

AN ABSTRACT OF THE THESIS OF

Silvina de Brum for the degree of Master of Arts in Design and Human Environment presented on March 6, 2014

Title: Designed to Fit: Tailored Technologies for Medical Practitioners

Abstract approved:

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Although electronic medical records systems (EMR) present promising benefits, they have not yet been widely adopted. A problem facing many EMR are that they are disruptive technologies; their complex hardware and software are not designed to account for the clinicians' characteristics and needs, thus, demanding a steep learning curve and diverted attention while being used. As a result, encounter time increases; clinicians' stress and discomfort arise from the interaction with disruptive technologies affecting doctor-patient communication and technologies are not adopted for further use. The objectives of this study were to apply the human-machine systems engineering (HMSE) and person-environment congruence theory to design and test a minimally disruptive device to improve the documentation of the medical exam. The focus of this project was 1) to reduce the interference that new technologies sometimes provoke during the medical encounter and affect the physician's routine and communication with the patient; and 2) promote interaction between physicians and patients by reducing the attention dedicated to interaction with technological systems. The design concept combines the capabilities of an electronic stethoscope, otoscope, ophthalmoscope, and a digital camera. It uses existing technologies to capture patient data from the physical examination and save it in the patient's EMR in real time. It aims to eliminate data acquisition time, entry errors, avoid instrument loss or damage and facilitate communication with patients. Seventy-five requirements were developed based on the results of task analysis, failure mode and effects analysis (FMEA), review of literature and the incorporation of user centered, and display design principles. Jordan's hierarchy model was used as a framework to organize and categorize these requirements. Based on the design criteria, a design concept of a multipurpose medical instrument (allscope) and its interaction with the EMR (iPad application Graphic User Interface) was developed. Physical and

digital models created using a 3D printer machine, and a software prototyping application were used to test the concept. Seven medical clinicians interacted with the models following a scripted scenario. A combination of quantitative survey and qualitative interview was used to evaluate the subjects' perceptions of their experience with the concept and verify requirements. Major findings from the case study were that the system fits overall user characteristics and needs, and that it was not perceived as a cause of interference of doctor-patient relationship but on the contrary as a communication facilitator. It is expected that the design solution will improve the documentation and analysis of the physical examination findings, minimize the interference with clinicians' interaction with patients and routine, and increase user satisfaction and adoption of new technologies. On the other hand, efficiency, a major concern in the medical community, could not be evaluated because of the use of a non-functional model. In this way, future studies should involve objective performance measurements using a fully functional prototype. Usability and emotional issues not previously considered were identified; half of the 18 requirements tested were verified. The requirements verified were related to usability, psychological and physiological pleasure. For example that the system presents useful functions, displays are clearly visible, displays presents information useful to achieve the correct diagnosis, and the device feels good in the hand. New requirements were created based on the study findings and its incorporation on a new design iteration would provide a system that fits users needs more accurately, enabling the enjoyment of the benefits that nowadays technologies can provide.

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Designed to Fit: Tailored Technologies for Medical Practitioners

by
Silvina de Brum

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I understand that my thesis will become part of the permanent collection of Oregon State University libraries. My signature below authorizes release of my thesis to any reader upon request

Silvina de Brum, Author

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DEDICATION

To my parents; Maria Eugenia and Daniel. Now that I am a mom too, I respect and understand even more all the hard work that we, children, bring to your life.

CHAPTER I

INTRODUCTION

With the development of new information technologies, there has been an increasing interest in adopting these technologies to transform traditional medical records into a digital information system (IS). Electronic medical records (EMR) present promising benefits such as easy access to patient data, diagnosis aids and reduction of medical errors. However, most of these benefits have not been experienced, mainly because of the EMR systems has not yet been widely adopted by physicians (Hu et al., 2002). According to (Boonstra & Broekhuis, 2010) this can be explained by several factors such as high cost, time involved in selecting and implementing a new system (Dave A. Ludwick and John Doucette, 2009), fear of potential legal consequences (Hu, Chau, & Sheng, 2002), complexity and limitations of the systems and interference with physicians' routines and communication with the patients (Ilie, Van Slyke, & Courtney, 2009).

Problem Statement and Objectives of the Study

There is a conflict between physicians' desires and resources provided by EMR systems. Physicians need systems that are easy to learn, can be used efficiently without interfering with their practice and provide benefits to them in their daily routine that they feel are worth investing time to learn. EMR are not yet to fit physicians' characteristics and needs, thus, demanding a steep learning curve and diverted attention while being used. As a result, encounter time increases; physician-patient communication interference increases and technologies are not adopted for further use. An EMR system without these barriers would promote use and therefore achieve all the potential benefits that EMR can provide.

A new system that takes advantage of existing technologies to provide different ways to collect, visualize, analyze and share patient data could improve medicine tremendously. A deep understanding of the physicians' characteristics, needs and desires is necessary to create a system that would be easily adopted by clinicians and truly provide benefits for their daily routine.

The overall purpose of this study was to design and evaluate a design concept for a new

medical instrument and its interaction with the ERM. The instrument records data from the physical exam into the patient records, and a tablet application graphic user interface (GUI) represents the link between the instrument and the medical records. The kit (instrument and application) was developed as part of a comprehensive health care toolkit and tested using non-functional models.

The intention of this kit is to capture real time patient data, save it directly into the patient's EMR, eliminate data entry errors, maintain simplicity, ease of use and comfort of use, and prevent various instruments from being misplaced by combined them into one. The system takes advantage of existing technologies such as compact sensor technology, wireless networks, cellular coverage, and cloud computing.

The focus of this project was 1) to reduce the interference that new technologies sometimes provoke during the medical encounter and affect the physician's routine and communication with the patient; and 2) promote interaction between physicians and patients by reducing the attention dedicated to interaction with technological systems.

The study was conducted through the following specific objectives:

- *Objective 1:* Understand the physical examination process and develop requirements for the new system that account for physicians' workflow and needs.
- *Objective 2:* Develop a concept design for a physical examination kit that causes minimal interference with physicians' routine or communication with the patient.
- *Objective 3:* Determine the effectiveness of the design solution using a non-functional model to evaluate the overall user experience, verify and validate the requirements and evaluate the general fit of the new system.

Theoretical Perspectives

To provide a comprehensive inquiry, several theories and concepts were used to examine object-user interactions from different perspectives. These include: Human Factors (HF), Person-Environment (P-E) Congruence theory (Kahana, 1982) and Patrick Jordan's (1997)

model of Hierarchy of Consumer's Needs including usability and emotional reaction to design. They guided both the design process and assessment of the concept developed during the testing procedure.

Human Factors Engineering

Human Factors Engineering (HFE) is a multidisciplinary field of study that focuses on the interaction between people and their environment. Its main concerns are to enhance health, safety and performance. It involves several different areas and domains of study such as aviation, human-computer interaction, workplace design and healthcare. The Human Factors perspective has generated several theories and methods that have been successfully used to improve healthcare by improving the design of existing devices, procedures and finding solutions to increase patient safety (Carayon, 2011). For this study, the use of task modeling tools such as IDEF0 (Integration Definition for Function Modeling) and FMEA (Failure Mode and Effects Analysis) guided the development of requirements, design concept and testing, and the process of understanding the physical examination procedure and workflow. Usability variables such as efficiency and prevention of user errors also influenced the design process and testing procedure.

Person-Environment Congruence

P-E Congruence is a theory from Environmental Psychology. It focuses on the interaction between humans and environments and how environment can affect human emotions, behavior and wellbeing. Environment is defined as anything that surround us, including cloth, people and physical reminders of our behavior (M. P. Lawton, 1983). According to this theory a suitable environment is defined by the interaction with the user and how the characteristics of both match. Eva Kahana, the developer of this theory, considers that people usually find or adapt environments to fit their needs (E. Kahana, 1982). However, when this is not possible and the environment that does not fit with their needs and characteristics, stress and discomfort arise and affects people's quality of life, especially if this situation is prolonged. Environments that do not match with user characteristics and needs can provoke stress, discomfort and frustration. This theory was developed to understand and improve the living situation of institutionalized older adults but it can be provide a framework to understand the physicians' use of EMR technologies, bringing a different perspective to the design process.

Hierarchy of Consumer Needs

Jordan believes that humans can have a bond or relationship with objects and this relationship affect our emotions. He believes that understanding people holistically, not only by their cognitive characteristics, is the key to create successful products. He provides a model that describes the hierarchy of human needs as a pyramid in which functionality (bottom), usability (middle) and pleasure needs (top) are satisfied by the relationship with the environment (Figure 2) (1997). Once a level is satisfied, the user will seek for the next. These needs and its hierarchy were considered in order to provide an overall positive user experience. Requirements were organized following Jordan's model and the user experience was evaluated during the testing procedure. It is assumed that considering functionality, usability and user emotions when designing new systems will provide a product that fit user needs and therefore have an impact on adoption of the system and how a clinician will interact with a patient during the medical encounter.

Theoretical Comparison

HFE and P-E Congruence present similar perspectives: they both focus on the interaction between humans and their environment, attempt to understand human needs and characteristics and how the environment should fit and adapt to those. Human factors focuses on performance, safety and satisfaction, whereas P-E Congruence focuses on well-being and the effect that the environment has on human behavior.

HFE has been applied to several different domains, among them healthcare. P-E theory has been developed and applied for understanding and improving the quality of life of institutionalized older adults. Human Factor provides existing tools already in use for the healthcare design, whereas the tools provided by P-E Congruence were used as an overall guide.

The model of hierarchy of needs proposed by Jordan provides a framework to understand the benefits that users expect from products and was, therefore used to understand and organize the desired benefits and attributes that the new system will need to provide to the user in order to create products that are congruent with their needs and desires.

Significance of the Study

A system that meets user needs and characteristics will allow the user to enjoy the benefits that technologies provide. Facilitating medical processes and understanding the patient's conditions without disrupting clinicians' workflow and relationship with the patients should improve the physicians' perceptions of technology. Satisfaction and reduced stress or frustration may increase adoption of the technology; an added benefit will be a reduction in the incidence of human errors.

The results of this research provide guidance for the design of EMR systems that adapt to physicians' daily activities and way of thinking and working. It also identifies elements that can engage physicians to use and incorporate the EMR system into their daily routine.

Designing systems that fit with physicians' ways of thinking and perceptions would not only improve the use of the EMR benefiting the patients and healthcare professionals, but also it will reduce healthcare costs. The US Department of Health and Human Services (2004) stated that "if used, the EMR have great potential to reduce medical errors in hospitals while at the same time saving the US economy \$140 billion a year or 10% of the current healthcare costs. It is expected that this benefit will be also seen in countries other than the US".

Assumptions of the Study

1. The communication / relationship between patient and physician plays a major role in the healing process. Technology should not come between; on the contrary, it should preserve it and promote it.
2. Technology itself is not good or bad; it is a mean to achieve a purpose. How good or bad the technology is depends on the purpose for which it was intended and the interaction with the user.
3. A device that is easy to use and designed with the user in mind will be more easily adopted by physicians, will not demand as many cognitive resources as a complex device, and therefore will be less intrusive with the physician's workflow and interaction with the patient.

Limitations

1. Non-functional models were used during the testing procedure. They do not present the exact appearance and characteristics of the final product. Results rely on the ability of participants to project themselves using the final device during their daily routine and on the researchers ability to facilitate that projection.
2. A non-random procedure was used to select the participants to test the final design. This sample of participants was not be representative of the population of interest and therefore, the results from the testing stage cannot not be inferable to this population.
3. Participants' bias with respect to technology may influence the results.
4. Interviewer present during the testing may influence the participants' reactions or responses.
5. Analysis of results may be affected by researcher personal biases.

CHAPTER II

REVIEW OF LITERATURE

This study focuses on the relationship between physicians' medical tools and electronic medical records (EMR). In particular, the research project intends to create interfaces for devices that improve the relationship between physicians and electronic medical records, without interfering with their practice or with patient-physician communication. The purposes of the literature review are: first to present information regarding the benefits of the EMR and the barriers or challenges that its implementation presents; and second, to provide insights into the theories that are guiding this study: Human Factors, Person-Environment Congruence and the model of hierarchy of needs.

Electronic Medical Records

Definition

Health care organizations or professionals keep confidential records about their patients' medical history. Medical records include patient identification data such as name, date and place of birth, ethnicity and occupation. Information about every previous encounter including symptoms, diagnosis, test results, treatment, evolution, surgeries, and family medical history are also recorded at the patient's records (Yamamoto & Khan, 2006).

The EMR (also called electronic health records - EHR), is an information system that was created to replace the paper based system of the patient medical records. Its main purpose is to collect, store and provide patient clinical information (Boonstra & Broekhuis, 2010). The scope of the EMR could be related to a specific domain of clinical information such as laboratory data or cover every aspect of the patient's clinical data (U.S. Department of Health and Human Services, 2004).

Benefits and Challenges

Electronic medical records (EMR) seek to improve the medical record system efficiency by saving time at the medical encounter, providing quick access to patient data in emergency

situations, facilitating quick diagnosis, decision aids, providing communication between doctors and specialists around the world and also reducing storage space that paper-based requires (Yamamoto & Khan, 2006). Ultimately, these improvements, among others, could reduce human error in many ways. The US Department of Health and Human Services (2004) stated that "...if used, the EMR have great potential to reduce medical errors in hospitals while at the same time save the US economy \$140 billion a year or 10% of the current healthcare costs". It is expected that this benefit will be also seen countries other than the United States.

The EMR could save great quantities of money per year by eliminating about 200,000 adverse drug events inside hospitals, and prevent illness by suggesting screening according to the patient age, gender and ethnicity and other risk factors. The EMR can also generate an appropriate following of chronic diseases, especially for those that need the interaction and communication among a variety of specialists such as diabetes or autoimmune diseases (Hillestad et al., 2005).

EMR also have impacts in different areas. According the review from Shachak and Reis (2009) about how EMR can affect the relationship between patients and physicians, computers and technology could potentially enhance patient-doctor communication (PDC). Computers and devices can be an educational tool to help the physician explain to patients their conditions and what treatment options and behavior changes are needed to deal with a specific disease or condition. Improving patient understanding of their health situation and what they need to do to improve their health condition could improve patient satisfaction, adherence to treatment and therefore improve their health conditions (Shachak & Reis, 2009).

The potential benefits of the EMR are promising. However, many of these benefits have not been achieved partly because EMR systems have not yet been widely adopted by physicians (J.G. Anderson & Aydin, 1997; Davidson & Heslinga, 2006; Boonstra & Broekhuis, 2010). This can be explained by many factors such as the limitations of the system itself and the commonly adverse attitude of physicians toward technology. These two factors will shape the focus of this study.

Several authors think that many EMR are a disruptive technology. According to Jacoby, EMR systems "... have changed the way physicians capture, retrieve and share information"

(Jacoby, 2008). Goedert suggest that because EMR have not been designed considering the physician's workflow, they don't provide easy access to information. He states that EMR have tried to imitate paper-based systems without providing all the benefits that technology allows. When using paper-based systems, the physicians interact with the patient while thinking about possible diagnosis or treatment, examine the patient and then write down the conclusions in a specific order at the patient visit record. The main purpose for this is to document patients' symptoms, signs and diagnosis so other doctors can use this information in future visits. EMR have changed the documentation process: doctors need to interact with computer devices, navigate to find or to enter information, type, and check that the information was saved. This is more complex than just writing information down on a paper. According to Boonstra and Broekhuis (2010) these new processes of dealing with complex interfaces require computer skills such as typing and also demand extra time to learn how to use the systems.

EMR complex hardware and software demand a lot of attention. Currently, they also can provoke stress and frustration when tasks cannot be completed easily. All these factors interfere with the physician's practice: attention needs to be divided between the patient and the system while stress reduces the problem solving ability and increases the likelihood of errors (Yamamoto & Khan, 2006). As a consequence, the use of EMR interferes with the physician's workflow and interaction with the patient.

Another challenge is that there are different kinds of EMR in the market; they are not standardized, and the interaction between them is a problem. According to the results of the review from Boonstra & Broekhuis (2010) there are more than 264 unique types of EMR in the market. Many physicians work for different clinics or organizations. This involves learning to use different versions of EMR. As they work differently, the knowledge learned from using one system is not transferable to another. Consequently, workload and demands over the clinicians arise.

On the other hand, many physicians do not present a positive attitude towards technology (Ilie et al., 2009). Many of them would rather keep using a paper-based system than EMR (James G Anderson, 1997; FitzHenry, Salmon, & Reichelt, 2000). However, most physicians are not against new technologies. On the contrary, they are willing to adopt or embrace techniques that benefit their practices (Chismar & Wiley-Patton, 2003; Ilie et al., 2009)

but they are not willing to accept new procedures that interfere with their practice or routine (J.G. Anderson & Aydin, 1997; Ilie et al., 2009)

Clinicians believe that EMR reduce their efficiency. Illie (2009) found out that physicians perceive the EMR system as complex and difficult to use due to difficulties related to poor usability and navigation, which slow down access to the information needed. All these factors were directly related to clinicians' perception that using EMR has a negative impact on their use of time (Ilie et al., 2009). Another important factor that damages clinicians' time efficiency is data entry. According to a review made by Boonstra and Broekhuis (2010) the time that requires physicians to enter data to the EMR is a common complaint and this can be related to the complexity of the system and/or the physician's lack of computer skills. This issue is particularly important, since time is a valuable resource for medical clinicians. They get paid per patient and not by the time spent with them. Because of time constraints many do not dedicate enough time to learn how to use and become familiar with EMR. Moreover, many clinicians do not have enough computer skills to effectively utilize an EMR during a medical encounter while simultaneously interacting with the patient (Ludwick & Doucette, 2009).

In addition to that, physicians may have fear of the unknown technologies. They may be afraid of not being seen as experts if they do not know how to use them, or afraid of not being able to get work done if they are not very good at typing or using a computer. Last, lack of information regarding the benefits of the EMR may also be responsible of their unwillingness to embrace this change (LeTourneau, 2004).

There are other barriers for implementation of EMR such as investment cost and adoption, the uncertainty about return of this investment, lack of reliability on these new systems, the time needed to select, purchase and implement a system, the time to convert previous records to digital form, uncertainties about vendors, lack of support and training from vendors, privacy, security and legal implications concerns, and so on (Boonstra & Broekhuis, 2010). However, since this study focuses on the interaction between physicians and EMR systems, and devices used for the physical examination, these factors are beyond the scope of this study.

To sum up, there is a conflict between physicians' needs and desires and what EMR systems provide. Physicians need systems that are easy to learn, can be used efficiently without interfering with their practice and provide benefits to them in their daily routine that are worth investing time to learn them. EMR are not yet designed to fit physicians' needs. An EMR that fulfills these needs should promote their use and therefore achieve all the potential benefits that EMR can provide.

