THE VALUE OF DESIGN RESEARCH

11TH EUROPEAN ACADEMY OF DESIGN CONFERENCE

APRIL 22-24 2015

PARIS DESCARTES UNIVERSITY
INSTITUTE OF PSYCHOLOGY

BOULOGNE BILLANCOURT
FRANCE

CONFERENCE ORGANIZERS:

PARIS DESCARTES UNIVERSITY
PARIS SORBONNE UNIVERSITY
PARIS COLLEGE OF ART
ISTEC PARIS

# A HEURISTIC EVALUATION OF THREE BLOOD PRESSURE MONITORS TO IDENTIFY THE POSSIBLE EFFECTS OF DESIGN INCONSISTENCIES ON LAY USER SAFETY: A METHOD SUGGESTION

**Abdusselam Selami Cifter** Mimar Sinan Fine Arts University, Istanbul, Turkey selami.cifter@msgsu.edu..tr

**Merve Ozyurt** Mimar Sinan Fine Arts University, Istanbul, Turkey merve.ozyurt@msgsu.edu.tr

**Yener Altiparmakogullari** Mimar Sinan Fine Arts University, Istanbul, Turkey yener@msgsu.edu.tr

## ABSTRACT

*Home healthcare technologies are today's one of the important trends of the healthcare industry which leads to a vast increase of medical devices in consumer market. In order to ensure the safe use of home use medical devices by lay people, the products themselves should lead users for their correct way of use by providing an intuitive design which is consistent with the users' correct mental model of the product. However the variation and inconsistency in the design of HUMDs in the consumer market, even within the same product type but from different brands, make it difficult for users to formulate the correct mental model and may lead to unexpected usability problems. In this research, a method which incorporates hierarchical task analysis into heuristic evaluation method is developed and tested with three different brands of wrist model blood pressure monitors by three evaluators. The method enabled the identification of invisible design inconsistencies and possible usability problems for lay users; also provided a holistic and graphical representation of the usability case for each device. The research also sought a set of heuristics, which can be used specifically for the usability inspection of HUMDs in the early phases of a design process. The results are presented and discussed in this paper.*

*Keywords: Home use medical devices, heuristic evaluation, hierarchical task analysis, usability testing*

## 1 INTRODUCTION

Home healthcare technologies are today's one of the important trends of the healthcare industry (FDA, 2012; Herman & Devey, 2011; Bitterman, 2011) which results in a vast increase of medical devices in consumer market. Such technologies enable the provision of health care services away from hospitals and provide a better life quality for patients (Thomson et al., 2013). These products are frequently called 'home use medical devices' (HUMD). One of the interesting facts about HUMDs is that although they are classified as medical devices, are used by lay people who vary significantly in terms of their needs (Cifter, 2011). In many cases, HUMDs are used by people who have deteriorated capabilities, lack motivation or have certain types of chronic illnesses.

The design of a medical device itself has an enormous effect on patient safety and its role should be well understood by all the stakeholder in the healthcare industry; from users to regulators of medical devices (Fairbanks & Wears, 2008). Design is even a more important factor for HUMDs, because their users may have a limited understanding regarding the device that they use and their own medical condition as well. Moreover, when compared with medical devices for clinical use, more environmental challenges need to be taken into account by designers of HUMDs, because these products are often used in transitory environments such as restaurants, schools or other public areas (FDA, 2010;

FDA, 2011). For these reasons, designing HUMDs share the characteristics of designing both the consumer products for general use and medical devices which are highly regulated and safety critical (Gupta, 2007; Cifter, 2011). Therefore; in order to ensure safety of lay users, HUMDs themselves should lead lay users for their correct way of use by providing an intuitive design, which is consistent with the users' correct mental model [Norman's (2002) concept of 'mental model' was taken as basis] of the product.. At the same time, they should have an aesthetically pleasing and unobtrusive design to meet the emotional needs of lay users (Sultan & Mohan, 2009; Gardner-Bonneau, 2011).

As suggested by Press & Cooper, 2003, designers require a thorough understanding of the context in which they are designing. The HUMDs market is highly competitive which is evident from the number of devices available in the consumer market. The market covers a variety of devices such as blood pressure monitors, blood sugar monitors, infant thermometers, nebulisers, epinephrine pens and even automated external defibrillators. However, the variation and inconsistency in their designs, even within the same product type but from different brands, make it difficult for patients to choose a device. These products also frequently offer different unique functions to get consumers' attention. In some cases pharmacists are also required to take an active role in assisting users to choose a device due to this variety (DiDonato & Graham; 2013), which puts an extra pressure and responsibility over them. Moreover, if the user has a previous experience with a different device, such inconsistencies in design may hinder users' ability to formulate the correct mental model with the new device and lead them to unexpected usability problems. In certain cases these usability problems are likely to compromise the well being of their users; therefore, designers need to be aware of how the other similar HUMDs in the market function too. Accordingly, this is what many designers tend to do when they start a new design project; i.e. investigating the available competitor products and make comparisons between their unique functions. This is a often considered to be a cheap and time efficient method in the early phase of a design process in order to develop an understanding of the context in which they are designing. Adoption of certain usability testing techniques may help designers of HUMDs to better structure and understand the existing design shortcomings and increase their efficiency.

