with the current structure it was not possible to easily extract the information from the website. They also suggested that the presentation of the information could be more interesting and designer friendly. Some of the designers mentioned that it was very hard to navigate around the website and to find the information that they were looking for.

- **Some information is obvious or simple:** Four designers mentioned that some of the information was very obvious or simplistic in the website. However, one of those designers and some other designers indicated that the website should include some level of basic information, particularly for novice designers. This suggested that it might be useful to separate the information intended for novice designers from that intended for experienced designers.
- **More Examples:** The designers suggested that the examples section be expanded, including more good and poor examples. One designer also mentioned that it would be useful to have some good examples of instruction manuals for home use medical devices.
- **Exclamation bullet point:** The designers found that the exclamation bullet point which was used to highlight important information looked more like a warning sign.
- **Comic Sans Font should not be used:** The designers mentioned that Comic Sans font should not be used in the website because it gave an unprofessional impression.
- **A flow path should be included:** The designers indicated that including a step by step flow path of the design process could be very useful particularly for novice designers. The designers also mentioned that the whole website could be designed in this style.
- **Short descriptions to useful links and documents:** The designers mentioned that the useful links and documents sections would benefit from short summary descriptions. The descriptions should explain what the website or the document is about and how it is relevant to the process.

One designer also mentioned that it would be useful to have an area in the 'Forum' section where the designers could make contacts with the end users of

the products, which was, in fact, included in one of the early concepts of the guidance (Refer to Section 6.1.1).

7.4.9 Other Information Sources

The designers were asked if they knew of other information sources for designers to assist them when designing home use medical devices, and all the designers mentioned that they had not come across any. However, one of the designers mentioned a National Patient Safety Agency's (NPSA) Patient Safety document where the designer herself was involved in the preparation of the document, although that document was not specifically prepared for home use medical devices.

7.5 Discussion

In this section, the methodological issues concerning the evaluation and the main findings of the study are discussed.

7.5.1 Methodological Issues and Limitations

The evaluation was based on the written and verbal comments of those designers given the opportunity to review the guidance website. It was not possible to test the guidance in an actual design due to the extensive and lengthy development process required for home use medical devices. In addition only three designers had prior experience in designing such devices. However, during the study the most useful information was collected from the designers who identified themselves as having 'very little experience'. Experienced designers mainly focussed on very specific informational requirements, such as specific regulations or material information. On the other hand, the designers with very little experience commented more on the requirements concerning the overall design process. Nevertheless, due to these facts, the study provides limited validation of the guidance website and this should be considered when interpreting the results. However, it is proposed that a comprehensive validation study will be conducted as a future study (Section 8.3.2).

The small sample size was another limitation (Gray, 2004; Bryman & Teevan, 2005). In order to maximise the validity and reliability of the results based on the data collected from the 12 designers, data and method triangulation was used; the

feedback was collected from questionnaires, interviews and sometimes supplemented with observation. It was not possible to apply any statistical testing methods to compare the results of designers with different levels of experience because of the small sampling size.

Due to very busy schedules, some designers were required to postpone or change the date of the interview several times. Eventually, six designers could not take part in the interview session, although they completed the questionnaire. The results from those designers were not included in the overall analysis presented in this chapter.

Face to face interviews were found to be the most valuable method, because the researcher had a chance to observe the designers during their interaction with the guidance website. However, as mentioned in Section 7.1.4, some of the designers wanted to be interviewed via phone or Skype which made observation impossible.

The researcher's lack of skills and knowledge of website development was also a limitation which in some cases directly affected the quality of the guidance.

7.5.2 Main Findings and Their Implications

The results of both the questionnaire and the interview suggested that the majority of the designers had positive feedback about the guidance website.

The guidance was found useful for designers

All the designers who took part in the study found the website useful. However, it was observed that there was a difference between designers with or without prior experience of designing medical devices. Those with experience found some of the information presented in the website too introductory and basic. However, designers with no experience found the same introductory information to be the most useful feature of the website. 'Regulations', 'Useful links', and the 'Forum' sections were found to be more useful by the experienced designers, while 'Home use medical devices' and/or 'Design considerations' sections were mentioned more by designers with no experience or very limited experience.

During the interviews one more designer group was identified whose members may differ in term of their requirements and expectations from the guidance: i.e. the designers who were experienced in designing medical devices but were new to designing home use medical devices.

The results suggested that the information presented in the website should be laid out in such a way as to highlight its relevance to visitors, depending on their level of experience.

Content of the guidance was generally good

The majority of the designers were satisfied with the content of the guidance. According to the designers the most useful features of the website included 'Regulations', 'Useful links', 'Design Considerations' and the 'Forum' sections. A few designers indicated the design process models were very academically-oriented and did not provide much information about the actual practice. In addition a few designers mentioned that the 'What designers think' section was more relevant to the PhD research rather than to the designers; therefore it might not necessarily be for the website.

The results suggested that the designers found the information presented in the website up-to-date and sufficient. Most of the designers found all the information presented in the website relevant and necessary. However, a few designers identified other types of information missing in the website, with the most mentioned being 'very specific information', particularly for experienced designers, regarding: different product categories and their relevant specifications, capabilities of different types of users, and detailed information about different types of medical conditions and the patients' attitudes toward those conditions.

The designers also mentioned other features that they would like to see in the website, and 'case studies' was the most mentioned feature. A few more features suggested included a 'classification calculator' (mentioned by two experienced designers) to help designers identify the correct class for their device in accordance with the Medical Device Regulation. A search bar, checklists for the

design process, and the allowance of others' contribution were some of the other interesting features suggested during the interviews.

The presentation of the information needs improvement

The design of the website could be improved, especially in terms of ease of use and navigation.

The designers suggested that this website should have a serious look and feel because it was associated with medical devices. Cartoons, the font and colour selection currently used in the website gave the wrong impression of the website's content.

Some of the designers mentioned that the information was not clearly structured which made it hard to access. A few designers indicated that there was too much text within the website, with some designers indicating they did not like to read too much. They mentioned that the information should be presented in a more interesting way, otherwise designers would not refer to it.

The results suggested that designers are very selective and pay a great deal of attention to the design and the presentation of information. If the presentation is poor, then they are less likely to use it as an information source. Therefore the design and the presentation of the information require careful consideration. As the researcher's knowledge in designing websites was very limited, the main focus of this evaluation study was on the content of the website.

Further improvements

Apart from the design of the website and the presentation of the information, the designers made a few more suggestions for further improvements. One of the most interesting comments revealed that a few designers wanted to have a step by step flow path in the website, which might make it easier, in particular for novice designers, to go through the whole process.

A few designers found some of the information presented in the website too simple and not necessary. However, that same 'common sense' information was found useful by novice designers. This suggests that the information should be tailored to different audiences.

Although the designers often found ‘Useful links’ and ‘Documents’ sections useful, some of the designers indicated that it would be useful to have short descriptions about the content of the links given in these sections; currently it is not possible to see the content of those links before opening them.

The designers found the examples very useful to categorise the different types of home use medical devices; however, they found the examples presented in the website to be limited and wanted them extended. One designer also mentioned that it would be useful to have some good examples of instruction manuals for home use medical devices.

Some of the designers also suggested simplifying the bullet points.

Lack of another direct information source

The designers could not identify any other direct information source to assist them during the design process of a home use medical device. The designers with experience in this field mentioned that in general there was not much information available about home use medical devices, therefore this guidance could be very useful because it compiled the necessary information in one place, and provided a space where the designers could share their experiences. As mentioned before, most of the designers took part in this evaluation study had some level of experience in designing home use medical devices. This also provides evidence that this guidance tool will be the first direct, comprehensive information resource in the UK for designers when designing home use medical devices.

Proposal of the new structure of the guidance

Based on the results of the evaluation study, a new content structure was proposed, shown in Figure 7.10.

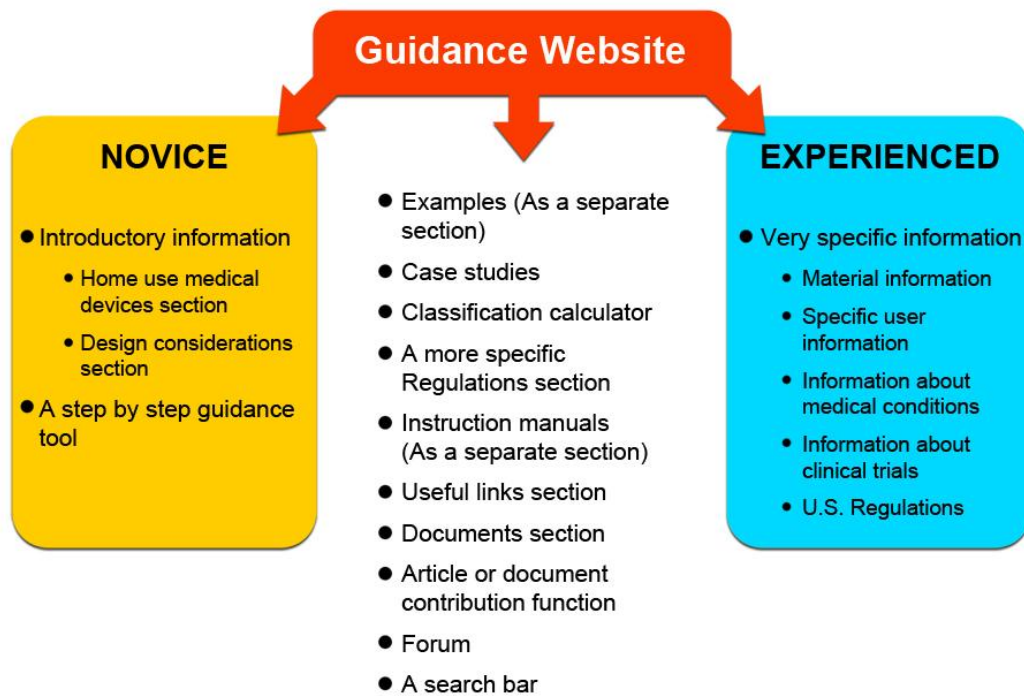


Figure 7.10 New proposal regarding the content and structure of the guidance

The proposed guidance website will provide two parts, taking consideration of the level of experience of designers. The part for novice designers will include more introductory information and a step by step tool to guide designers throughout the design process. The part for experienced designers will include more specific and comprehensive information. This way experienced designers can skip basic introductory information, and novice designers will not be overloaded with complex and over specific information.

In Figure 7.10, the middle area shows the common features of the website for both types of designers. A number of new features will be added to any future versions of the website:

- Examples which categorises different types of home use medical devices
- Case studies of the real life design process
- A ‘classification calculator’
- A checklist (similar to the one developed for the instruction manuals, refer to Section 6.3.3) for the design process of home use medical devices will to be added to the ‘Documents’ section
- An interactive section where the designers can upload and share documents, articles and case studies
- A search bar for designers looking for specific information

The new design of the guidance website will be more professional so that information provided can be taken more seriously. Different types of bullet points will be removed. More diagrams will be added and the text used within the sections will be reduced.

7.6 Summary

This chapter presented the results of the evaluation of the first draft of the guidance website developed to assist designers when designing home use medical devices. The guidance website was evaluated by 12 professional designers (with/without experience in designing home use medical devices) by means of an online questionnaire and semi-structured interviews. The study was carried out as the 'Descriptive Study 2' of this research, with reference to the DRM (Blessing et al., 1995). Two objectives were achieved:

- **To evaluate designers' perspectives on whether the guidance is effective in meeting their needs:** The results suggested that the majority of the designers had very positive comments on the guidance website, and all the designers found the website useful for designing home use medical devices. The designers found the content of the website to be of good quality and sufficiently informative.
- **To identify ways in which the guidance could be improved, so as to better meet the needs of designers when designing home use medical devices:** This study helped to identify ways of improving and optimising the content. The results showed that the design of the website and the presentation of the information require further improvements. It was also found that the information presented in the website should be tailored for those with differing levels of experience of designing home use medical devices. A number of new content ideas were identified during the interviews. With reference to the comments of the designers on the first draft of the guidance website, a new content structure was formulated.

On the other hand the guidance was not tested in the context of a real design project because of the complexity and the very long development process of home use medical devices. However, there are propositions to improve the

guidance website and validate it through their actual use in real life projects in future. This will be discussed in Chapter 8.

The next chapter will present the overall conclusions of the PhD research and the future work.

CHAPTER 8: CONCLUSIONS AND FUTURE WORK

This research focussed on the design aspect of home use medical devices. The aim was:

To assist designers in developing home use medical devices by providing information and suggestions regarding lay users and how to address their needs and expectations.

For this purpose three research questions were identified (refer to Section 8.1) and several studies were carried out in accordance with the DRM (Blessing et al. 1995). The findings of these studies were presented and discussed in the relevant chapters (Chapter 2-6).

This chapter draws the overall conclusions from the PhD studies, discusses the contributions of this research, and outlines the future works.

8.1 Key Conclusions

Home healthcare is a fast developing and growing trend in the healthcare industry. However, there is a lack of existing knowledge in this area.

This research adopted an inclusive approach which investigated both lay users' characteristics and designers' perspectives regarding home use medical devices. Throughout this PhD research three questions were addressed:

- Who are lay users and what are their characteristics?
- What are the challenges faced by designers in developing home use medical devices?
- How to support the design of home use medical devices?

8.1.1 Lay Users and Their Characteristics

The users of home use medical devices are often described as 'lay users', therefore it was important to understand who these lay users are and what their characteristics might be. However the literature review (Chapter 2) revealed that although the term of 'lay users' was frequently used, there were very few attempts to provide a comprehensive definition, this was also noted by Hogg &

Williamson (2001). Therefore, during this research a definition of ‘lay users’ was formulated, combining a number of definitions and other findings derived from the literature. Accordingly, a lay user is:

“A user of a product or a system who has not undergone extensive training in the subject field (which enables him/her to be eligible to act as a member of a profession), but uses the system or the product due to his/her special interest or needs.”

In terms of the characteristics of lay users, it was found that there was a gap in the literature with no clear description of what their characteristics might be. Rather lay users’ characteristics were frequently assumed, or inferred, by comparing them with those of professionals. Thus, professional users were portrayed as possessing superior characteristics and lay users’ as inferior by comparison; lay users were only defined with respect to the way in which they compared with professional users. The researcher, thus, attempted to synthesise lay user characteristics from a multitude of diverse sources. However, the extent to which these characteristics were applicable when lay users were no longer compared with professional users was not clear. Therefore observational studies were carried out in order to gain an in-depth understanding of lay user characteristics (Chapter 4).

The observational studies suggested that lay users were very diverse. Therefore it was not possible to consider them as one single group of people. Although all the lay user characteristics found through the literature review were confirmed during the observational studies, some of them were found to be specifically relevant to some of the lay user groups but not applicable to all. A number of other characteristics were also identified during the study. The complete list of lay user characteristics observed during the study is summarised in Appendix G.

Although younger lay users were found to be the most successful lay groups when interacting with digital products, all the lay user groups experienced several interaction problems during the studies; not only with the products provided, but also with the accompanying instruction manuals. It was also found that lay users were not always aware of the interaction problems experienced. Their interaction problems were grouped under three categories:

- **User - product: usage related problems** are avoidable mistakes, where the solution is provided by the designers, but users may make mistakes or experience difficulties due to not referring to these solutions.
- **User capability - product: matching problems** emerge when the product requires a higher level of capability than that of the user.
- **User - designer: understanding problems** are the most critical ones which emerge if the solutions developed by designers do not match users' mental model, resulting in users' confusion.

It was also found that these three types of problems are interrelated, and one type of problem may lead to another.

8.1.2 Challenges Designers Face in Developing Home Use Medical Devices

In order to understand the challenges designers face in developing home use medical devices, two separate studies were carried out: a literature review (Chapter 2) and the questionnaire survey with designers (Chapter 5).

The literature review identified that the UK has little prior research regarding home use medical devices, and limited information was available about the designers' requirements. The literature review suggested that, although home use medical devices are everyday products, they include three important challenges to the design process: (1) the knowledge level of lay users when using products, (2) the usability of home use medical devices, and (3) contexts of use of home use medical devices.

As this research focused on the design process of home use medical devices, it was necessary to understand designers' perspectives. For this purpose a questionnaire survey (Chapter 5) was carried out. The results suggested that designing home use medical devices requires a different approach from designing other everyday products. This contradicted the results of the study carried out by Gupta (2007). He found that the majority of the product developers argued that designing either a consumer product or a professional medical device is achieved by basically the same process as designing a home use medical device. However of the 13 different aspects of the design process of

home use medical devices that the current research identified (Section 5.3.2), four of them were found to be unique to home use medical devices:

1. **Home use medical devices, by their nature require an intrinsically greater attention to matters of lay users' safety and risks to the lay users.** This aspect was mentioned as a part of 'the knowledge level of lay users'. However the results of this study suggested that it is not only the knowledge level of lay users, but also the reliability and the accuracy of the device. These factors should be optimised during the design process of the device.
2. **A considerable amount of attention should be given to lay users and their characteristics, in relation to demographic variety and diverse capabilities.** The requirements and expectations of lay users also differ from those of professionals. It is not only the knowledge level of lay users, but also their emotional requirements and attitudes towards a specific medical condition, which should be taken into account during the design process in order to address those requirements and expectations.
3. **Home use medical devices are subject to medical device regulations.** It was found that there are no regulations specifically prepared for home use medical devices; therefore, the designers should derive this information from the same regulatory framework for medical devices.
4. **The functionality and usability of home use medical devices should be optimised in order to prevent user errors, because misuse may have more serious implications than that of everyday products.** As discussed in the literature, the results of this research also suggested that it is not only the usability of the device, but also the information provided to the lay user with the device is critical.

These aspects give rise to different information requirements, which makes the process unique. Gupta (2007) described home use medical devices as the intersection area of consumer products and medical devices (Figure 8.1a). In his research he identified the design and development process issues as falling within this intersection. However, this research suggests that, although the design process of home use medical devices shares some similarities with that of consumer products and medical devices, its process also involves other specific

requirements that stem from the unique nature of home use medical devices. Figure 8.1b illustrates the requirements for designing HUMD.

