Emergency Usability Lab - Concept to Evaluate the Usability of Healthcare Systems in Emergencies

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Abstract. In the healthcare sector the number of patients rises while the staffs cover is decreasing. Due to cost pressure hospital stays are shortened. Thereby more and more clinical activities are migrated into the home environment, especially if these activities have a nursing character. Examples for these activities are infusion therapies or the need of a respiratory device. Due to this trend and the increasing cost pressure in healthcare more and more patients are incorporated as agents in their own care. Thereby more and more clinical products are used by patients and their nursing relatives. This raises the question whether the used medical devices have a proper usability for the use in home healthcare. For such investigations we introduce the "Emergency Usability Lab". Focus of this lab is to evaluate and ensure usability of a medical product for the homecare environment in critical situations and emergencies.

Keywords: Healthcare · Home environment · Emergency · Usability

1 Introduction

Healthcare is experiencing a major system redesign as well as paradigm shift [1]. Cost pressure and an increasing number of patients cause the system to find new ways of delivering efficient healthcare services. Thereby an increasing number of health services are migrated from clinical setting to the patient's household. In this home healthcare settings the patient self is in charge of providing the necessary operations [2, 3]. Therefore some researches even speak of 'do it yourself healthcare' [4]. In most cases these transferred activities have a nursing character like for example home based dialysis or infusion therapy [5]. Due to the rapid speed of this ongoing process most patients use devices which were developed for a clinical context. Thereby more and more complex medical devices from clinical practice migrate into home healthcare [6]. Besides this trend also counter movement exists. More and more consumer products like smartphones or other smart devices get integrated into classical healthcare services [7]. Thereby healthcare is changing and classical domains like clinical context and home healthcare get mixed up [1].

Due to this process classical methods and paradigms regarding the design and usability of medical devices needs to be reconsidered and maybe changed. Devices

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used in home healthcare needs to fit different requirements then devices for clinical practice. Not every household is designed and equipped the same way. Furthermore patients and their nursing relatives have a different level of experience in performing health activities then experienced and educated health professionals (see Fig. 1).

Fig. 1. Example of a possible critical situation in future of personal home healthcare.

Especially if we think about the operation of medical devices like a dialysis machine or an infusion pump by a patient or a nursing relative, topics like prior experience, training and knowledge are different than in a clinical context [8]. Additionally topics like fear or daily form become important for this setting. Therefore the ergonomic considerations and usability guidelines of medical products as well as smart devices need to be reconsidered.

In case of an emergency existing guidelines and best practices for clinical setting applied to home healthcare needs to be reconsidered. In clinical practice unsuitable usability could be addressed by training but in the described home healthcare setting this seems unrealistic due to time and cost factors [8]. Therefore a new approach is needed to ensure suitable usability of medical devices in home healthcare even in case of an emergency.

In medical terms emergencies are defined as time pressures decision making in a situation related to life threatening harm of a patient [9]. Taking the approach of work under extreme conditions proposed by Luczak (1991) it is possible to transfer the definition of an emergency into the field of human factors and ergonomics [10]. Luzcak introduced this concept to link environmental conditions like heat or noise with the performance of an individual. He explains that stressors like heat or noise reduce the individual's abilities and performance based on the stress and strain concept [10, 11]. Based on the stress and strain concept extreme conditions could be seen as mismatch between the individuals' abilities and the necessary demand due to the stressor to cope the job. Taking the idea of work under extreme conditions and linking it to the stress and strain concept we are able to access emergency situations in home healthcare in terms of human factors and ergonomics.

As defined above in an emergency the clinical professional has to work under time pressure and the knowledge of life threatening harm to a patient. Thereby he or she works under at least two different stressors. The effect of these two stressors might be decreased by experience and training of the professional regarding performance in emergency situations. Now we exchange the clinical professional by a patient who operates the medical device solving the emergency situation him- or herself. Also in this case we have the two already defined stressors but now we could extend this list of stressors for example by fear or pain. On the other side according the stress and strain concept abilities like training or experience might be missing. Due to this usability becomes much more important as a bad one additionally reduces the patient's performance. In home healthcare more situations are problematic than just mentioned emergencies. Also daily form and mood of a patient could influence his or her ability to operate a medical device. Again in clinical setting these stressors can be compensated by training, but due to the missing training in home healthcare also these stressors needs to be considered as a critical factor. The mentioned combination of stress and strain concept and work under extreme conditions allow us to model situations in home healthcare as described. By differentiating the severity of stressors we are able to differentiate between several levels of severity of an emergency.