In this paper, a combination of hierarchical task analysis (HTA) and heuristic evaluation (HE) methods is suggested for designers' use, which is also tested on three wrist-cuff blood pressure monitors to identify their usability problems. This research also presents a case study on the identification of usability problems derived from the design inconsistencies between similar products but from different brands in the market of HUMDs, which may result in invisible usability problems due to negative transfer of previous experience.

## 2 STUDY METHOD

BPMs are chosen as the product type, because they are one of the most commonly used, non-invasive HUMDs around the world. Despite the fact that these devices are frequently used by older people, the results of a research carried out in the UK with 20 participants (10 younger and 10 older participants) suggests that in fact only one older participant was able to use the device correctly as intended by the manufacturer (Cifter, 2010).

THE VALUE OF DESIGN RESEARCH

11TH EUROPEAN ACADEMY OF DESIGN CONFERENCE

APRIL 22-24 2015

PARIS DESCARTES UNIVERSITY
INSTITUTE OF PSYCHOLOGY

BOULOGNE BILLANCOURT
FRANCE

CONFERENCE ORGANIZERS:

PARIS DESCARTES UNIVERSITY
PARIS SORBONNE UNIVERSITY
PARIS COLLEGE OF ART
ISTEC PARIS



During the sampling of the devices, the aim was to include different popular brands from the HUMDs market in Turkey. All the BPM are chosen as wrist-cuff type, and in terms of their outer appearance they looked very similar (Figure 1). This research focuses only on their primary function of measuring blood pressure. Although all the devices also offer additional functions (such as setting time or saving the measurements to the memory), these functions are excluded


and not focussed in this research.

*Figure 1: BPMs which are used in this research*

### 2.1 HIERARCHICAL TASK ANALYSIS

HTA is a commonly used task analysis method which involves decomposition of a defined goal into tasks and subtasks in an effort to present their complex hierarchical organisation (Faulkner, 2000; Wickens et al., 2004; Stanton et al. 2005). It presents the complete task structure to the researcher in a holistic way (Chung et al., 2003) and for this reason it is often used by designers and usability engineers (Faulkner, 2000). “The output of HTA provides a comprehensive description of the task…” and allows further human factors analysis such as error analysis or interface design (Stanton et al., 2005: pp. 50]. Such task analysis methods represent a graphical representation of the case and provides means for expressing the problem (Clarkson et al., 2007).

In this research, the holistic HTA diagrams enabled the researcher to focus on the hidden differences of the task structures for taking a blood pressure measurement of three very similar looking BPMs. Therefore, the task goal for the HTA is identified as “taking a blood pressure measurement”. The task structure is investigated from the time when the lay user takes the device out of its protective case to measure his/her BP, and until puts the device back to its protective case. The information about each product’s way of use is investigated from its users’ manual accompanied with the device.

### 2.2 HEURISTIC EVALUATION

HE is a method frequently used by usability engineers. This method “involves having one or more usability specialists individually examine the interface and judge its compliance with recognized usability principles” (Winters & Story, 2007: pp. 460). It is considered as a cheap and quick method which enables discovering and the comparison of problematic aspects of user interfaces (BSI, 2008).

In this research, firstly the identification of heuristic which are applicable for evaluating HUMDs, was a requirement for HE; and this information was sought from the relevant literature. Although this method derives its origins from usability of interface design, literature suggests its previous application on medical device design (Zhang et al., 2003; Ginsburg, 2005). In their study, Zhang et al. (2013), identified 14 heuristics to evaluate the usability of medical devices. For this purpose they combined the ten heuristics by Neilsen (1994) and the eight golden rules by Shneiderman (1998), which mainly focus on user interface designs. Since this study focuses particularly on HUMDs, we also included certain important principles (based on the purpose of this research) of the ten design considerations identified by Gardner-Bonneau (2011) for home healthcare products. In total, 20 heuristics are identified in this phase.

Afterwards, we evaluated these heuristics with the seven principles of universal design (UD); because, as suggested by Wiklund & Wilcox (2005), HUMDs are required to be designed inclusively due to the high variation of their users. UD principles are also previously used by Afacan & Erbug (2009) as a set heuristics in an interdisciplinary study to evaluate universal building design. Moreover, the applicability of these principles for medical device design is investigated by Story (2007), and their importance is emphasized due to the extreme diversity of users in today’s medical device market.

Therefore; in this research, we allocated the previously identified 20 heuristics under the seven principles of UD (The Center for Universal Design, 1997) in order to see if they sufficiently cover all the various aspects of UD. However it was found that, none of these 20 heuristics cover “Low physical effort” and “Size and space for approach and use”. For this reason, the guidelines identified by The Center of Universal Design for each UD principle are also included as heuristics to complement the missing aspects of each principle. Nevertheless, the 20 heuristics identified from Nielsen (1994), Shneiderman (1998) and Gardner-Bonneau (2011) enriched the coverage of UD principles for HUMDs. In total 41 heuristics are identified (Table 1). Although all these heuristics are not applicable to every HUMD, one of the aims of this research is to identify a broad range of heuristics for evaluating HUMDs in general; so that designers and researcher could also use these heuristics in their works.