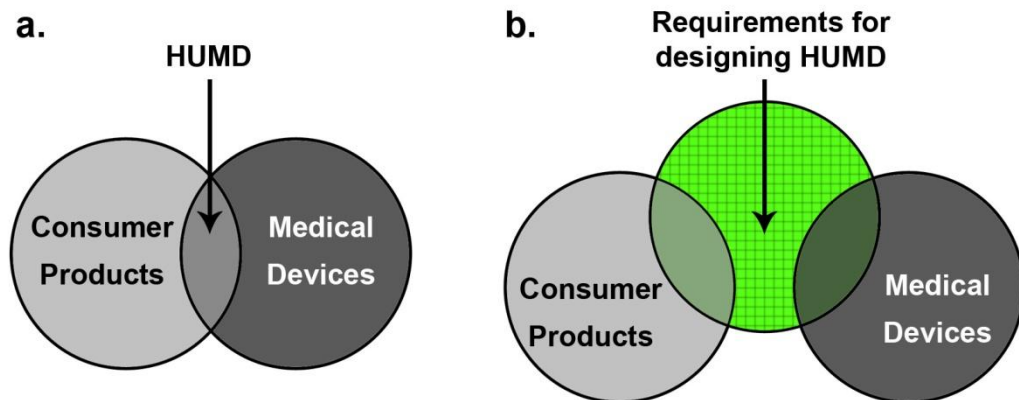


Figure 8.1 (a) Gupta's (2007: p.189) definition of HUMD, (b) requirements for designing home use medical devices

8.1.3 Supporting the Design of Home Use Medical Devices

Designers frequently require information during the design process (Press & Cooper, 2003; Persad, et al., 2007). In this research it was necessary to understand what type of information designers require when designing home use medical devices and in what format. For this purpose a questionnaire survey was carried out (Chapter 5).

Six types of information requirements were identified by the designers during the survey: i.e. (1) context of use, (2) lay user information, (3) regulations and legislation, (4) medical knowledge relevant to the design project, (5) current market information, and (6) information from stakeholders.

It was also found that designers (with or without experience in designing home use medical devices) use a variety of information sources during the design process, and the most frequently used information sources were: (1) (the consultation of) a specialist, (2) observation and (3) the internet. However the results also suggested that designers were less likely to use available information (e.g. books, magazines, academic journals, etc) when designing home use medical devices and they frequently turn to customised information (such as, interviews, observation, etc) where they actively take part in the collection of the necessary information. This also suggested that there was a lack of information

for designers during the design process of home use medical devices. Therefore it would be valuable to provide support for designers in this field.

In order to deliver the right support for designers, a survey was conducted with designers to ascertain their information requirements. As a result, four content sections were identified in accordance with the designers' wishes, which led to the structure of the design guidance.

- Background information about home use medical devices
- Specific information regarding the design process of home use medical devices
- Regulatory information²⁸
- Other useful sources and documents where designers could find more specific or additional information about a particular subject²⁹

The majority of the designers preferred a web-based information source; therefore the guidance took the form of a website.

The guidance website was evaluated with 12 professional designers. The results showed that all the designers who took part in the survey found the guidance website useful for designing home use medical devices. They also found the content of the website to be of good quality and sufficiently informative.

During the evaluation study, none of the designers could identify any other information source addressing the requirements home use medical device designers as comprehensive. This was consistent with the findings of the literature review study carried out during this research, and suggests that the guidance was the first comprehensive information source in the UK for the emerging home use medical device field.

8.1.4 Overall Conclusion

Designing home use medical devices is a unique process. Although these devices are, in fact, medical devices, they are used by lay people who may not have sufficient medical knowledge to operate them correctly. The context of use is

²⁸ Only the European Regulatory information was included in the guidance.

²⁹ Later on it was decided that the useful sources and documents sections to be prepared as separate sections in the guidance.

also not clearly defined for home use medical devices. Therefore the safety and reliability of these devices is critical, especially as, in some cases, lay users are dependent on these devices in order to sustain their wellbeing. This puts emphases on the functionality and usability of these devices in an effort to prevent the errors in their use. However these devices still must meet the same regulatory requirements for medical devices for professionals' use. Owing to these issues, the design process of home use medical devices differs from both the processes for medical devices and for general consumer products. These factors bring additional challenges for designers.

Designers require a diverse range of information when designing home use medical devices. This research, however, showed that in the UK very little information is at the disposal of designers in this field, particularly regarding lay users. Providing the necessary information for designers in a designer friendly way, may result in an effective and accurate management of the design process and may also help designers to design good devices which satisfy the needs and expectations of lay users. However it is necessary to understand designers' requirements in order to provide them with the right support.

This research developed a guidance tool in the form of a website, providing designers with a comprehensive information source of home use medical devices. The content of the website was developed in accordance with the designers' requirements identified in this research. The guidance website includes the information presented throughout this PhD thesis, and provides information and suggestions in order to address the needs and expectations of lay users when designing home use medical devices. Therefore this research has achieved its aim:

To assist designers in developing home use medical devices by providing information and suggestions regarding lay users and how to address their needs and expectations.

8.2 Contributions of the Research

This research has made three distinct contributions to the field of design and home use medical devices.

8.2.1 Shedding Light on Lay Users and Their Characteristics

Although the users of home use medical devices were frequently described as lay users, there was a lack of information about them and their characteristics. This research, for the first time, outlined lay user characteristics based on empirical studies with different groups of people, and provided a comprehensive definition of lay users. It showed that lay users were diverse, and could not be treated as a single user group; therefore, unhelpful to simply contrast lay and professional users as is often the case of literature in this area.

8.2.2 Identification of the Designers' Requirements when Designing Home Use Medical Devices

Although designing for home use medical devices is an emerging field in the healthcare industry, very limited information is currently available for designers. No prior research was identified that focussed on the requirements of designers when designing such devices in the UK. This research provided an in-depth insight into the challenges of designing medical devices for use in the home environment, and identified the requirements of designers regarding the design process of home use medical devices.

8.2.3 Creation of a Support Tool for Designing Home Use Medical Devices

An important outcome of this research was the design guidance website which can be found at <http://www.homeusemedicaldevices.com/>. The aim of this website was to assist designers during the design process of home use medical devices. As mentioned by the designers in the evaluation study, the guidance was the first comprehensive information source in the UK for the emerging home use medical device field, where little support is currently available.

8.3 Future Work

Home healthcare is an underexplored area. This research specifically focussed on the two important aspects of home use medical devices: the design process and lay users. However there are remaining aspects to be explored, which could extend the website's design guidance content. Some of those important aspects

have been identified, and offer opportunities for investigation within ongoing future research.

8.3.1 Improvement of the Design Guidance Website

During the evaluation study a number of suggestions for improvement to the guidance website were made. The knowledge and skills of the researcher in terms of website development were very limited, which affected the visual quality of the guidance. The majority of improvements suggested by the designers related to presentation of information and the design of the website; therefore the design of the website and the presentation of the information will be further developed and improved. For this purpose professional help will be sought in order to find the most appropriate means of designing the website and restructuring the information to make it more accessible and appropriate.

The designers had a number of ideas for new content and other features for the website, e.g. ‘a classification calculator’ and ‘case studies’. The researcher will compile more case studies in the future, and intends to pursue funding and professional help for developing the classification calculator, the aim of which is to identify the correct class for their device in accordance with the Medical Device Regulation.

The information presented in the website will be tailored for different levels of experience, i.e. novice/experienced designers in designing home use medical devices.

8.3.2 Validation of the Design Guidance Website

As mentioned in Chapter 7, during the evaluation the designers did not use the website in a real design project, but commented on its effectiveness. This is because testing the guidance in real design projects was not possible due to the extensive development process of home use medical devices. In addition, only 3 out of the 12 designers had prior experience in designing home use medical devices. Therefore the validation had its limitations.

However it is proposed that a comprehensive validation study be carried out after the website has been improved in accordance with the comments of the designers. This further study will involve testing the guidance using actual design

projects. For that purpose, a similar strategy to *cultural probes* may be used. A cultural probe is a participatory design strategy, used for collecting inspirational data (Gaver et al., 1999). The method involves three key stages:

A ‘design probe package’ will be prepared (including tools such as questionnaires and a disposable camera), and sent to the designers. The participants will be asked to use the guidance website for an actual design project, record their experiences by means of the tools provided, and send the package back to the researcher. Once the packages have been analysed, follow-up interviews will be arranged with the designers in order to gain an in depth understanding of their experience. The data collected will provide sufficient evidence as to whether the guidance is effective and useful in a real design process.

The study will involve designers with or without prior experience in designing home use medical devices. The new designer group identified in this PhD research, i.e., designers who have experience in designing medical devices, but who are however new to designing home use medical devices, will also be included in this study. As argued by Gardner-Bonneau (2011), most of the available data (e.g. standards) for designers’ use when designing medical devices are collected from able-bodied clinicians, hence it may not be applicable when designing products for lay people. Therefore the requirements of this designer group may differ. Although they have a great understanding of the issues relevant to designing medical devices for professionals’ use, they require different types of information when designing such devices for the home environment. The study will also provide an understanding of the requirements of this designer group.

8.3.3 Understanding Lay Users’ Perspectives on Home Use Medical Devices

Although this research defined the ‘lay users’ and identified their characteristics, it did not provide information about what the lay users’ perspectives on home use medical devices are. However, it is important to investigate their views in order to obtain an in-depth understanding of their requirements and expectations.

As mentioned before, lay users can buy many over-the counter devices without the requirement of a prescription; and often they have a wide range of choices (i.e. different models or brands) for a specific device. However, what is the rationale for lay users' decision when obtaining a new device? Understanding this may help designers to better address lay users' expectations.

Lay users' experiences of using home use medical devices would be particularly helpful when identifying environmental challenges which are likely to occur in regular use. Although two European standards [EN ISO 14971:2009 (BSI, 2009a), EN 60601-1-11:2010 Part 1-11 (BSI, 2010a)] which include information to address environmental challenges were identified, these documents mainly cover the environmental operating conditions, e.g. temperature, humidity, electromagnetic fields, etc. There might be other factors affecting lay users' experiences when using their devices in an uncontrolled environment, such as their lifestyle, cultural diversity, capabilities or preferences.

In addition, during this PhD research, the designers, in particular those with experience of designing home use medical devices, indicated that they would be interested in knowing the effects of emotional factors on lay users and their attitudes towards their medical condition and their device. These point out the requirements of lay users via first hand information obtained from them.

Therefore it has been found necessary to understand lay users' perspectives, which will help designers to better address the requirements and expectations of lay users during the design process. For this purpose, frequent users of home use medical devices will be contacted and in-depth qualitative studies will be carried out involving ethnographic studies and semi-structured interviews.

8.3.4 Understanding Professionals' Perspectives on Home Use Medical Devices

Lay users obtain their home use medical devices in different ways. In some cases devices are provided to them by medical professionals in order to continue their treatment at home. Kearns et al (2010) suggests that healthcare professionals are given the extra responsibility of answering patients' questions and helping them to understand or interpret the results given by the devices. During the observational studies carried out with lay users, a number of participants

indicated that when they take possession of a new home use medical device they often check the accuracy of their device with their doctor or nurse. In other words, medical professionals are also one of the important stakeholders of home use medical devices, and their opinions may have an important effect on lay users' decisions during the early phases of their introduction to such devices.

The results of the survey conducted with designers as a part of this PhD research also suggested that designers frequently 'consult specialists' in order to collect necessary information when designing home use medical devices. Therefore it is necessary to understand professionals' perspectives on such devices and their understanding of the home use medical device market. It is proposed that semi-structured interviews be carried out in order to understand these perspectives and clarify issues such as:

- What professional users think about the emerging trend of home use medical devices?
- What the role of professionals is in this emerging trend?
- Do professionals consider home use medical devices as consumer products, medical devices or something else?
- What sort of help do lay users frequently seek from professionals about their home use medical devices?
- What should designers consider when designing home use medical devices?

8.4 Summary

This research focussed on two important aspects of home use medical devices: lay users and the design process. A number of studies were carried out to address three research questions. The main answers were as follows:

1. What are the challenges faced by designers when developing home use medical devices?

Four unique challenges were identified regarding the design process of home use medical devices when compared with everyday consumer products:

- Home use medical devices require more attention be given to matters of health and safety and associated risks to lay users

- Understanding of lay users and their characteristics is critical
- Home use medical devices are subject to medical device regulations
- Functionality and usability require more attention in case of home use medical devices, due to the potentially serious implications of misuse

However the biggest challenge was found to be the lack of available and comprehensive information for designers to overcome these challenges.

2. Who are lay users and what are their characteristics?

The lay users are defined in this research as *“a user of a product or a system who has not undergone extensive training in the subject field (which enables him/her to be eligible to act as a member of a profession), but uses the system or the product due to his/her special interest or need.”*

Lay users are diverse therefore it is not possible to consider them as one single group. Some of the common lay user characteristics identified during this PhD research were:

- High level of personal/and demographic variation
- Prefer easy to use devices with specific functions
- May have little or no training
- Little or no knowledge regarding the task and/or the product
- Frequently have expectations regarding the way that products should be used
- Often rely on their prior experiences with similar products
- Poor at identifying errors

3. How to support the design of home use medical devices?

Based on the designers’ requirements, this research has focused on developing a design guidance website to support designers.

The design guidance has incorporated a range of information for designers, and the evaluation with professional designers suggested that it is the first comprehensive information source for home use medical devices in the UK.

To conclude, this research has made three main contributions to the field of design and home use medical devices:

- Shedding light on lay users and their characteristics
- Identification of the designers' requirements when designing home use medical devices
- Creation of a comprehensive guidance for designers of home use medical devices

Future work will focus on the improvement of the design guidance website, a thorough validation of the support provided by the design guidance website, and the development of an in-depth understanding of both lay users' and professionals' perspectives on home use medical devices.

REFERENCES

- Ahmed, S. (2000). *PhD Thesis: Understanding the Use and Reuse of Experience in Engineering Design*. Cambridge: Cambridge University Engineering Department.
- Alexander, K., & Clarkson, P. J. (2002). A Validation Model for the Medical Devices Industry. *Journal of Engineering Design* , 13 (3), 197-204.
- Alexander, K., Clarkson, J., Bishop, D., & Fox, S. (2001). *Good Design Practice for Medical Devices and Equipment - A Framework*. Cambridge: University of Cambridge Engineering Design Centre, University of Cambridge Institute for Manufacturing.
- Backinger, C. L., & Kingsley, P. A. (1993). *Write It Right*. Centre for Devices and Radiological Health, Food and Drug Administration.
- Baskinger, M., & Hanington, B. (2008). Sustaining Autonomous Living for Older People Through Inclusive Strategies for Home Appliance Design. In P. Langdon, J. Clarkson, & P. Robinson, *Designing Inclusive Futures* (pp. 117-126). London: Springer-Verlag London Limited.
- Benktzon, M. (1993). Designing for Our Future Selves: the Swedish Experience. *Applied Ergonomics* , 24 (1), 19-27.
- Blackler, A., Popovic, V., & Mahar, D. (2010). Investigating Users' Intuitive Interaction with Complex Artefacts. *Applied Ergonomics* , 41, 72-92.
- Blessing, L., Chakrabarti, A., & Wallace, K. (1995). A Design Research Methodology. *Proceedings of the 10th International Conference on Engineering Design (ICED 95)*, (pp. 50-55). Praha, Czech Republic.
- Bordens, K. S., & Abbott, B. B. (2008). *Research Design and Methods: A Process Approach*. New York: McGraw-Hill.
- Braddock, D., Rizzolo, M. C., Thompson, M., & Bell, R. (2004). Emerging Technologies and Cognitive Disability. *Journal of Special Education Technology*, Vol. 19 , 49-56.
- Brannen, J. (2004). Working Qualitatively and Quantitatively. In C. Seale, G. Gobo, J. F. Gubrium, & D. Silverman, *Qualitative Research Practice* (pp. 312-326). London: Sage Publications.
- Brennan, P. F. (2006). *The "Self-Managed" Patient*. Retrieved 06 21, 2010, from Improving Health Care Accessibility Through Point-of-Care Technologies: <http://www.nibib.nih.gov/publicPage.cfm?pageID=4534>

- Bryman, A., & Teevan, J. J. (2005). *Social Research Methods*. Ontario: Oxford University Press.
- BSI. (2003). *BS EN ISO 13485:2003 Medical Devices - Quality Management System - Requirements for Regulatory Purposes*. British Standards Institute (ISO 13485:2003 identical copy).
- BSI. (2005). *BS 7000-6:2005, Part 6: Managing Inclusive Design - Guide*. British Standards Institute.
- BSI. (2008a). *BS EN ISO 9001:2008 Quality Management Systems - Requirements*. British Standards Institute (ISO 9001:2008 identical copy).
- BSI. (2008b). *EN 1041:2008 – Information supplied by the manufacturer of medical devices*. British Standards Institute.
- BSI. (2008c). *BS EN 62366:2008 - Medical Devices - Application of Usability Engineering to Medical Devices*. British Standards Institute.
- BSI. (2008d). *BS EN 980:2008 - Symbols for Use in the Labelling of Medical Devices*. British Standards Institute.
- BSI. (2009a). *BS EN ISO 14971:2009 Medical Devices - Application of Risk Management to Medical Devices*. British Standards Institute (ISO 14971:2007, Corrected version 2007-10-01).
- BSI. (2009b). *BS EN ISO 18113-1:2009 - In Vitro Diagnostic Medical Devices - Information Supplied by the Manufacturer (Labelling) - Part 1: Terms, Definitions and General Requirements*. British Standards Institute.
- BSI. (2010a). *BS EN 60601-1-11:2010: Medical electrical equipment, Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare*. British Standards Institute (IEC 60601-1-11:2010, Approved by CENELEC on 01-06-2010).
- BSI. (2010b). *EN ISO 18113-5:2009 - Information supplied by the manufacturer (labelling) – Part 5: In vitro diagnostic instruments for self-testing*.
- BSI. (2010c). *BS ISO 15223-2:2010 - Symbols to be Used with Medical Device Labels, Labelling, and Information to be Supplied*. British Standards Institute.
- Buckle, p., Clarkson, P. J., Coleman, R., Lane, R., Stubbs, D., Ward, J., et al. (2003). *Design for Patient Safety*. London: Department of Health and Design Council.