Development of New Medical Equipment

Healthcare professionals use different instruments in their routine to assess patients' physical condition. Examples of these instruments are a stethoscope, otoscope and ophthalmoscope. Before the EMR development, physicians would perform the physical examination and write down their perceptions and conclusions of the physical data in the patient's health records. Now they can record those perceptions and conclusions and also can save digital files, and have access to previous multimedia records recorded in previous visits.

Today, technology allows for saving and storing multimedia data captured from medical instruments in a different way than traditional records. Examples of these new possibilities are an audio file of heart sounds, a video of an image of the eye, and a picture of a skin lesion, among others. Having the possibility to save multimedia files in medical records provides numerous benefits. First, as a diagnostic aid, digital files allow access as often as needed and they provide a means to compare with databases to find similarities with different conditions. This is helpful because usually the doctors diagnoses or identifies conditions by comparing what they are hearing or seeing with what they remember about different conditions. For example, to know that a patient has a valve condition, the doctors listen to heart sounds and compare the sounds with what they remember about how normal or abnormal heart conditions sound. This is very easy for physicians who have a lot of experience but very difficult for students, or physicians with little experience. Second, the evolution of conditions can be evaluated easily by comparing files from different medical encounters. Third, the sharing of digital files, for example heart or lung sounds, allows doctors to seek opinions or advice from other doctors or specialists when facing a challenging diagnosis. This can be extremely beneficial for doctors in rural areas or in emergencies when fast decisions need to be made. Finally, software can be developed to analyze

these digital files and provide early diagnosis by detecting abnormalities in early stages when signs are not strongly evident through human perception.

Medical instrumentation had very little development in the last decades, and the set of tools of a common medical encounter have remained similar. Common tools include otoscope, ophthalmoscope, stethoscope and dermatologic camera (digital camera). It is common knowledge that many instruments or pieces of them get misplaced daily by health care professionals. For example, otoscopes and ophthalmoscopes get lost so easily that they are now commonly mounted on the wall of medical offices so they are always available when needed. There is a niche for evolution of the design of these tools, and an obvious one that solves the problem of a multi-piece tool set is the development of a multi-function device. This goes well with the development of EMR and Bluetooth and WiFi technologies, since it enables the direct communication and data recording from the tools into the EMR.

The previous benefits are just a few of a long list of opportunities that technology provides today. Having new technology and new capabilities also implies new ways of doing things. New devices are developed to provide the previous features described as well as others. New devices and technologies are disruptive and intrusive just because they change the way physicians have been practicing medicine all these years; now they need to record, save, find files in the patient records and learn how to do it. However, the amount of disruption will depend on the device and how well it considered user characteristics, limitations and needs. A device can provide several different features, but until the user can use it with ease and accomplish his/her goals that device is a promise or a dream, but not helpful. This study is based on the assumption that technology is useful when it is finally accepted, put into practice and provides real benefits to the user without creating other problems. Also, products created having the user in mind will allow achieving all the benefits that current technology can provide.

Evaluation of New Medical Equipment

After the development of new devices and tools, different evaluation methods allow to test their benefits and drawbacks, and are described below.

Human Factors Testing Methods

Human factors engineering methods use several usability testing to assess the efficiency, effectiveness and satisfaction provided by new devices. These methods can be divided in two groups: analytical and empirical. Empirical methods use information from the actual user and analytical methods could use evaluators that are not the final user (Liljegren, 2006).

There are many different usability evaluation methods that have been developed for different uses. Liljegren (2006) recommend four usability evaluation methods to study of medical devices, three empirical and one analytical. These methods are hierarchical task analysis (HTA), cognitive walk-through (CW), heuristic evaluation (HE) and usability tests (UT).

Hierarchical Task Analysis (HTA)

Hierarchical task analysis (HTA) is a procedure that involves systematic decomposition of the main task's goal into several sub-goals (Hollnagel, 2003). Every operation needed for that sub-goal are described together with a listing of the conditions under which these operation have to be carried on in order to achieve a successful outcome (Kirwan & Ainsworth, 1992). According to Liljegren (2006), HTA provides knowledge about which hierarchy of subgoals is needed to perform a task successfully and under which conditions these tasks should be performed. Examples of Usability issues detected by HTA are “overly complex tasks and illogical task sequences” (Liljegren, 2006).

Cognitive Walk-Trough (CW)

Cognitive walk-trough (CW) evaluates how easy, a specific user will successfully perform a task based on the interface's characteristics (Polson, Lewis, Rieman, & Wharton, 1992). According to Liljegren (2006) the main objective is to identify which steps of the process will be most difficult for the users or where they could commit mistakes. It is useful at the design stage, but it is also important when the product is finished for its evaluation. CW consists of three stages. During the first one, preparation, the user is defined and the tasks for evaluation are selected. Here, the way the user is supposed to accomplish each step is also described. The next step involves analysis of the procedures and evaluates whether the users will be able to identify the actions they would need to take in order to achieve a desired goal and to identify failure or

mistake prone steps due to system-user communication. The last stage generates of a list of possible usability problems for every step in the procedure (Liljegren, 2006).

Heuristic Evaluation (HE)

During a heuristic evaluation (HE) a usability specialist evaluates if the interface follows usability principles (Mack & Nielsen, 1993). According to Nielsen, HE is the most informal method to study usability (J. Nielsen, Mack, & Shirk, 1996). Liljegren (2006) stated that HE is performed in two steps: first different evaluators inspect the interface alone checking for the presence or absence of usability principles and documenting the conflicts founded. During the second stage, a list of usability problems or principles violated is made with the documentation of all evaluators.

Usability Testing (UT)

UT consists of three stages: preparation, test and follow up. The preparation consists of selecting users that share the characteristics of the final users, for testing the system. For example for EMR testing, physicians and nurses would need to test the devices. This step also involves defining what is going to be tested. During the test the participants perform the selected tasks and they are encouraged to record what they are thinking during every step. The last stage involves the analysis of the data recorded during the test (Nielsen, 1993). According to Jordan (P, (1998), there is no other test that provides as much information as observing people trying to use a product.

The information provided by usability tests is much more valuable for studying the development of EMR than the HTA, CW and HE tests, due to the fact that it would involve clinicians to test the concept idea, and it provide insight about their way of thinking and needs.

Benefits Of An All-In-One Instrument

An all-in-one medical instrument is a multipurpose device that combines different tools used by the medical practitioner in their daily routine such as stethoscope, ophthalmoscope, otoscope and other tools such as digital photo and video camera. This device would communicate through wireless Internet or Bluetooth with the EMR and will be able to share patient data with specialists who are long distances away. An instrument of this kind would be of

great importance when a physician is facing a challenging diagnosis; especially if they are in rural areas where they do not have a specialist in every area or at emergency situations.

An all-in-one device allows the medical practitioner to have all the instruments together. This decreases the chances of losing instruments or exchangeable piece of them, something that occur frequently in common practice. Last but not least, interacting with one device with multiple functions instead of many different devices from different vendors will reduce the physicians' stress and workload of learning several different instruments that may not work similarly. Physicians will need to learn to use only device, this will reduce learning and implementation time.

Last, if users invest less cognitive resources while dealing with an EMR, they will be able to dedicate more attention to the interaction with the patient and following the medical process that will end up in the patient's healing. In addition to this, less complex devices will not provoke anxiety and frustration, which reduces the ability to process information and problem solve (Yamamoto & Khan, 2006). According to Yamamoto, the incidence of errors will be reduced when using less attention-demanding interfaces. This can also be explained by the reduction of stress and anxiety and because the system will prevent mistakes or provide an easy solution to revert them. As a result, most of clinicians' cognitive resources will be dedicated to the patient's situation.

Theoretical Framework

Human factors (HF) and Person-Environment (P-E) Congruence are used in this study as theoretical frameworks. Apart from this, Jordan's model of hierarchy of consumer needs will be used as a guide to structure the application of these theories and paradigms.

Human Factors

Human Factors (HF) and Ergonomics are terms that are often used interchangeably (Demiris et al., 2010). There are many different definitions available but a formally approved definition does not exist (Licht, Polzella, & Boff, 1990). The International Ergonomics Association defined these terms since the year 2000 as the "scientific discipline concerned with the understanding of the interactions among humans and other elements of a system, and the

profession that applies theoretical principles, data and methods to design in order to optimize human well being and overall system performance” (International Ergonomics Association, 2000).

HF studies the relationship between people and their environment, considering environment as the natural or artificial surrounding, including other people. The main goals of HF are to increase safety, satisfaction and to enhance performance (Wickens, Gordon, & Liu, 2004b). (Mondelo, Gregori, & Barrau, 1999) also included the promotion of health and wellbeing as important goals.

Human Factors Engineering (HFE) is defined as a systematic process of applying HF knowledge about human characteristics, needs, limitations and desires to design new systems (devices, furniture, equipment, and environments). HFE uses information from HF to create a world adapted to humans. It provides guidance to the creation of devices, machines and tools that are comfortable, do not create damage to our body and at the same time are easy to understand how to use them based on how we learn or how our mind works.

Human-Machine Systems & User Centered Design

Human machine systems Engineering (HMES) and user centered design (UCD) are specific approaches of Human Factors. A system is a group of connecting elements forming a complex whole that accomplish a function. A human-machine system consists of one or more people, one or more machines and the interface among them.

HMSE analyzes the interaction between humans and machines, or other humans as a system. The focuses of attention are the three elements of the system; the human, the machine, and the interface. In this system every element has a function and if some elements do not work the whole system will not work. The machine may have magnificent functions but if the interface does not communicate the appropriate way to use it, the human will not be able to use it as intended and the machine will become useless.

Ergonomics or HF studies this system as a set of elements (human, material and organizational) that interacts in a determined environment pursuing a common goal. HF tries to

improve and optimize the human-machine interaction (Mondelo et al., 1999) by considering the characteristics, limitations and capabilities of humans and machines.

User center design (UCD) is defined by ISO 13407 (ISO - International Organization for Standardization & ISO - International Organization for Standardization, n.d.) as an approach for interactive systems that focuses on making usable systems. It is a multidisciplinary activity. It was first defined by Norman (1988) as a “philosophy based on the needs and interests from the user, with an emphasis to make products usable and understandable. Machines or devices should let the user clearly figure out what is happening and how to interact with them. The designer is the one responsible to ensure this happens (Norman, 1988). UCD focuses on human-machine systems in order to create optimum and harmonic relationships between the users and devices.

In the book *The Design of Everyday Things* (Norman, 2002) Norman enlists a number of design principles according to the author should be followed in order to develop UCD products. These principles (Appendix 1) were considered while developing requirements.

There are two approaches of UCD (Eason, 1995); design by users and design for users. *Design by users* or participatory ergonomics involves the end users in the design process so that they define what is the best for themselves. The ergonomist's role in this case is to be a facilitator between users and designers. By doing this, the final product will be congruent with the user needs goals and believes. On the other hand, the user may lack technical or professional knowledge or also may not be aware of some needs.

When applying the *design for users* approach the ergonomist is the one who defines what is the best for the user. This is good when products are generics and not for a specific user. The main limitation of this approach is how much the ergonomist knows about the user.

This study approach was design for users. The users needs and limitations and other characteristics were taken into account during the design process. However, users were not be in charge of design process.

Human Factors Methods

Human factors methods are multiple and varied. Quantitative, qualitative and combined methodology can be used to conduct a study.

HF research covers a wide variety of disciplines and it could be held to answer different questions such as how brain process information, which are physical and physiological limits of the body but also how mind and body works in the interaction of different systems or environments, and how these environments should be in order to adapt to the humans characteristics needs, limitations and desires(Wickens, Gordon, & Liu, 2004a, p. 10).

Wickens (2004) divide HF methodology in two categories; experimental research and descriptive methods. Experimental research evaluates the causal relationship among variables with a high level of control of these, whereas descriptive methods describe relationship that exist but could not be manipulated by the researcher, for example the frequency of car accidents when the driver is talking by cellphone. Examples of descriptive methodology used by HF are surveys, literature reviews, models and simulation and incident and accident analysis.

The methodology used for design solutions to human factors problems involves the use of published research, data compendiums, human factors standards and design principles and guidelines. Data compendiums used by HF are developed in several different forms, one of them are categorized databases with information about human capabilities, limitations (Wickens et al., 2004a) among other kind information. HF design standards support design by providing specific recommendation about very specific topics or areas (Wickens et al., 2004a) Last, HF principles and guidelines are flexible and abstract rules. The designer has to define how to apply these rules for each specific project. For example, display design principles (Wickens, Gordon, & Liu, 2004b)(appendix 1) and UCD principles were used for this study.

Applications of Human Factors

Practitioners of ergonomics, ergonomists, contribute to the planning, design and evaluation of tasks, jobs, products, organizations, environments and systems in order to make them compatible with the needs, abilities and limitations of people.

According to Creedon, Malone, Dutra, and Perse, (1998) HF tools and methodologies have been used for the design of complex systems spacecraft, aircrafts, process control systems, information management systems, manufacturing systems, navy and commercial ships. The role of Human Factors in the design of these systems was to define the roles of humans as opposed to machines, evaluate requirements to improve human performance and safety and design

interfaces (the interactions between people and objects) which enable humans to achieve their goals while using a product.

Creedon, Malone, Dutra, & Perse (1998) applied Human Factors tools and methodology to develop an electronic medication compliance device for the elderly population in which they developed requirements for this device based on interview responses of one hundred seniors regarding their capabilities, limitations and needs. A design concept was developed with an emphasis on ease of use, reduction of errors, user needs and safe operation.

Human Factors was considered for this study in order to provide a clear methodology to develop systems adapted to Humans characteristics and needs. HF methodology and guidelines have been applied before in the development of new tools, devices and objects many times before achieving successful results in term of safety, performance and wellbeing.

Person Environment Congruence Theory

Person Environment (P-E) Congruence theory is an environmental psychology theory, which focuses on the interrelation between humans and their environments. The theory, developed by Eva Kahana in the seventies, provides systematic guidelines for creating residences that fulfill the needs of the older individuals (Kahana, 1982) and explaining adequate care alternatives for older people by assessing their fit with the environment (Steggell et al., 2003).

The concept of environment involves more than just the physical characteristics of the surroundings; it also includes people, physical reminders of their behavior, and the interaction of two or more people (M. P. Lawton, 1983). It includes everything that surrounds us, including clothing. Since the work of Levin and Moos, the idea that environment affects our behavior has been well established. Situational and environmental variables are responsible for a great portion of the variances in human behavior (Moos, 1969). Human behavior is a result of the relationship between the person and the environment (Lewin, 1935). Apart from influencing behavior (attitudes and activities), environmental variables have also an effect on people's well being (Kahana, 1982).

P-E Congruency theory is an operational approach to understand the relationship between people and the environment as determinants of satisfaction and well-being (Kahana,

1974; M. Lawton & Nahemow, 1979 ; E. Kahana & Kahana, 1983). This theory proposes that a good or bad environment should be defined based on how the individual interacts with it. A good environment for someone may be bad for another; there is no common universally optimum environment for everybody.

According to Kahana, individuals usually find places that match their needs (Kahana, 1982). An environment that fits with individual characteristics and needs will promote satisfaction and psychological wellbeing (Kahana, Lovegreen, Kahana, & Kahana, 2003). Absence of congruence refers to a mismatch between the individual characteristics and needs, with what the environment offers. This mismatch, the absence of P-E fit, is considered an important source of chronic stress that likely will have physical and mental consequences (Caplan, 1987; E. Kahana & Kahana, 1996). P-E congruence theory proposes that when stress occurs, it arises not just from the person or environment but from the interaction between them.

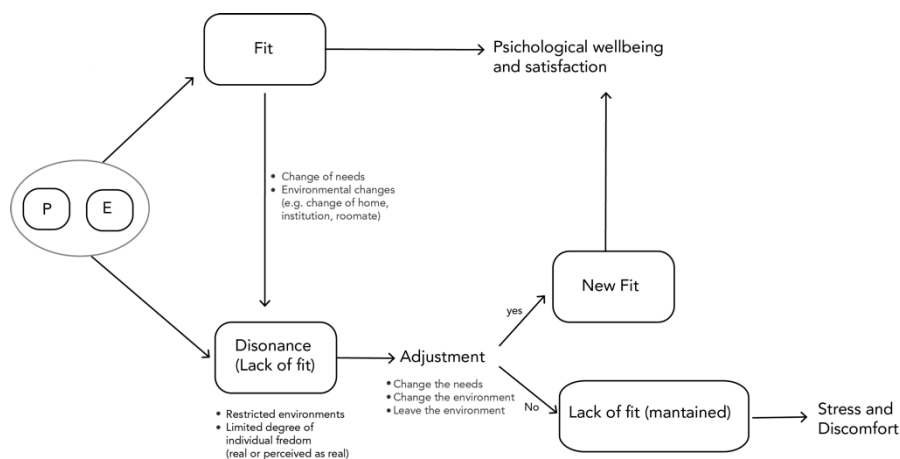


Figure 1 Model of Person-Environment Congruence. Based on Kahana, 1982. Reprinted from de Brum, S. (2012). Person-environment congruence. In A. Ziebart & C. Steggell (Eds.), *A field guide to housing theory*, p.51. Zulu Press

It is very unlikely to find a perfect environment that matches every need and characteristics of the individual. Therefore, a congruent relationship would not imply a perfect match between individuals and environment. There are four strategies to define how congruent or not an environment is. The first two strategies present a quantitative approach. The first one focuses on the number of areas that present mismatch while the second one focus on the total cumulative score of mismatch degree present in each area. The third strategy focuses on the salient areas of mismatch. This is based on the fact that not all the areas are equally important for

the individual and therefore a mismatch on an important area would be more salient than less relevant areas. The fourth, and last, approach would consider the big picture of mismatch (or fit) considering at the same time all aspects of person and environment together. This was the approach used by this study.

In order to define the presence of congruency, Kahana (1982) proposed three models: cumulative differences, critical-difference, and optimal discrepancy. The first one, cumulative differences, is a continuous and directional model. The greater the difference and the amount of difference between individual and environment, the worst the mismatch and therefore, the more negative effects on the individual. The second, critical differences, is a non-continuous model which assumes that the negative effects of mismatch only occur when these reach a tolerance threshold. Last, contrary to the previous models, the optimal discrepancy model assumes that some optimal amount of discrepancy of congruence have a positive outcome. It is related to Helson's (1964) adaptation-level model, in which an optimal degree of variation from individual congruence is positive, whereas beyond that range is negative.

As is shown in Figure 1 whenever there is a dissonance between individuals' needs and their situation (this could happen due to change in the environment or a change of needs or characteristics) the individual tries to adapt to the environment to increase the fit to this new situation or move to another environment. If these options are not possible, due to limitations of the environment or the individual itself, the maintained lack of fit could cause discomfort or stress (Kahana, 1982).

Person-Environment Congruence Methods

The methods for studying the person, the environment and the interaction between them are varied. Individual characteristics should be assessed in relation to the environment of interest because many individual characteristics that are applicable to define the congruence with the environment may not be applicable for other environment or context (E. Kahana, 1982).