| UD PRINCIPLES | CATEGORIZED HEURISTICS |
|---|---|
| EQUITABLE USE | • Provide the same means of use for everyone<br>• Ensure that the product is equally safe, private and secure for everyone<br>• Minimize memory load<br>• Provide an aesthetic and unobtrusive design<br>• Avoid stigmatizing users |
| FLEXIBILITY IN USE | • Provide adjustable features for diverse users<br>• Support efficiency by providing flexibility in use<br>• Consider portability of the device (if applicable)<br>• Ensure adaptability of the product to user's pace<br>• Facilitate user's accuracy and precision |
| SIMPLE AND INTUITIVE USE | • Support learnability and intuitiveness<br>• Eliminate unnecessary complexity<br>• Consider a wide range of literacy and language skills<br>• Ensure consistency of functional features<br>• Assure the match between system and world<br>• Ensure that users are in control<br>• Make system state visible<br>• Provide clear closures in tasks |
| PERCEPTIBLE INFORMATION | • Consider different modes of information<br>• Consider users' sensory limitations<br>• Provide a minimalist design<br>• Use users' language<br>• Provide informative feedback<br>• Provide help when needed<br>• Provide good error messages<br>• Maximize legibility of essential information |
| TOLERANCE FOR ERROR | • Prevent error before occuring<br>• Protect users from unintended misuses<br>• Support conscious actions that require vigilance<br>• Provide necessary warnings<br>• Arrange elements in a way to minimize hazards or errors<br>• Ensure that the device is durable<br>• Provide help and support for recovering problems<br>• Ensure the actions are reversible |
| LOW PHYSICAL EFFORT | • Maintain a neutral body position<br>• Ensure that the required operating forces reasonable<br>• Minimise repetitive actions<br>• Minimise sustained physical effort |
| SIZE AND SPACE FOR APPROACH AND USE | • Provide a clear line of sight to important elements for any seated or standing user<br>• Make sure that all components are comfortable to reach for any seated or standing user<br>• Provide adequate space for the use of assistive devices or personal assistance<br>• Accomodate variations in hand and grip sizes |

*Table 1 - Heuristics identified for HUMDs*

### 2.3 EVALUATION PROCEDURE

This research is carried out in three inter-related parts. In the first part, the task structures of the three selected BPMs (i.e., OMRON RS3, Braun TrueScan Plus, Medisana HGV and these three devices are randomly coded as BPM 1, BPM 2 and BPM 3 in this paper) are examined by the main researcher. For this purpose, firstly a cognitive walkthrough method is used. This method involves “a structured review of user requirements for the performance of predefined tasks” (EN 62366, 2008; pp. 55). Afterwards the task structures of the three devices are generated by using HTA and compared with each other in order to identify any operational differences and inconsistencies. Major differences are highlighted in the tasks and subtasks with a red outline on the HTA diagrams.

Secondly a HE is conducted in order to evaluate the three devices’ potential usability problems against the heuristics which are categorized under the UD principles. As suggested by Zhang et al. (2003), in order to capture 60-70% of the usability problems, 3-5 evaluators are needed. In this research, 3 evaluators were involved; all having a major degree in industrial design and a postgraduate degree on a human centred design related subject. Prior to their participation, they were also introduced and trained regarding HE method by a pilot study and the relevant literature. The evaluators evaluated the products separately and identified all the possible usability problems. During the HE, the same task was considered with the HTA; i.e. “taking a blood pressure measurement”.

In the third part, all the usability problems identified by the three evaluators were added all together in order to formulate a complete list for each device. In this phase, rather than each researcher evaluating the severity rating of the usability problems by his/her own, this procedure was done all together in a group discussion. Afterwards, a workshop was organised with all the evaluators’ attendance to decide on the heuristic violations for each usability problem. In order to facilitate and stimulate the discussion during the workshop, seven cards were prepared representing one for each UD principle, which also writes all the relevant heuristics inside. Each of these cards was also coded with a different colour and was accompanied by the same colour of stickers. The previously prepared HTA diagrams for all the devices were also present. Figure 2 shows the tools used during the workshop.

*Figure 2 - Tools used during the workshop*

## 3 RESULTS

In order to obtain accurate readings, the significance of the correct use of the devices are emphasised in the users' manuals of all the three BPMs. Figure 3 shows the task structures of the products used in this research. Although seven main tasks and their subtasks are required for all the three BPMs to achieve the goal, certain major and minor differences were identified in their subtasks and manner of use. To measure your BP, the necessary seven main tasks for all the three devices are: (1) Take the device out of its protective box; (2) Attach the device to your wrist; (3) Measure your blood pressure; (4) See the results; (5) Turn the device off; (6) Remove the device from your wrist; (7) Put the device away.

Some of the differences between the devices in their manner of use are found to be major, because these are directly relevant to the devices' performance and accuracy of the measurement. As highlighted with red colour in Figure 3, the differences are mainly observed in the second and the third tasks and their subtasks, in which the device performs its main function of measuring BP. Main differences are identified in: (1) the application of the cuff over the wrist, (2) position of the body/arm during the measurement and (3) the guidance/feedback systems of the devices. However, as suggested by Khoshdel et al. (2013); when using wrist-cuff blood pressure monitors, the body/arm position during the measurement is of utmost importance and may influence the accuracy of the measurement. "Although published recommendations insist that the wrist should be at heart level during measurement, there is no agreement on arm position" (Khoshdel et al., 2013: pp. 120). It is found that the intended position of the body during the measurement (which are indicated in the users' manuals of the devices) depends on the way of the device applied on the wrist and the limb position to take the device to the level of heart. With respect to the correct arm and body position during the measurement, it was found that this information varies for each device. This is considered to be an invisible usability problem; because, the users are likely to negatively transfer their previous experience due to the differences in the manner of use among different brands of BPMs, which may result in unintended misuses.