- Burns, C. M., Vicente, K. J., Christoffersen, K., & Pawlak, W. S. (1997). Towards Viable, Useful and Usable Human Factors Design Guidance. *Applied Ergonomics* , 28, 311-322.
- Buurman, R. (1997). User-centred design of smart products. *Ergonomics* , 40, 1159-1169.
- Cardoso, C. (2005). *PhD Thesis: Design for Inclusivity: Assessing the Accessibility of Everyday Products* . Cambridge: Cambridge University, the Department of Engineering and Design.
- Carthey, J. (2007). Healthcare Designers and Information Use. *International Conference on Design Education*. Sydney, Australia: University of New South Wales.
- Charness, N. (2008). Aging and Human Performance. *Human Factors* , 50 (3), 548-555.
- Choi, Y. S., Yi, J. S., Law, C. M., & Jacko, J. A. (2006). Are "Universal Design Resources" Designed for Designers? *Proceedings of the 8th International ACM SIGACCESS Conference on Computer and Accessibility* (pp. 87-94). Portland: ASSETS'06.
- Cifter, A. S., & Dong, H. (2009). Focusing on Users. *Include 09 Proceedings*. London: Helen Hamlyn Centre, Royal College of Art.
- Clarkson, J., Coleman, R., Hosking, I., & S, W. (2007). *Inclusive Design Toolkit*. Cambridge University: Kall Kwik Cambridge.
- Clarkson, P. J., Buckle, P., Coleman, R., Stubbs, D., Ward, J., Jarrett, J., et al. (2004). Design for Patient Safety: A Review of the Effectiveness of Design in the UK Health Service. *Journal of Engineering and Design* , 15 (2), 123-140.
- Cockton, G., & Lavery, D. (1999). A Framework for Usability Problem Extraction. In M. A. Sasse, & C. Johnson, *Human - Computer Interaction - INTERACT '99* (pp.344-352). Amsterdam: IOS Press.
- Coleman, R., Clarkson, J., Dong, H., & Cassim, J. (2007). *Design for Inclusivity*. England: Gower Publishing Ltd.
- Creswell, J. W. (2009). *Research Design*. London: Sage Publications.
- Crilly, N., Moultrie, J., & Clarkson, P. (2004). Seeing Things Consumer Response to the Visual Domain in Product Design. *Design Studies* , 25 (6), 547-577.
- Cross, N. (1996). *Engineering Design Methods: Strategies for Product Design*. Sussex: John Wiley & Sons Ltd.

- Crotty, M. (2004). *The Foundations of Social Research*. Wiltshire: Sage Publications.
- Czaja, S. J., & Lee, C. C. (2007). The impact of Ageing on Access to Technology. *Universal Access in the Information Society* , 5, 341-349.
- DCA. (2010). *News*. Retrieved 04 21, 2010, from <http://www.dca-design.com/clikstar-wins-good-design-award.html>
- Dewsbury, G., Rouncefield, M., Sommerville, I., Onditi, V., & Bagnall, P. (2007). Designing Technology with Older People. *Universal Access in the Information Society* , 6, 207-217.
- Dong, H. (2004). *Barriers to Inclusive Design in the UK*. Department of Engineering, University of Cambridge.
- Dörnyei, Z., & Taguchi, T. (2010). *Questionnaires in Second Language Research: Construction, Administration, and Processing*. Oxon: Routledge.
- DTI. (1989). *Instructions for Consumer Products: Guidelines for Better Instructions and Safety Information for Consumer Products*. London: Her Majesty's Stationery Office.
- EC. (1998). The In Vitro Diagnostic Medical Devices Directive (98/79/EC). *Official Journal of the European Communities* .
- EC. (2001). Guidelines for the Classification of Medical Devices MEDDEV 2.4/1. *DG Enterprise, Directorate G, Unit 4 - Pressure Equipment, Medical Devices, Metrology* .
- EC. (2007). DIRECTIVE 2007/47/EC. *Official Journal of the European Union* .
- EC. (2010a). *Medical Devices - Regulatory Framework*. Retrieved 05 13, 2010, from http://ec.europa.eu/enterprise/sectors/medical-devices/regulatory-framework/index_en.htm
- EC. (2010b). *Reference Documents*. Retrieved 11 30, 2010, from European Commission: http://ec.europa.eu/consumers/sectors/medical-devices/documents/index_en.htm
- Eckert, C. M., Clarkson, P. J., & Stacey, M. K. (2003). Research: a methodological view on integrated design research. *Proceedings of the 14th International Conference on Engineering Design*. Stockholm: Design Society.
- Edworthy, J., Hellier, E., N, M., Grey, C., Aldrich, K., & Lee, A. (2004). Linguistic and Location Effects in Compliance with Pesticide Warning Labels for Amateur and Professional Users. *Human Factors* , 46, 11-31.

EEC. (1990). The Active Implantable Medical Devices Directive (90/385/EEC). *Official Journal of the European Communities* .

EEC. (1993a). The Medical Devices Directive (93/42/EEC). *Official Journal of the European Communities* .

EEC. (1993b). *The Medical Devices Directive 93/42/EEC*. Retrieved 05 12, 2010, from Europa: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0042:EN:HTML>

Eisma, R., Dickinson, A., Goodman, J., Syme, A., Tiwari, L., & Newell, A. F. (2004). Early User Involvement in the Development of Information Technology-Related Products for Older People. *Universal Access in the Information Society* , 3, 131-140.

Entwistle, V. A., Renfrew, M. J., Forrester, J., & Lamont, T. (1998). Lay Perspectives: Advantages for Health Research. *British Medical Journal* , 316 (7129), 463-466.

Erler, S. F., & Garstecki, D. C. (2002). Hearing Loss - and Hearing Aid - Related Stigma: Perceptions of Women with Age-Normal Hearing. *American Journal of Audiology* , 11, 83-91.

Faulkner, X. (2000). *Usability Engineering*. Hampshire: Palgrave.

FDA. (1997). *Design Control Guidance for Medical Device Manufacturers*. U.S.: Center for Devices and Radiological Health, Food and Drug Administration.

FDA. (2005). *Medical Device Recalls: Abbott Blood Glucose Meters*. Retrieved 04 29, 2011, from U.S. Food and Drug Administration: <http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm063864.htm>

FDA. (2009a). *Brochure - Home Healthcare Medical Devices: A Checklist*. Retrieved 06 29, 2010, from FDA: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ucm070217.htm>

FDA. (2009b). *Home Healthcare Medical Devices: Blood Glucose Meters - Getting the Most Out of Your Meter*. Retrieved 06 29, 2010, from FDA: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ucm070212.htm>

FDA. (2009c). *Brochure - Home Healthcare Medical Devices: Infusion Therapy - Getting the Most Out of Your Pump*. Retrieved 06 29, 2010, from FDA: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ucm070208.htm>

- FDA. (2009d). *Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory and Home Use*. Retrieved 01 07, 2011, from FDA:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094140.htm>
- FDA. (2010a). *CDRH Home Health Care Committee*. Retrieved 05 12, 10, from <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ucm070198.htm>
- FDA. (2010b). *Home Use Devices*. Retrieved 05 04, 2010, from FDA:
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/HomeUseDevices/default.htm>
- FDA. (2010c). *Unique Considerations in the Home*. Retrieved 03 17, 2011, from U.S. Food and Drug Administration:
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/HomeUseDevices/ucm204452.htm>
- FDA. (2010d). *Medical Device Home Use Initiative*. CDRH, Food and Drug Administration Agency, U.S.
- Field, A. (2005). *Discovering Statistics Using SPSS*. London: Sage Publications Limited.
- Fischer, G. (2001). User Modeling in Human-Computer Interaction. *User Modeling and User-Adapted Interaction* , 11, 65-86.
- Floyd, J., & Fowler, J. (2002). *Survey Research Methods*. California: Sage Publications.
- Foster, J. (2002). *Data Analysis Using SPSS for Windows*. London: Sage Publications Limited.
- Frankfort-Nachmias, C., & Nachmias, D. (1996). *Research Methods in the Social Sciences*. New York: St Martin's Press.
- French, M. (1999). *Conceptual Design for Engineers*. London: Springer-Verlag London Limited.
- French, S. (1994a). Dimensions of Disability and Impairment. In S. French, *On Equal Terms: Working with Disabled People* (pp. 17-34). Oxford: Butterworth-Heinemann Ltd.
- French, S. (1994b). The Disabled Role. In S. French, *On Equal Terms: Working with Disabled People* (pp. 47-60). Oxford: Butterworth-Heinemann Ltd.

- Fries, R. C. (2001). *Handbook of Medical Device Design*. New York: Marcel Dekker.
- Fries, R. (2006). *Reliable Design of Medical Devices*. Boca Raton: Taylor & Francis Group, CRC Press .
- Gardill, M. C., & Jitendra, A. K. (2001). Advanced Story Map Instruction: Effects on the Reading Comprehension of Students with Learning Disabilities. *The Journal of Special Education* , 33, 2-17.
- Gardner-Bonneau, D. J. (2011). Home Health Care. In M. E. Weinger, M. E. Wiklund, & D. J. Gardner-Bonneau, *Human Factors in Medical Device Design* (pp. 747-770). Boca Raton: CRC Press.
- Gaver, B., T. D., & Pacenti, E. (1999). Cultural Probes. *Interactions* , 21-29.
- Gestern, R., Fuchs, L. S., Williams, P. J., & Baker, S. (2001). Teaching Reading Comprehension Strategies to Students with Learning Disabilities: A Review of Research. *Review of Educational Research* , 71, 279-320.
- Ghandi, A. (2005). *The Home-Healthcare Marketplace*. Retrieved 06 14, 2010, from Frost & Sullivan: <http://www.frost.com/prod/servlet/market-insight-top.pag?docid=36801787>
- GHTF. (2008). *Role of Standards in the Assessment of Medical Devices*. Study Group 1 of the Global Harmonization Task Force.
- Gill, J., & Johnson, P. (2010). *Research Methods for Managers*. London: Paul Chapman.
- Gillham, B. (2000). *Developing A Questionnaire*. New York: Continuum.
- Goodman, J., Langdon, P., & Clarkson, P. J. (2007). Formats for User Data in Inclusive Design. *Proceedings of the 12th International Conference on Human-Computer Interaction*. Beijing: HCI 2007.
- Gossink, R., & Souquet, J. (2006). Advances and Trends in Healthcare Technology: Stopping Diseases Before They Start. In G. Spekowius, & T. Wendler, *Advances in Healthcare Technology: Shaping the Future of Medical Care* (pp. 1-14). Dordrecht: Springer.
- Gray, C., & Malins, J. (2004). *Visualizing Research: A Guide to the Research Process in Art and Design*. Hants: Ashgate Publishing Ltd.
- Gray, D. E. (2004). *Doing Research in the Real World*. London: Sage Publications.

- Gregor, P., Newell, A. F., & Zajicek, M. (2002). Designing for Dynamic Diversity - Interfaces for Older People. *Proceedings of the Fifth International ACM Conference on Assistive Technologies*. Edinburgh, UK: ASSETS 2002.
- Gupta, S. (2007). *Design and Delivery of Medical Devices for Home-Use: Drivers and Challenges*. Cambridge: Department of Engineering.
- Gwynne, J. W., & Kobus, D. A. (2011). Documentation. In M. B. Weinger, M. E. Wiklund, & D. J. Gardner-Bonneau, *Handbook of Human Factors in Medical Device Design* (pp. 153-200). Boca Raton: CRC Press.
- Haak, M., Jong, M. D., & Schellens, P. J. (2003). Retrospective vs. Concurrent Think-Aloud Protocols: Testing the Usability of an Online Library Catalogue. *Behaviour & Information Technology*, 22, 339-351.
- Hague, P. N. (1993). *Questionnaire design*. Kogan Page.
- Hall, I., & Hall, D. (2004). *Evaluation and Social Research: Introducing Small-Scale Practice*. New York: Palgrave Macmillan.
- Hawthorn, D. (2003). How Universal is Good Design for Olders? *The Proceedings of 2003 ACM Conference on Universal Usability (CUU03)*, P. 38-45. Vancouver, Canada.
- Hawthorn, D. (2007). Interface Design and Engagement with Older People. *Behaviour & Information Technology*, 26, 333-341.
- Henn, M., Weinstein, M., & Foard, N. (2006). *A Critical Introduction to Social Research*. Wiltshire: Sage Publications.
- Herman, W. (2001). Health Technology is Coming Home (And How). *FDA Consumer*, 35 (3), 36.
- Herman, W., Marlowe, D., & Rudolph, H. (1998). *Future Trends in Medical Device Technology: Results of an Expert Survey*. Retrieved 04 29, 2009, from FDA: <http://www.fda.gov/cdrh/ost/trends/TOC.html>
- Heskett, J. (2002). *Design: A Very Short Introduction*. Oxford University Press.
- Hisham, S., & Edwards, A. D. (2007). Ageing and its Implications for Elderly Web Experience. In S. Kurniawan, & P. Zaphiris, *Advances in Universal Web Design and Evaluation: Research, Trends and Opportunities*. London: Idea Group Publishing.
- Hector, R. (2009). Healthcare at Home. *Medical Design Technology*, 13 (1), 8-12.

- Hoelscher, U., Liu, L., Gruchmann, T., & Pantiskas, C. (2011). Cross-National and Cross-Cultural Design of Medical Devices. In M. E. Weinger, M. E. Wiklund, & D. J. Garnder-Bonneau, *Human Factors in Medical Device Design* (pp. 771-794). Boca Raton: CRC Press.
- Hogg, C., & Williamson, C. (2001). Whose Interests do Lay People Represent? Towards an Understanding of the Role of Lay People. *Health Expectations* , 4, 2-9.
- Horen, F. M., Jansen, C., Meas, A., & Noordman, L. G. (2001). Manuals for the Elderly: Which Information Cannot Be Missed. *Journal of Technical Writing and Communication* , 31, 415-431.
- Horen, F., Jansen, C., Noordman, L., & Maes, A. (2005). Manuals for the Elderly: Text Characteristics That Help or Hinder Older Users. *2005 IEEE International Professional Communication Conference Proceedings* (pp. 334–342). Limerick, Ireland: Institute of Electrical and Electronics Engineers.
- Horn, J. L., & Cattell, R. B. (1966). Refinement and Test of the Theory of Fluid and Crystallized General Intelligences. *Journal of Educational Psychology* , 57, 253-270.
- Howard, K., & Sharp, J. A. (1983). *Management of a Student Research Project*. Aldershot: Gower.
- Huppert, F. (2003). Designing for Older Users. In J. Clarkson, R. Coleman, S. Keates, & C. Lebbon, *Inclusive Design: Design for the Whole Population* (pp. 88-103). London: Springer-Verlag London Limited.
- Hurtienne, J., Horn, A. M., & Langdon, P. M. (2010). Facets of Prior Experience and Their Impact on Product Usability for Older Users. In P. Langdon, J. Clarkson, & P. Robinson, *Designing Inclusive Interactions* (pp. 123-132). London: Springer-Verlag London Ltd.
- Johnson, B. M. (2003). The Paradox of Design Research: The Role of Informance. In L. Brenda, *Design Research: Methods and Perspectives* (pp. 39-40). London: The MIT Press.
- Jordan, B., & Henderson, A. (1995). Interaction Analysis: Foundations and Practice. *The Journal of the Learning Sciences* , 4, 39-103.
- Jordan, P. (2002). *An Introduction to Usability*. London: Tylor and Francis.
- Kaye, R., & Crowley, J. (2000). *Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management: Guidance for Industry and FDA Premarket and Design Control Reviews*. U.S. Food and Drugs Administration, Centre for Devices and Radiological Health.

- Kearns, A. J., O'Mathuna, D. P., & Scott, P. A. (2010). Diagnostic Self-Testing: Autonomous Choices and Relational Responsibilities. *Bioethics* , 24 (4), 199-207.
- Keates, S., & Clarkson, J. (2004). *Countering Design Exclusion: An Introduction to Inclusive Design*. Springer-Verlag London Ltd.
- Keates, S., & Clarkson, J. (2003). Design Exclusion. In J. Clarkson, R. Coleman, S. Keates, & C. Lebbon, *Inclusive Design: Design for the Whole Population* (pp. 88-102). London: Springer-Verlag London Ltd.
- Keates, S., Adams, R., Bodine, C., Czaja, S., Gordon, W., Gregor, P., et al. (2007). Cognitive and Learning Difficulties and How They Affect Access to IT Systems. *Universal Access in the Information Society* , 5, 329-339.
- Kemp, J. A., & Gelderen, T. V. (1996). Co-Discovery Exploration: An Informal Method for the Iterative Design of Consumer Products. In P. Jordan, B. Thomas, B. A. Weerdmeester, & I. McClelland, *Usability Evaluation in Industry* (pp. 139-146). London: Tylor & Francis Ltd.
- Kerlinger, F. N. (1986). *Foundations of Behavioural Research*. Orlando: Rinehart and Winston.
- King, N. (1994). The Qualitative Research Interview. In C. Cassell, & G. Symon, *Qualitative Methods in Organisational Research* (pp. 14-36). London: Sage.
- Kinnear, P. R., & Gray, C. D. (2004). *SPSS 12 Made Simple*. Sussex: Psychology Press.
- Klatzky, R. L., & Ayoub, M. M. (1995). Health Care. In R. S. Nickerson, *Emerging Needs and Opportunities for Human Factors Research* (pp. 131-157). Washington D.C.: National Academy Press.
- Langdon, P., Lewis, T., & Clarkson, J. (2007). The Effects of Prior Experience on the Use of Consumer Products. *Universal Access in the Information Society* , 6, 179-191.
- Law, C. M., Yi, J. S., Choi, Y. S., & Jacko, J. A. (2008). A Systematic Examination of Universal Design Resources: Part 1, Heuristic Evaluation. *Universal Access in the Information Society* , 7, 31-54.
- Law, C. M., Jaeger, P. T., & McKay, E. (2010). User-Centered Design in Universal Design Resources? *Universal Access in the Information Society* , 9, 327-335.
- Lazar, J. K., & Norcio, A. F. (1999). To Err or Not To Err, That is The Question: Novice User Perception of Errors While Surfing The Web. *IRMA International Conference Proceedings* (pp. 321-325). PA, USA: Idea Group Publishing.