In order to evaluate environment characteristics, objective and subjective assessment of the environment can be done. However, it has been found that there is not a high correlation between each other. Self-perceived environmental features are more reliable as predictors of environmental satisfaction and psychological wellbeing than the objective measures.

Quantitative and qualitative studies and a combination of them are used to study P-E congruency. Quantitative methods, such as surveys, have been most used method to measure individual and environmental dimensions that leads to a congruence of fit. However, qualitative studies can also be used to explore and determine individual needs and limitations of specific populations of interest.

In terms of time, (E. Kahana, 1982) suggest that the Person-Environment fit can be tested through a cross-sectional study, however in order to test the congruence adaptation model a longitudinal study would be needed.

Application of Person-Environment Congruence

P-E Congruence was developed to understand and model the relationship of institutionalized older adults and their environment. Institutionalized older adults are commonly living in places that they did not choose. These places often provide an environment that due to physical or social elements are not congruent with their needs or preferences (Kahana, Kahana, & Chirayath, 1999). Characteristics of the person, environment and their fit are predictors of residential satisfaction, understanding these three elements would imply an adequate prediction of residential satisfaction and therefore affect well being and quality of life (Kahana et al., 2003).

Individuals tend to find an environment that fits their needs. However, this is not always the case for older people who may not have the economic resources, have mental or health conditions or may have lost their social role and, as a consequence, they have limited resources to make changes in their environment.

E. Kahana, Liang, Felton, Fairchild, and Harel (1977) tested the theory, trying to examine the predictive power of different congruent measures in relationship with different congruence models. They interviewed 124 individuals from three different institutions (a nonprofit home for the aged, sponsored by a protestant Church, a Jewish home for the aged, and a nonsectarian nursing home in which residents pay for their own care). Individual preferences and environment characteristics and their effect on morale were evaluated. They found that the dimensions that relate individuals need with environment characteristics "...play an important role explaining morale..." (Kahana, Liang & Felton, 1977). This study suggests that the concept of congruence is useful for understanding morale.

Although this model's classic applications are related to older adults' dwellings (home or institutions), the theory can also be applied to understand other levels or other populations. For example, Kahana extended the theory to community setting evaluating the relationship between older residents and their neighborhood (Kahana et al., 2003).

Baillie et al. (Baillie, Hill, & Walters, 1991) applied the concepts of this theory to understand the gender differences in environmental influences on marital satisfaction. The authors selected 86 members of American Association of Pastoral Counselors and their wives to complete a self-administered questionnaire. As a result, they found that the environment has an effect on marital satisfaction. However, this effect is not the same on wives that in husbands. These results suggest that in order to achieve or improve marital well-being and satisfaction, the needs of both members of the couple are different, and should be considered.

Model of Hierarchy of Consumer's Needs

According to Jordan (1997), products are living objects with which users can have an emotional bond or relationship; products are able to make people happy or angry, proud or ashamed, frustrated or secure. The author describes, using the example of a pyramid (Figure 2), how functionality, usability and pleasure are related to the practical benefits associated with products. Functionality is the base of this pyramid; a product is defined by its function and it is useless if it does not accomplish the tasks that it is made for. Usability, in the middle, is how easy the function is accomplished. Pleasure, on top, is related to the understanding of how people respond to different characteristics of design, not just the functionality, but also the physical characteristics, the language the object use, and also the aesthetics (Jordan, 1997).

The international Standards Organization, ISO, (1998) defined usability as “ the effectiveness, efficiency and satisfaction with which specified user achieves specified goals in particular environments”. Nielsen (1993) defines usability associated to 5 components. First, *learnability*; the system should be easy to learn so the user can rapidly begin getting some work done with the system. Second, *efficiency*; once the user knows the system, a high level of productivity is possible. Third, *memorability*; the system should be easy to remember, so when there is an interruption of use, the user does not need to learn how to use it again. Forth, *errors*; the system should have a low error rate, so that users make few errors during the use of the

system and error recovery is easy. Fifth *satisfaction*; the system should be pleasant to use, so users are subjectively satisfied when using it.

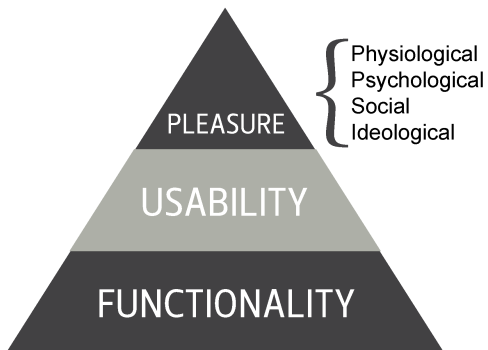


Figure 2 Hierarchy of consumer's needs. Model based on Jordan (1997).

Jordan defines four types of pleasures; physiological, social, psychological and ideological pleasure. The first one, physiological, is the one that came from the physical perception, from the senses touch, smell and taste. Social pleasure is the joy of being with others, of being part of a social unit. Psychological pleasure is related to the satisfaction of accomplish a task. Ideological pleasure comes from conveying adequate ideas about the user's set of values. Jordan concludes that to consider user pleasure in the different levels is highly important due to the fact that people "...always have and always will seek for pleasure..." (Jordan, 1997).

This model guided the development of requirements during this study and was use to determine the overall fit of the system. Considering affective responses of objects to the design of medical devices may improve the interaction between physicians and equipment and therefore promote their use and adoption.

Application of the Theoretical Framework to this Study

Human Factors

Human Factors provide methodology to create systems adapted to humans, their characteristics and needs. HF methods could improve the lack of congruence between physicians and medical technology. Many studies have successfully used human factors and user centered

design tools to solve problems related to medical equipment. Yamamoto and Khan state that the “validity and usability of EMR usability largely depend on Human Factors” (Yamamoto & Khan, 2006).

Person-Environment Congruence

Studies have demonstrate that the theory can help to define a congruence between people and environment, specially when people cannot choose the environment where they live and work, and the chances of adaptation strategies are limited (due to the environment or the individual itself). The environment has an effect on people's behavior and wellbeing. Creating environments that fit people needs and characteristics will promote human health and wellbeing. It is, therefore, a social responsibility, to help improving the characteristics of the environment in relation to the individuals that interact with it, and not only the individuals to adapt to it.

The application of this theory to other population or community such as clinicians who interact with new technology in their daily routines is considered due to the next reasons. On the one hand, as we discussed before, the environment has an important effect on individual's behavior and well-being. Therefore it may be reasonable to think that incongruence between physicians and technological instruments may cause stress and this will influence the way they think, work and interact with the patients. Many clinicians already live stressful lives, working in shifts and under time pressure. Medical instruments and other technological tools should not create more stress or other problems. Creating instruments that are congruent with physicians' characteristics and needs would collaborate in their satisfaction and psychological wellbeing.

On the other hand, the congruence concept is especially important when environmental and individual options are limited. In this case, health professionals are not able to change their near environment and they are enforced to interact with instruments and technology that they did not choose, since they are not responsible for those kinds of decisions.

Jordan's Model of Hierarchy of Consumers' Needs

Jordan's practical model was the main structure to guide the design and test of the possible solutions found in this study. The importance of this model is that it presents factors beyond usability that influence the success of the relation between people and objects. According to Jordan objects can provoke emotions and this emotions influence how we perceive and

interact with objects. Applying these concepts into medical devices seems to be a new but interesting perspective that can provide solutions to the adoptions of EMR system and the ability to enjoy the benefits that they can provide.

CHAPTER III

DESIGN METHODOLOGY AND RESULTS

The purpose of this study was to design and test a new medical device concept to support the physical examination and its documentation. This product is intended to capture real time patient data, save it in the patient's electronic health records, reduce data entry errors, and prevent the instruments from loss or damage. The specific objectives of this study were:

- Understand the physical examination process and develop requirements for the new system that accounts for physicians' workflow and needs
- Develop a concept design for the physical examination kit that cause minimal interference with clinicians' routine or communication with the patient
- Determine the effectiveness of the design solution using a non-functional model to evaluate the overall user experience, verify the requirements and evaluate the general fit of the new system.

Based on the objectives, the methodology consisted of three stages: 1) development of requirements, 2) development of a design concept and 3) testing the concept using a non-functional model. This chapter describes the methodology and results from the first two stages. Chapter IV, Testing Methodology and Results, focuses on the last stage, user testing. Figure 3 shows the theoretical framework and methods used at each step of the process.

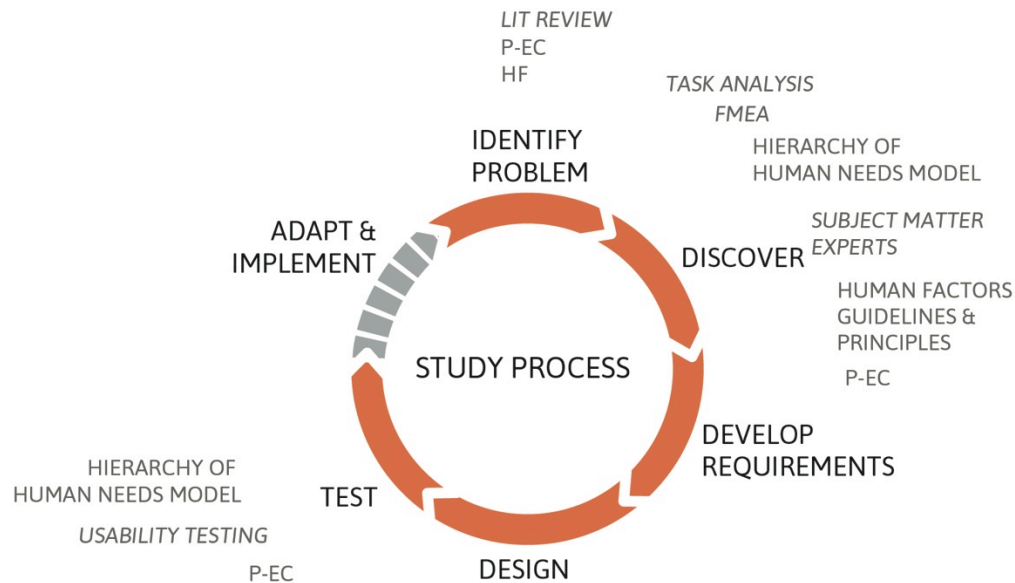


Figure 3 Study process and its relation with the theoretical framework (gray and all-caps) and methodologies (grey italics)

Development of Requirements

The first objective of this study was to understand the physical examination process and develop requirements for the new system that account for clinicians' workflow and needs. A set of requirements was developed to lead the design stage. These requirements were created following Human Factors and P-E Congruence theories and methodology, and issues founded on the literature. Sources for the development of requirements include 1) the developing of an IDEF0 (Integration Definition Functional Model) and a task analysis to understand the physical examination process, 2) a failure mode and effects analysis (FMEA) 3) review of literature and 4) user centered and display design principles. Organization and categorization of the requirements was guided by the model, proposed by Jordan (1997), of the user's hierarchy of needs. This model uses a pyramid to describe how functionality (base), usability (middle) and pleasure (top) are related to the practical benefits associated with products (Figure 2, page 25).

IDEF0 Model

IDEF0 is a functional modeling language that allows representing and understanding the functions, activities, or processes at different levels of abstraction (Areias, 2003, NIST, 1993).

An IDEF0 functional model (appendix 1) was developed to understand the physical examination process conducted with the patient during a medical encounter after the clinician interrogation. A-0, the top-level diagram, explains the physical examination as a process in which the clinician assesses the state of the systems of a patient with the aid of certain instruments (Figure 3.2).

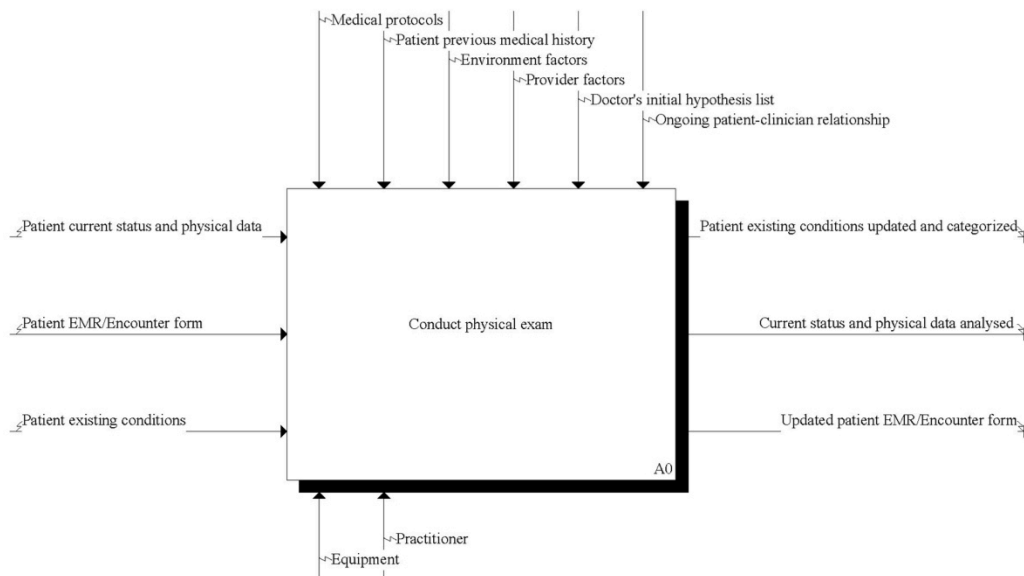


Figure 4 IDEF0 Model – A-0 Diagram

The information gathered contributes to the development of a working diagnosis, the evaluation of the state and evolution of a certain conditions, and confirms previous diagnoses. This process is controlled by medical protocols, the patient's medical history, and environmental and provider factors. The A1 level (appendix 1) describes the examinations upon which this project is focused: heart, lungs, ears, eyes, and dermatologic exam. During the evaluation of each system, the clinician uses the patient's symptoms and other information gathered during the interrogation to guide the physical examination. The review of each system usually involves four

tasks; inspection, palpation (feeling with the hand), percussion (tap with fingers to determine by resonance the condition of internal organs) and auscultation (listening the sounds of internal organs). Some examinations involve the four stages or process and others just some of them. For example, dermatologic examinations just include inspection and palpation, while eye examinations do not involve percussion or auscultation. Most evaluations involve the identification, characterization, and categorization of elements. For example, during the cardiac auscultation, the clinician identifies heart sounds, describes characterize, and categorizes them. During this process clinicians are comparing what they hear and see with their memory of what a normal condition would look and sound and if this is different, a comparison between the patient signs and characteristics are compared with the way different diseases . The patients' symptoms influence this process. Finally, clinicians reach a conclusion and categorize their findings. After that they will achieve a diagnosis and record their findings in the patients' medical records.

FMEA (Failure mode and effects analysis)

Failure Modes and Effects Analysis (FMEA) is a method for systematically analyzing what could go wrong in a prospective product or process, allowing practitioners to prevent potential failure. It involves rating each potential failure across three dimensions: severity, probability of occurrence, and non-detectability. Based on the IDEF0 model, an FMEA evaluation (Appendix 1) was developed by considering events that could go wrong on each level of the IDEF0 model. The evaluation was focused on the failures that can occur while using analog instruments and digital electronic medical records. For example, failing to correctly categorize a mole during a dermatologic exam could lead to the misdiagnosis of a lethal tumor and have fatal consequences such as death. Identifying what could go wrong (table 1) was useful to consider ways by which the system could prevent mistakes, errors and mishaps.

Literature review and other sources of requirements

The literature review has revealed issues related to the use and adoption of EMR, such as the complexity of the systems and the time required to enter data. Requirements were developed to provide ways to prevent these issues. Design principles and guidelines (appendix 1)

have proven to improve the user experience and reduce errors during the use of systems. These principles also influenced the development of requirements for this design concept.

Table 1 **List of potential failures**

A	Activity / Process	Potential Failure Mode
A0	Conduct Physical Exam	Not save the data at patient's file Get distracted and omit tasks
A13	Conduct Cardiovascular auscultation	Not examine all the areas Confuse a normal sound with an abnormal sound and vice-versa Wrongly describe an abnormal sound
A14	Conduct Cardiovascular auscultation	Wrongly categorize findings
A15	Conduct Cardiovascular auscultation	Not identify S3 or S4 Save data in the wrong field
A2	Conduct Pulmonary Auscultation	Not inspect all the areas Not identify a suspicious lesion
A3	Conduct skin, hair and nails exam	Describe lesions wrongly
A14-A25-A33	Update EMR/Encounter form	Enter incorrect data (error when documenting, writing something different of what was intended) Save data at other patient's record Document data incompletely

Requirements Results

Based on the previously mentioned sources, 75 requirements were developed. These requirements were organized and categorized following the three levels of the model of practical benefits of the products (Figure 2) proposed by Jordan (1997). Appendix 2 presents a detailed list of the specific procedure or literature source that inspired each requirement. The following requirements were developed to guide the device and application interface design.