### 3.1 RESULTS OF THE HEURISTIC EVALUATION

The total numbers of possible usability problems for three BPMs identified by the three evaluators are shown in Figure 4. As can be seen from the figure, most of the usability problems are found in Task 2 and Task 3. These two tasks accounts for 69%, 73% and 63% of the total problems, respectively for BPM 1, BPM 2, and BPM 3. The highest number of usability problems is identified with BPM 1.

The evaluators discussed the severity rating of each usability problem and rated from 0 to 4 (0: cosmetic problem, 4: violation of lay user safety). The results are shown in Figure 5 for each device. For these three BPMs, none of the problems were rated as "4" which stands for "violation of lay user safety". Most of the problems are considered to be "minor" or "troublesome". However, a number of "major problems" are also identified for each device; these problems are the ones which are likely to affect the accuracy of the devices during the

11TH EUROPEAN ACADEMY OF DESIGN CONFERENCE

APRIL 22-24 2015

PARIS DESCARTES UNIVERSITY
INSTITUTE OF PSYCHOLOGY

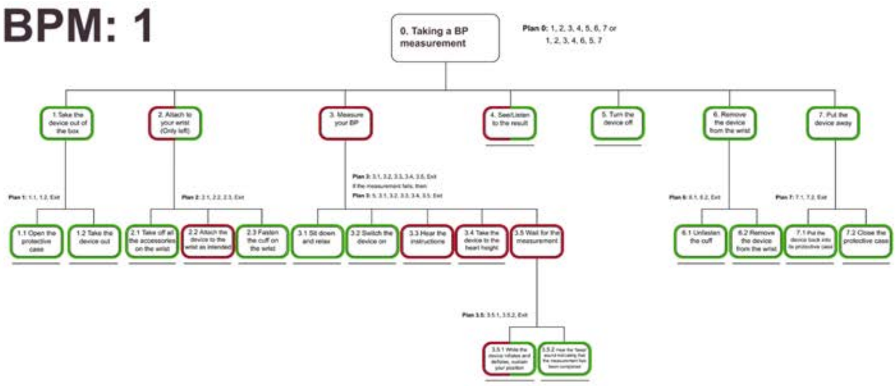
BOULOGNE BILLANCOURT
FRANCE

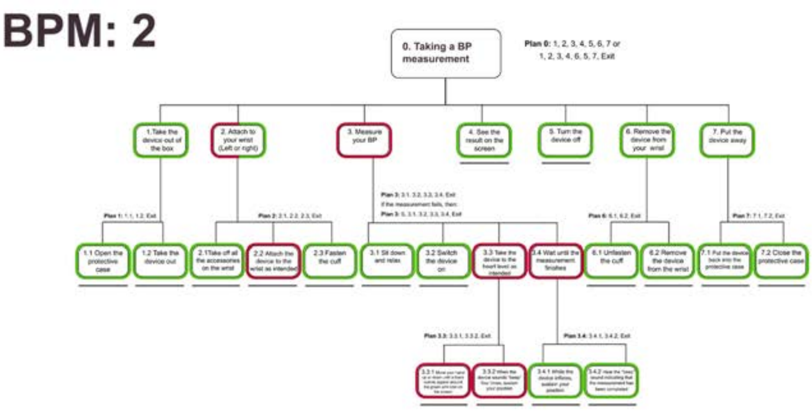
CONFERENCE ORGANIZERS:

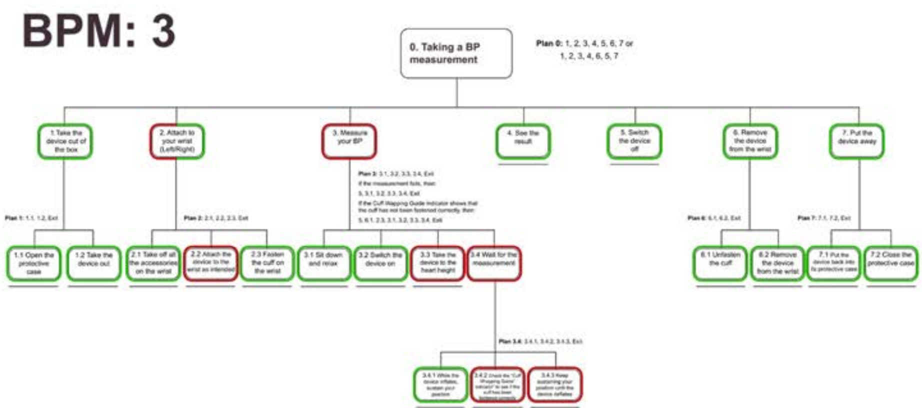
PARIS DESCARTES UNIVERSITY
PARIS SORBONNE UNIVERSITY
PARIS COLLEGE OF ART
ISTEC PARIS

measurement or compromise the devices' robustness.