Thereby it is possible to link the methods of the field of Human Factors and Ergonomics with the medical context of diseases and their critical and life-threatening situations.

2 Method

Based on the stress and strain concept and the idea of work under extreme conditions we will introduce in this chapter the 'Emergency Usability Lab' and how it is developed. The idea behind this lab is to incorporate well known stressors from clinical stress research into lab based usability studies to simulate extreme conditions. Following three studies are presented which give more insight into the 'Emergency Usability Lab'. Figure 2 gives an overview how these studies are connected.

2.1 Study ET1: Physiology Under Simulated Extreme Condition

Research Questions. This exploratory laboratory experiment investigates different stressors independently due to their physiological impact on an individual. Investigated stressors are traffic noise [12], white noise [13], cold pressor [14] and the PASAT-C test [15]. The objective of this experiment is to determine the physiological impact of different stressors on the human operator respective intra- and interindividual differences measured by the Empatica E4 [16].

Method. In total 60 participants separated in two age groups (AG1: 20–40 yrs; AG2: 60–80 yrs) take part in this study. All participants will experience each stressor in random order. Between each exposure the participants will be given a break to recover. The participants' tasks during each stressor exposure are employed to investigate the physiological change in performance. Therefore the Purdue Pegboard [17] and TAP 2.3 [18] will be incorporated. To investigate the intraindividual influences in more detail, the participants will take part in this experiment twice at two different days. The experiment will only take part in the morning due to natural change in performance during the day [13]. Dependent variables in this experiment are participants' performance, electrodermal activity and heart-rate-variability. Both will be measured by the Empatica E4 [16]. Furthermore the subjective mental workload during the stressor exposure will be assessed by the Rating scale of mental effort [19]. Control variables in

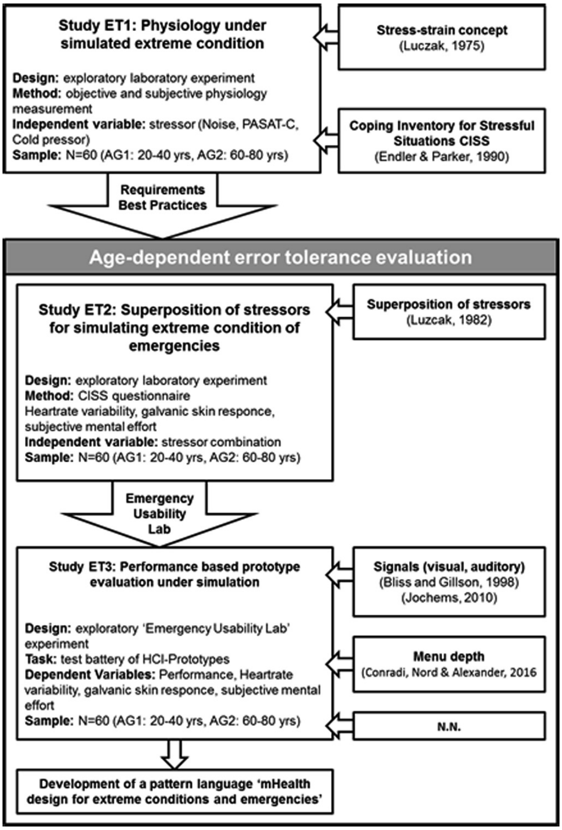

Fig. 2. Concept on age-dependent evaluation of error tolerance.

this experiment are stress in personal life measured by the perceived stress scale [20] and coping strategies for stressful situations accessed by the Coping inventory for Stressful Situations [21].

2.2 Study ET2: Superposition of Stressors for Simulating Extreme Conditions of Emergencies

Research Questions. In critical and emergency situations in most cases individuals do not experience just one stressor individually but several ones in combination. A common combination is time pressure and pain [9]. In the field of Human Factors and Ergonomics such combinations of stressors are referred as superposition [22].

In the context of clinical stress tests superposition of several stressors is a common concept to increase the effect of the physiological stress reaction of the individual [23].