Functionality:

- 1 The system shall provide means to communicate with the electronic medical records
- 2 The system shall provide means to send and receive text messaging
- 3 The system interface shall provide access to patient electronic medical records
- 4 The system shall provide means to update patient electronic medical records with exam data and findings
- 5 The system shall record data in the absence of an internet connection
- 6 The system should provide means to record and recognize user voice sounds
- 7 The system shall provide means to guarantee the safety of the users (physician, patient, maintenance staff) when it is in use
- 8 The system shall provide means to listen to and record heart sounds
- 9 The system shall provide means to correctly record sounds from the physical examination in presence of noisy environments
- 10 The system shall provide means to calculate and record the heart rate
- 11 The system shall provide means to listen to and record lung sounds
- 12 The system should provide means to record data from the dermatologic inspection
- 13 The system shall provide means to view and capture images and videos of the eyes
- 14 The system shall provide means to capture pictures with a resolution at 1900*1200
- 15 The system shall provide means to view and capture images and videos of the ears
- 16 The system should provide means to record handwritten notes
- 17 Corners and edges of fixed and handheld equipment to which the bare skin of the user could be exposed shall be rounded

Usability:

General requirements

- 18 The system shall be portable
- 19 The system shall have a means for grasping, handling, and carrying
- 20 The system shall weigh less than or equal to one pound
- 21 The system shall be resistant to impact from dropping or bumping
- 22 The system shall adapt to a clinician's "mental model" of exam flow
- 23 The system shall operate in an "intuitive" manner, requiring no written instructions
- 24 The system elements shall be smaller than 14"x 9"x 3"
- 25 System interfaces shall be easy to navigate

- 26 The system should use “knowledge in the world” and “knowledge in the head”
- 27 The system should simplify the tasks; do not overload memory, short term or long term, provide memory aids for easy retrieval of information and be sure the user has control over the task
- 28 The system should use graphics to make things understandable
- 29 The system should use and exploit constraints. Guide the user to achieve the intended action by limiting the repertoire of activities offered by the system
- 30 The system auditory displays should be distinguishable from environmental noise
- 31 The system's auditory displays should not interfere with clinician or patient activities
- 32 The system should provide legible or audible displays
- 33 The system interface should avoid absolute judgment limits
- 34 The system interface should exploit top-down processing
- 35 The system interface should exploit redundancy
- 36 The system interface should use discriminable elements
- 37 The system interface should exploit the principle of pictorial realism
- 38 The system interface should use the principle of the moving part
- 39 The system interface should minimize information access cost
- 40 The system interface should use the proximity compatibility principle
- 41 The system interface should use the principle of multiple resources
- 42 The system interface should provide predictive aiding
- 43 Procedures for performing similar tasks shall be consistent
- 44 System messages shall be specific and informative
- 45 The system shall provide user interfaces that are efficient, e.g., with reduced training time, task time, errors, and frustration
- 46 The system interfaces should provide means to promote physician-patient communication
- 47 The system may provide means to promote the patient's understanding of their conditions
- 48 The system may provide means to promote collaboration between clinicians

Error prevention/mitigation

A – Prevention

- 49 System shall be capable of continuous and autonomous operation for no less than 2 hours
- 50 The system shall be easy to clean
- 51 The system shall have a germ-resistant surface
- 52 The system may provide assistance to the physician to make an appropriate diagnosis

53 The system interface should adapt to physician's workflow and do not interfere with it

54 The system interface may facilitate the access to patient information

B – Detection

55 The system shall provide feedback to the users with regards their actions and the consequences of them

56 The system shall provide a means to inform the users when it is not working properly or needs calibration.

C – Correction

57 The system shall provide mechanisms to prevent or correct mistakes that may occur when using the system

58 The system should be designed for error. Plan every possible error that can be made and provide a recovery solution them allowing the user to recovery from any possible mistake

Pleasurability:

59 The system shall promote an “engaging” interaction with the user

60 The system should provide a “pleasurable experience” to the user while interacting with the product

61 The system may provide an emotion detection software

62 The system may provide means to “promote” communication between clinicians and patients

63 The system should not interrupt clinicians when they are interacting with the patient or analyzing the patient information

64 The system may provide means to prevent the physician from feeling incompetent or insecure (because not knowing how to use it)

65 The system should be easy to carry around

66 The system should feel good in the hand

67 The system should fit well and be comfortable against the face

68 The system should confer high cultural status (physician-clinician

69 The system textures shall be comfortable to the user

70 The system material's temperature shall be comfortable to the user

71 The system may be fun to use

72 The system may promote sociological pleasure

73 The system should not interfere with patient-clinician relationship

74 The system may promote patient-clinician relationship

75 The system should give aesthetic pleasure

Design concept development

The second objective of this study was to develop a concept design for a physical examination kit that causes minimal interference with clinicians' routine or communication with the patient. Based on the design requirements, several ideas and configurations were explored in order to find a design solution. The idea of a multipurpose device that combines the most frequently used instruments was chosen because it would be easier to use during a medical exam than using several different instruments. It could prevent instrument loss, and it would be easier to learn how to use only one device instead of many. This instrument would record data from the medical exam and save it directly at the patient's electronic medical records.

The design idea evolved through time, three iterations of the design concept were created (Figure 3). The main focus of these concepts was achieving a form that fits users' face and body comfortably (clinician and patient), a way of use that is similar to analog instruments, and minimal disruption. Each design iteration is explained below.



Figure 5 Design concept iterations. The first iteration is on the left; the second in the middle and the third and last iteration is at the right.

1. All-in-one device (Appendix 3) Inspired by a smartphone concept, this device combines a stethoscope, otoscope, ophthalmoscope and camera, access to the patient's record to retrieve and save information (digital files + findings). It includes a touch screen to control the device and visualize the information, control the instruments and save data. Presents exchangeable instruments pieces.
2. All in-one device + iPad application (Appendix 3). Inspired by a remote control concept plus the way traditional medical instruments are commonly used, this device includes the same instruments from the previous version. The device has physical buttons and controls but no touch screen. An iPad application is used to visualize and analyze the images and videos recorded from the device. Instead of exchangeable instruments, a rotational piece that includes ophthalmoscope and otoscope on each end allow the user to use both instruments with the same viewfinder window and camera. The device saves information automatically in a tablet computer EMR application.
3. All-in-one device (Figure 7). This device is similar to the previous one in shape and features, but with the difference that this one combines the ophthalmoscope and otoscope piece and it does not have a rotational piece. The device saves the information wirelessly in the iPad. The clinician visualizes and reviews this information using an iPad or tablet computer application (Figure 9). This concept and model were used when testing the concept.

Final Design Description

The final design solution (Iteration Number 3) for objective 2 consists of a multifunction, hand-held, portable to be used by clinicians during the physical exam, and its interaction with the patient medical record. It functions allow sensor scanning, data analysis, recording and transferring data to EMR (Figure 6). The device gathers information from the physical examination and transfers it wirelessly to the patients' records available at the iPad. The iPad access wirelessly to the patient records, retrieve information, allows visualization and manipulation of data and saves it at the EMR (Figure 6)

Clinicians would collect real time data from lungs, heart and other organs, evaluate it, and save it to the patient medical record as audio, image or video files. The designed system intends to aid the analysis of the data to improve diagnosis and differentiation between normal or abnormal conditions. It also intends to provide means to share the recorded data with other experts when facing a challenging diagnosis and advice is needed.

The potential users of the designed system include physicians, residents, interns, nurses, and also medical experts of different fields. The use of this system requires minimal computer skills and associated skills such as typing. Only a short training should be provided to users to help them start using this product.

The system will be used at the places where the physical examination is conducted: at the physicians' offices, in wards where patients are hospitalized or in emergency rooms. The system could also be used in rural environments. Environmental light will be needed to distinguish the controls and used the device appropriately. Electrical power should be provided to charge the batteries of the wireless instrument and iPad. The examination space should provide wireless Internet for the wireless instrument, iPad and EMR server to communicate. In order to interact with the iPad touch screen, the user should avoid the use of gloves.

The following sections describe the multipurpose device and the iPad application graphic user interface, and the models that were developed for the testing.

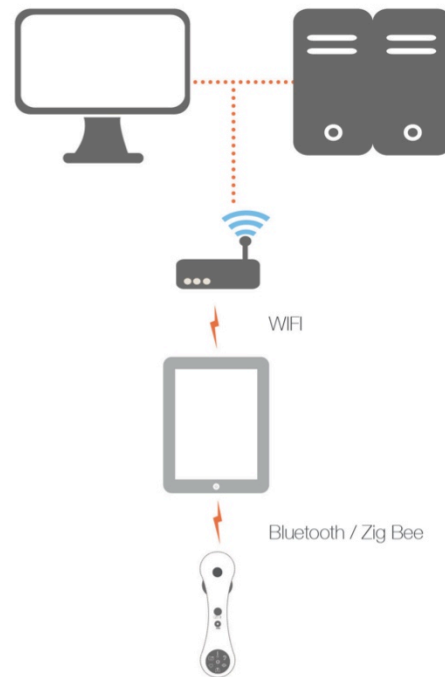


Figure 6 The all-in-one device transfer data from the physical exam to the iPad application. The iPad connects with the EMR database to retrieve and save information.

Multipurpose device

The designed device is a portable, multipurpose, hand held device similar in philosophy to a Swiss Army Knife to take health measurements. It works as a stethoscope (to hear lung, heart, abdominal and vascular sounds), otoscope (to see ear and throat) ophthalmoscope (to see eyes), dermatologic camera (to capture images of skin lesions) and a thermometer (to take temperature). The device can also take still photos, videos, and sound files from these organs, record them and save them in the patient's electronic records.

Its shape and dimensions adapt easily to the users' hands and patients' face and body. It can be easily handled and carried inside of a pocket. The surface is smooth in order to prevent colonization by bacteria and reduce cross infections between patients. In its final form, materials will be either polypropylene or melamine because they can provide smooth surface finish and resist cleaning products. The non-functional model tested was fabricated on a 3D printer using

PC-ABS, which is a polycarbonate-acrylonitrile butadiene styrene blend and then hand painted with an acrylic medium. This result is different from the finished surface of polypropylene or melamine. Lights colors evidence the dirt and promote cleanliness.

The front side of the device features the controls and the back part the sensors. It communicates wirelessly with the patient's EMR that is being used by the clinicians' tablet computer and it saves the information to the EMR database (Figure 6). It has six different modes of use: heart, lungs, eyes, ears, temperature and camera (Figure 7). When activated, the height of mode button is reduced. A light on the mode button indicates which of the modes is currently on. Once the user selects one of the six modes, the device is ready and the record button allows the user to record the data from the selected instrument to the patient's EMR. The selected mode automatically directs the information to the correct section of the EMR that is open on the electronic tablet. For example if the user press the heart mode, the sounds from the stethoscope will be saved directly to the cardiac exam section of the patient's record opened at the EMR.

The device has been denominated as an allscope, instrument that combines the capabilities of different wireless medical instruments. Hans is the commercial name of this particular design iteration.

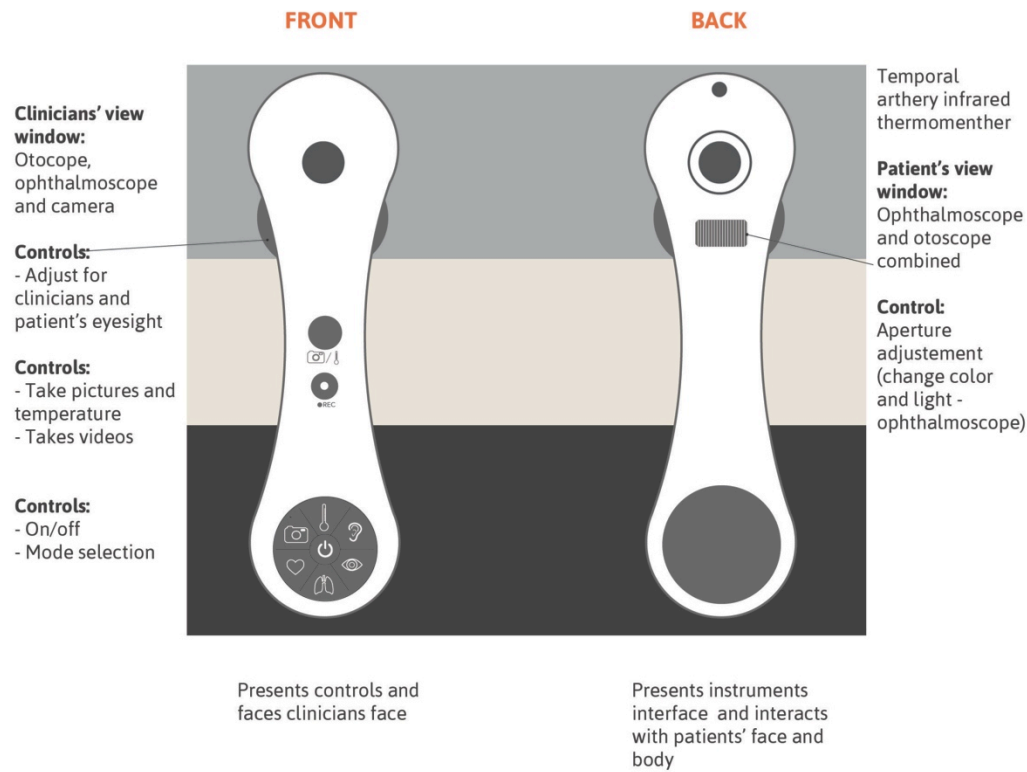


Figure 6 Hans concept sketch. A multipurpose device that collects data from a physical examination and transfers it wirelessly to the electronic medical records. It records temperature, pictures and videos from skin, eyes and ears, and also heart and lung sounds.

A functional mock up and physical model of the second iteration were developed by a senior capstone project at the School of Mechanical, Industrial and Manufacturing Engineering (appendix 5).

3D Model Development

According to Jordan (1997) models are suitable for testing if the product would fit into its environment of use and to evaluate if the physical dimensions are suitable for the product's purpose. For this study, a non-functional model of the allscope was created using *Solidworks*, a 3D cad modeling software, produced on a 3D printing machine, and then hand painted. Figure 8 shows the allscope model, how it fits the user hands, and how to use it for each instrument

function. This model, along with the iPad app mock up, was used for the user testing and evaluation phase of this study.



Figure 7 All-scope model and instrument's use.

iPad Application's Graphic User Interface:

The iPad application (figure 9 and appendix 3) allows the user to evaluate, save or delete information from the allscope. It is not an independent app but is intended to be an integrated part of the main electronic medical records software, in the physical examination section. Therefore, the way the clinician inputs data at every section of the physical exam EMR was not designed. It was assumed that is combination of typing, menu selection and voice recognition, and would allow the users to record their findings at the EMR.

The new functionalities allow visualization of images, videos, sounds their comparison with libraries of images, videos and sounds, and the ability to share that information with other clinicians. Also, the system will analyze the recorded data and aid the clinician identifying and categorizing information. Results are recorded at the patient records and clinicians can edit that if they do not match their findings (appendix 3).

A static mock up was created using *App Cooker*, an iPad prototype development application. The screen examples (appendix 3) are focused on the cardiac auscultation to serve as an example of how all the files from the different organs (i.e., eyes, ears, heart) would be visualized, evaluated and compared with the patient's previous records and other exam results. After saving the patient's physical data, the user can compare it with databases of examples of normal or abnormal situations, share it with other physicians seeking advice, or review other examinations in order to understand the patient's condition.

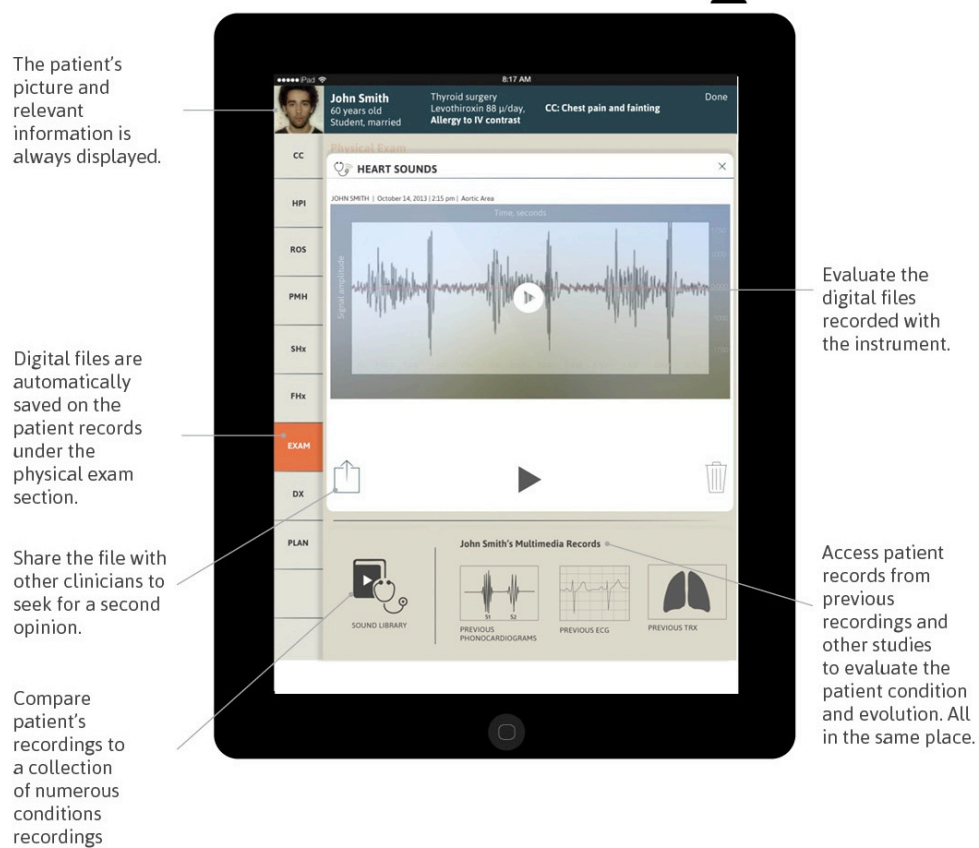


Figure 8 iPad application. After obtaining the data transmitted by the allscope, the clinician can evaluate, save, delete, or share that information using a tablet computer. Images, videos and sounds from the eyes, ears, lungs, heart and skin examinations are transferred wirelessly to the patient's medical records.

Summary of Design Procedures and Results

Seventy five requirements were developed based on the analysis of the physical examination, literature findings and existing user centered design and display guidelines and principles. The categorization was structured according to Jordans' model of hierarchy of needs. The requirements drafted not only drafted the functionalities of the new system, universal usability principles, but also defined the device personality to match the user needs. Little information was found available on the literature regarding the emotional needs of the user with regards to product preferences.

A design concept was developed following the requirements. It consists of a multipurpose device and the GUI for an iPad application that would interact with the EMR. A physical model (Figure 6) and a mock up of the iPad GUI (Figure 9) were created to be used during the testing stage. The design concept was created to be a silent technology that helps the clinician but minimally disrupts workflow and patient interaction. The allscope shape and dimensions were intended to adjust to clinicians' and patients' physical's characteristics because the device will be in close contact to the patients' face and body. Temperature of materials and surface texture were considered so it would be comfortable and safe for both users (clinician and patient)

As this is a new technology and therefore will change the way the users perform their activities, the main objective was to allow the user to perform their task in a similar way to what they are used to. The use of each function was designed to be similar to the instruments the clinicians already use. Furthermore, all the new functionalities for the EMR application are physically placed in the same sections that the clinician would report them in the paper-based system, consistently with user expectations and therefore navigation and finding what they are looking for is expected to be easy. For example, the images of the eyes would be saved at the eye exam in that specific day.

The allscope presents no digital screen, only physical buttons. It can be used without looking at it following tactile cues. The clinician will therefore focus on the patient, not on the technology.

CHAPTER IV

TESTING METHODOLOGY AND RESULTS

The purpose of this study was to design and test a new medical device concept to support the physical examination and its documentation. The methodology applied to the first two study objectives (development of requirements and design concept) and their results were outlined in Chapter III: Design Methods and Results. This chapter presents and discusses the methods applied to determine the effectiveness of the design solution using a non-functional model to evaluate the overall user experience, verify the requirements and evaluate the general fit of the new system. x

Population of Interest and Participant Selection

The population of interest in this study consists of clinicians who conduct the physical examination during the medical encounter (physicians, residents, interns, nurse practitioners). The study utilized a convenient sample of Oregon clinicians supplemented by a chain of reference sample procedure. Since this is a non-randomized sampling technique, no claim to represent a larger population can be made. However, the results of this study may guide the direction of future studies.

Recruitment Procedure

After IRB (Institutional Review Board) approval, seven participants were recruited by contacting medical professionals from Oregon and then continuing through a chain referral process. Personal contacts were reached through email and invited to participate at the study.

Description of the sample

The sample consisted of seven clinicians. The demographic characteristics of the subjects of this study are given in Table 2 below.