Lewis, C. (2001). Home is Where the Heart Monitor is. *FDA Consumer* , 35 (3), 11-15.

Lewis, T., Langdon, P. M., & Clarkson, P. J. (2008). Prior Experience of Domestic Microwave Cooker Interfaces: A User Study. In P. Langdon, J. Clarkson, & P. Robinson, *Designing Inclusive Features* (pp. 95-106). London: Springer-Verlag London Ltd.

Liddle, D. (2007). Adopting Technology. In B. Moggridge, *Designing Interactions* (pp. 242-251). MIT Press.

Lincoln, Y. S., & Guba, E. G. (1985). *Naturalistic Inquiry*. California: Sage Publications.

Lockton, D. (2010). Retrieved 04 22, 2011, from Design with Intent: http://www.danlockton.com/dwi/Main_Page

Loizos, P. (2007). Video, Film, Photographs as Research Documents. In M. Bauer, & G. Gaskell, *Qualitative Researching with Text, Image and Sound* (pp. 93-107). London: Sage Publications.

Lotring, K. (2009). Healthcare at Home. *Medical Design Technology* , 13 (1), 8-12.

Ludgate, S. (2003). Why the MHRA Needs Your Help. *The Pharmaceutical Journal* , 271 (7278), 780.

Lundvall, B. (1985). Product Innovation and User-Produces Interaction.

Magrab, E. B. (1997). *Integrated Product and Process Design and Development: The Product Realisation Process*. Florida: CRC Press LLC.

Margolin, V. (1997). Getting know the user. *Design Studies* , 18, 227-236.

Marshall, R., Case, K., Porter, M., Summerskill, S., Gyi, D., Davis, P., et al. (2010). HADRIAN: A Virtual Approach to Design for All. *Journal of Engineering Design* , 21, 253-273.

McKinney, J. D. (1984). The Search for Subtypes of Specific Learning Disabilities. *Journal of Learning Disabilities* , 17, 43-50.

Meadows, M. (2005). Use Caution Buying Medical Products Online. *FDA Consumer* , 39 (1), 28-34.

Meyer, J. W., Ramirez, O. F., & Soysal, Y. N. (1992). World Expansion of Mass Education. *Sociology of Education* , 65, 128-149.

MHRA. (2006a). *Bulletin No. 8 - Information about the EC Medical Devices Directives*. Medicines and Healthcare Products Regulatory Agency.

MHRA. (2006b). *Bulletin No.13 - Standards*. Medicines and Healthcare Products Regulatory Agency.

MHRA. (2006c). *Bulletin No.6 - The Notified Body*. *Medicines and Healthcare Products Regulatory Agency*.

MHRA. (2006d). *Bulletin No. 10 - The Classification Tools*. Medicines and Healthcare Products Regulatory Agency.

MHRA. (2006e). *Guidance Note 19 - Guidance on the In Vitro Diagnostic Medical Devices Directive*. Retrieved 11 30, 2010, from Medicines and Healthcare Products Regulatory Agency:
http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CO N007521&RevisionSelectionMethod=Latest

MHRA. (2007). *Bulletin No.2 - The CE Mark*. Medicines and Healthcare Products Regulatory Agency.

MHRA. (2008a). *Bulletin No.4 - Conformity Assessment Procedures*. Medicines and Healthcare Products Regulatory Agency.

MHRA. (2008b). *Guidance Note 6 - Requirements for UK Notified Bodies*. Medicines and Healthcare Products Regulatory Agency.

MHRA. (2008c). *How we make regulatory decisions about medicines and medical devices*. Retrieved 05 16, 2010, from
<http://www.mhra.gov.uk/Howweregulate/Howwemakeregulatorydecisionsaboutmedicinesandmedicaldevices/index.htm>

MHRA. (2008d). *Medicines & Medical Devices Regulation: What you need to know*. Medicines and Healthcare products Regulatory Agency.

MHRA. (2009a). *Medical Device Alert: Ambulatory Insulin Pump. Accu-Check Spirit Manufactured by Roche Diagnostics (MDA/2009/027)*. London: Medicines and Healthcare products Regulatory Agency.

MHRA. (2009b). *Medical Device Alert: MiniMed Paradigm Veo Insulin Pump Manufactured by Medtronic (MDA/2009/083)*. London: Medicines and Healthcare products Regulatory Agency.

MHRA. (2009c). *How we regulate devices*. Retrieved 05 16, 2010, from
<http://www.mhra.gov.uk/Howweregulate/Devices/index.htm>

MHRA. (2010). *Device Bulletin: Adverse Incident Reports 2009 - DB2010(03)*. Medicines and Healthcare products Regulatory Agency .

Mieczakowski, A., Langdon, P. M., & Clarkson, P. J. (2010). Investigating Designers' Cognitive Representations for Inclusive Interaction Between Products

- and Users. In P. Langdon, J. Clarkson, & P. Robinson, *Designing Inclusive Interactions* (pp. 133-143). London: Springer.
- Mintel. (2007). *Self-Diagnostic - UK - September 2007*. London: Mintel Group Ltd.
- Myerson, J. (2007). A Groving Movement. In R. Coleman, J. Clarkson, H. Dong, & J. Cassim, *Design for Inclusivity* (pp. 23-31). England: Gower Publishing.
- Nemeth, C. P. (2004). *Human Factors Methods for Design: Making Systems Human-Centred*. Florida: CRC Press.
- Newell, A. F., & Gregor, P. (1999). Extra-ordinary Human-Machine Interaction: What can Be Learned from People with Disabilities? *Cognition, Technology & Work* , 1, 78-85.
- Newell, A. F., & Gregor, P. (2002). Design for Older and Disabled People- Where Do We Go from Here? *Universal Access in the Information Society* , 2, 3-7.
- Newell, A. (2003). Inclusive Design or Assistive Technology. In J. Clarkson, R. Coleman, S. Keates, & C. Lebbon, *Inclusive Design: Design for the Whole Population* (pp. 172-181). Cambridge: Springer-Verlag London Limited.
- Nickerson, R. S. (1995). *Emerging Needs and Opportunities for Human Factors Research*. Washington D.C.: National Academy Press.
- Nickpour, F., & Dong, H. (2010). Developing User Data Tools: Challenges and Opportunities. In P. Langdon, J. Clarkson, & P. Robinson, *Designing Inclusive Interactions* (pp. 79-88). New York: Springer.
- Norman, D. A. (2002). *The Design of Everyday Things*. New York: Basic Books.
- Norman, D. A. (2007). *The Design of Future Things*. Philadelphia: Basic Books.
- Omron. (n.d.). Instruction Manual R7 Omron Automatic Blood Pressure Monitor.
- ONS. (2009a). *Statistical Bulletin: Older People's Day 2009*. Newport: Office for National Statistics.
- ONS. (2009b). *Aging: Fastest Increase in the 'Oldest Old'*. Retrieved 06 15, 2010, from National Statistics:
http://www.statistics.gov.uk/cci/nugget_print.asp?ID=2157
- Oppenheim, A. N. (2001). *Questionnaire Design, Interviewing and Attitude Measurement* . New York: Continuum.

- OPSI. (1995). *Disability Discrimination Act 1995*. The Office of Public Sector Information.
- OPSI. (2002). *Statutory Instrument 2002 No. 618*. Retrieved 05 16, 2010, from <http://www.opsi.gov.uk/si/si2002/20020618.htm>
- Pahl, G., Beitz, W., Feldhusen, J., & Grote, K. H. (2007). *Engineering Design: A Systematic Approach*. Springer-Verlag London Limited.
- Parette, P., & Scherer, M. (2004). Assistive Technology Use and Stigma. *Education and Training in Developmental Disabilities* , 39, 217-226.
- Patterson, P. A. (2004). *Home Alone: Designing Information for Device Users*. Retrieved 06 19, 2010, from MDDI Online: <http://www.mddionline.com/article/home-alone-designing-information-device-users>
- Penforinis, A. (2011). Performance of a New Reusable Insulin Pen. *Diabetes Technology & Therapeutics*, 13, 373-379.
- Perakyla, A. (1998). Reliability and Validity in Research Based on Tapes and Transcripts. In D. Silverman, *Qualitative Research: Theory, Method and Practice* (pp. 201-220). London: Sage Publications.
- Persad, U., Langdon, P., & Clarkson, J. (2007). Characterising User Capabilities to Support Inclusive Design Evaluation. *Universal Access in the Information Society* , 6, 119-135.
- Popovic, V. (1999). Product Evaluation Methods and Their Importance in Designing Interactive Artifacts. In W. S. Green, & P. W. Jordan, *Human Factors in Product Design: Current Practice and Future Trends* (pp.26-35). Philadelphia: Taylor and Francis.
- Potter, J. (2000). Discourse Analysis and Constructionist Approaches: Theoretical Background. In J. T. Richardson, *Handbook of Qualitative Research Methods* (pp. 125-140). Leicester: BPS Books.
- Press, M., & Cooper, R. (2003). *The Design Experience: The Role of Design and Designers in the Twenty-First Century*. Alshgate Press.
- Pugh, S. (1991). *Total Design: Integrated Methods for Successful Product Engineering*. London: Addison-Wesley Publishers Ltd.
- Pullin, G., & Bontoft, M. (2003). Connecting business, inclusion and design. In J. Clarkson, R. Coleman, S. Keates, & C. Lebbon, *Inclusive Design: Design for the Whole Population* (pp. 206-214). London: Springer-Verlag London Limited.
- Pullin, G. (2009). *Design Meets Disability*. Cambridge: MIT Press.

- Ram, B. M., Browne, N., Grocott, P., & Wier, H. (2005). *Methods To Capture User Perspectives in the Medical Device Technology Life Cycle: A Review of the Literature In Health Care, Social Science, and Engineering & Ergonomics*. Multidisciplinary Assessment of Technology Centre for Health.
- Robson, C. (2002). *Real World Research: A Resource for Social Scientists and Practitioner*. Blackwell Publishing.
- Rogers, W. A., Mykityshyn, A. L., Campbell, R. H., & Fisk, A. D. (2001). Analysis of a "Simple" Medical Device. *Ergonomics in Design* , Winter 2001, 6-14.
- Rose, D. (2007). Analysis of Moving Images. In M. W. Bauer, & G. Gaskell, *Qualitative Researching with Text, Image and Sound* (pp. 245-262). London: Sage Publications.
- Rosson, M. B., & Carroll, J. M. (2002). *Usability Engineering: Scenario-Based Development of Human-Computer Interaction*. Academic Press.
- Rude, C. D. (1988). Format in Instruction Manuals: Applications of Existing Research. *Journal of Business and Technical Communication* , 2, 63-77.
- Sapsford, R., & Jupp, V. (2006). *Data Collection and Analysis*. London: Sage Publications.
- Sarantakos, S. (2005). *Social Research*. New York: Palgrave Macmillan.
- Saunders, M. N., & Seepersad, C. C. (2009). The Characteristics of Innovative, Mechanical Products. *Proceedings of the ASME 2009 International Design Engineering Technical Conference & Computers and Information in Engineering Conference*. San Diego, USA: IDETC/CIE 2009.
- Sawyer, D. (1996). *An Introduction to Human Factors in Medical Devices*. Food and Drug Administration, Center for Devices and Radiological Health.
- Schweber, B. (2005). Home Defibrillators Give the Market a New Kind of Shock. *EDN* , 50 (20), 114.
- Shah, S. G., & Robinson, I. (2008). Medical Device Technologies: Who is the User? *International Journal of Healthcare Technology and Management* , 9 (2), 181-197.
- Shelfbine, S., Farmer, R., Clarkson, J., & Eason, S. (2002). *Good Design Practice for Medical Devices and Equipment: Requirements Capture*. Cambridge: University of Cambridge Engineering Design Centre.
- Sim, J., & Wright, C. (2000). *Research in Health Care: Concepts, Designs and Methods*. Cheltenham: Stanley Thornes.

- Slater, R. (1988). Memory in Later Life: An Introduction to the Basics of Theory and Practice. In B. Gearing, M. Johnson, & T. Heller, *Mental Health Problems in Old Age* (pp. 89-95). Colchester: The Open University.
- Smith, J. A. (2000). Evolving Issues for Qualitative Psychology. In J. T. Richardson, *Handbook of Qualitative Research Methods* (pp. 189-201). Leicester: BPS Books.
- Smith, T. P. (2003). *Manufacturer's Guide to Developing Consumer Product Instructions*. US Consumer Product Safety Commission.
- Stanton, N. (2004). Product Design with People in Mind. In N. Stanton, *Human Factors in Consumer Products* (pp. 1-17). London: CRC Press.
- Valett, R. E. (1969). *Programming Learning Disabilities*. Fearon Publishers.
- Vanderheiden, G. (2000). Fundamental Principles and Priority Setting for Universal Usability. *Proceedings of Conference on Universal Usability (CUU2000)* (pp. 32-38). New York: ACM Press.
- Vatanasombut, B., Stylianou, A. C., & Igbaria, A. (2004). How to Retain Online Customers. *Communications of the ACM*, 47 (6), 65-69.
- Vaus, D. (2001). *Research Design in Social Research*. Surrey: Sage Publications.
- Vermeeren, A. P., Bouwmeester, K. D., Aasman, J., & Ridder, H. D. (2002). DEVAN: A Tool for Detailed Video Analysis of User Data. *Behaviour & Information Technology*, 21, 403-423.
- Vet, J. H. (1993). *User-Interface Specification Guidelines for Consumer Products*. Eindhoven, The Netherlands: Institute for Perception Research.
- Ward, J., Clarkson, J., Bishop, D., & Fox, S. (2002). *Good Design Practice for Medical Devices and Equipment - Design Verification*. Cambridge: University of Cambridge Engineering Design Centre, University of Cambridge Institute for Manufacturing.
- Whelan, C. (2009). *Professional and Consumer Healthcare Technologies Converge*. Retrieved 05 31, 2010, from MDDI Online:
<http://www.mddionline.com/print/2403>
- WHO. (2003). Retrieved 05 12, 2010, from Medical Device Regulations: Global Overview and Guiding Principles:
www.who.int/medical_devices/publications/en/MD_Regulations.pdf
- Wiklund, M. E., & Weinger, M. B. (2011). General Principles. In M. B. Weinger, M. E. Wiklund, & D. J. Gardner-Bonneau, *Handbook of Human Factors in Medical Device Design* (pp. 1-22). Boca Raton: CRC Press.

Wiklund, M., & Wilcox, S. (2005). *Designing Usability into Medical Products*. Florida: CRC Press.

Woods, R., & Britton, P. (1988). Cognitive Loss in Old Age-Myth or Fact? In B. Gearing, M. Johnson, & T. Heller, *Mental Health Problems in Old Age* (pp. 96-103). Colchester: The Open University.

Wilcox, S. (2003). *Applying Universal Design to Medical Devices*. Retrieved 06 13, 2010, from MDDI online: <http://www.mddionline.com/article/applying-universal-design-medical-devices>

Wright, I. (1998). *Design Methods in Engineering and Product Design*. Berkshire: McGraw-Hill Press .

Wright, P. (2000). Supportive Documentation for Older People. In P. Westendorp, J. Carel, & R. Punselie, *Interface Design & Document Design*, pp. 81-100 (pp. 81-100). Amsterdam: Rodopi.

Zeithaml, V. A. (1988). Consumer Perceptions of Price, Quality, and Value: A Means-End Model and Synthesis of Evidence. *Journal of Marketing* , 52, 2-22.

APPENDICES

APPENDIX A1: Sample of the lay user consent form

Approved by: 22/01/2009

Consent Form

The participant should complete the whole of this sheet him/herself

(Please tick the appropriate box.)

| | Yes | No |
|--|--------------------------|--------------------------|
| I have read and understood the research information sheet. | <input type="checkbox"/> | <input type="checkbox"/> |
| I have had an opportunity to ask questions and discuss this study. | <input type="checkbox"/> | <input type="checkbox"/> |
| I have received satisfactory answers to all my questions. | <input type="checkbox"/> | <input type="checkbox"/> |
| I understand that I am free to withdraw from the study: | | |
| - at any time | <input type="checkbox"/> | <input type="checkbox"/> |
| - without having to give a reason for withdrawing | <input type="checkbox"/> | <input type="checkbox"/> |

For Participant to Fill

Signature of Research Participant _____ Date ____ / ____ / ____

For Researcher to Fill

Signature of Researcher _____ Date ____ / ____ / ____

Name in capitals _____

APPENDIX A2: Information sheet for lay users

Ethics Approval Date: 22/01/09

Investigation of User Characteristics

Research Participant Information Sheet

Hello! My name is Abdusselam Selami Cifter. I am a research student in Brunel University, School of Engineering and Design. I would like to invite you to take part in my PhD study. I am conducting a study to understand the characteristics of users reflected by their product usage. Please take time to read the following information carefully. I have tried to explain why this research is being carried out and what it involves. If you find any part unclear or want more information, please feel free to ask me.

Purpose of the Study

Understanding users is crucial for designers and user determination is one of the most important phases in the design process. If designers do not have enough knowledge about the users then it is impossible for them to address users' needs and expectations. The information about user characteristics is not easily accessible nor sufficient. In some occasions designers erroneously exclude some user groups such as old users and disabled users. This situation has unexpected effects on both users and designers.