For instance, one of the devices starts working and inflates unintentionally inside of its protective case when held tightly in hand; or another device requires to be attached to the wrist in an unintuitive position.



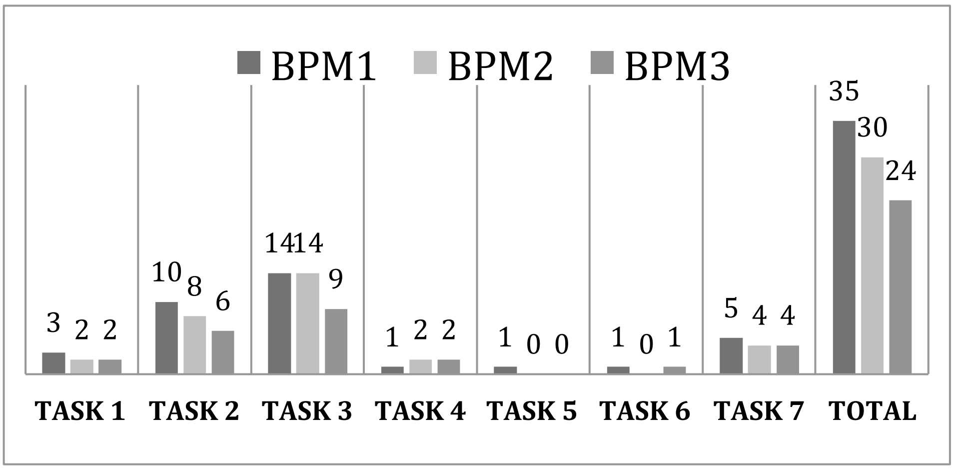



*Figure 3 – HTAs of the three selected BPMs*

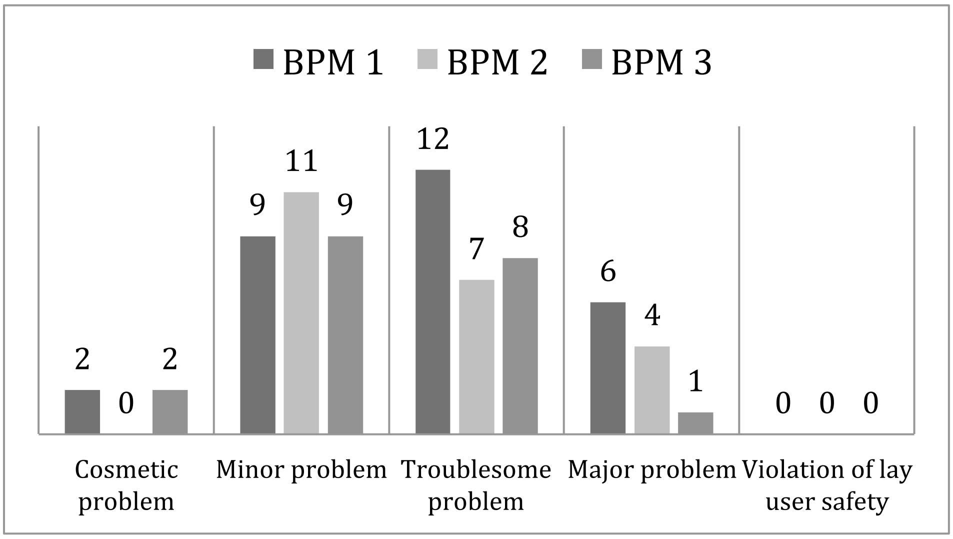
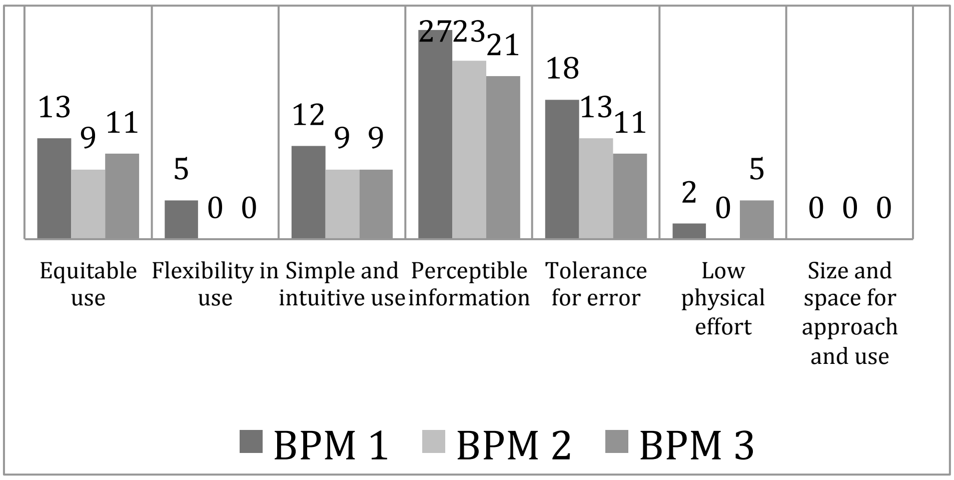



*Figure 4 - Number of possible usability problems identified for each task*

*Figure 5 - Severity ratings for the problems identified for all the devices*

*Figure 6 - The numbers of heuristic violations of each UD principle category*




### 3.2 RESULTS OF THE WORKSHOP

During the workshop the three evaluators discussed on which of the usability problems violates which heuristic or heuristics. As mentioned before, in order to facilitate the discussion, all the heuristics are categorized under the seven UD principles, and a separate card was prepared for each principle with a colour code (Figure 2). Based on the consensus about the violation, a round sticker having the same colour with the relevant principle (or principles) is applied on the HTA diagram of the device under the task where the usability problem was considered to possibly occur. If the severity rating of the usability problem was rated as 2 and over, then this information was also indicated on the middle of the coloured stickers.