Table 2 Demographic Characteristics of the Sample

	n	%
Job title		
general medicine: physician	1	14
general medicine: nurse practitioner	1	14
specialist: family physician	2	29
specialist: family physician resident	2	29
specialist: pediatrician	1	14
Working environment		
clinic	6	86
private practice	1	14
Work experience		
≥15 years	5	71
6 – 14 years	0	0
≤ 5 years	2	29
Gender		
male	3	43
female	4	57
Age		
21 - 29	1	14
30 - 39	1	14
40 - 49	1	14
50 – 59	3	43
60 or older	1	14
Frequency of smart phone and/or electronic tablet use		
Never	1	14
1- 3 days a week	0	0
4-6 days a week	0	0
Every day	6	86

Note: n=7. Percentages have been rounded to sum to 100%.

Data Collection

Once the design for the device was finalized, an individualized case study approach with exploratory purpose was used to:

1. Evaluate the overall user experience, and system fit physicians' needs and characteristics.
2. Evaluate physician's perception about system interference with the their communication with the patient or workflow.
3. Verify requirements developed and detect relevant requirements not previously considered.

Participants were introduced and interacted with the system using a scenario script. Each participant conducted a mock examination using the device model and then responded to a written questionnaire and a qualitative semi-formal interview. Information collected from participants (questionnaire responses and interview audio recordings and transcriptions) were stored and locked. Participants were assigned a number, which was not associated with their names. Information was shared with researchers in charge of the coding process (one faculty and one graduate student).

Instruments

Scenario Script

A *scenario* is a hypothetical story that sets up a situation and leads to interaction with a system (Kaner, 2001). Scenarios are commonly used to connect testing with documented requirements, identify failures to deliver desired benefits, explore how users would use the program, and identify requirements, issues or requirements not-yet developed (Kaner, 2001).

In this case, the story described a patient that requires a cardiovascular examination (appendix 5). The scenario guided the interaction with the system while performing a cardiologic auscultation. Clinicians walked through the process showing how they would perform different actions to examine and analyze the patient's heart sounds.

Questionnaire

After conducting the scenario, each participant responded to an electronic questionnaire (appendix 8), which was implemented using Qualtrics TM, an online survey provider. It consisted of 32, mostly close-ended questions and a checklist with 16 items. The first questions (from 1 to 7) gathered demographic data. The next section was related to the participant's experience with the system and included two scales modified from the System Usability Scale (SUS, appendix 5) and Jordan's pleasure with products index (appendix 5). These scales provide an overall score of the system usability (SUS) and the product pleasurability (pleasure with products index). The questions 8 to 17 were from the System Usability Scale (SUS) (appendix 5). The ten-items of the SUS, with a 0-5 Likert response scale provide a global view of the subjective

evaluation of usability. It covers a variety of aspects of system usability and presents a high level of validity for measuring the usability. It also correlates well with other measures of usability (Brooke, 1996). Questions 18 to 32 correspond to Jordan's pleasure with products index (appendix 5). This questionnaire provides a way to measure the overall product pleasurability. It consists of 14 Likert scale questions that have been previously validated and evaluated for reliability, and used for the evaluation of consumer electronic products (Jordan, 2002). Because participants interacted with non-functional models, the tense of the questions were modified from present to conditional tense in order to allow participants to respond to questions while imagining that the product is fully functional (see appendix 5). The last section of the questionnaire, called *system attributes checklist*, gathered information with regard to some of the usability and pleasurability requirements developed in earlier stages. Functional requirements were not included on this questionnaire because they could be verified by other sources. Participants marked their level of agreement using a Likert scale.

Interview Guide

Qualitative, semi-formal interviews were conducted one-on one with the seven participants, either at their place of work or at the OSU campus. The researcher followed a written questionnaire guide (appendix 5) of 12 open-ended questions to obtain more feedback and detailed information than close-ended questions would provide. Its purpose was to gather information regarding the overall user experience with the system, identify and understand possible issues related to the design concept not previously considered, verify that the requirements were met, detect missing requirements, and evaluate the fit of the product with the user.

Procedure

First Stage: Introduction

After signing an informed consent (appendix 4), the participants were introduced to the system, and questions regarding its use were answered.

Second Stage: Scenario

The participants interacted with the models following the scenario script (appendix 5)

while pretending to conduct a cardiac examination on the interviewer. They went through a series of steps to record, email and compare the patient heart sounds with a heart sound database.

Third Stage: Post-test

A combination of an online questionnaire and semi-formal, qualitative interview were conducted at the end of stage two. The participants filled out the questionnaire using an iPad. After that, a one-on-one interview was conducted to obtain detailed information regarding the user perceptions and experience with the system. Questions addressed their perception about the usability and satisfaction with the system, what they liked or disliked about it, how they would improve it and their perception of the interference that the system might create with patient communication or their daily routine. Interviews were audio recorded and transcribed.

Data Analysis

Quantitative Analysis

This study utilized a small sample and was exploratory in nature. Inferential statistics were not appropriate. Therefore, data from the questionnaires were analyzed using descriptive statistics. Each of the 10 Likert scale items of the SUS survey provided a different value. Following Brooke's procedure (1986), an overall usability score, from 0 to 100, was calculated after transforming each answer and multiplying the sum of each answer value by 2.5. Values from each question of the pleasurability scale were then transformed back to the original scale (from 1-5 to 0-4) and added to create an overall pleasure ranking. Descriptive statistics were used to analyze the participants' opinions about which requirements were met.

Qualitative Analysis

Responses from the interviews were transcribed and analyzed using accepted qualitative methods with open coding. With open coding, researchers ask the data a specific and consistent set of questions, analyze the data minutely, frequently interrupt the coding to write a theoretical memo, and never assume the analytical relevance of any variable (Berg, 2012). A second and third reading of the text strengthens the coding scheme.

Any data that could link the responses to the participants were deleted from the records. In order to minimize potential researcher bias, two researchers (a fellow graduate student and the researcher) independently coded the transcripts using the open coding procedure. Responses were first read through using minimal coding, then a second time with a more rigorous coding scheme. In a third iteration, the data were reviewed and re-coded for clarity; unhelpful codes were eliminated or combined. Finally, the coding was reviewed by a senior researcher (supervising faculty).

Codes were analyzed for the presence of overarching themes, as well as the frequency and magnitude of codes. Themes were observed as patterns, important repeated details, and underlying values. The coding scheme included participants' perceptions of the functionality, usability and pleasure provided when interacting with the system.

Quantitative Evaluations Results

Overall User Experience and System Fit

System Usability Scale Results

The modified System usability scale questionnaire indicates participants' level of agreement with ten statements related to the system usability (appendix 5). Table 3 shows the final scores calculated from participants' responses. The mean's score results among the sampled participants was 73 (standard deviation =7), 71 % of participants (n=5) results were above average and 28 % of the participants score were bellow average. According to Sauro (2011) 68 is the SUS baseline value to determine when a result is above or bellow average.

Table 3 Participants results to the System Usability Scores

	Min Value	Max Value	Mean	Standard Deviation	Total Responses
SUS	57.5	80.0	73.2	8.0	7

Pleasurability Scale Results

Subjects were asked to respond to a modified version of Jordan' pleasure with products general index (appendix 5). Possible responses ranged from strongly disagree (0) to strongly agree (4). It is important to note that all the statements on the scale were positive and that there were no "strongly disagree" responses. Table 4 show results for the fifteen items on the pleasurability scale.

Evaluation of Pleasurability

An overall product pleasurability score was calculated by summing the individual scores. Possible scores were 0 to 52. Scores were categorized as follows:

- 42-56: very high product pleasurability
- 28-41: high product pleasurability
- 14-27: low product pleasurability
- 0-13: very low product pleasurability

Table 4 summarizes participant's total responses to the modified pleasurability of the systems questionnaire (see table 4). 28% of the subjects (n=2) found the system pleasurability very high, 42% high (n=3), and 28% low (n=2). The mean score was 33.3 (7 standard deviation).

Table 4 Participants results from the Pleasure with products evaluation

Product pleasurability	Min Value	Max Value	Mean	Standard Deviation	Total Responses
Very high	42	43	42.5	0.7	2
High	31	39	36	4.4	3
Low	25	25	25	0.0	2
Very low	-	-	-	-	0

Requirements Checklist Results

Participants evaluated eighteen system requirements that were generated through objective one. Possible responses ranged from strongly disagree that the requirement was meet

(1) to strongly agree (5). Results were categorized by mean responses to each item.

- High positive degree of agreement (80%-100%, mean ≥ 4)
- Positive degree of agreement (61% - 79%, mean: 3.5 - 3.9)
- Low degree of agreement (60%, mean: 3.0 - 3.4).
- Negative degree of agreement ($\geq 59\%$, mean ≥ 2.9)

Overall, nine requirements received a strong degree of agreement, three received a positive degree of agreement, and six requirements a low degree of agreement. None of the requirements presented a negative degree of agreement. Table 5 summarizes the results for each requirement.

Table 5 Evaluation of System Requirements

Requirement	N+	Mean	Min	Max	Standard deviation
The system can be comfortably carried	7	4.6	4	5	0.5
The system feels good in the hand	6	4.4	4	5	0.5
The system has useful functions	6	4.4	2	5	1.1
The system's displays are clearly visible	7	4.4	3	5	0.8
The system is safe to use (does not provide harm to the users)	7	4.3	3	5	0.8
The system displays provides information from the patient that is useful to achieve the correct diagnosis	6	4.3	2	4	0.8
The system's displays are legible	7	4.1	4	5	0.5
The system is easy to navigate	6	4	4	5	0.5
The system is easy to clean	5	3.9	3	5	0.8
The system's displays are useful to understand how to use the system	6	3.7	2	5	1.1
The system's display presents information in a consistent manner	4	3.6	4	5	0.4
The system is resistant to impacts and droppings	2	3.4	3	5	0.7
The system could be used without requiring written instructions	4	3.4	3	5	0.6
I like the look and feel of this system	3	3.3	2	4	0.8
Using this system would enhance my social image	1	3	3	4	0.5
I would feel proud if other see me with this system	1	3	2	4	0.6
Having this system makes me feel better about myself	2	3	2	4	0.6

N+: number of positive responses

Qualitative interview results

To gather more detailed information and feedback regarding the effectiveness of the design solution, the needs and characteristics of the users and to identify new requirements, semi-formal qualitative interviews were conducted (appendix 5). Responses from the qualitative interviews were analyzed using an open-coding process to identify common themes among subject responses in the following categories: interference with patients or workflow, perceptions of the system, and users' needs and characteristics. Tables 6, and 7 summarize the most frequently occurring responses to interview questions

Table 6 Summary of Qualitative Interview Responses Related to System Fit

Themes	Responses	n
Functionality		
Most useful features	Built in camera	6
	Record directly to EMR	5
	Documentation	5
	Compare and evaluate (patient)	5
	Compare and evaluate (databases)	3
	Share information with specialists	2
Least Useful features	Thermometer -	5
	Compare and evaluate (patient) -	2
	Compare and evaluate (databases) -	2
Usability		
Ease of use	Strongly +	5+
	Headphones -	2
	No carrying mechanism -	4
Easy to learn	Positive +	1
	Labeling -	1
Probability of Mistakes	Buttons -	2
Efficiency	Positive	3
	Neutral	2
	iPad -	2

Table 6 (Continued)

Themes	Responses	n
Usability (Cont.)		
Satisfaction	Buy after trial period	3
	Buy ++	2
	Buy if it works as promised	3
	Buy depending on cost	5
	Recommend +	5
	Overall +	4
	Overall -	1
Pleasurability		
Physiological	Easy to hold +	4 ⁺
	Small dimensions -	1
	No coat Pockets -	3
Ideological	Unified (multifunctional concept) +	7 ⁺
	Design +	4 ⁺
	iPad as technology -	4
Psychological	User confidence +	1
	Pleasure of use +	4
	Pleasure of use -	1
	Useful functions +	5 ⁺
Sociological	Communication & education (patient)+	4 ⁺
	Communication with other doctors +	4
	Learning +	1
	Learning -	1
	Status -	1
	Toy-	1

Overall User Experience and Fit

Functionality, Features, Relevance and Use

The most useful functions described by the participants were:

- Recording data (images, videos, sounds) directly to the patient's record
- Documenting the clinical exam more accurately by using multimedia files

- Taking pictures (mostly for skin conditions but also for ears)
- Recording heart and lung sounds
- Comparing and evaluating patient conditions across time
- Comparing patient conditions with a database of reference
- Share information with other clinicians

FEATURES: Participants expressed that the features provided by the multifunctional device would be the ones that they use more frequently (stethoscope, otoscope, ophthalmoscope and camera). However, the majority of them expressed that they rarely use a thermometer because the nurse that see the patient prior to their encounter takes and record the temperature among other vital signs.

Many participants perceived the ability to document findings with images, videos and sound files as a very useful function. They mentioned that this would allow other doctors a better understanding of their findings.

“It would be great for documentation. Sometimes is really hard to describe what an ear looked like”

Taking pictures of skin conditions was described by most of the participants as a very convenient feature in terms of documentation and communication between clinicians. They expressed that sometimes is hard to imagine skin lesions by reading the descriptions of other doctors and therefore evaluate if it has changed or evolved since that time. One participant noted:

“I had a patient who had kind of a pimple or an abscess on his elbow. He had been seen by another provider four days earlier and I'm just looking at her note trying to imagine what it looked like and then now I'm seeing it later and I'm trying to think, [how it looked like] ”

In addition to the benefit of skin documentation, several participants expressed that it would be useful to document other systems as well. For example, one participant would record children's' heart murmurs so that other clinicians, when seeing the same patient in the future, would be able to determine if the murmur they now have are the same they had during their infancy or is a different one. Besides this, clinicians mentioned that having a system that

automatically analyzes patient's heart sounds and records its characteristics would save them time filling this information at the patient's record.

Participants were optimistic about the system's ability to automatically save files into the patient's chart.

"In terms of the camera I would be really excited about that. Right now I guess sometimes I've had students take their iPhone out, take a picture then I tell them to mail it to me then I have to email it to our medical records person and ask them to upload it into the system and label it. And then I have to review it again. Or the other option is this medical record person who's downstairs I can call up and say, "Well you bring up the digital camera," they'd take a picture and then she has to download it and then send it to me and then I have to review all the photos." ²

Subjects' opinions about being able to compare patient's sounds or images with a database differed. Two subjects stated that they wouldn't record or compare heart sounds with a library. If they are concerned about the patient's heart sounds they would order an echocardiogram. On the contrary, three participants perceived the sound library functionality as being very useful.

"Listening to heart sounds, I don't know, that's always challenging. Even though I've been practicing a long time you sometimes hear things and you don't know, is this a significant murmur? is this just a normal flow murmur of a young, healthy male athlete? . . . But maybe with this you could feel more confident that, Oh, this is just a benign murmur, or, Oh, this is one I should order an echo. So I could see that being real useful."

Two participants mentioned that the ability of sharing patients' files as useful to get feedback from other clinicians without having them see the patient. One of them also mentioned that it would be beneficial to use in academic settings where clinicians review and discuss the files on challenging patients.

Usability

EASE OF USE: Five subjects reported that the system seemed easy to use. Below there are some examples of their comments:

- *"I could foresee it being a very easy device to use"*

- “Seems easy to use and well thought out”
- “I could see where you could go really crazy if it is really that easy”

During the interviews two participants realized that the stethoscope functionality might not be as easy as the analog comparison. They described it as the biggest adjustment that they foresee. They would need to plug in the headphones to the device, put them on their ears, then unplug them and store. They also thought that if they were similar to traditional headphones the cable could get tangled. Further, there is a chance that they would lose them. One mentioned that there are times where ambient noise is so high that they could not use the speakers on the device so they would have to use headphones.

Another common concern mentioned by participants was that as they do not wear white coats (with pockets) in their daily routine they could not carry the device easily. They would have to carry it by hand. One participant mentioned:

“I'm not really good at remembering things unless it's attached to my body when I walk out of the room, so like pens; I always had to stick them in my pony tail because I'll forget things and my stethoscope is around my neck. If I don't have those things attached to my body I'll forget.”

PROPENSITY TO MAKE MISTAKES: Two subjects mentioned that they would be concerned about pressing buttons accidentally. One problem could be the device's small dimensions. The other problem could be when patients are children who might interact with the device by activating controls or saving files to EMR that were not intended.

LEARNING: One participant mentioned that as the use of each function would be similar as the existing instruments it would be very easy to learn how to use them. However, another participant suggested labeling the recording buttons - they were not labeled on the physical model - because if they were not “the learning curve could be a pain”.

SYSTEM EFFICIENCY: The majority of participants mentioned that the all-in-one device would make the physical exam faster. They would have only one device to conduct most of the exam. However, some participants also mentioned that the iPad could slow them down, or that they did not have time to “play with the iPad” while seeing the patient. One participant

expressed the uncertainty about how helpful the system would be in terms of efficiency.

"I don't know if it would make anything much faster or more efficient; I don't know."

OVERALL SATISFACTION: Most participants expressed a very positive overall satisfaction with the system, especially related to the all-in-one instrument.

"I was kind of skeptical when I first heard somebody's going to show me a prototype. Oh yeah, they're going to have something that's going to be stupid or -but I'm actually pleasantly surprised."

BUY AND RECOMMEND: When asked whether they would buy the system if it was on the market, opinions were mixed. Some would buy it, some would do it after a trial period or after seeing it work and evaluated if it has compatibility issues or high maintenance requirements, and one would buy it if it presents the additional suggested features. Many said that the decision to buy would depend on the price of the system; they assumed that a device like this one would be expensive because of the technology involved. Last, most participants would recommended it to other users, while one would do so only after trying it. One participant noted that if the product is good a recommendation would not be needed.

Pleasure

PHYSIOLOGICAL PLEASURE: Four participants indicated that the all-in-one device was easy to hold. One participant noted that the device dimensions fit in her hands perfectly but may be an issue for people with bigger hands, who might not use it comfortably or accidentally press the wrong controls.

As stated before at the usability section, three subjects mentioned that they do not need to wear white coats anymore outside of hospital setting and therefore they might not have a placeholder for the device. One participant claimed that if the device is not attached to her body she might forget it when she leaves the room.

IDEOLOGICAL PLEASURE: All participants liked the unified functions of the all-in-one device. Subjects described it as handier, or nicer to just have one thing in their hands. They also

liked the design, the concept, the idea of the product.

PSYCHOLOGICAL PLEASURE: Most participants described the device as useful, or having useful functions. Examples of their comments include:

“It’s a unique concept,...it combines all the elements that I would like to have”

“I think it would be really useful. “

As mentioned before at the usability section, several participants found the system easy to use. One participant also mentioned that he would feel more confident when listening to heart murmurs if he could compare them with the sound library:

“You could feel more confident. This is just a murmur”

A family medicine resident indicated that it would be a great learning tool.

“I like the most is probably the ability to digitize all that information to be able to share it and see it later.