Examples for such superposition stress tests are the 'Mannheimer Multicomponent-Stress-Test' [13] as well as the 'Maastricht Acute Stress Test' [25].

Therefore the basic question of this study is which combination of stressors is best to induce stress without an intra- and interindividual interference. Objective of the identification of the most suitable combination is the development of an 'Emergency Usability Lab' incorporating this combination for usability investigations of healthcare systems for emergencies.

Method. Based on the best practices and requirements investigated by study ET1 different combinations of the stressors should be employed as superposition. All participants will experience the combinations in random order. Again a sample of 60 participants divided into two age groups will take part in this study. Participants' tasks will be the same as in study ET1 if there is no indication for a redesign based on the results of study ET1. Dependent variables within this study are again participants' performance, subjective mental workload as well as electro dermal activity and heart-rate-variability. Due to the results of study ET1 further dependent variables might be defined.

2.3 Study ET3: Performance Based Prototype Evaluation Under Simulation

Research Questions. Aim of this study is to investigate different human computer interaction prototypes with in the developed Emergency Usability Lab to evaluate guidelines and define design best practices for patient centred smart device based healthcare systems. Design aspects evaluated in this context are for example alarm signaling in visual as well as auditory form [25, 26]. Further questions investigated are suitable font sizes or colorization. In Addition appropriate menu depth will be investigated [27]. The object of this study is to develop basic software design guidelines for use under extreme conditions.

Method. In total a number of 60 Participants separated in two age groups will take part in this study. All participants will operate the prototypes via a self-developed test battery app. By representing the participants several prototypes differentiated by levels of font size, colorization and menu depth, suitable combinations for use under extreme conditions should be determined. Dependent variables in this study will be chosen based on the results of the studies ET1 and ET2. Considered variables are participants' performance, electro dermal activity and heart-rate-variability.

3 Initial Results of the Emergency Usability Lab

Initial tests showed that it would be best to use a quiet and clean room. Therefore with in our laboratory a white colored and soundproof room was set up (see Fig. 3). Thereby participants are not distracted by their surrounding and can focus on the product and tasks. Stressor exposure is done via headphones. We decided to use the 't.bone

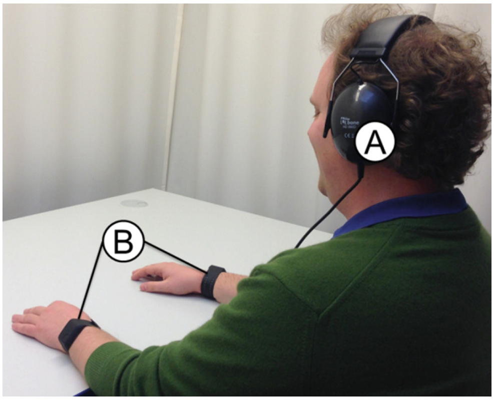

Fig. 3. Experimental setting of the Emergency Usability Lab (A = Headphones, B = E4 Wristbands).

HD990D' which has full size earcups reducing outside sounds up to 22 dB. Furthermore these headphones are able to produce sounds up to 105 dB which is a lot higher than the usually used 80 dB in clinical stress tests [12, 13, 24]. Recording of physiological reaction is done by the 'Empatica E4' [16]. For the pre-test we incorporate two Empatica wristbands, one for the dominant and one for the non-dominant hand wrist, to get as accurate data as possible.

Within an initial approach six participants (1 female, 5 male) in the age of between 24 years and 34 years took part in the pre-test of study ET1. For all participants electro dermal skin conductance and heartrate were recorded meanwhile they were exposed to three different stressors (white noise [12], traffic noise [13] and PASAT-C test [15]). The experiment was time triggered. After start all participants completed the experiment guided by an audio file, they were ordered to listen to. Further tasks were not defined. Thereby interference with this experiment by the investigator as well as a certain task was avoided. The experimental timeline is shown in Fig. 4.