Owing to these, the main purpose of my study is to provide a better understanding of user characteristics and compare the information between different user groups. By means of this research, I will try to provide the designers a better understanding of users in terms of their behavioral patterns and expectations.

How Can You Participate in the Study?

If you would like to be a participant then you will be asked to fill a consent form. Then we will arrange a time to your convenience. Participation time is flexible and all participants will participate one by one.

Explanation of the Study

You will be asked to come to Brunel University at the arranged time. The study consists of three parts:

- In the first part I will give you a short questionnaire asking about the general information of yours.
- In the second part I will give you two digital devices and a list of tasks. In this part of the research you will be alone in the room. You will try to complete the tasks with the devices provided. During this part of the study, a video camera will record your behaviour. Please do not forget, you will be free to withdraw from the study if you encounter any difficulties or if you do not want to continue the test.
- In the last part, you will be asked to complete a short questionnaire about the tasks and your general preferences and expectations about the products that you daily use. This part will also be recorded by the video camera.

Confidentiality of the Study

All the information that you provide for my research will not be shared with any third party and will be kept securely. Any information recorded about you will have your name and address removed so that you cannot be recognised from it. This study has been approved by the Brunel University Research Ethics Committee.

The Estimated Time for the Study

The estimated time for this study is 45 minutes. Some refreshments, such as tea and biscuits will be provided during the test.

Results of the Study

If you would like to see the results, they will be sent to you in any way you prefer. The results will be used as an input for my PhD study, and for papers to be submitted to conferences and journals in Design

Thank you very much for your time!!

If you would like to get any more information, please feel free to ask. For further questions you can contact me via mail, email or mobile phone.

Abdusselam Selami Cifter

PhD Student

School of Engineering and Design

Brunel University

Uxbridge UB8 3PH

Email: a.cifter@brunel.ac.uk

Mobile Number: 07 737 747 634

APPENDIX A3: Information sheet for designers

MEET LAY USERS...





© A.S.Cifter

Summary of the Overall PhD Research:

There is an increasing and evolving demand from the end-user market for the adaptation of products originally designed for professional-use to the use of lay users. We can see these products in different market segments such as hobby products, medical devices, computer accessories, educative products and toys, etc... Particularly home use medical devices are the good examples of this adaptation process. Today we can see more and more medical devices are migrating to home environment. These devices differentiate significantly than the medical devices used at the clinical environment in terms of their users and context of use of the devices.

This research focuses particularly on the design process of home use medical devices. **It aims to provide design guidance, particularly to be used during the design process of home use medical devices.**

The guidance will include:

- The regulatory framework covering home use medical devices in Europe
- Information about the users of home use medical devices
- Guidance for preparing instruction manuals of home use medical devices
- Information about the context of use of home use medical devices
- A design process suggestion for designing home use medical devices
- A checklist for evaluating the final product
- A list of useful resources

What is This Paper About?


This paper presents only a **summary of the study carried out to identify lay users and their characteristics, as well as to present their diversity.** The study was carried out in two parts:

- Literature review on lay users
- User observation study with 40 lay users involving different types of lay users, i.e. 10 younger and able bodied people, 10 older people, and 20 people with different types of disabilities.

PhD Researcher: Abdusselam Cifter Supervisor: Dr. Hua Dong


Page 1

MEET LAY USERS...



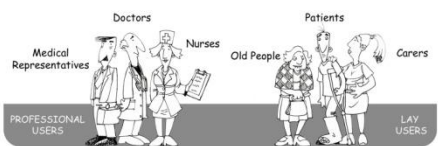
The Definition:

A user of a product or a system who has not gone through an extensive training into the subject field, which enables he/she to be eligible to act as a professional within a profession, but uses the system or the product due to his/her special interest or needs.



Who are Lay Users?

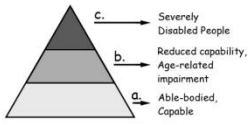
In order to make the distinction between lay people and professional people, the knowledge of the individual regarding a specific task should be considered. Lay users are the users of a specific type of product to carry out a specific tasks, where they have limited or no understanding of the task. However they may develop an understanding about the task and become experienced from being novice lay users. The figure below shows the professional users and the lay users of medical devices.



Lay User Types:

Lay people vary significantly in terms of their needs, expectations and capabilities. They can be healthy people, older people who suffer from chronic diseases, or disabled people. When designing for lay people their diversity should be taken into account.

Lay users were identified according to Thiberg's user pyramid, which is explained in Benktzon's (1993) paper.



According to this figure, able bodied and fully capable people, as well as including older are with minor disabilities are shown in the lower portion (a) of the pyramid. Middle portion (b) of the pyramid represents people with reduced strength and mobility, caused by disease and more severe age related impairment. The top layer of the pyramid represents the people with severe disabilities, who need help with their daily activities. The figure suggests that if the product is set for the higher portion of the pyramid, the end-users who can benefit from the product can be maximised.


In conclusion there types of lay user types were identified for this research:

- Younger and able bodied lay people
- Older lay people
- Lay people with disabilities

PhD Researcher: Abdusselam Cifter Supervisor: Dr. Hua Dong

Page 2

MEET LAY USERS...

 **Brunel UNIVERSITY WEST LONDON**

Lay User Characteristics:

Lay user characteristics were derived from the literature review and tested through an experimental study. The experimental study involved the observation of the volunteer participants when interacting with two selected digital devices i.e. a blood pressure monitor and a digital camera.

40 people from three types of lay users groups were involved in this study as:

- 10 Younger and able bodied participants (aged between 18-64)
- 10 Older participants (65+)
- 20 Disabled participants (aged between 18-64)

According to literature review on lay users and the results of the experimental study, lay users:

- ✓ vary significantly from age to capability
- ✓ may have little or no training
- ✓ use products reflecting their special needs or interest
- ✓ have little or no knowledge regarding the task and/or the product
 - ✓ may lack of confidence
 - ✓ may be poor at identifying problems or errors
 - ✓ may be poor at overcoming device limitations
- ✓ may have difficulty in dealing with unexpected situations
- ✓ prefer easy to use devices with specific functions
- ✓ may not follow the accompanying instructions
- ✓ may have difficulty in understanding specific terminology

During the experimental study, the different types of lay user groups presented different characteristics regarding their interaction with the products.

| | |
|-----------------|--|
| YOUNGER | <ul style="list-style-type: none"> • Previous experience has a big effect on the user behaviour and in some cases can mislead the user. • They tend to solve encountered problems by experimenting. • People who used similar devices before tend to not to use accompanied instruction manuals. |
| OLDER | <ul style="list-style-type: none"> • They experience difficulty in understanding digital interface. • Often unmotivated to use digital devices. • Most of them experience difficulty in understanding terms and indicators on the product and in the instruction manual. • They experience difficulty in seeing smaller indicators and buttons on the product, also with pressing such buttons due to limited dexterity. • They tend to blame themselves when they encounter difficulties. • They tend to follow the given steps rather than trying to understand the logic behind them. • They experience difficulty in using instruction manuals. |
| DISABLED | <ul style="list-style-type: none"> • Disabled users vary significantly therefore it is worth investigating them in accordance with their specific impairments, i.e. physical, sensory and cognitive impairments. • People with cognitive disabilities were found to be the most critical when interacting with the products and accompanying instruction manuals. |

PhD Researcher: Abdusselam Cifter Supervisor: Dr. Hua Dong

MEET LAY USERS...

 **Brunel UNIVERSITY WEST LONDON**

Future Work:

The guidance for the design process of home use medical devices is in progress of development. The guidance will be presented to the designers who would like to take part in a short interview study, and their opinions will be asked for the further improvement.


It would be greatly appreciated if you kindly agree to take part in the interview study. If so, please contact with the researcher through the contact details indicated in this page.

Online Publications of the Researcher:

A few publications relevant to this research can be found through the links below:

- Cifter A S, Dong H (2010) *Instruction Manual Usage: A Comparison of Younger People, Older People and People with Cognitive Disabilities*. In: Winter R, Zhao J L, Aier S. DESRIST 2010, LNCS 6105, pp. 410-425, 2010, Springer-Verlag Berlin Heidelberg 2010 <http://www.springerlink.com/content/51758u58x23p1887/>
- Cifter A S, Dong H (2009) *User Characteristics: Professional vs Lay Users*, Include 2009 Proceedings, Helen Hemlyn Center, RCA <http://www.hhc.rca.ac.uk/2084/all/1/proceedings.aspx>
- Cifter A S (2010), *Defining Lay Users and Their Characteristics*. In: Dong H, Design for All: Inclusive Design Research in Action, Design for All Institute of India, Vol. 5, No. 6, June 2010 http://www.designforall.in/newsletter_june2010.pdf#page=37

Contact Information:



Abdusselam Selami Cifter
 School of Engineering and Design
 Brunel University, Uxbridge,
 UB8 3PH, UK

Email: selami.cifter@gmail.com
a.cifter@brunel.ac.uk
acifter@msgsu.edu.tr

Tel: (0) 18952 67675
 (0) 77377 47634

Thank you very much for your time!

PhD Researcher: Abdusselam Cifter Supervisor: Dr. Hua Dong


APPENDIX B: Details of lay users that participated in the observational studies


| | Participant Code | Gender | Age | Education | Ethnicity | Occupation | Disability |
|---------------------|------------------|--------|-------|-----------------------|-----------|------------|--|
| Able Bodied Younger | A1 | Female | 18-24 | College graduate | Irish | Student | - |
| | A2 | Male | 18-24 | High school | Turkish | Student | - |
| | A3 | Male | 18-24 | College | Turkish | Student | - |
| | A4 | Male | 18-24 | College graduate | Russian | Student | - |
| | A5 | Female | 50-64 | Less than high school | British | PA | - |
| | A6 | Female | 18-24 | College graduate | Romanian | Student | - |
| | A7 | Female | 35-49 | High school | British | PA | - |
| | A8 | Male | 25-34 | College graduate | Spanish | Student | - |
| | A9 | Male | 25-34 | College graduate | British | Student | - |
| | A10 | Male | 25-34 | College graduate | Turkish | Student | - |
| Older | O1 | Female | 65+ | Less than high school | British | Housewife | Impaired vision |
| | O2 | Female | 65+ | College | British | Retired | - |
| | O3 | Male | 65+ | Less than high school | British | Retired | Impaired sight and hearing (Uses hearing aid) |
| | O4 | Female | 65+ | High school | British | Retired | Impaired sight and hearing |
| | O5 | Female | 65+ | High school | British | Retired | Impaired sight and arthritis |
| | O6 | Male | 65+ | High school | British | Retired | Heart problems, blood pressure, impaired sight and dexterity |

| | | | | | | | |
|------------------------------|-----|--------|-------|-----------------------|---------|--------------------------------------|---|
| | O7 | Female | 65+ | High school | British | Retired | - |
| | O8 | Female | 65+ | Less than high school | British | Housewife | Impaired sight |
| | O9 | Female | 65+ | High school | British | Retired | Diabetes Type 2 |
| | O10 | Female | 65+ | Less than high school | British | Housewife | - |
| Motor and Sensory Disability | DP1 | Female | 25-34 | College | British | Yateley Industries | Right side Hemiplegic, Stutter |
| | DP2 | Female | 35-49 | College | British | Shop Assistant/Receptionist | Spina Bifida, Hydrocephalus |
| | DP3 | Female | 25-34 | College | Indian | Student | Electric wheelchair user, Spinal Muscular Atrophy Type 2 – Neuromuscular. Weakness of arms and legs |
| | DP4 | Female | 50-64 | College | British | Packer/Counter at Yateley Industries | Cerebral Palsy |
| | DP5 | Female | 50-64 | College | British | Charge hand | Tetraplegic |
| | DS1 | Male | 35-49 | College graduate | British | Researcher | Profoundly deaf |
| | DS2 | Female | 35-49 | College graduate | British | BSL presenter + Specialist | Profoundly deaf |
| | DS3 | Male | 18-24 | College | Indian | Student | Very poor vision due to keratoconus |
| | DS4 | Male | 25-34 | Postgraduate | British | Computer science | Cortical visual impairment |
| | DS5 | Female | 25-34 | College | British | Housewife | Deafness and usher syndrome |
| Cognitive Disability | DC1 | Female | 35-49 | College | British | HR admin assistant | Learning disability |
| | DC2 | Female | 35-49 | High school | British | - | Down Syndrome |
| | DC3 | Male | 35-49 | Less than high school | British | Handy person | Learning disability |
| | DC4 | Male | 35-49 | Less than high school | British | - | Learning disability |
| | DC5 | Female | 35-49 | College | British | Fundraising admin assistant | Speech impediment, hearing |

| | | | | | | | |
|------|--------|-------|---------|--|---------|--|--|
| | | | | | | | loss, heart murmur, high blood pressure, learning disability |
| DC6 | Male | 25-34 | College | | British | Campaign representative, Information assistant | Learning disability |
| DC7 | Female | 25-34 | College | | British | Unemployed | Learning disability, communication difficulty |
| DC8 | Female | 25-34 | College | | British | Campaign office assistant, reception assistant | Learning disability |
| DC9 | Male | 35-49 | College | | British | Campaign assistant | Hard of hearing, diabetic, learning disability |
| DC10 | Female | 50-64 | College | | British | Admin assistant | Learning disability |

APPENDIX C1: Pre-questionnaire used during the observational studies with lay users

SCHOOL OF ENGINEERING AND DESIGN



The information that you provide in this questionnaire will not be shared with any third party without your prior consent and will be used only for research purpose.

Investigation of Lay-User Characteristics

A study to understand the characteristics of lay-users reflected by their product usage.

CONTACT DATA

1) Your Name: _____

2) Your Gender (Please tick the appropriate box)

Male / Female

3) Your Age (Please tick the appropriate box)

| | |
|-------------|--------------------------|
| Under 18 | <input type="checkbox"/> |
| 18-24 | <input type="checkbox"/> |
| 25-34 | <input type="checkbox"/> |
| 35-49 | <input type="checkbox"/> |
| 50-64 | <input type="checkbox"/> |
| 65 or older | <input type="checkbox"/> |

4) Your education (Please tick highest level completed)

| | |
|-----------------------|--------------------------|
| Less than high school | <input type="checkbox"/> |
| High School | <input type="checkbox"/> |
| College | <input type="checkbox"/> |
| College Graduate | <input type="checkbox"/> |
| Postgraduate Degree | <input type="checkbox"/> |

5) What is your ethnicity?

6) What is your occupation?

7) Do you have any disability or impaired ability?
(Please circle the appropriate answer)

YES / NO


If 'YES', please indicate:

8) Your telephone:

9) Your e-mail address:

Thank you very much for your help. Your contact details will not be used for any other purposes.

APPENDIX C2: Task list sheet used during the observational studies with lay users

SCHOOL OF ENGINEERING AND DESIGN

Please try to be as realistic as possible during the tasks to show your actual behavior. After each task, please tick the box relevant to that task, and then go to the next task.

- You may encounter difficulties during the tasks. Try to solve them in the allotted time. If you cannot complete the task, move on to the next.
- If you would like, you can use instruction manuals provided for each device in all tasks.

BLOOD PRESSURE MONITOR TASKS

TASK 1:

Please prepare the device to be used.

TASK 2:

Measure your blood pressure and write down the score.
(Maximum of 15 minutes to complete task. If you are not confident about the score, you can perform it again but please allow at least 3 minutes between readings.)

SCORE: _____

TASK 3:

Switch off the device as if it will not be used for a long time.

DIGITAL CAMERA TASKS

TASK 4:

Please prepare the camera to be used.

TASK 5:

Take your own picture reflected in the mirror provided.

Please try to take at least one good picture.

(Maximum of 10 minutes to complete task. You can try as many times you like.)

TASK 6:

Take a picture of the toy car. Please try to take at least one good picture.

(Maximum of 10 minutes to complete task. You can try as many times you like.)

TASK 7:

Erase the unwanted pictures and switch off the device.


(Maximum of 10 minutes to complete task.)

THANK YOU VERY MUCH!

APPENDIX C3: Post-questionnaire used during the observational studies with lay users

Brunel
UNIVERSITY
WEST LONDON

SCHOOL OF ENGINEERING AND DESIGN

 Please answer the questions in order.

USE OF A BLOOD PRESSURE MONITOR

1) Have you ever used a blood pressure monitor before? YES / NO
(Please circle the appropriate answer)

2) Have you ever seen a blood pressure monitor being used before? YES / NO
(Please circle the appropriate answer)

3) Have you ever used a similar device to a blood pressure monitor? YES / NO
(Please circle the appropriate answer)

If 'Yes', please indicate what device(s):

4) Did you use the instruction manual on any part of blood pressure monitor tasks? YES / NO
(Please circle the appropriate answer)

If 'Yes', please indicate which task(s):

5) Did you encounter difficulties in using the 'blood pressure monitor'? (Please circle the appropriate answer) YES / NO

If yes, please indicate the difficulties:

6) Do you think that it was easy to understand how to use the blood pressure monitor? (Please circle the appropriate answer) YES / NO / NOT SURE

If your answer is "No" or "Not Sure" please indicate why:

7) Are you confident about the output of the device? (Please circle the appropriate answer) YES / NO / NOT SURE

Please indicate why:

8) Are you confident that you have completed the 'blood pressure monitor' tasks correctly? (Please circle the appropriate answer) YES / NO / NOT SURE

Please indicate why:

USE OF A DIGITAL CAMERA

9) Have you ever used a digital camera before? YES / NO
(Please circle the appropriate answer)

10) Have you ever used a similar device to a digital camera? YES / NO
(Please circle the appropriate answer)

If 'Yes', please indicate what device(s):

11) Did you use the instruction manual on any digital camera tasks? YES / NO
(Please circle the appropriate answer)

If 'Yes', please indicate which task(s):

12) Do you think that it was easy to understand and find the functions of the
digital camera? (Please circle the appropriate answer) YES / NO / NOT SURE

If your answer is "No" or "Not Sure" please indicate why:

13) Are you confident that you have completed the 'digital camera' tasks correctly? (Please circle the appropriate answer)

YES / NO / NOT SURE

Please indicate why:

GENERAL QUESTIONS

14) Generally do you try to learn all the functions of a product or only the functions that are relevant?