On the contrary, another responded:

“It’s good for people who already know what they’re doing so not good for students because then it could take away the learning purposes of having to recognizing those.”⁷

SOCIOLOGICAL PLEASURE: Several participants were excited about how the system would be a useful teaching tool, increasing the understanding of patient’s own conditions and their evolution.

“This is what your asthma sounds like last two weeks ago and now you’re doing so much better. Listen, now you sound like this,”

Some participants mentioned that having a device like this one would affect their *social image*. Depending on patients’ perception of technology, this device could improve patients

'perception of technology:

"Especially working with students because they want to know their providers are on the cutting edge of technology.I think it makes them feel like you're not some dumb dinosaur who doesn't know what they're doing. So yeah, it might be helpful."

Conversely, one expressed concerned about losing prestige because not having the stethoscope around her neck as a symbol of status indicating that she is a doctor.

"You would lose the prestige as a doctor if you don't have the stethoscope around your neck"

Subjects also mentioned that the system would facilitate communication among clinicians. They mentioned that it could be useful as a consultation tool to discuss the status of a patient's condition, a long distance consultation or to present information in academic settings.

Last, a pediatrician mentioned that she gives instruments to patients as a distractor while she examines them. With just one multifunctional device, she would need to find another distractor for kids during the exam.

Device Interference with Clinician's Relationship with Patient or Workflow

Relationship with patient

Subjects indicated that this device would affect their relationship with the patient, particularly during the learning process. However, all but one stated that the device would not disrupt their communication or relationship with patient after they have learned how to use it.

PROMOTE COMMUNICATION WITH PATIENT: Four participants mentioned that the system would be really useful as a communication tool through which they could explain their patients' conditions and evolution to them.

"I was thinking about its potential to share that information with them because once they experience it, whether they hear it or see it in whatever sense it becomes more real for them. If we can say your heart, this is what a normal heart sounds like and this is what yours does. I think it will provide that experience to them that will kind of solidify their knowledge and experience."

PATIENTS' PERCEPTIONS OF TECHNOLOGY: Opinions varied concerning patients' perceptions of the technology. Some felt that young patients may like to have technological devices at their encounter. On the other hand, some suggested that older patients would expect to be analyzed with the traditional analog instruments.

"I think depending on the age of the patient, if they're more the older generation that would probably – for the old stethoscope on the skin; ophthalmoscope -- it's more relationship-building, kind of like a ritual, versus the younger generation I don't think they care. They grew up with electronics anyways. Like, "That looks cool. What is that?" I think it depends on generation."

Clinician's workflow

The main characteristic associated with the improvement of clinician's workflow was the integrated abilities of the system. Clinicians mentioned that using one device instead of many could save them time. On the contrary, a few participants felt that the iPad functionalities might slow them down.

"if you're a researcher that makes perfect sense. If you're a practicing physician it's a luxury of time that you don't have. It would be very interesting but does it fit into my day? No."

Clinicians' characteristics and Needs

The most common concern expressed by participants was time constraints. One participant mentioned that some days she has only 10 minutes per patient. Participants reported that the most time-consuming activity reported was typing and interacting with technology.

Other commonly cited concerns were the quality, maintenance requirement and reliability of medical instruments. Participants mentioned the stethoscope as an always-reliable instrument because it does not use a battery. Instruments that have batteries require them to be charged or replaced and often cannot be used at the time they are needed.

*"The battery just died, so that's why I wonder how good the battery is going to be...because it gets really frustrating when your battery's going dim and then there's not a spare battery around and how complicated is it to change it."*²

In addition to battery concerns, subjects had practical concerns about the general maintenance of the hardware and software.

“how often does it need to be updated?”, “is it compatible with other systems?”, “how often would I need to change the light bulbs and how easy would that be?”

Recommended Additions and Alterations

Participants mentioned that the most cumbersome part of the exam is to record their findings in the patient records. Many indicated that they first conduct the exam and then, either during or after the visit, fill the information using a computer. The difficulty they experience recalling details from the exam when they had to fill it later were of concern to them.

“Now when I do a physical I'm not interacting with the computer at all... Then I have to come back later ... Because what happens is I do my physical exam then I talk to my patient, counsel them, order the prescriptions, then you're looking at, “Oh, I'm five minutes behind, I've got a patient waiting.. you don't do the physical exam until maybe my lunch hour when I'm done seeing patients and I'm having to remember details....was it the right leg or the left leg”

Because of the difficulty recalling details from the exam and the time it takes to record it in the patient’s record participants suggested the need of *recording their findings while conducting the exam*. Voice recognition software was one of the most frequent suggestions. One suggested having a button to click on the different sections of the exam whenever the patient was within normal limits (“ear exam ok, eye exam ok,) and then being able to select from a menu the other findings or record them using a microphone at the device and voice recognition

Participants also suggested that a high quality screen display included in the all-in-one device would provide them instant feedback regarding the quality of the images that they have recorded. Also, if they have this they would not need to interact with the iPad while conducting the physical exam

Other suggested features included:

- Diagnostic aid, treatment and exam suggestions based on patient history
- Tonometer – to measure intraocular pressure

- Tympanometer – to measure ear pressure in tympanic membrane
- Measurement of dimensions of skin lesions
- Echocardiogram

Table 7 Participants' suggestions

Suggestions	n
Record Physical exam in real time into the EMR	3 ⁺
Voice recognition	3 ⁺
Screen display (high quality)	2 ⁺
Diagnostic aid	1
Treatment and test suggestion	1
Tonometer	1
Tympanometer	1
Measure dimensions of skin lesions	1
Echocardiogram	1

Summary of Testing Results

User Experience and General Fit

Positive Findings

Quantitative and qualitative analysis indicate that the users perceived the system as useful, having capabilities that match their daily routine in many ways. The perceived positive functional aspects of the system includes: the instruments capabilities provided by the device, the ability to document in more detail and save automatically to the patient chart, visualize and evaluate patient files, and the system as a tool to communicate with the patient and other doctors.

In terms of usability, the positive comments of the participants referred to the perceived ease of use and learn, especially the multifunctional device. Most of the participants expressed satisfaction with the system concept and many expressed interest in buying after a testing period.

Participants were overall pleased with the concept idea, the design itself, and the way the device feels in the hand. Some expressed that they would enjoy using the system and it may improve their confidence in their findings. Many participants valued the fact that the system would facilitate communication with patients and other doctors as well.

Negative findings

A majority of participants said that they would not use the thermometer and two other participants mentioned that they do not need help to interpret the physical exam results. Regarding usability, the way of using the stethoscope (with headphones) was perceived as difficult. The fact that they would need to plug in headphones every time they examine a patient seemed very uncomfortable and cumbersome. Besides that, participants mentioned that they do not wear coats with pockets anymore; this would imply that they would need to carry the device in their hands.

The participants main concern was time, they have very limited time per patient. Because of this they were interested in finding out how these new functions would affect their time. Some perceived that the iPad functionalities - to evaluate files - would hinder their practice. Also, many participants referred to the iPad as the technology piece and being such, it could get in the way of their practice or relationship with the patient. They seemed to have an overall negative perception of technology therefore, in this area the system do not match clinicians needs. On the other hand, they did not refer to the allscope as technology.

One important issue in terms of pleurability is that this system does not convey the social status of a doctor. Also, pediatricians use to give the instruments they are not using their patients in order to distract them and examining them. If they use an all-in-one device they would need to find another solution to entertain patients.

Interference

Participants mentioned that the system would not interfere with their relationship with the patient; on the contrary it could help them communicate with them and some patients may even modify their image of their clinicians because they are using technological devices. With regards to workflow, some characteristics of the system were perceived as beneficial and others as having the chance of slowing them down, depending on how well technology works.

All in all, the system seems to fit the overall many needs of the users, and the multifunctional device seemed to be more accepted than the iPad application. However, one salient need is time and the system may not account for this as much as it could. The system was perceived as that it would positively affect clinicians' relationships with patients but were not as sure about how it would affect their routine; in some ways it could improve it while in others it might not fit with their routine.

Requirements

Half of the requirements tested were verified. The other half ranged from 60% of agreement to 79% of agreement. The requirements verified were related to usability and psychological and physiological pleasure. The ones not satisfactorily verified were related to social pleasure, usability and look and feel of the system (Physiological pleasure).

Limitations

This was an exploratory study; the non-random sample and the small sample size did not allowed to identify every usability related issues (Jordan, 2002), accurately determine the degree of fit between users and devices, nor be generalizable to the population of interest (Ramsey & Schafer, 2002). However, as this evaluation was done at early stages of the design cycle, even the small sample size might provide insight about the major issues related to design and guide the development of future stages of the system.

Interviews conducted in person may present social desirability bias (Jordan, 2002; Ramsey & Schafer, 2002). Respondents may present a desire to be seen as pleasant and respond based on what they think will not disappoint the evaluator. In addition, the designer conducted the interviews; respondents could be especially prone to report positive reactions. However, self-reported data in person provide more positive feedback than when using anonymous surveys.

CHAPTER V

DISCUSSION

System Experience and General Fit

The presence of fit was evaluated based on Jordan's model of user needs (figure 2). This model presents needs that are related to functionality, usability and pleasure. Participants comments related to each level were analyzed based on their needs for that level. The fit was evaluated based on what participants reported as positive or negative and how important that seemed to be to them and their comments about their needs. The system presents an overall fit with clinicians needs. It combines the instruments that they most frequently use, provides useful functions that meet most of their relevant needs; such as those of documentation and communication with patients. The following is an analysis of the areas of fit and lack of fit at each level of the model.

Functionality

A majority of participants found the system useful. The selection of instruments included seemed to match the needs of clinicians, except the thermometer. Participants mentioned they would rarely use a thermometer; nurses usually take the temperature and other vital signs prior to the doctor's visit. Future iteration of the design should consider removing this instrument capability to reduce the complexity of the system.

The ability to save files automatically in the patient chart was found to solve the problem that many participants face now when they want to save pictures or other data in the patient records. Some participant needs to contact someone in charge of medical records, send them the image to be uploaded to the patient file. The time of this process would now be reduced to seconds if the system works as intends.

Some of the experienced clinicians (with more than 15 years of experience) reported that they do not need help to understand or characterize the physical exam findings. By contrast, other clinicians with low level of experience found these functionalities great tools that would allow them to improve their knowledge and make decisions more confidently. These differences might be explained by the fact that experts become efficient performing tasks and also more certain about their findings than novices who might need more time to perform the same task or

to make decisions regarding the patients' condition. The system diagnostic aid functionalities might, therefore, be more useful for this last group than for the more experienced clinicians. The need of this functionality might also be determined by the kind of patient that the doctor sees most frequently; if they regularly do sick visits, urgent care, or just periodical check ups.

As well as the physical exam diagnosis tools, the ability to share information with other doctors might be more useful for students, inexperienced doctors, and rural doctors who do not work in teams, than for experienced doctors who do not usually need diagnostic aids.

The multipurpose device seems to overall match the needs of the interviewed clinicians. The functions provided by the iPad seem to match the needs of novice clinicians better than experienced doctors. Anyway, as doctors can choose whether to use those functionalities or not, experienced clinicians could use the multipurpose instrument to examine the patient without recording any data if they do not think is necessary, or might not use some of the functions at all.

Usability

System Usability Scale (Overall User Experience)

The majority of the participants' results were above the average, which according to Sauro (2011) is 68. It should be noted that participants filled out this questionnaire based on how they thought a fully functional system would work. This perception varied depending on their ability to project the functionality of the system as well as the interviewer's ability to clearly communicate about the system. Testing a fully functional system on a randomly selected population would provide more reliable and representative results. Nevertheless, SUS results could indicate that participants perceived that the system would provide an overall positive user experience.

Usability Findings from Qualitative Interview

The system was perceived as easy to use and learn. This would satisfy the clinicians need for systems that require little time to learn and are easy to use. Boonstra and Broekhuis (2010) stated that clinicians do not have time to dedicate to learn how to use new products. The

perceived ease of use and learning might be because the device use is intended to be similar to the use of familiar instruments. Several requirements were dedicated to exploit user expectations and mental model so clinicians could transfer their previous knowledge to the use of the new device easily.

The majority of participants expressed a very positive overall satisfaction with the system and especially to the allscope. The device combines the instruments they most regularly use, allows better documentation, and provides useful functions and is used in a similar manner to those they already use. Many participants expressed that they would buy it and recommended it, two factors that according to Tullis & Albert (2008) are satisfaction indicators. One interesting factor is that many participants specified that they would like to have a trial period before deciding to buy it— some even mentioned a month long trial - to evaluate how they would work in their routines. This might be explained by the fact that, as mentioned before, clinicians decisions to adopt new technologies are mainly related to efficiency and that is something that cannot be evaluated by a non-functional model. Also, many clinicians might be skeptical after trying new promising technologies that did not work as expected.

This may be related to the fact that we were testing an idea, not a working on the shelf device and also that they might been skeptical after having tried new promising technologies, that did not end up working as smoothly as promoted.

Other factors involved at the decision of buying would be the cost and maintenance of the systems. Clinicians reported to have little time to maintain systems (change batteries, upgrade software, etc). These two factors are not directly related to the scope of this study but have to be considered as important variables that determine the success of the product. Another fact that should be considered is that many times the buying decision is not made by the clinician but by the institution in which they work. Usually these decisions are based on cost savings. A study that measures the efficiency and efficacy of the system in terms of time to transfer data, mistakes prevented and accuracy improved or reliable documentation in case of a lawsuit may provide useful information for the institutions to make buying decisions.

In order to really suit the needs of clinicians the system would need to have a positive impact on their time, allowing them to devote more time to the patient and less time

documenting and interacting with technology. A study of this kind with a non-functional model cannot measure the effect of the new system on the encounter time. From their perspectives, some aspects of the design could save them time while others could slow them down, depending how well the system works. So far there is no evidence that the system will fit this important need. However, the ability to record the exam in real time suggested by participants seems to be a great possibility to achieve this result, especially because documenting findings in the patient records seems to be the most time consuming task reported.

Usability Issues Discovered

EASE OF USE: Two participants foresaw the stethoscope piece of the device as the biggest adjustment. Plugging headphones every time they conduct an exam would be cumbersome and speakers would not be useful in high ambient noise. Clinicians have listened to body sounds (auscultation) in the same way for hundreds of years, it is understandable that a device is used in a different way would be perceived as a big adjustment. A study using a functional prototype would permit to measure how well the speakers work in noisy environments. There might be a chance that if the speakers are of good quality and they can regulate the sound volume, some clinicians may prefer to listen to the sounds through speakers and no longer use ear bugs. Nevertheless, the headphones experience needs to be redesigned. Wireless headphones could be used instead or maybe even integrate the headphones to the device so they are attached and there is no need to plug them to use them. Less dramatic improvements could include magnetic mechanism to guide and facilitate their connection with the device line out.

When asked about their use of white coats, many participants responded that they do not wear white coats anymore, unless they are in a hospital setting. This characteristic of use implies that the device, which was designed to fit in the coat pockets, would not adequately provide means for carrying, other than in the hand. However, all the participants indicated on the questionnaire that the system could be comfortably carry around. It can be assumed that they answered this question based on the fact that they were expecting to carry it by hand and that they consider it easy to hold. Anyway, a different carrying mechanism should be evaluated when improving the device design. Maybe the carrying experience and the new headphones could be associated, or the device could be carried along with the iPad in a iPad cover; in this case it would be beneficial to investigate whether clinicians carry around tablets or there is one on every

room. A more detailed consideration on carrying mechanisms should be considered when redesigning the device.

DIFFICULTY TO MAKE MISTAKES: Another issue mentioned was the chance of accidentally pressing buttons, either by themselves or their patients. Detailed consideration to this issue needs to be taken during the redesign of the system. For example, buttons could not be as salient in height as they are now or the device dimensions could be modified to provide more clearance to the user's hands when using the device. A comparative study in which the users test models of different dimensions and buttons' height and would provide a better understanding of this issue.

Pleasure

The results from the pleurability score (see table 5) indicate that most participants found the system pleasurable. Even though this result seems positive, a fully functional prototype would be needed in order to predict the overall user experience of the system.

Physiological

Results from the requirements questionnaire indicated a strong level of agreement with the "statement the system feels good in the hand." In qualitative portion of the session, most participants confirm the finding and expressed that the system was easy to hold. There was also a unanimous agreement at the requirement checklist that the system can be comfortably carried around, despite the fact that some clinicians indicated that they do not wear a coat anymore and therefore have no pockets in which to carry the device. Many participants interviewed were doctors working in clinics where might usually stay in the same office and patients come and go. It would be interesting to evaluate how doctors from hospitals perceived this issue.

When asked about the look and feel of the system (requirements checklist), responses were mixed. During the qualitative interview several participants mentioned that they liked the design. However, the term design does not only refer to the way something looks or feels. More information is needed to understand what they do like, what they might not and the importance of the look and feel of an instrument for a clinician.

Psychological

Participants seemed to envision the system as useful and usable. Some expressed that they would enjoy using the device and even feel more confident about their findings. According to Chismar et al (2003) perceived usefulness was the primary indicator of intention of use in the medical community. Therefore this might indicate that if the system provides the promised benefits the users would be interested in using this device. Having considered the user needs and characteristics when designing the system seemed to have paid off.

Ideological

Participants express delight with the design concept. This is a positive finding indicating that the design concept is in the right direction. Also, many subjects indicated that they liked the design, but unfortunately it is not very clear if they were referring to the design aesthetics or not. More research would be needed to provide more insights with regard this matter.

Sociological

In terms of sociological pleasure, participants indicated that the system would promote their communication with the patients and doctors. Further detail into clinician social preferences would be useful for the design implementation. For example, clinicians could send files asking for advice to other doctors who might not be interested in answering them. The specifics of how the system would be implemented should also be considered. For example, there could be a person in charge of answering those emails or the email could be sent into a forum, not an specific person and the medical community could optionally choose to respond.

When participants were asked if the system would enhance their social image (requirement checklist) the mean response was 3. In the interview, an infrequent but very relevant concern was that a clinician could “lose the status provided by carrying the stethoscope around [the] neck”. This is an important matter for some due to the fact that that the

stethoscope around the neck is the only indication that one is a doctor, since nurses do not wear one. Careful consideration to the symbolic meanings should be taken when redesigning the device.

Another concern expressed was the use of instruments as toys or distracters with very young patients. The multi-use device would be in constant use and another distractor would need to be provided. Based on this and other issues seems that this device, conceived with an internal medicine doctor in mind, might not fit the needs of a pediatric clinician. It might be useful to create a pediatric version of the all-in-one instrument, or since allowing a young patient to hold the instruments used in an examination may be helpful to reduce anxiety, a non-functioning replica may be provided for pediatric settings.

To sum up, is still unclear how important device aesthetics and appearance is for clinicians, but it seems reasonable to consider systems that do not present a highly technological appearance because most participants expressed a negative attitude towards technology (consistent with Jordan, 2002). Otherwise the system seems to fit participants' needs in terms of form and dimensions, with the exceptions reviewed previously. The system seems to fit the clinician's relationship with patients, does not interfere with their relationship and might provide means that promote communication among them. In terms of social interaction between clinicians, the system was perceived positively providing means to facilitate communication when desired. The system does not seem to fit the need to convey professional status among co-workers and also to patients so therefore more research is needed to determine a system that better fits this need.