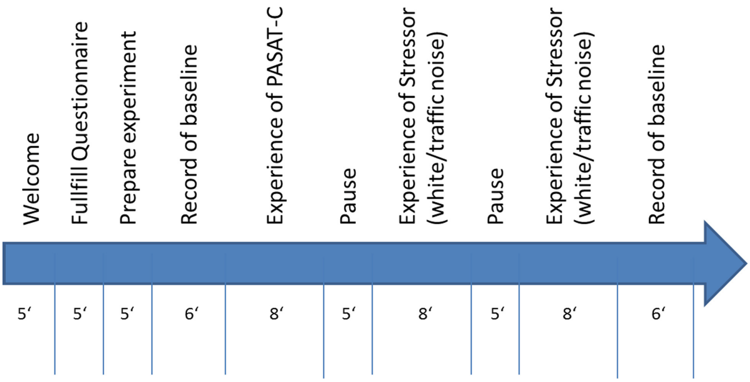

Fig. 4. Procedure of the experiment with time in minutes for each step.

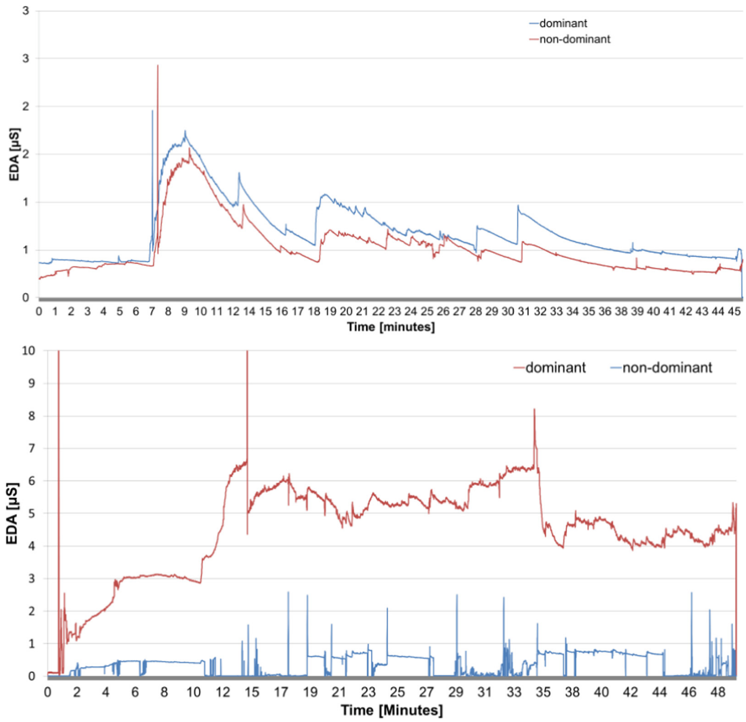

Fig. 5. Example of EDA record for a good (upper) and bad (lower) connection between skin and E4 wristband.

Figure 5 shows the recorded EDA signal over duration of the experiment. The upper part of Fig. 5 shows the EDA signal in case the E4 wristbands are adjusted in a suitable way. The lower part of Fig. 5 shows recorded data for the case the E4 wristband is not adjusted the right way. In this special case the signal for the non-dominant hand got lost during the experiment (see Fig. 5). This problem indicates the usefulness of measuring EDA signal at both hands to have backup data in case the E4 losses proper connection to the participant's skin.

Due to incomplete data the recorded EDA signal of participants ID2, ID3 and ID6 were excluded. Figures 6 and 7 show the recorded EDA signal over the duration of the experiment.

The comparison of the Figs. 6 and 7 shows that EDA signal measured at the wrist of each participant just differs in its amplitude. The signal is weaker for the dominant hand than for the non-dominant one. Furthermore shows this initial data a difference between the first stressor (PASAT-C) and all following stressors. Based on this data PASAT-C was objectively measured the most stressful stressor. Subjective evaluation by the participants showed different results. Participants ID1 and ID4 reported white noise followed by traffic noise to be the most stressful stressors. Participant ID5 named the PASAT-C test followed by white noise to be the most stressful stressors. These initial results indicate that it is useful to measure objective stress level as well as subjective one.