- I try to learn all the functions
 I use only the functions that are relevant

15) Generally do you prefer simple products with specific functions or sophisticated products with a broad range of functions?

- I prefer simple to use ones
 I prefer sophisticated products with a broad range of functions

16) Please indicate why you used or not used instruction manual for both blood pressure monitor and digital camera:

17) When operating the blood pressure monitor and the digital camera, how similar did you find the process? Please rate from '1 to 5' where '1' is totally different and '5' is very similar.

Please write your answer into the box

18) Please rank the following features that you might expect from a product. 1 is the most and 4 is the least important feature.

- Simplicity
- Efficiency
- Pleasure
- Easy to Learn

19) Do you think that all the tasks were clear?
(Please circle the appropriate answer)

YES / NO

If your answer is 'No' please indicate:

Your comments and suggestions about the tasks or the questionnaire

Help in the further study,

- I would like to participate in the further study
- I will not be able to participate again.

THANK YOU VERY MUCH FOR YOUR HELP!!

APPENDIX D1: Interaction problems observed with the blood pressure monitor

(‘A’ = Able bodied younger participants, ‘O’ = older lay participants, ‘DP’ = participants with physical disabilities, ‘DS’ = participants with sensory disabilities, DC = participants with cognitive disabilities) + (D = difficulty, M= mistake, F = failure)

| BLOOD PRESSURE MONITOR | | | | |
|--|------------|---------|---------|-----------|
| USER –PRODUCT USAGE RELATED PROBLEMS | Difficulty | Mistake | Failure | TOTAL |
| Device was attached to the wrist in an incorrect position | | | | |
| A1M, A2F, A3M, A4M, A7M, A9F, A10F | - | 4 | 3 | 7 |
| O1F, O2M, O4M, O5M, O7F, O8F, O9M, O10M | - | 5 | 3 | 8 |
| DC1F, DC2F, DC3M, DC4F, DC5F, DC6M, DC7M, DC8M, DC9M, DC10M | - | 6 | 4 | 10 |
| DP2F, DP3F, DS1M, DS3F, DS4M | - | 2 | 3 | 5 |
| T: 30/40 | | | | |
| Batteries inserted wrongly | | | | |
| DC2M, DC4M, DC6M, DC8M | - | 4 | - | 4 |
| DP3M | - | 1 | - | 1 |
| T: 5/40 | | | | |
| Device was initially attached to the right hand | | | | |
| A2M, A6M, A7M | - | 3 | - | 3 |
| DC2M, DC6M, DC8M, DC10M | - | 4 | - | 4 |
| DP2M, DS2M, DS5M | - | 3 | - | 3 |
| T: 10/40 | | | | |
| Wrist was not bare | | | | |
| A9M | - | 1 | - | 1 |
| O1M, O9M | - | 2 | - | 2 |
| DC1M, DC4M, DC5M, DC9M | - | 4 | - | 4 |
| DS2F | - | - | 1 | 1 |
| T: 8/40 | | | | |
| Wrong posture during the measurement | | | | |
| A2F, A3F, A6F, A7F, A8F, A10F | - | - | 6 | 6 |
| O3F, O8F, O10F | - | - | 3 | 3 |
| DC1F, DC2F, DC6F, DC7F, DC8M | - | 1 | 4 | 5 |
| DP2F, DP4F, DS3F, DS5F | - | - | 4 | 4 |
| T: 18/40 | | | | |
| Beeping ignored | | | | |
| O7M, O10M | - | 2 | - | 2 |
| DC1M, DC5M, DC8M, DC10M | - | 4 | - | 4 |
| DP1M, DP4M | - | 2 | - | 2 |
| T: 8/40 | | | | |

| | | | | |
|---|-----------------|---|---|---|
| Batteries were left inside | | | | |
| A2F, A7F, A9F | - | - | 3 | 3 |
| O3F, O4F, O6F, O7F, O8F | - | - | 5 | 5 |
| DC2F, DC3F, DC4F, DC9F | - | - | 4 | 4 |
| DP1F, DP2F, DP4F, DS2F | - | - | 4 | 4 |
| | T: 16/40 | | | |
| Trial and Error | | | | |
| A8, A9 | - | - | - | 2 |
| O3, O5, O7, O8, O9, O10 | - | - | - | 6 |
| DC1, DC2, DC3, DC4, DC6, DC7, DC9 | - | - | - | 7 |
| DP1, DP3, DS2, DS3, DS4, DS5 | - | - | - | 6 |
| | T: 21/40 | | | |
| USER CAPABILITY – PRODUCT: MATCHING PROBLEMS | | | | |
| Difficulty in inserting the batteries | | | | |
| DP3D, DP4D | 2 | - | - | 2 |
| | T: 2/40 | | | |
| Difficulty in opening the battery lid | | | | |
| DP4D | 1 | - | - | 1 |
| | T: 1/40 | | | |
| Difficulty in pressing the buttons on the device | | | | |
| DP4D | 1 | - | - | 1 |
| | T: 1/40 | | | |
| Difficulty in performing actions which require use of both hands | | | | |
| DP1D, DP5D | 2 | - | - | 2 |
| | T: 2/40 | | | |
| Difficulty in removing the batteries | | | | |
| O1D, O10D | 2 | - | - | 2 |
| DC5D, DC7D, DC8D | 3 | - | - | 3 |
| | T: 5/40 | | | |
| Difficulty in replacing the battery lid (Dexterity) | | | | |
| DC8D | 1 | - | - | 1 |
| DP3D | 1 | - | - | 1 |
| | T: 2/40 | | | |
| Difficulty in attaching the device to the wrist (Physical) | | | | |
| DP1D, DP4D, DP5D | 3 | - | - | 3 |
| | T: 3/40 | | | |
| Difficulty caused due to using an assistive device | | | | |
| DP2D, DP3D | 2 | - | - | 2 |
| | T: 2/40 | | | |
| Difficulty in opening the protective case | | | | |
| O7D, O9D | 2 | - | - | 2 |
| DC3D, DC5D, DC8D | 3 | - | - | 3 |
| DP1D, DP4D, DP5D | 3 | - | - | 3 |
| | T: 8/40 | | | |
| Difficulty in taking the device off the wrist (Physical) | | | | |
| DP1D, DP5D | 2 | - | - | 2 |
| | T: 2/40 | | | |
| Difficulty in reading instruction manual | | | | |
| O1D, O3D, O4D, O5D, O6D, O8D, O10D | 7 | - | - | 7 |

| | | | | |
|---|-----------------|---|---|----|
| DS3D, DS4D | 2 | - | - | 2 |
| | T: 9/40 | | | |
| Difficulty in hearing the beeping sound | | | | |
| O4D | 1 | - | - | 1 |
| DC9D | 1 | - | - | 1 |
| DS1N, DS2N, DS5N | 3 | - | - | 3 |
| | T: 5/40 | | | |
| Difficulty in realising when the measurement had been taken | | | | |
| DC9D | 1 | - | - | 1 |
| DS1D, DS2D, DS5D | 3 | - | - | 3 |
| | T: 4/40 | | | |
| Difficulty in understanding terminology used in the manual | | | | |
| A4D, A5D, A6D, A7D, A8D, A10D | 6 | - | - | 6 |
| O1D, O4D, O5D, O7D, O9D, O10D | 6 | - | - | 6 |
| DC1D, DC2D, DC3D, DC4D, DC5D, DC6D, DC7D, DC8D, DC9D, DC10D | 10 | - | - | 10 |
| DP1D, DP3D, DP4D, DP5D, DS1D, DS3D, DS5D | 7 | - | - | 7 |
| | T: 29/40 | | | |
| USER – DESIGNER: UNDERSTRANDING PROBLEMS | | | | |
| Difficulty in opening the protective case (due to confusion) | | | | |
| DC2C | - | - | - | 1 |
| | T: 1/40 | | | |
| Descriptions within the manual led to confusion | | | | |
| A1C, A6C, A8C | - | - | - | 3 |
| O3C, O5C, O7C, O8C, O9C | - | - | - | 5 |
| DC1C, DC5C, DC6C, DC9C | - | - | - | 4 |
| DP2C, DP3C, DP4C, DP5C, DS1C, DS2C | - | - | - | 6 |
| | T: 18/40 | | | |
| Difficulty in replacing the battery lid (Confusion) | | | | |
| DC1C, DC3C, DC5C, DC6C | - | - | - | 4 |
| | T: 4/40 | | | |
| Difficulty in putting the device back into its protective case (Confusion) | | | | |
| A1D, A2D, A7D, A8D | - | - | - | 4 |
| DC2C, DC5C | - | - | - | 2 |
| DP3C, DP5C, DS1C, DS2C | - | - | - | 4 |
| | T: 10/40 | | | |
| Difficulty in understanding how to fasten the velcro tape | | | | |
| O8C | - | - | - | 1 |
| DC3C | - | - | - | 1 |
| DS1C | - | - | - | 1 |
| | T: 3/40 | | | |
| Waiting for the device to work | | | | |
| A4C, A5C, A8C, A9C | - | - | - | 4 |
| O1C, O3C, O4C, O5C, O7C, O8C, O9C, O10C | - | - | - | 8 |
| DC1C, DC2C, DC3C, DC4C, DC6C, DC7C, DC9C | - | - | - | 7 |
| DP2C, DP4C, DS2C, DS3C, DS4C, DS5C | - | - | - | 6 |
| | T: 25/40 | | | |
| Beeping confused | | | | |
| DC2C, DC3C, DC4C, DC8C, DC10C | - | - | - | 5 |

| | | | | |
|--------------------------------------|-----------------|---|---|----------|
| DS3C | - | - | - | 1 |
| | T: 6/40 | | | |
| Device worked accidentally | | | | |
| A8C, A9C, A10 | - | - | - | 3 |
| DC1C, DC5C, DC6C, DC8C, DC10C | - | - | - | 5 |
| DP3C, DP5C, DS3C, DS5C | - | - | - | 4 |
| | T: 12/40 | | | |
| Scared by wristband inflation | | | | |
| DC2C | - | - | - | 1 |
| | T: 1/40 | | | |

APPENDIX D2: Interaction problems observed with the digital camera

(‘A’ = Able bodied younger participants, ‘O’ = older lay participants, ‘DP’ = participants with physical disabilities, ‘DS’ = participants with sensory disabilities, DC = participants with cognitive disabilities) + (D = difficulty, M= mistake, F = failure)

| DIGITAL CAMERA | | | | |
|---|------------|-----------------|----------|-------|
| USER –PRODUCT USAGE RELATED PROBLEMS | Difficulty | Mistakes | Failures | TOTAL |
| Batteries inserted in a wrong way | | | | |
| A2M, A3M, A8M | - | 3 | - | 3 |
| O1M, O2M, O3M, O8M | - | 4 | - | 4 |
| DC3M, DC5M, DC9M | - | 3 | - | 3 |
| DP3M, DP4M, DS5M | - | 3 | - | 3 |
| | | T: 13/40 | | |
| Batteries inserted randomly | | | | |
| DC3M, DC4M, DC8M, DC9M | - | 4 | - | 4 |
| DP3M | - | 1 | - | 1 |
| | | T: 5/40 | | |
| No attention to the flashing message on the screen (Ignored, not recognized or not read) | | | | |
| A1M, A2M, A5M, A7M, A9M | - | 5 | - | 5 |
| DC1M, DC3M, DC5M, DC7M, DC8M, DC9M, DC10M | - | 7 | - | 7 |
| DP1M, DP2M, DP4M, DP5M, DS1M, DS3M, DS5M | - | 7 | - | 7 |
| | | T: 19/40 | | |
| Mistakenly pressed a wrong button | | | | |
| A5M | - | 1 | - | 1 |
| O6M, O10M | - | 2 | - | 2 |
| DC7M | - | 1 | - | 1 |
| DP1M, DP5M | - | 2 | - | 2 |
| | | T: 6/40 | | |
| Accidentally took a picture | | | | |
| DC3M, DC9M | - | 2 | - | 2 |
| | | T: 2/40 | | |
| Incorrectly assuming a task had been completed | | | | |
| O3M, O4F, O6M, O7M, O9M, O10M | - | 5 | 1 | 6 |
| DC5M, DC6M | - | 2 | - | 2 |
| DP2M, DS4M | - | 2 | - | 2 |
| | | T: 10/40 | | |
| Trial and error | | | | |
| O2, O4, O5, O7, O8, O10 | - | - | - | 6 |
| DC1, DC2, DC3, DC4, DC6, DC7, DC8, DC9, DC10 | - | - | - | 9 |
| DP1, DP2, DP3, DP5, DS4, DS5 | - | - | - | 6 |

| | | | | |
|--|-----------------|---|---|---|
| | T: 21/40 | | | |
| Accidentally changed the settings of the device | | | | |
| A5M | - | 1 | - | 1 |
| O2M, O4M, O10M | - | 3 | - | 3 |
| | T: 4/40 | | | |
| USER CAPABILITY – PRODUCT: MATCHING PROBLEMS | | | | |
| Difficulty in opening the battery lid | | | | |
| DC10D | 1 | - | - | 1 |
| DP4D | 1 | - | - | 1 |
| | T: 2/40 | | | |
| Difficulty in performing actions which require the use of both hands | | | | |
| DP1D, DP5D | 2 | - | - | 2 |
| | T: 2/40 | | | |
| Dropped the device due to physical impairment | | | | |
| DP3D, DP5D | 2 | - | - | 2 |
| | T: 2/40 | | | |
| Difficulty in inserting the memory card into the device (Physically) | | | | |
| DP3D, DP4D | 2 | - | - | 2 |
| | T: 2/40 | | | |
| Difficulty in seeing the buttons or their indicators on the camera | | | | |
| O1D, O5D, O6D, O8D, O10D | 5 | - | - | 5 |
| DP3D, DS3D, DS4D | 3 | - | - | 3 |
| | T: 8/40 | | | |
| Difficulty in understanding how to use the digital interface | | | | |
| O1D, O3D, O4D, O5D, O7D, O8D, O9D, O10D | 8 | - | - | 8 |
| DC2D, DC3D, DC7D, DC8D, DC10D | 5 | - | - | 5 |
| DP2D, DP3D, DP5D | 3 | - | - | 3 |
| | T: 16/40 | | | |
| Difficulty in reading the text based descriptions in the manual due to impaired sight | | | | |
| O1D, O5D, O6D, O8D | 4 | - | - | 4 |
| DS3D, DS4D, DS5D | 3 | - | - | 3 |
| | T: 7/40 | | | |
| Difficulty in pressing buttons | | | | |
| O3D, O5D, O6D, O10D | 4 | - | - | 4 |
| DP1D, DP5D | 2 | - | - | 2 |
| | T: 6/40 | | | |
| Difficulty in locating the battery compartment | | | | |
| DC2D | 1 | - | - | 1 |
| | T: 1/40 | | | |
| Difficulty in understanding the symbols due to unfamiliarity | | | | |
| O3D, O4D, O9D, O10D | 4 | - | - | 4 |
| DC1D, DC2D, DC3D, DC4D, DC7D, DC8D, DC10D | 7 | - | - | 7 |
| DP2D, DP3D, DP5D, DS4D | 4 | - | - | 4 |
| | T: 15/40 | | | |
| USER – DESIGNER: UNDERSTRANDING PROBLEMS | | | | |
| Blamed him/herself | | | | |
| O2, O3, O4, O8, O9, O10 | - | - | - | 6 |
| DC4, DC5, DC8, DC9, DC10 | - | - | - | 5 |

| | | | | |
|---|---|---|---|----|
| DP1, DP2, DP5, DS1 | - | - | - | 4 |
| T: 15/40 | | | | |
| Difficulty in understanding the way of opening the battery compartment lid | | | | |
| DC4, DC8 | - | - | - | 2 |
| DP3 | - | - | - | 1 |
| T: 3/40 | | | | |
| Tried to take a picture when the device was off | | | | |
| O1, O4, O7, O8 | - | - | - | 4 |
| T: 4/40 | | | | |
| Difficulty in understanding the manner in which the battery lid closes | | | | |
| O4, O5, O7, O8 | - | - | - | 4 |
| T: 4/40 | | | | |
| Confusion about multiple functions buttons | | | | |
| A5 | - | - | - | 1 |
| O3, O4, O9, O10 | - | - | - | 4 |
| DC1, DC8 | - | - | - | 2 |
| DP2, DP5, DS4 | - | - | - | 3 |
| T: 10/40 | | | | |
| Symbol used on the device or in the manual misled the participant | | | | |
| O5, O7, O8, O9 | - | - | - | 4 |
| DC1, DC3 | - | - | - | 2 |
| DP2, DP3, DP5, DS1 | - | - | - | 4 |
| T: 10/40 | | | | |
| Confusion as to the manner of use | | | | |
| A9 | - | - | - | 1 |
| O2, O4, O5, O7 | - | - | - | 4 |
| DC2, DC7 | - | - | - | 2 |
| T: 7/40 | | | | |
| Difficulty in putting the memory card in due to confusion | | | | |
| O1, O3, O4, O7, O8 | - | - | - | 5 |
| DC2, DC3, DC4, DC7, DC8, DC9, DC10 | - | - | - | 7 |
| DP3 | - | - | - | 1 |
| T: 13/40 | | | | |
| Manual led to confusion | | | | |
| O3, O4, O5, O7, O8, O9, O10 | - | - | - | 7 |
| DC1C | - | - | - | 1 |
| DP2C, DP3C, DP5C | - | - | - | 3 |
| T: 11/40 | | | | |
| Confusion due to variety of buttons on the device | | | | |
| O1, O2, O3, O4, O5, O6, O7, O8, O9, O10 | - | - | - | 10 |
| DC1, DC2, DC3, DC4, DC7, DC8, DC9, DC10 | - | - | - | 8 |
| DP2, DP3, DP5, DS4, DS5 | - | - | - | 5 |
| T: 23/40 | | | | |
| Difficulty in recalling actions performed previously | | | | |
| O1, O5, O7, O8 | - | - | - | 4 |
| DC1, DC5, DC7, DC8, DC9 | - | - | - | 5 |
| DP2C, DP3C, DP5C, DS5C | - | - | - | 4 |
| T: 13/40 | | | | |
| Expectation that the memory card should be inserted somewhere other than the allocated space | | | | |

| | | | | |
|----------------------------|-----------------|---|---|----------|
| A5, A7, A8, A9 | - | - | - | 4 |
| O1, O2, O3, O5, O6, O7, O9 | - | - | - | 7 |
| DC3, DC6, DC8 | - | - | - | 3 |
| DP1, DP5, DS2, DS3, DS4 | - | - | - | 5 |
| | T: 19/40 | | | |

APPENDIX E: Three types of interaction problems observed during the blood pressure monitor tasks

The three types of interaction problems were described in Section 4.11.3. Figure A.1 exemplifies these three categories by giving examples of the interaction problems observed during the blood pressure monitor tasks. In the Figure they are shown as a triangle in order to emphasise their relationship with each other. The severity of the problem increases from 'user - product usage: related problems' to 'user – designer: understanding problems': this is highlighted to some extent in Figure A.1 by the colours used in the circles. Some of the interaction problems observed during the blood pressure monitor tasks were found to be relevant to two different types of problems. These are shown the edge of the triangle. The distance to the corners is proportional to the relevance to these problems.