Interference with Patient-Clinician Communication and Clinician's Workflow

Relationship with Patient

Disruption

The system might disrupt patient-clinician relationship during the learning process because they would need to dedicate cognitive resources to the device and also because of the patient reaction to this new technology, depending on their own perception of technology. Subjects

were concerned that older patients may expect the clinician to use the traditional instruments whereas younger populations might value the use of cutting edge technologies and therefore perceive their health provider in a positive way. More and more, the population is getting used to new technologies, older populations might also appreciate technological solutions if they can evidence their benefits. Furthermore, systems that accounts for older users characteristics, that present information use readable font sizes and considers their mental models might increase the acceptance of these new technologies by these populations.

Communication

Participants did not consider the system would interfere with their relationship with the patient, on the contrary it could help them communicate with them. Subjects were enthusiastic about the possibilities that the system provides in terms of communicating with the patient about their conditions or evolution. They all agree that the system would not interfere with clinician relationship with patients. By the lack of perceived interference it could be inferred that the system does not generate stress and discomfort when used and therefore match the clinicians needs and characteristics.

Interference with Clinician Workflow

With regards to workflow, some characteristics of the system were perceived as beneficial (all in one device and documenting time) and others as the chance of slowing them down (evaluating images and files) depending on how well technology work. Clinicians do not have much time per patient (Dugdale, Epstein, & Pantilat, 1999). For example, one participant mentioned that she usually sees 20 patients in one morning. Affecting workflow and efficiency is a major issue for clinicians' practices, even if is a small change. The increase in time has to be considered carefully, a one minute increase per patient may have a serious impact when the clinician has only about eight minutes per patient. Any new technology introduced will need to account for the small time that they have to see the patient and maybe if it adds time due to a valid and useful function it may need to reduce time of other process involved so it has no greater impact on the overall visit.

Requirements Verification

Due to the limitations of having a non-functional model that do not exactly replicate some characteristics of the system (i.e., weight) only a few requirements related to usability and pleasurability were evaluated.

The following is a list of the requirements that were strongly verified by the users:

- The system is portable
- The system can be comfortably carried
- The system feels good in the hand
- The system has useful functions
- The system's displays are clearly visible
- The system is safe to use (does not provide harm to the users)
- The system displays provides information from the patient that is useful to achieve the correct diagnosis
- The system's displays are legible
- The system is easy to navigate

The requirements about display visibility, legibility and navigation were also reflected in participant's opinions regarding the ease of use and learning to use the system. Also, the iPad application was created considering the users mental model of the paper base medical records, this might also facilitated the perception of a system "easy to navigate". No issues were mentioned related to these requirements, which support their verification, by the sampled population. Participants also perceived the device as being safe to use. This last requirement should be considered by inspection and testing without involving users.

The following requirements participants expressed positive but not strong agreement.

- The system is easy to clean
- The system's displays are useful to understand how to use the system
- The system's display presents information in a consistent manner
- The system is resistant to impacts and droppings

- The system could be used without requiring written instructions
- I like the look and feel of this system

Requirements related ease of cleaning and resistance to impacts would be better analyzed using a fully functional model in which the user could evaluate the materials and details of the system. Anyway the participant's perception related to ease of cleaning could be related to the height of buttons and might be solved using less salient buttons and reducing device crevices.

Overall responses to "The system could be used without requiring written instructions" might be related to deficits of the concept itself or the fact that participants did not have a time a training time where they interacted with the system. A fully functional device and a longer training session at during the testing procedure would provide feedback to their actions and may allow the testing of how easy is the learning process would be.

The following are requirements that were not verified by participants:

- Using this system would enhance my social image
- I would feel proud if other see me with this system
- Having this system makes me feel better about myself

As mentioned previously, the participants did not indicate that the system would enhance their social image (sociological pleasure), or generate a feeling of pride or enhance self-image (ideological pleasure). As participants expressed a negative attitude toward technology, having a technological device would not enhance their social image. What is more as this is a device that would usually be bought by the institution in which they work, clinicians may feel that the instruments they use are reflection of their institution chooses and therefore do not reflect their values. Stethoscopes however, are instruments that clinician's own and do not like to share with other clinicians. Stethoscopes are personal objects. Maybe if the device would have the ability to interact with any EMR to save files at patient's chart, clinicians may in the future feel the need to have their own device and bring it with them wherever they go.

Little information about the pleasure (emotional) needs of the clinicians was found at the time the first requirements were drafted. Chismar and Wiley-Patton (2003) stated that clinicians are a special group and the variables that influence technology acceptance differs from other populations. Therefore other population's behavior or preference cannot be assumed for clinicians. The qualitative interview had shed some light about their preferences and needs but more research is needed to provide detailed information about users' preferences, specially in terms of pleasurability characteristics and needs.

Requirements not Previously Considered

The following requirements were based on the results from the case study. The original list of requirements is presented at appendix 2

Functionality:

- The system batteries should last at least 3 days
- The system shall provide the ability to document the physical exam in real time
- The system speakers should provide high quality sound
- The system speakers should allow the clinician to hear the sound despite of high ambient noise
- The system may provide the ultrasound functionalities
- The system may provide the means to calculate intraocular pressure (Tonometer)
- The system may provide the means to calculate the ear pressure at the tympanic membrane (Tympanometer)

Usability:

- The system should allow fast documentation of the physical exam
- The system should allow accurate documentation of the physical exam
- The system should require little maintenance by the user
- The system buttons physical characteristics should minimize the accidental activation (difficulty to make mistakes)
- The system headphones should easily connect and disconnect to the multifunctional device

- The system headphones should never provide means to avoid tangling
- The system headphones should provide means to easily put them on and take them off
- The system should provide means to prevent headphones lost
- The system should provide means to prevent being lost or stolen

Pleasure:

Physiological

- The system should provide means to be comfortably carried around
- The system should fit comfortably against the patient face and body

Psychological

- The system should enable to take pictures quickly
- The system should enable to record videos and audio files quickly
- The system should present means to easy recharge the batteries
- The system shall be fun to charge
- The system shall be easy to maintain
- The system shall be fun to maintain
- The system may present means to recharge the batteries while the user carries it around
- The system should be easy to use at the first attempt

Ideological

- The system should give aesthetic pleasure
- The system aesthetics should not emphasize on its technological aspect
- The system should confer the impression of doctor status to the user

Sociological

- The system should be operable without disturbing the patient or embarrassing the user

Results and Theory

PEC introduced the concept of how the lack of fit between user and environment could provoke stress, discomfort and frustration, which in this case, could affect the clinicians' relationship with patients or their own work. The system designed was perceived as providing an overall fit to clinician's needs and characteristics. Although an evaluation with a fully functional prototype would be needed to evaluate if the system use would provoke stress or discomfort, none of the participants mentioned that at all during the interview. A system of these

characteristics would allow the user to enjoy the benefits that technologies provide and will have an impact on further adoption. HF provided methodology to understand the exam process, needs and limitations, errors to then develop requirements and conduct user testing provided an structure to create products that fit user needs and characteristics. HF will also provide means to evaluate the fully functional prototype in terms of performance and determine if the system is efficient and do not affect clinician's time per patient. Jordan's pleasure framework provided an invaluable resource that enriched the process tremendously, considering the emotional reactions that a product could create on doctors broaden the perspective of this study

CHAPTER VI

CONCLUSION

Task analysis, FMEA, and literature review developed for this study provided a deeper understanding of the physical exam process and clinicians' needs and characteristics. The requirements crafted based on those were essential for the design of the new system. Jordan's hierarchy of needs was found to be an especially useful framework to organize the requirements, clinician's needs and guide the design of the system.

The designed system seems to account for clinician's needs and characteristics. It combines the instruments that they most frequently use, was perceived as easy to use and learn and, most importantly, was not expected to disrupt clinicians' relationships with patients or their routine.

Quantitative data about the participant perceptions of system's usability and plesurability and the requirements verification were collected by questionnaire and also qualitative interviews. Although the use of existing questionnaires provided validity, their results would be more useful for testing fully functioning prototypes.

Non-functional models were useful for testing the product fit with the environment and tasks as well as for checking the product dimensions (P.W. Jordan, 1997). However, as it did not replicate the tactile characteristics of materials such as temperature, weight, and buttons' feedback, a proper evaluation of them could not be achieved. Furthermore, non-functional models did not allow evaluation of efficiency, an important factor for the participants.

Qualitative interviews shed light on usability issues, the overall fit of the system and clinician needs and characteristics. Subjects needs for new EMR systems were consistent with previous studies that observed that a fluent workflow is very important for clinicians. EMR that slow their workflow and demand time to learn the new system and time to interact with it results in an increase of documentation time, and increase in time per patient but decreases the time actually dedicated to the patient (Boonstra & Broekhuis, 2010). Some of the occurring themes related to clinicians needs are summarized in the following list:

- Clinicians do not value technology itself but the benefits that could be achieved from them.
- Clinicians will be willing to adopt new technologies that make their workflow more efficient.
- Clinicians consider that technology can get in the way, disrupting their relationship with their patients
- Clinicians need tools that facilitate their communication with patients and may also benefit from tools that facilitate their communication with other clinicians.
- Clinicians value systems those are easy to use, learn and maintain.
- Clinicians strongly need systems that increase the efficiency of the physical exam documentation process.
- Clinicians' systems need to communicate status and prestige to the user as a doctor's icon or symbol to be easily identified by other clinicians as well as patients.

In summary, the concept Design has accomplished its goals to fit clinicians' needs and characteristics. Several needs not previously considered have been discovered and turned into new requirements. Future iterations and testing will ensure that their most relevant needs are accounted for. It is expected that clinicians would easily adopt a system that presents those benefits and work as promised.

Significance

The information presented in this study summarizes the clinician's needs related to the documentation of the physical exam, and provides a design solution to meet these needs. The design concept provides the opportunity to record digital files from the physical exam to the patient's records, evaluate them if needed and share them with the patients or other clinicians. Overall, the system seems to fit the clinicians' needs without disrupting clinicians' workflow and relationship with the patients. If the system works as promised and includes the recommendations from this study it should promote its adoption and clinicians' positive perceptions of technology. Furthermore, if used it presents the potential to reduce the incidence of human errors.

This study provides guidance for the design of EMR systems that fits physicians' daily activities and way of thinking and working. It has also identified several clinicians' needs and characteristics that could be accounted for in order to engage clinicians to use and incorporate EMR systems into their daily routine. This will not only benefit patients and clinicians but also reduce healthcare costs.

Limitations of the Study

1. Results are only applicable to the subjects interviewed. A non-random sampling method was used so there is no evidence of how representative the sample was. Data gathered through this case study cannot be generalized or inferred to the whole population of interest.
2. The small convenience sample did not represent all the subpopulations of interest (i.e., internal medicine physicians, and those who work in hospital settings)
3. The construction of the model was limited by the skills of the researcher and the resources available.
4. Mock-ups used during the testing procedure were not functional, nor did they present the exact appearance of the final product. Results relied on the ability of participants to project themselves using the final device during their daily routine and on the researcher's ability to facilitate that projection. Findings of this study cannot predict the overall experience that people will have when using it.
5. Participants' bias with respect to technology may have influenced the results.
6. Interviewer may have influenced the participants' reactions or responses during the testing.
7. Analysis of results may be affected by researcher personal biases.

Recommendations for Future Research

While this study's results are limited by its sampling methods and data analysis, they do provide important insights into the clinician's needs and preferences for medical devices and systems to assist the physical examination process. Further research should extend from this work and consider additional methods to enrich the data.

This study involved only seven participants; to apply the results to larger populations, future studies would benefit from having a greater number of subjects randomly selected from different specialties, levels of expertise and working settings. It is likely that clinicians from different specialties would have different needs or preferences. Both the larger sample size and the inclusion of different clinicians would further the understanding this population.

Studies that provide detailed information about clinician's pleurability needs would provide invaluable information to the design of new systems. For example, determine how relevant is the appearance of a device for a clinician, what design elements could represent status and prestige and how important this is for them, among others.

Future studies that continue with this project would benefit from the use of fully working prototypes that would allow the objective evaluation of the system efficiency and its effect over clinicians' time. This is highly relevant based on the fact that clinician's adoption of new technologies would be highly related to efficiency. Models that represents same design elements (surface finishing, graphics, weight) as the fully manufactured product will enable the subjects to experience the product fully (P.W. Jordan, 1997) and allow the complete experience of the product. A fully functional prototype would allow predicting the overall user experience. Furthermore, The design concept and model used for this study were useful to explain the idea and interface to clinicians but it does not represent a fully define design. A shape and color study is highly recommended to assist refining the details of this product. The iPad application model used only showed the stethoscope functionality to hear and evaluate heart sounds. A detailed representation of the different subsystem and functionalities would allow a better evaluation of usability issues for each system and overall user experience.

Last, several participants described the iPad application as technology but not the

multifunctional device. This might be related to the lack of screens and technological appearance. As clinicians presented negative attitudes towards technology, a study that evaluates the use of a screen on the multifunctional device and its effect on user perceptions and its use and disruption would highly benefit further design decisions for medical devices.

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Appendix 1: Requirement Sources

User Centered Design Principles.

Extracted from Norman, 2002.

1. Use knowledge in the world and knowledge in the head
2. Simplify the tasks; do not overload memory, short term or long term, provide memory aids for easy retrieval of information and be sure the user has control over the task.
3. Make things visible. The user should be able to guess how to use an object just by seeing it.
4. Use graphics to make things understandable (Get the mapping right)
5. Use and exploit constraints. Guide the user to achieve the intended action by limiting the repertoire of activities offered by the system.
6. Design for error. Plan every possible error that can be made and provide a recovery solution them allowing the user to recovery from any possible mistake.
7. Standardize when everything else fails.

Display Design Principles.

Extracted from Wickens et al. (2004b)

Perceptual Principles:

1. Make things noticeable; visible, audible. (i.e. Make text legible by using an adequate font size, contrast, and color combination.) Texture could be also used in order to make things noticeable.
2. Avoid absolute judgment limits. (Using a small number of color or sounds for coding). This principle acknowledges humans limitations to distinguish and remember differences between different hues, or sounds. This fact may prevent the user to understand a color coding that has different hues of the same color.

3. Exploit top-down processing. Our expectations and previous experiences guide our perception. The user will search for things, buttons or information in the place he expects them to be based on his/her past experience.
4. Exploit Redundancy. A message is more likely to be interpreted correctly when is expressed more than once, specially if it is presented in alternative physical forms (voice and print, text and pictures, color and shape)
5. Discriminability. Similarity causes confusion. Use discriminable elements. Remark the differences of things when they need to be perceived as different.

Mental Model Principles

6. Apply pictorial realism. A display should look like the variable it represents
7. Principle of the moving part. The moving element of a display should to display dynamic information should move in a pattern or direction that is compatible the user mental model.

Principles Based on Attention

8. Minimize information access cost. Reduce the number of actions needed to access the desired information. How many steps are needed to achieve a goal? How many menus need the user to navigate before arriving to the desired information?
9. Proximity compatibility principle. When two or more sources of information are related to the same task and must be integrated to complete the task this information is defined to have mental proximity. If the display presents this information close to each other (display proximity) this will reduce the information access cost and simplify the task. Display proximity can also be achieved by linking the information sources together by assigning them the same color or connect them with lines or other graphical solution.
10. Use multiples resources. As processing a lot of information is a very demanding task, the display can facilitate this task by dividing this information and present it using different resources for example presenting visual and auditory information concurrently.

Memory Principles

11. Replace memory with visual information (knowledge in the world) (Norman, 2002).
Norman stated the importance of presenting knowledge in the world about what to do and what is going on. Using affordance theory allows the designer to provide this knowledge.
12. Predictive aiding. As predicting future situations based on actual status is a hard process, specially when the user is paying attention to many variables, displays should provide predictive information about future status or future actions that will be needed.
13. Be consistent. Being consistent with other displays or other systems so the user can apply the knowledge learned before to this display. Also, consistency is a good principle to follow across the display, using the same colors, codes, placements for information will allow the user to understand fast and correctly the display.