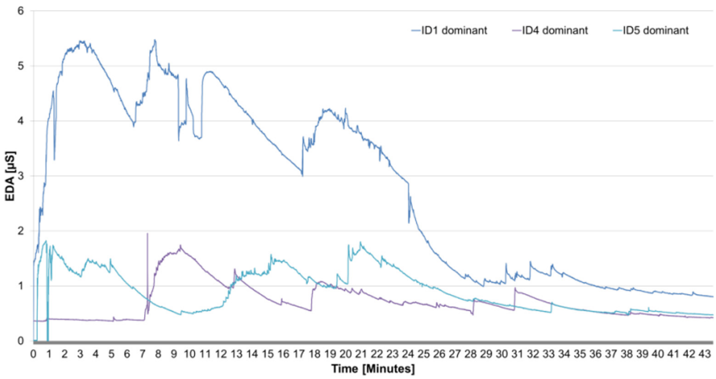

Fig. 6. Results of the experiment for dominant hand of participants.

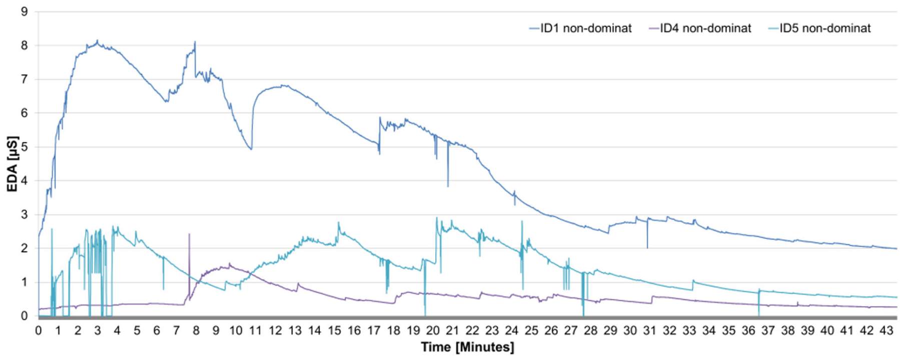

Fig. 7. Results of the experiment for non-dominant hand of participants.

Figure 8 shows the heartrate signal recorded for all six participants. The heartrate was measured for each hand wrist. For this figure the mean heartrate per participant was calculated.

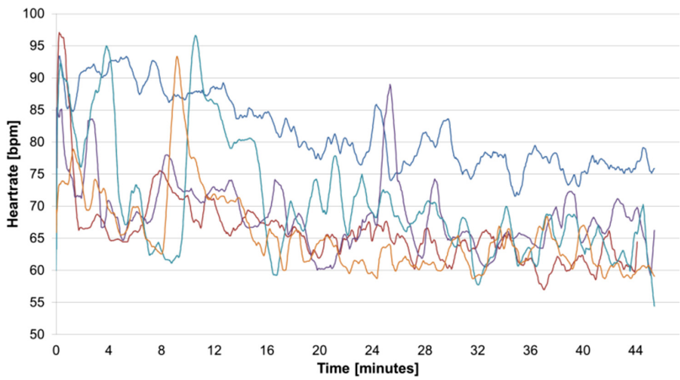

Fig. 8. Heartrate per participant during experiment

Recorded heartrate signals are interesting as they show a habituation to the experiment. In the beginning of this experiment all participants had a high heartrate, during the experience of the three different stressors heartrate decreased. A more detailed analysis of this data, for example with Kubios HRV will give more insights.

4 Concept for Transferring Knowledge into Practice

An Emergency Usability Lab alone is not sufficient to address the future challenges in the health sector. In 2016, the European Commission and the European Parliament adopted a revision of the regulations on medical devices within their scope [28]. According to this revision, simple software solutions, also known as medical apps, are classified as active medical products. This means that established manufacturers, such as start-ups, are obliged to submit software and applications to a conformity assessment procedure in accordance with the Medical Devices Act. In order to take the error and emergency robustness into consideration when developing medical software and apps, it is important to find a way to transfer the findings gained in the application of the Emergency Usability Lab into practice. The concept of the design pattern language, which originates from the architecture and has been used intensively in computer science for several years, is suitable for this purpose.

A pattern language consists of several individual design patterns, which represent recurring problems together with the corresponding solution [29]. On the basis of these problems and solutions, as well as their connection among one another, an entire language can arise, ranging from basic requirements for the design to detailed solutions for certain products and clinical pictures.

The aim of this pattern language is to provide a solution space for users and developers, who will help them to design User interfaces and medical software solutions for home healthcare, being the error and emergency robust design the top priority.

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