The numbers of heuristic violations identified for each UD principle category and device are shown in Figure 6. The most violated principle is “Perceptible information” for all the devices. In this category, the violations are most pertinent to the heuristics of “Consider user’s sensory limitations”, “Maximize legibility of essential information” and “Provide informative feedback”. An instance of a violation is the very low contrast level of the texts used over the buttons of BPM 1.

On the other hand, when these violations are further examined inconjunction with their severity ratings of the associated usability problem, the case looks different. Table 2 presents this information with the percentages of the severity ratings for each UD principle category. As can be seen from the results, although “Perceptible information” has the highest numbers of violations for all the devices, the number of major problems in this category is reasonably low when compared with the other categories. Having said that, the category of “Tolerance for error” has the highest numbers of major problems for both BPM 1 and BPM 2. An example of a major problem in this category is that BPM 1 can only be used on left wrist although other two devices can take a measurement from both left and right wrists; however there is no warning on the device to prevent the possible misuse of the users. Another example is that when the protective case of the BPM 2 is turned upside down while the device is inside, its lid does not carry the weight of the device and result in its drop on the floor.

No heuristic violations are identified for the principle "Size and space for approach and use" on neither devices. However the reason behind this is considered to be the type of HUMD used in this study.

| UD PRINCIPLES | SEVERITY | BPM 1 | % | BPM 2 | % | BPM 3 | % |
|---|---|---|---|---|---|---|---|
| **Equitable use** | Major | 3 | **23** | 1 | **11** | 1 | **9** |
| | Troublesome | 4 | **31** | 3 | **33** | 4 | **36** |
| | Others | 6 | **46** | 5 | **56** | 6 | **55** |
| **Flexibility in use** | Major | 3 | **60** | 0 | **0** | 0 | **0** |
| | Troublesome | 0 | **0** | 0 | **0** | 0 | **0** |
| | Others | 2 | **40** | 0 | **0** | 0 | **0** |
| **Simple and intuitive use** | Major | 2 | **17** | 3 | **33** | 0 | **0** |
| | Troublesome | 6 | **50** | 4 | **45** | 1 | **11** |
| | Others | 4 | **33** | 2 | **22** | 8 | **89** |
| **Perceptible information** | Major | 1 | **4** | 2 | **9** | 0 | **0** |
| | Troublesome | 14 | **52** | 9 | **39** | 3 | **14** |
| | Others | 12 | **44** | 12 | **52** | 18 | **86** |
| **Tolerance for error** | Major | 4 | **22** | 4 | **31** | 0 | **0** |
| | Troublesome | 4 | **22** | 1 | **8** | 7 | **64** |
| | Others | 10 | **56** | 8 | **61** | 4 | **36** |
| **Low physical effort** | Major | 0 | **0** | 0 | **0** | 1 | **20** |
| | Troublesome | 0 | **0** | 0 | **0** | 2 | **40** |
| | Others | 2 | **100** | 0 | **0** | 2 | **40** |
| **Size and space for approach and use** | Major | 0 | **0** | 0 | **0** | 0 | **0** |
| | Troublesome | 0 | **0** | 0 | **0** | 0 | **0** |
| | Others | 0 | **0** | 0 | **0** | 0 | **0** |

*Table 2: Severity ratings for each UD principle category*

THE VALUE OF DESIGN RESEARCH

11TH EUROPEAN ACADEMY OF DESIGN CONFERENCE

APRIL 22-24 2015

PARIS DESCARTES UNIVERSITY
INSTITUTE OF PSYCHOLOGY

BOULOGNE BILLANCOURT
FRANCE

CONFERENCE ORGANIZERS:

PARIS DESCARTES UNIVERSITY
PARIS SORBONNE UNIVERSITY
PARIS COLLEGE OF ART
ISTEC PARIS

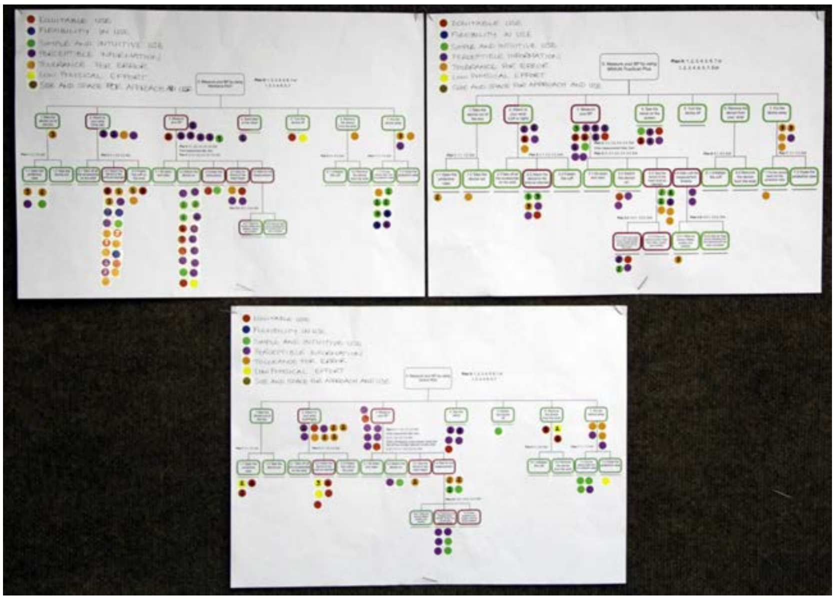


As the result of the workshop, a unique HTA diagram is generated for each device showing all the heuristic violations:

- With their relevance to one of the seven UD principles
- With their severity ratings
- Under which task they might occur.

Moreover, these diagrams enabled the evaluators to holistically and visually see the case of usability for each device and facilitated their comparison with each other in order to identify any hidden inconsistencies in their manner of uses. In addition, this method is likely to present clues to designers about which parts of the operational structure have potentials for improvement and may stimulate designers' thoughts for new solutions.  Figure 7 presents these unique HTA diagrams of the three BPM used in this research. From the figure it can be clearly seen that, heuristic violations are mainly gathered under Task 2 and Task 3 for all the devices, where BPM 1 has the highest number of heuristic violations.

*Figure 7 - Unique HTA diagrams as the outcome of the workshop*



## 4 DISCUSSION AND CONCLUSIONS

During the early phases of a design process, designers often investigate similar products on the market and compare their functional features, although they do not always carry out this procedure in a structured manner. Adoption of certain usability testing methods may help designers to develop a better understanding of the context in which they are designing.

This research particularly focussed on HUMDs market; because despite the fact that there are many similar looking devices currently available in the HUMDs market, in certain cases, their manner of use may vary significantly. This may result in a confusion of lay users, because; as suggested by Jordan (1998), consistency is one of the principles of usable design and inconsistencies are very

***A heuristic evaluation of three blood pressure monitors to identify the possible effects of design inconsistencies on lay user safety: A method suggestion***

*Abdusselam Selami Cifter, Merve Ozyurt, Yener Altiparmakogullari*

likely to lead users to errors. In this research, HE is considered to be an effective method to use in the early phases of a design process, in where the available products on the market is analysed. As suggested in the literature, HE is a fast and cheap method (Wickens et al. 2004; Stanton et al., 2005; BSI, 2008), however is often used in combination with other methods (BSI, 2008). The method used in this study incorporates HTA into HE method, which resulted in a more graphical and holistic representation of the evaluation thus a more designer friendly way of a usability inspection.

One of the challenges faced in this research was to identify the applicable heuristics for HUMDs due to their unique characteristics: although HUMDs are used by extremely diverse users, in fact, they are medical devices which are safety critical in essence. It should also be considered that lay users may not sufficiently refer to the information (such as users' manuals) accompanied with the device as carefully as the manufacturers anticipate. Also some lay user groups such as older people, may not be familiar with new technologies and digital interfaces (Gardner-Bonneau, 2011). Therefore; the inclusivity of HUMDs' designs is important (Wiklund & Wilcox, 2005). For these reasons, 41 heuristics are identified in total from a combination of resources; i.e. Nielsen (1994), Shneiderman (1998), Gardner-Bonneau (2011) and the guidelines of the seven UD Principles (The Center for Universal Design, 1997). Based on their relevance, all these heuristics are categorized under the seven principles of UD in order to facilitate their inspection during the evaluation process.

The method was tested by the involvement of three evaluators where they evaluated three different brands of wrist-cuff blood pressure monitors in terms of their task structures and possible usability problems which might result in a violation of the heuristics identified. The results suggest that all the three very similar looking wrist-cuff BPMs used in this study have different manners of use and also hidden differences in their task structures, which was clearly visible from the unique HTA diagrams generated as the result of the workshop organised in this research. This suggests that the effective transfer of experience of lay users from one device to another, even in the same product group, is an important issue in the HUMDs market, and as a usability principle, "consistency", requires more attention during the design process of such products. The results also suggest that the most encountered heuristic violations are found under the "Perceptible information" category for all the BPMs; however, the highest number of "major" usability problems is identified in "Tolerance for error" (for only BPM 1 and BPM 2). No heuristic violations are identified concerning the "Size and space for approach and use" category on neither devices.

A limitation of this research is that the results are based on researchers' own experience with the suggested method. For this reason, in the further work, two separated but interlinked studies are proposed to be conducted. Firstly, an observational study will be carried out in which real users will use the same selected devices in order to observe what percentage of their usability problems had previously been identified by this research. This will validate the efficiency of the suggested method. Secondly, the method introduced in this paper will be tested by professional designers by means of a workshop study and their feedback will be sought in an effort to assess the methods' efficiency and applicability in real design contexts.