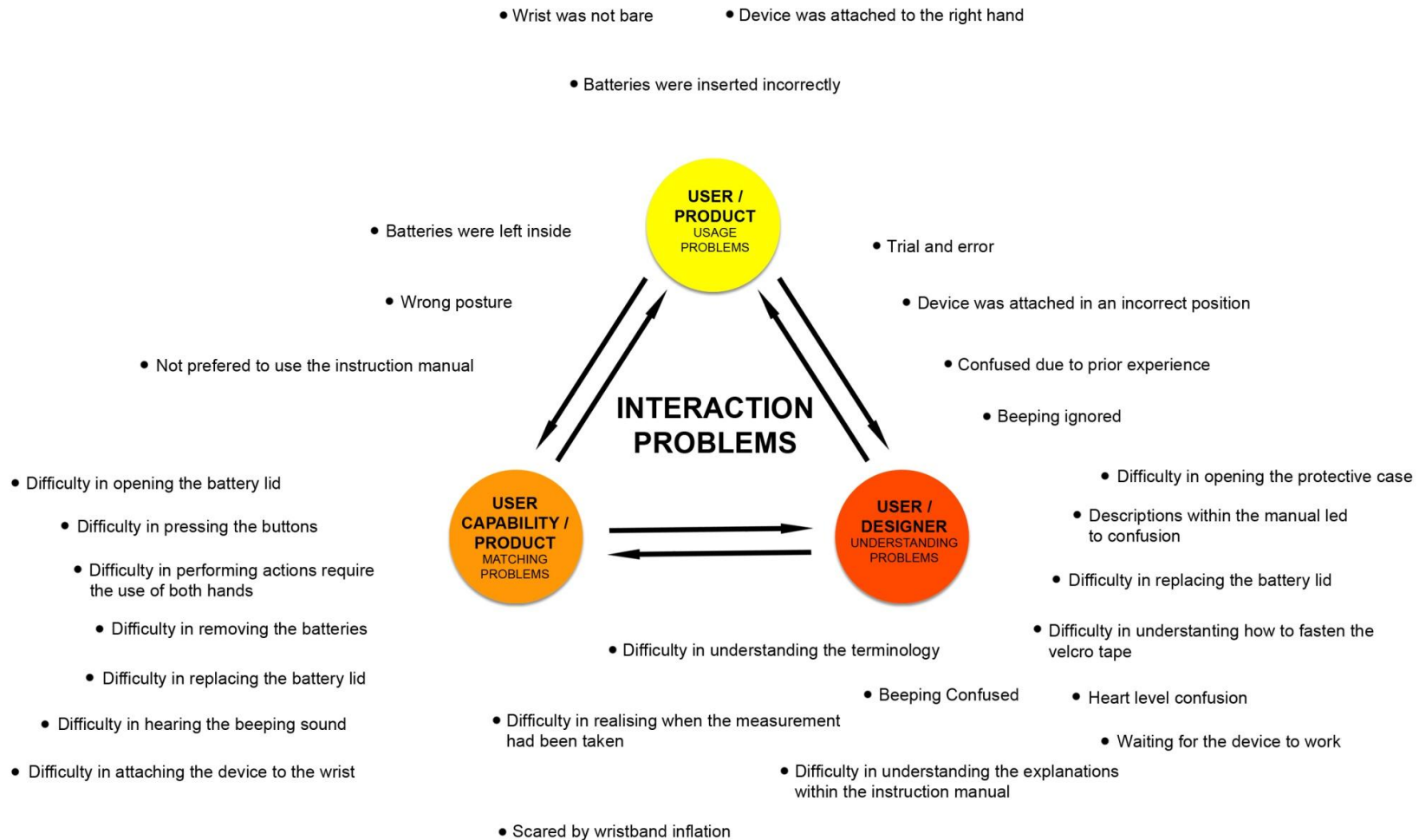


Figure A.1 Three types of problems and their relation to the interaction problems observed during the blood pressure monitor tasks

APPENDIX F: Answers given to the first two sections of the post-questionnaire

| POST-QUESTIONNAIRE QUESTIONS | YP | | | OP | | | M/SDP* | | | CDP | | |
|--|-----|----|----|-----|----|----|--------|----|----|-----|----|----|
| | Yes | No | NS | Yes | No | NS | Yes | No | NS | Yes | No | NS |
| SECTION 1 – BLOOD PRESSURE MONITOR | | | | | | | | | | | | |
| Q1: Have you ever used a blood pressure monitor before? | 5 | 5 | | 3 | 7 | | 0 | 9 | | 6 | 4 | |
| Q2: Have you ever seen a blood pressure monitor being used before? | 10 | 0 | | 10 | 0 | | 9 | 0 | | 9 | 1 | |
| Q3: Have you ever used a similar device to a blood pressure monitor? | 1 | 9 | | 4 | 6 | | 3 | 6 | | 5 | 5 | |
| Q4: Did you use the instruction manual on any part of blood pressure monitor tasks? | 8 | 2 | | 10 | 0 | | 9 | 0 | | 6 | 4 | |
| Q5: Did you encounter difficulties in using the blood pressure monitor? | 2 | 8 | | 3 | 7 | | 9 | 0 | | 7 | 3 | |
| Q6: Do you think that it was easy to understand how to use the blood pressure monitor? | 10 | 0 | 0 | 5 | 0 | 5 | 3 | 3 | 3 | 7 | 2 | 1 |
| Q7: Are you confident about the output of the device? | 7 | 3 | 0 | 10 | 0 | 0 | 4 | 3 | 2 | 8 | 0 | 2 |
| Q8: Are you confident that you have completed the blood pressure monitor tasks correctly? | 8 | 1 | 1 | 9 | 0 | 1 | 8 | 1 | 0 | 10 | 0 | 0 |
| SECTION 2 – DIGITAL CAMERA | | | | | | | | | | | | |
| Q9: Have you ever used a digital camera before? | 9 | 1 | | 4 | 6 | | 7 | 2 | | 9 | 1 | |
| Q10: Have you ever used a similar device to a digital camera? | 9 | 1 | | 3 | 7 | | 7 | 2 | | 7 | 3 | |
| Q11: Did you use the instruction manual on any digital camera tasks? | 5 | 5 | | 10 | 0 | | 5 | 4 | | 5 | 5 | |
| Q12: Do you think that it was easy to understand and find the functions of the digital camera? | 8 | 0 | 2 | 3 | 5 | 2 | 6 | 1 | 2 | 7 | 0 | 3 |
| Q13: Are you confident that you have completed the digital camera tasks correctly? | 9 | 1 | 0 | 7 | 1 | 2 | 6 | 1 | 2 | 10 | 0 | 0 |

(NS = Not Sure; the grey cells means that, 'Not Sure' option was not available on those questions)

*One M/SDP did not take part in the post-questionnaire.

APPENDIX G: Summary of lay user characteristics

(‘♦’ = Less or not likely to have this characteristics, ‘✓’ = likely to have this characteristics)

| LAY USER CHARACTERISTICS | YOUNGER | OLDER | DISABLED ³⁰ |
|---|---------|-------|------------------------|
| High level of personal and/or demographic variation | ✓ | ✓ | ✓ |
| Use products reflecting their special needs or interests | ✓ | ✓ | ✓ |
| Prefer easy to use devices with specific functions | ✓ | ✓ | ✓ |
| May have little or no training | ✓ | ✓ | ✓ |
| Little or no knowledge regarding the task and/or the product | ✓ | ✓ | ✓ |
| Frequently have expectations regarding the way that products should be used | ✓ | ✓ | ✓ |
| Often rely on their prior experiences with similar products | ✓ | ✓ | ✓ |
| Limited control over the product they use due to lack of confidence | ♦ | ✓ | ✓ |
| Prior experience may mislead due to over-confidence in using technology | ✓ | ♦ | ♦ |
| Poor at identifying problems or errors | ✓ | ✓ | ✓ |
| Poor at overcoming device limitations | ♦ | ✓ | ✓ |
| May experience difficulty in dealing with unexpected situations | ♦ | ✓ | ✓ |
| Tend to adopt a trial and error approach when experiencing difficulties | ♦ | ✓ | ✓ |
| Likely to blame themselves when encountering difficulties | ♦ | ✓ | ✓ |
| Often unmotivated to use digital devices | ♦ | ✓ | ✓ |

³⁰ Includes lay users with motor, sensory and/or cognitive disabilities

| | | | |
|--|---|---|---|
| May experience difficulty in interacting with digital interfaces | ♦ | ✓ | ✓ |
| Have tendency to give up when experiencing difficulties with products | ♦ | ✓ | ✓ |
| May use the products in various environments | ✓ | ✓ | ✓ |
| Tend to follow a random, non-systematic approach when obtaining a device | ✓ | ✓ | ✓ |
| May not follow instructions manual provided | ✓ | ♦ | ✓ |
| Likely to experience difficulty in using instruction manuals | ♦ | ✓ | ✓ |
| May have difficulty in understanding specific terminology | ✓ | ✓ | ✓ |
| May experience difficulty in seeing smaller indicators, texts and buttons on the product and in the manual | ♦ | ✓ | ✓ |
| Likely to experience difficulty in understanding the interface metaphors and symbols on the product, and in the instruction manual | ♦ | ✓ | ✓ |
| Tend to follow the given steps in the manual, rather than trying to understand the logic behind them | ♦ | ✓ | ♦ |
| May experience difficulty in understanding figures presented within the information provided with the device | ♦ | ♦ | ✓ |
| May experience difficulties due to reading skills and comprehension | ♦ | ♦ | ✓ |
| Likely to have short attention spans | ♦ | ♦ | ✓ |
| May experience difficulty with hearing audio signals | ♦ | ✓ | ✓ |
| May experience difficulty due to impaired dexterity (e.g. pushing small buttons) | ♦ | ✓ | ✓ |
| May experience difficulty in performing the tasks which require using both hands | ♦ | ♦ | ✓ |
| May not be able to adopt a specific posture due to limited motor capabilities | ♦ | ♦ | ✓ |
| May not be able to use products as envisaged by designers and may need to develop alternative methods | ♦ | ♦ | ✓ |

APPENDIX H: Online questionnaire to obtain the requirements of designers when designing home use medical devices

[SURVEY PREVIEW MODE] Design for lay users – Questionnaire to designers Survey

Design for lay users – Questionnaire to designers [Exit this survey](#)

1. Brunel University

Thanks for participating in the survey. This survey is conducted as part of my PhD study at the School of Engineering and Design, Brunel University.

I am researching into the adaptation of products from professional use to lay use, specifically focusing on medical devices (i.e. medical devices used in the professional environment to home-use medical devices). My aim is to develop guidance for designers to assist them during the design process, therefore your assistance is much appreciated.

I assure you that all the information gathered from this study will be anonymised and will only be used for academic purposes. This survey is secured with SSL (Secure Sockets Layer) encryption which ensures the security of the information.

Thank you for your time.

A. Selami Cifter
School of Engineering and Design
Brunel University
<http://www.inclusivedesignresearch.org>

*** 1. How many years of experience do you have as a professional designer?**

*** 2. What was the subject of your degree? (e.g. Industrial Design and Technology BA, Design Engineering BSC, Product Design BSC, etc)**

*** 3. Do you have any previous experience in designing home-use medical devices? (e.g. blood pressure monitors, fertility test kits, etc)**

Yes

No

*** 4. Comparing 'home-use medical devices' and 'everyday consumer products', do you think there is any differences in terms of the design approach?**

Yes

No

Please briefly explain the reason:

[http://www.surveymonkey.com/..._MODE=DO_NOT_USE_THIS_LINK_FOR_COLLECTION&sm=Ax2Q41n3mHPcHFye2tOHMjEK9K5pdXgkEQ%2fLQw4HeuE%3d\[10.01.2011 16:50:19\]](http://www.surveymonkey.com/..._MODE=DO_NOT_USE_THIS_LINK_FOR_COLLECTION&sm=Ax2Q41n3mHPcHFye2tOHMjEK9K5pdXgkEQ%2fLQw4HeuE%3d[10.01.2011 16:50:19])

*** 5. Please rank the types of information regarding your requirement during the design process of a home-use medical device.**

| | Not important 1 | 2 | Average Importance 3 | 4 | Extremely Important 5 |
|--|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Medical knowledge relevant to the design project | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| User information | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Context of use of the product | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Legislations and regulations | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

If you have any other specific information requirement, please add below:

*** 6. When designing a product, what source(s) do you generally use for collecting information? (If you have been involved in the design of a home-use medical device before, please answer this question based on that experience)**

- | | |
|--|--|
| <input type="checkbox"/> The internet | <input type="checkbox"/> Observation |
| <input type="checkbox"/> Books | <input type="checkbox"/> By asking colleagues |
| <input type="checkbox"/> Magazines | <input type="checkbox"/> A toolkit |
| <input type="checkbox"/> Academical journals | <input type="checkbox"/> Intuition |
| <input type="checkbox"/> Questionnaires | <input type="checkbox"/> Consulting a specialist |
| <input type="checkbox"/> Interviews | |

Other (please specify)

*** 7. If guidance for designing home-use medical devices was available, would it be useful for you? (If your answer is no then please move to 10)**

- Yes
 No

8. Which of the following would be useful in the guidance?

- Suggestions on the design process
- Characteristics of different user groups in using home-use medical devices
- List of "Do's and "Don't's
- Overall information about regulations relevant to home use medical devices
- A checklist for evaluating the design process
- A checklist for evaluating the final product
- List of useful resources

Other (please specify)

9. Which format would you prefer the guidance to be in? (Multiple choice)

- Web based
- Booklet
- Software
- A physical toolkit

Other (please specify)

*** 10. Would you like to participate in a follow-up interview (less than an hour) where prototype of the guidance will be demonstrated?**

- Yes
- No

If you would like to participate, please leave your name and contact details below. (I will not be able to return back to you unless you do not leave your name and email address):

Thank you very much for your time!



APPENDIX I: The highlights provided in the guidance checklist for developing instruction manuals of home use medical devices for the European market

Identification of Lay Users

- When considering users, these lay user groups are included: older people, disabled people, and patients with impaired capabilities
- Target lay users' capabilities are identified
- Target lay users' requirements are identified regarding the intended purpose of the device

Documentation of the Content

- The relevant Directive has been checked about the labelling and the instructions for use requirements
- According to the classification, the device requires an accompanying instruction for use
- The relevant standards have been checked about the labelling and the instructions requirements
- Content of the instruction manual compiles with the regulatory requirements
- Content of the instruction manual reflects the intended purpose of the device
- When preparing the content, the knowledge and the training level of the potential lay users are taken into account
- Technical information level meets the expectations and requirements of the target lay users
- Brief description of the product is given
- The overview of all the elements of the device is indicated
- If applicable, the information about setting up the device is given
- The functions of the controls and indicators are clearly explained in the instruction manual
- Any warnings or precautions regarding the lifecycle of the product are clearly indicated in the instruction manual
- The information regarding the foreseeable environmental conditions which may affect the performance of the device is indicated in the instruction manual

- Indicate in the manual if the device is intended to be used in combination with other devices or equipment, or if there are any restrictions which may affect the specific performances of the devices
- Sufficient information is given to prevent production of incorrect results
- If the device is for single use, indicate this in the instruction manual
- Where appropriate the storage information is given
- Where appropriate the maintenance information is given
- Where appropriate the disposable information is given
- Where appropriate the information about troubleshooting is given

Design

- Instruction manual has a durable cover and the outlook is appealing
- The graphical symbols used conform to the Harmonised Standards
- The instruction manual includes a ‘table of contents’
- When using the instruction manual, make sure it is easy to find the relevant information
- Descriptions are easy to follow
- Graphical descriptions are clear and legible
- Text size is big enough for the potential users of the device
- Descriptions are easy to understand
- Jargon and technical terms are avoided, or kept to minimum where necessary
- The name or trade name and address of the manufacturer are included
- The CE mark is included with an accompanied identification number of the notified body responsible
- Date of issue of the latest revision is indicated

Testing

- The manual has been tested with different types of lay users
- The manual tested and evaluated with the device together
- The manual tested in the real life settings of the device
- The improvements have been made in corresponding to the users’ feedback

APPENDIX J: Summary of the Essential Requirements of the Council Directive 93/42/EEC on Medical Devices


ESSENTIAL REQUIREMENTS
The Council Directive 93/42/EEC on Medical Devices

General Requirements:

General requirements mainly cover the design and manufacturing aspects of the device in relation to the intended purpose. The device must be designed and manufactured in a way which is consistent with the purposes indicated in the definition of a 'medical device' (in Article 1, Section 2(a)), and achieve the performances* as intended by the manufacturer. The possible risks associated with the intended use must be acceptable when weighed against the benefits to the patients.