***A heuristic evaluation of three blood pressure monitors to identify the possible effects of design inconsistencies on lay user safety: A method suggestion***

*Abdusselam Selami Cifter, Merve Ozyurt, Yener Altiparmakogullari*

## 5 REFERENCES

Afacan Y. & Erbug C. (2009). An Interdiciplinary Heuristic Evaluation Method for Universal Building Design. Applied Ergonomics, V. 40, pp 731-744

Bitterman N. (2011). Design of Medical Devices – A Home Perspective, European Journal of Internal Medicine. V. 22, pp. 39-42

BSI. (2008). BS EN 62366:2008 - Medical Devices - Application of Usability Engineering to Medical Devices . British Standards Institute.

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. (s. 47-53). Cambridge: Fitzwilliam College, Cambridge University, 22-25 Mart.

Cifter A. S. (2011). An Inclusive Approach towards Designing Medical Devices for Use in the Home Environment, PhD Thesis, Brunel University: School of Engineering and Design

Clarkson, J., Coleman, R., Hosking, I., & S, W. (2007). Inclusive Design Toolkit. Cambridge University: Kall Kwik Cambridge.

Chung P. H., Zhang J. and Johnson T. R. (2003). An Extended Hierarchical Task Analysis for Error Prediction in Medical Devices, AMIA 2003 Symposium Proceedings, Marriott Wardman Park Hotel, Washington DC, USA, November 8-12, pp. 165-169

DiDonato K. L., Graham M. R. (2013). Home Testing and Monitoring Devices: A Description of an Interactive Lab Experience, Currents in Pharmacy Teaching & Learning, V.5, pp. 295-302

Fairbanks R. J. and Wears R. L. (2008). Hazards with Medical Devices: The Role of Design, Annals of Emergency Medicine, V.52:5, pp. 519-521

Faulkner X. (2000). Usability Engineering. Palgrave: New York,

FDA (2010) Medical Device Home Use Initiative, CDRH, Food and Drug Administration Agency U.S.,

FDA (2012). Design Considerations for Devices Intended for Home Use – Draft Guidance. CDRH, Food and Drug Administration Agency U.S.

Gardner-Bonneau D. J. (2011). Home Health Care. In Weinger M. E., Wiklund M. E., & Garnder-Bonneau D. J., Human Factors in Medical Device Design, Boca Raton: CRC Press, pp. 747-770

Ginsburg G. (2005). Human Factors Engineering : A Tool for Medical Device Evaluation in Hospital Decision-Making. Journal of Biomedical Informatics, V. 38., pp. 213-219

Gupta S. (2007). Design and Delivery of Medical Devices for Home-Use:Drivers and Challenges. PhD Thesis, Cambridge: Department of Engineering

Herman W. & Devey G. (2011). Future Trends in Medical Device Technologies: A Ten Year Forecast, CDRH, Food and Drug Administration Agency U.S.

Jordan P. (1998). An Introduction to Usability. Tylor and Francis: London

Khoshdel A. R., Carney S. and Gillies A. (2010). The Impact of Arm Position and Pulse Pressure on the Validation of a Wrist-Cuff Blood Pressure Measurement Device in a High Risk Population, International Journal of General Medicine, V.3, pp. 119-125

Neilsen J. (1994). Usability Engineering. Boston: AP Professional

Norman D. (2002). The Design of Everyday Things. Basic Books: New York

Press, M., & Cooper, R. (2003). The Design Experience: The Role of Design and Designers in the Twenty-First Century. Alshgate Press.

Shneiderman B.(1998). Designing User Interface. Reading Massachusetts: Addison Wesley

Stanton N., Salmon P. M., Walker G. H., Baber C. and Jenkins D. P. (2005). Human Factors Methods: A Practical Guide for Engineering and Design, Ashgate Publishing Limited: Surrey

Story M. F. (2007). Applying the Principles of Universal Design to Medical Devices. In: Winters J. M. & Story M. F., Medical Instrumentation : Accessibility and Usability Considerations. Boca Raton: CRC Press, pp. 83-92

Sultan S. and Mohan P. (2009). How to Interact: Evaluating the Interface between Mobile Healthcare Systems and the Monitoring of Blood Sugar and Blood Pressure. Proceedings of the 6th Annual International Conference on Mobile and Ubiquitous Systems: Networking and Services, July, pp 1-6

The Center for Universal Design (1997), Principles of Universal Design. State University : Raleigh, North Carolina

Thomson R., Martin J. L. and Sharples S. (2013). The Psychosocial Impact of Home Use Medical Devices on the Lives of Older People: A Qualitative Study. BMC Health Services Research, V.13:467

Wickens C. D., Lee J. D. and Liu Y. (2004). An Introduction to Human Factors Engineering, Pearson Education: New Jersey

Wiklund M. & Wilcox S. (2005). Designing Usability into Medical Products. Florida: CRC Press

Winters J. M. & Story M. F. (2007). Medical Instrumentation : Accessibility and Usability Considerations. Boca Raton: CRC Press

Zhang J., Johnson T. R., Patel V. L., Paige D. L. & Kubose T. (2003). Using Usability Heuristics to Evaluate Patient Safety of Medical Devices. Journal of Biomedical Informatics, V. 36, pp. 23-30