According to the Directive, intended purpose means "the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials".

The safety of the users/patients is frequently emphasised in the general requirements.




*According to the Directive, the users of the device are indicated as, lay users, professionals, disabled people or other users. Also it was highlighted that their technical knowledge, experience, education, training levels and where applicable, their medical and physical conditions should be taken into account when developing the product.

Requirements Regarding Design and Construction:

The design and construction requirements of the Directive is described under seven headings:


- **Chemical, physical and biological properties**
The requirements regarding chemical, physical and biological properties, e.g. the choice of the materials used, or possible effects of the materials, substances and gases in the environment which are in contact with the device during its normal use.
- **Infection and microbial contamination**
Such as reducing the possible risk of infection to the patients, users and third parties, or packaging systems for sterile and non-sterile products.
- **Construction and environmental properties**
Requirements regarding the risks due to the device are used in combination with other devices as a part of a system or used in the same environment with other devices. It also covers the risks of reasonably foreseeable environmental conditions such as temperature or magnetic fields.
- **Devices with a measuring function**
Involves the requirements in relation to the measuring functions, such as providing sufficient accuracy and stability, or the ergonomic principles regarding the feedback given by digital devices.
- **Protection against radiation**
Such as reducing the radiation emitted by the device, or giving visual/audible warnings of hazardous emissions.
- **Requirements for medical devices connected to or equipped with an energy source**
Requirements regarding the energy source, such as protection against electrical risks, or necessary alarm systems in order to signal any power failure.
- **Information supplied by the manufacturer**
Requirements regarding the information supplied by the manufacturer such as labelling or information for use.




Home-Use Medical Devices
guidance for designers
www.homeusemedicaldevices.com

APPENDIX K: Summary of the Essential Requirements of the Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

ESSENTIAL REQUIREMENTS
Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

| | |
|--|--|
| <p>General Requirements:</p> <p>General requirements mainly cover the design and manufacturing aspects of the device in relation to the intended purpose. The device must be designed and manufactured in a way which is consistent with the purposes indicated in the definition of an 'in vitro diagnostic medical device' (in Article 1, Section 2(b)), and achieve the performances* as intended by the manufacturer. The possible risks associated with the intended use must be acceptable when weighed against the benefits to the patients.</p> <p>According to the Directive intended purpose means "the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials".</p> <p>The safety of the users/patients is frequently emphasised in the general requirements.</p> <p> *According to the Directive, it is highlighted that the device must achieve the performances stated by the manufacturer, particularly in terms of analytical sensitivity, diagnostic sensitivity, analytic specificity, accuracy, repeatability, reproducibility, including control of known relevant interference, and limits of detection.</p> | <p>Design and Manufacturing Requirements:</p> <p>The design and manufacturing requirements of the Directive are described under eight headings:</p> <ul style="list-style-type: none">• Chemical and physical properties Covers the requirements against chemical and physical detrimental effects which may influence the performance of the device, e.g. chemical incompatibility between the materials used and the specimens, and possible risks due to the physical property of the device such as leakage.• Infection and microbial contamination Such as, reducing the possible risk of infection to the patients, users and third parties, or packaging systems for sterile and non-sterile products.• Manufacturing and environmental properties Requirements regarding the risks may be caused by manufacturing or environmental properties, such as removing the risk of injury due to the physical features of the device, and reducing the possible risks of reasonably foreseeable environmental conditions such as temperature or magnetic fields.• Devices which are instruments or apparatus with a measuring function Involves the requirements regarding the measuring functions, such as providing sufficient accuracy and stability.• Protection against radiation Such as minimising the radiation emitted by the device, or giving visual/audible warnings of hazardous emissions.• Requirements for medical devices connected to or equipped with an energy source Requirements regarding the energy source, such as avoiding the risk of accidental electric shocks due to a fault condition, or protection against mechanical and thermal risks.• Requirements for devices for self-testing Requirements in particular for the self-testing devices, where the users are lay users. For example ensuring the device is easy to use for the intended user.)• Information supplied by the manufacturer Requirements regarding the information supplied by the manufacturer such as labelling or information for use. |
|--|--|



Home-Use Medical Devices
guidance for designers
www.homeusemedicaldevices.com

Appendix L: Summary of the Essential Requirements relevant to instruction manuals of home use medical devices identified in MDD and IVDMD

This document presents you a summary of the Essential Requirements relevant to instruction manuals of home use medical devices for both Directives. **PLEASE REFER TO THE ORIGINAL DIRECTIVES FOR THE FULL LIST, AND ALSO CHECK THE LABELLING REQUIREMENTS.**

| MDD 93/42/EEC (ANNEX I, 13.6) | IVDMD 98/79/EC ANNEX I, 8.7) |
|--|---|
| <p>(b) The performances referred to in Section 3¹ and any undesirable side effects.</p> <p>N/A</p> <p>N/A</p> <p>N/A</p> <p>(c) If the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination.</p> <p>(d) All the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times.</p> <p>(f) Information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment.</p> <p>(g) The necessary instructions in the event of damage to the sterile packaging and, ...</p> | <p>(d) The performances referred to in section 3 of part A².</p> <p>(g) A detailed description of the procedure to be followed in using the device.</p> <p>(k) Information appropriate to users on: -internal quality control including specific validation procedure -the traceability of the calibration of the device</p> <p>(l) The reference intervals for the quantities being determined, including a description of the appropriate reference population.</p> <p>(m) If the device must be used in combination with or installed with connection to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe and proper combination.</p> <p>(n) All the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely; information about safe waste disposal.</p> <p>N/A</p> <p>(p) The necessary instructions in the event of damage to the protective packaging and, ...</p> |


¹ According to Section 3 in Annex I of the MDD, "the devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions" referred to in the definition of 'medical device' in Article 1 (2) (a).

² According to the part A section 3 in Annex I of the IVDMD, "the devices must be designed and manufactured in such a way that they are suitable for the purpose" referred to in the definition of 'in vitro diagnostic medical device' in Article 1 (2) (b). A number of performance types are also identified in the part A section 3.

| | |
|--|---|
| <p>(h) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging, and ... any restriction on the number of reuses.</p> <p>If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used.</p> <p>This point is mentioned in 13.6 (l) in ANNEX I, and must be included in the instructions for use in order to allow the staff to brief the patient on any contra-indications and any precautions to be taken.</p> <p>N/A</p> <p>N/A</p> <p>This point is mentioned in 13.6 (q) in ANNEX I, and must be included in the instructions for use in order to allow the staff to brief the patient on any contra-indications and any precautions to be taken.</p> | <p>(q) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging, and ... any restriction on the number of reuses.</p> <p>(r) Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.</p> <p>(s) Precautions to be taken against any special, unusual risks related to the use or disposal of the device including special protective measures; where the device includes substances of human or animal origin, attention must be drawn to their potential infectious nature.</p> <p>(t) Specifications for devices for self-testing: -the results need to be expressed and presented in a way that is readily understood by a lay person; information needs to be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate results) and on the possibility of false positive or false negative results, -specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device, -the information provided must include a statement clearly directing that the user should not take any decision of medical relevance without first consulting his or her medical practitioner, -the information must also specify that when the device for self-testing is used for the monitoring of an existing disease, the patient should only adapt the treatment if he has received the appropriate training to do so.</p> <p>(u) Date of issue or latest revision of the instructions for use.</p> |
| <p align="center">(Prepared by Abdusselam Selami Cifter, 2010, http://www.homeusemedicaldevices.com)</p> | |

APPENDIX M: Online-questionnaire for the designers' initial evaluation of the guidance website

[SURVEY PREVIEW MODE] Evaluation of "www.homeusemedicaldevices.com" Survey



Home-Use Medical Devices guidance for designers

EVALUATION SURVEY

[Exit this survey](#)

Evaluation of "www.homeusemedicaldevices.com"

1. Thank you very much!

Thank you very much for checking the website and kindly completing this questionnaire. This questionnaire will help me to make further improvements.

If you are based in the UK, I would also like to hold a short interview (a maximum of 45 minutes) with you, at your convenience, to hear your thoughts about the website in more detail. If you would like to participate please leave your email address at the end of the questionnaire.

*** 1. Your name:**

*** 2. Are you a designer?**

Yes

No

*** 3. Do you have any previous experience in designing home-use medical devices? (e.g. blood pressure monitors, fertility test kits, etc)**

I have experience

I have very little experience

I do not have any experience

*** 4. Please rate the following features of the website:**

| | 1 Very poor | 2 | 3 | 4 | 5 Excellent |
|---|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Relevance of the information | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Content of the 'Home Use Medical Devices' section | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Content of the 'Design Considerations' section | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Content of the 'Regulations' section | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Content of the 'Useful Links' section | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Content of the 'Documents' section | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Overall content of the website | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| How easy is it to use the website? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

*** 5. Please rate the following features of the website**

| | 1 Totally disagree | 2 | 3 | 4 | 5 Totally agree |
|---|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| The website would be useful for designers when designing home use medical devices | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| The website would only be useful for novice designers | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| The level of detail is sufficient | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| The information is up to date | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| The information is presented in an effective way | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

6. I would really much like to hear your insights about the website for further improvements. If you are a designer based in the UK and would like to take part in the follow up interview session then please leave me your contact details below. The interviews will take a maximum of 30 minutes and will be arranged at your convenience.

Submit

[http://www.surveymonkey.com/s.aspx?PREVIEW_MODE=DO_NOT_USE_THIS_LINK_FOR_COLLECTION&sm=Wk8EBWmf3xy7cPXXajGM4XyIlnBiCh8T3%2br1M9HWTQ8%3d\[10.01.2011 17:00:16\]](http://www.surveymonkey.com/s.aspx?PREVIEW_MODE=DO_NOT_USE_THIS_LINK_FOR_COLLECTION&sm=Wk8EBWmf3xy7cPXXajGM4XyIlnBiCh8T3%2br1M9HWTQ8%3d[10.01.2011 17:00:16])

APPENDIX N: Interview questions for the designers' evaluation of the guidance website

Name of the Participant:

Date:

INTERVIEW QUESTIONS:

- First of all I would be interested to hear your general observations about the website.
- (Depending on the answer) Why did you find the website (not) useful for designers?
- What features of the website did you find the most useful, and why?
- What features of the website did you find the least useful, and why?
- Do you think any of the information is unnecessary or irrelevant for designers, and why?
- What kind of information is missing in the website?
- What other features would you like to see in the website?
- What can be improved?
- Do you know any of other information source for designers to assist them when designing home use medical devices?

APPENDIX O: Answers given by the designers to the interview questions during the evaluation study

| Level of Experience | Participant Code |
|-------------------------------|-----------------------|
| I have experience | D4, D6, D8 |
| I have very little experience | D5, D7, D10, D11, D12 |
| I do not have any experience | D1, D2, D3, D9 |

| General Observations about the Website | Participant Code |
|--|---|
| Positive observations | D1, D2, D3, D5, D6, D7, D8, D9, D10, D11, D12 |
| Has an inappropriate visual style | D4, D5, D6, D7, D8, D9, D11, D12 |
| Content is good | D3, D5, D7, D8, D9, D10, D12 |
| A good starting point for a HUMD design project | D1, D5, D7, D9 |
| Too much information was presented | D2, D4, D5 |
| Website can work as a reference point | D1, D5 |
| Too many words included | D3, D11 |
| Some of the information was very basic and introductory | D4, D11 |
| Generality should be around medical conditions not users | D4 |
| As a portal it is good | D4 |
| The objective of the website was not very clear | D8 |
| Would the Website be Useful for Designers? | |
| The website would be useful for designers | D1, D2, D3, D4, D5, D6, D7, D8, D9, D10, D11, D12 |
| The current website is more useful for novice designers | D1, D3, D4, D5, D6, D7, D9, D11 |
| The current website is useful for experienced designers | D2, D6, D7, D8, D10 |
| Most Useful | |
| Regulations | D1, D2, D4, D5, D6, D7, D9, D11, D12 |
| Useful links | D3, D4, D5, D6, D9, D11, D12 |
| Design Considerations | D1, D2, D3, D5, D7, D10 |
| Forum | D2, D4, D7, D8, D9, D10 |

| | |
|---|--------------------------|
| Examples | D1, D2, D3 |
| Documents | D3, D6, D9 |
| Lay users | D9, D11 |
| Home use medical devices | D2 |
| Do's and Don'ts | D3 |
| References made | D4 |
| The sections about instruction manual development | D6 |
| The checklist for instruction manuals | D8 |
| Context of use | D9 |
| Least Useful | |
| Academic process models | D3, D4, D8, D12 |
| What designers think | D2, D9 |
| Home use medical devices | D6, D10 |
| For novice designers everything was useful | D1 |
| Useful links | D7 |
| Design Considerations | D11 |
| Unnecessary – Irrelevant | |
| Cannot see anything unnecessary or irrelevant | D1, D6, D7, D9, D10, D12 |
| Bullet points were unnecessary | D3, D5, D10, D11 |
| What designers think | D2 |
| Website does not need a home page | D3 |
| Not necessary to mention that the website was the outcome of a PhD study | D3 |
| Having a logo for the website was unnecessary | D5 |
| Introductory points were unnecessary | D11 |
| The regulations which are not relevant to HUMD were unnecessary | D8 |
| Missing Information | |
| Very specific information for experienced designers | D4, D5, D8, D9, D11 |
| I do not know | 2 |
| US regulations | D1, D9 |
| Attitudes of lay users towards their condition | D4, D6 |
| Information about how to carry out a trial | D6, D8 |
| Other methodologies for designing home use medical devices | D2 |

| | |
|--|---|
| Time scale | D6 |
| What happens after the design phase | D6 |
| Information about how to protect your ideas | D6 |
| Other Features | |
| Case studies | D1, D2, D3, D5, D6, D10 |
| Checklist for the design process of HUMD | D2, D8 |
| Search bar | D2, D5 |
| Links to other existing products | D4, D9 |
| Classification calculator | D6, D8 |
| Others' contribution | D7, D8 |
| Regular updates | D7, D10 |
| Customised content | D2 |
| Videos | D3 |
| Interviews | D3 |
| Material information | D4 |
| Good examples of instruction manuals of HUMD | D9 |
| Site content map | D10 |
| News letters or email alerts | D10 |
| Linking designers to designers/companies | D3 |
| Improvement | |
| Design should be improved | D1, D2, D3, D4, D5, D7, D8, D9, D10, D11, D12 |
| Presentation of the information should be improved | D2, D3, D4, D5, D6, D7, D8, D9, D10, D11, D12 |
| Some information was very obvious or simple | D3, D4, D9, D11 |
| More examples could be added | D2, D9, D12 |
| Exclamation bullet point gives the wrong impression | D5, D6, D10 |
| Comic Sans font should not be used | D5, D6, D11 |
| A step-by-step flow path is required for novice designers | D2, D8, D12 |
| Short descriptions for the useful links and documents | D7, D8 |
| The information about the bullet point could be given in every page | D2 |
| Forum for could be developed for both users and designers | D7 |
| Other sources | |
| I have not seen any | D1, D2, D3, D4, D5, D6, D7, |

| | |
|--|-----------------------|
| | D8, D9, D10, D11, D12 |
| Not a direct source but maybe NPSA guidelines | D11 |

APPENDIX P: List of Publications

Cifter, A. S., & Dong, H. (2009). Focusing on Users. *Include 09 Proceedings (Poster Presentation)*. London: Helen Hamlyn Centre, Royal College of Art, 6-8 April

Cifter, A. S., & Dong, H. (2009). Designing Medical Devices for Lay Use. *Proceedings of ReSCon 09*. (pp. 129-131) London: School of Engineering and Design, Brunel University, 22-24 June

Cifter, A. S., & Dong, H. (2009). User Characteristics Professional VS Lay Users. *ReSCon 09 (Poster Presentation)*. London: School of Engineering and Design, Brunel University, 22-24 June

Cifter, A. S., & Dong, H. (2009). Understanding User Characteristics. *1st Conference of the Brunel Institute of Ageing Study (Poster Presentation)*. London: Brunel University, 22 June

Cifter, A. S. (2009). Doctoral Consortium. *DESRIST 09*. Philadelphia: Penn State University, 6-8 June

Cifter, A. S., & Dong, H. (2010). Lay User Characteristics Reflected by Their Interaction with a Digital Camera and a Blood Pressure Monitor. *Proceedings of the 5th Cambridge Workshop on Universal Access and Assistive Technology (Poster Presentation)*. (pp. 47-53). Cambridge: Fitzwilliam College, Cambridge University, 22-25 March.

Cifter, A. S., & Dong, H. (2010). Instruction Manual Usage: A Comparison of Younger People, Older People and People with Cognitive Disabilities. In Winter, R., Zhao, J. L., Aier, S., *LNCS 6105 Global Perspectives on Design Science Research: Proceedings of the 5th International DESRIST Conference*. (pp. 410-225). New York: Springer –Verlag Heidelberg.

Cifter, A. S., & Dong, H. (2010). How Users Differ in Using Instruction Manuals. *Proceedings of ReSCon 10*. (pp. 68-71). London: School of Engineering and Design, Brunel University, 21-23 June

Cifter, A. S., & Dong, H. (2010). Older People Friendly User Test Methods. *British Society of Gerontology 39th Annual Conference: Identities, Care and Everyday Life*. (pp. 73). London: Brunel University, 6-8 July

Cifter, A. S., Dong, H., Barnett, J., Qin, S. F. (2011). Are Home Use Medical Devices Easy to Use?. *Proceedings of Ergonomics and Human Factors 2011*. Lincolnshire: Stoke Rochford Hall, 12-14 April

Cifter, A. S., & Dong, H. Developing Guidance on Instruction Manuals for Home Use Medical Devices (Under review in *Applied Ergonomics*)