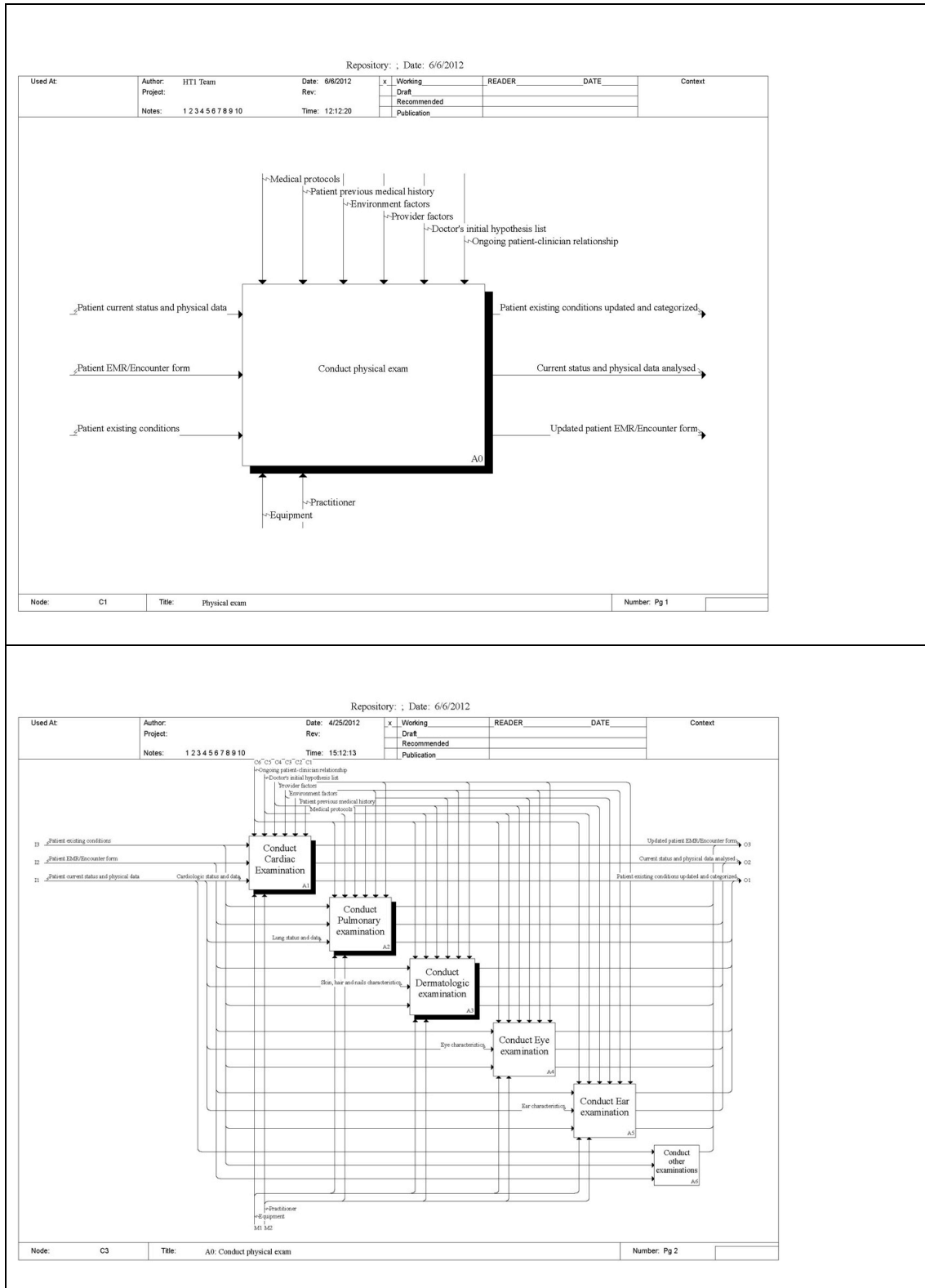


Figure A 1 IDEF0 model. Above A-0, below A0

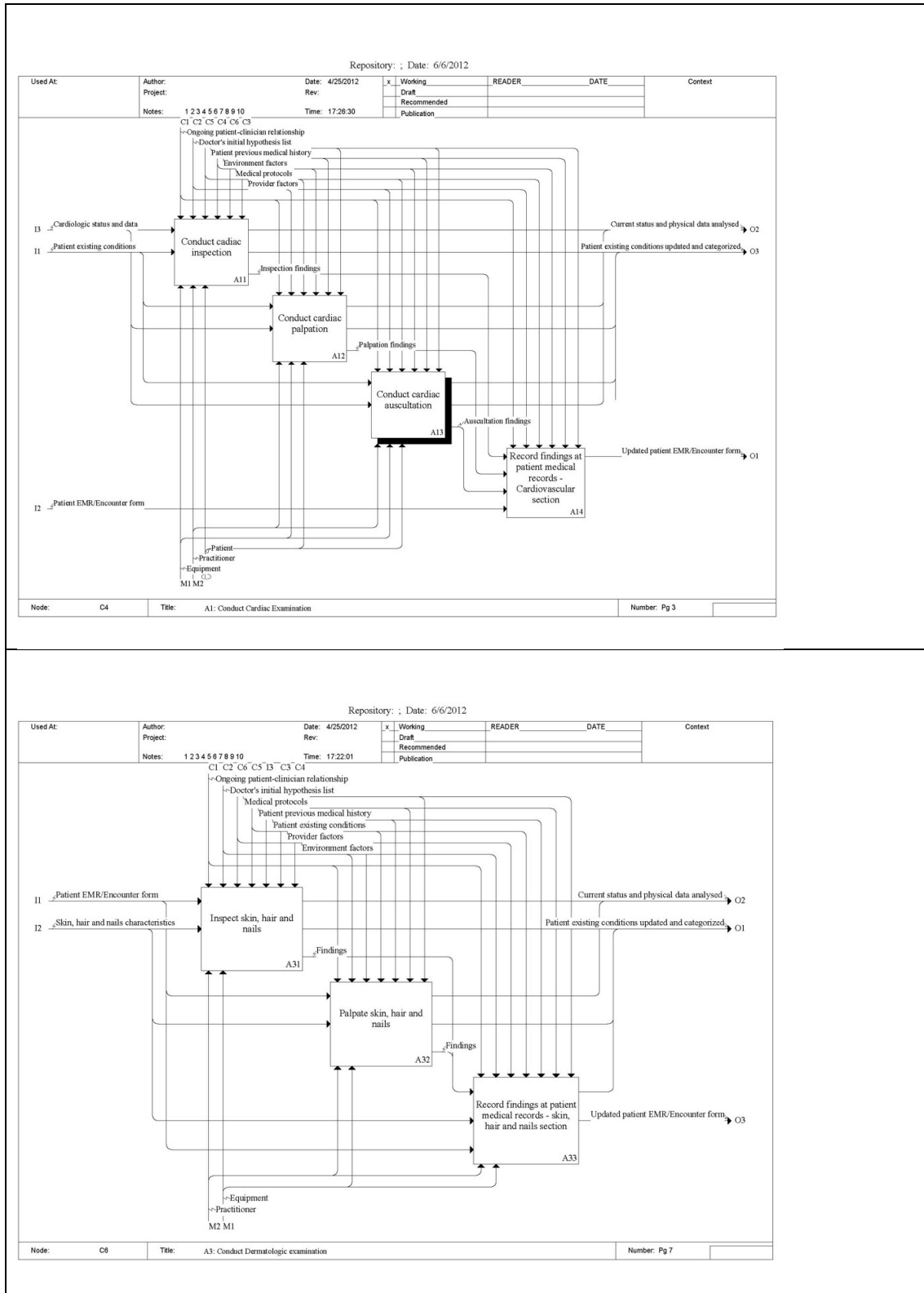


Figure A 2 IDEF0 model. Above A1, below A3

Figure A 3 IDEF0 model. Above A13, below A12

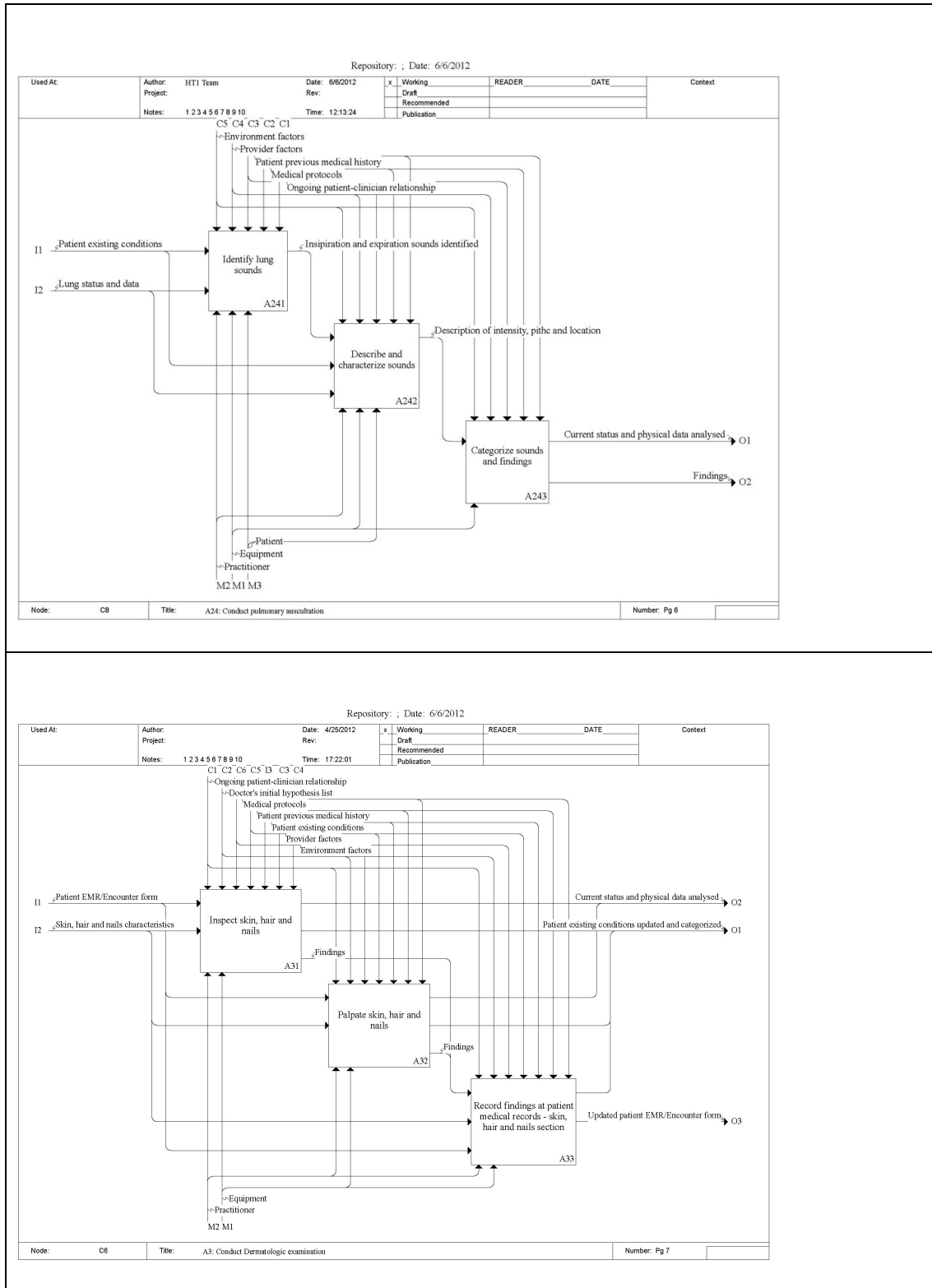


Figure A 4 IDEF0 model. Above A24, below A3

Table A 1 **Heart exam task analysis**

Place device at desired area	Location of areas	Decide which area to examine	5 seconds	Grab device, Place device	Room temperature, Light, patient attitude
Listen to heart sounds	Auscultation training		Varies	Hold device, Wear headphones	Ambient noise, patient attitude, physician thoughts
Identify Heart Sounds	Knowledge about heart sounds	Evaluate heart sounds	Varies	Listen, think, remember	Ambient noise, patient attitude, physician thoughts
Identify Heart sounds	Knowledge about heart sounds	Evaluate heart sounds	Varies	Listen, think, remember	Ambient noise, patient attitude, physician thoughts
Characteristics Describe and characterize Heart Sounds	Describe and characterize Heart Sounds	Evaluate heart sounds	Varies	Listen, think, remember	Ambient noise, patient attitude, physician thoughts
Record heart sounds	Know how to use device (IPad or multifunctional device)	Position of buttons / Decide to record	10 seconds	Think, activate control	Device with batteries, Ambient noise, distractions
Play heart sounds	Know how to use device (IPad)	Grab Ipad/ play sound	Varies	Think, activate control	Device with batteries, Ambient noise, distractions
Delete heart sounds	Know how to use device (IPad)	Delete recorded sound	10 seconds	Think, activate control, confirm action	Device with batteries, Ambient noise, distractions
Email heart sounds	Know how to use device (IPad)	Uncertainty about sounds / seek for advice	Varies	Think, activate control, write/speak,	Device with batteries, Ambient noise, distractions
Review sound example at database	Know how to use device (IPad)	Uncertainty about sounds,	Varies	Think, activate control,	Device with batteries, Ambient noise, distractions
Compare sound with example	Know how to use device (IPad)	Decide what example to search	Varies	Listen Think, activate control,	Device with batteries, Ambient noise, distractions
Review previous exams	Know how to use device (IPad)	Evaluate the cause, meaning or consequences of heart sounds	Varies	Listen, Think, activate control, listen	Device with batteries, Ambient noise, distractions

Table A 2 FMA

A #	Activity / Process / Function	Potential Failure Mode	Contributing Factors	Potential Effects of Failure Mode	Severity	Probability	Non detectability	RPN	Potential Remediation
A0	Conduct Physical Exam	Data not saved at patient file	Wireless internet connection problems	Potential loss of data	5	5	4	100	Save data at the device whenever internet connection is disrupted
A0	Conduct Physical Exam	Distraction from other tasks	Complex tasks, complex interface	Reduced attention to the patient, Interruption at patient-doctor communication, interruption of clinician routine	5	2	5	50	
A1 3	Conduct Cardiovascular auscultation	Poor audio quality from stethoscope bell	Poor acoustical fit between the bell and the device could degrade digital recording quality	Poor or misleading recording of acquired body sounds making later clinical use difficult or impossible	5	3	4	60	
A1 3	Conduct Cardiovascular auscultation	Not examining all the areas	Forgetting, not considering it relevant, interruptions	Not diagnosing a possible condition	3	3	7	63	To get proper and complete feedback from patient regarding symptoms
A1 3	Conduct Cardiovascular auscultation	Confuse a normal sound with an abnormal sound and vice-versa	Inexperience of the doctor, small lesions that are not easily identified, ambient noise, status of the physician(tired, stress), top down processes, not auscultating all the areas	Wrong diagnosis	3	3	4	36	Repeating the task again to double check the signals
A1 4	Conduct Cardiovascular auscultation	Wrongly describe an abnormal sound	Inexperience of the doctor, small lesions that are not easily identified, ambient noise, status of the physician (tired, stress), top down processes	Wrong diagnosis	4	3	3	36	To check with the experts or check for similar instances in prior reports online
A1 5	Conduct Cardiovascular auscultation	Wrong categorization of findings	Inexperience of the doctor, small lesions that are not easily identified, ambient noise, status of the physician(tired, stress), top down processes	Wrong diagnosis, wrong treatment, patient condition could aggravate	4	3	2	24	Corroborate categorization

A1 5	Conduct Cardiovascular auscultation	Not identifying S3 or S4	Inexperience of the doctor, small lesions that are not easily identified, ambient noise, status of the physician(tired, stress), top down processes	Not giving diagnose for a possible condition	4	2	4	32	To maintain surroundings quite and calm
A2	Conduct Pulmonar Auscultation	Save data in the wrong field	Rapid pace of the encounter might lead to incorrect area selection at the screens menu	Errors on location of lung conditions - Mistreatment -	5	5	6	150	Prevent mistake or detect it easily
A2	Conduct Pulmonar Auscultation	Instrument is not correctly calibrated	No instrument preventative maintenance program	Instrument acquire and record wrong data	4	2	4	32	
A3	Conduct skin, hair and nails exam	Not inspecting all the areas	Top down process, forgetting due to distractions	Fail to detect an important lesion	4	3	6	72	To get proper and complete feedback from patient regarding symptoms
A3	Conduct skin, hair and nails exam	Not identifying a suspicious lesion	Not paying attention, experience of the doctor,	Fail to detect an important lesion such as cancer, it spreads fast, fatal consequences	4	2	6	48	
A3	Conduct skin, hair and nails exam	Describe lesions wrongly	Knowledge, Lack of previous experience, not paying special attention	Wrong diagnosis, fatal consequences	5	3	6	90	To check with experts or check for similar instances in prior reports online or database
A1 4- A2 5- A3 3	Update EMR/Encounter form	Enter the incorrect data (error when entering data, writing something different of what was intended)	Relevant information missing and data is inconsistent, clinician stressed and distracted, failed to detect mistake	Wrong data gets updated to EMR	3	3	5	45	Double check/ Automatic checks for inconsistencies
A1 4- A2 5- A3 4	Update EMR/Encounter form	Saving data at other patient's record	High pace visits, time pressure, distractions, system not clear	Wrong data updated to the patient form. Future consequences when treating the patient	4	1	2	8	Double checking, providing ways to identify the patient
A1 4- A2 5- A3 5	Update EMR/Encounter form	Incomplete identification or documentation of a specific datum	Each datum acquired during the encounter must be correctly identified with appropriate metadata	Missing or incorrect data acquired on the device and transferred to other systems; potential for misdiagnosis or inappropriate treatment	5	4	5	100	

Appendix 2: Requirements

Table A 3 Requirements

	FUNCTIONALITY		SOURCE
1	The system shall provide means to communicate with the Electronic medical records	A0	Conduct Physical examination
2	The system shall provide means to send and receive text messaging.	A0	Conduct Physical examination
3	The system interface shall provide access to patient electronic medical records.	A0	Conduct Physical examination
4	The system shall provide means to update patient electronic medical records with exam data and findings.	A0	Conduct physical examination
5	The system shall record data in the absence of an internet connection.	A0	Conduct physical examination
6	The system should provide means to record and recognize user voice sounds	A0	Conduct physical examination
7	The system shall provide means to guarantee the safety of the users (physician, patient, maintenance staff) when it is in use.	A0	Conduct physical examination
8	The system shall provide means to listen to and record heart sounds.	A13	Conduct Cardiovascular Auscultation
9	The system shall provide means to correctly record sounds from the physical examination in presence of noisy environments	A0	Conduct physical examination
11	The system shall provide means to caculate and record the heart rate.	A13	Conduct cardiac Auscultation
12	The system shall provide means to listen to and record lung sounds.	A23	Conduct Pulmonar Auscultation
13	The system should provide means to record data from the dermatologic inspection.	A3	Conduct skin, nails and hair examination
14	The system shall provide means to view and capture images and videos of the eyes.	A4	Conduct eye examination

15	The system shall provide means to capture pictures with a resolution at 1900*1200.	A3- A4- A5	Conduct eye examination/Conduct ear examination/Conduct Skin inspection
16	The system shall provide means to view and capture images and videos of the ears.	A5	Conduct physical examination
17	The system should provide means to record handwritten notes.	A0	Update EMR/encounter form / P-E congruence (Independence)
18	Corners and edges of fixed and handheld equipment to which the bare skin of the user could be exposed shall be rounded.		De Brum
<hr/>			
USABILITY			
- GENERAL			
19	The system shall be portable.	A0	Conduct physical examination / P-E congruence (Physician with device)
20	The system shall be hand held.	A0	Conduct physical examination (P-E congruence)
21	The system shall have a means for grasping, handling, and carrying		NASA-STD 9.3.1.12
22	The system shall weigh less than or equal to 1 lbs.		
23	The system shall be resistant to impact from dropping or bumping.	A0	Conduct physical examination
24	The system shall adapt to a physician's *mental model* of exam flow.		P-E congruence (Change vs sameness) / Human Factors
25	The system shall operate in an *intuitive* manner, requiring no written instructions.		P-E congruence (continuity) / Human Factors
26	The system elements shall be smaller than 14"x 9"x 3".		
27	System interfaces shall be easy to navigate	A0	Conduct physical examination
28	The system should use *knowledge in the world* and *knowledge in the head*		User centered principle (Norman, 2002)
29	The system should simplify the tasks; do not overload memory, short term or long term, provide memory aids for easy retrieval of information and be sure the user has control over the task.		User centered principle (Norman, 2002)
30	The system should use graphics to make things understandable		User centered principle (Norman, 2002)

31	The system should use and exploit constraints. Guide the user to achieve the intended action by limiting the repertoire of activities offered by the system.	User centered principle (Norman, 2002)
32	The system auditory displays should be distinguishable from environmental noise	P-E congruence
33	The system's auditory displays should not interfere with physician or patient activities	P-E congruence
34	The system should provide legible or audible displays	Principles of display design / P-E congruence
35	The system interface should avoid absolute judgment limits	Principles of display design
36	The system interface should exploit top-down processing	Principles of display design
37	The system interface should exploit redundancy	Principles of display design
38	The system interface should use discriminable elements.	Principles of display design
39	The system interface should exploit the principle of pictorial realism	Principles of display design
40	The system interface should use the principle of the moving part	Principles of display design
41	The system interface should minimize information access cost	Principles of display design
42	The system interface should use the proximity compatibility principle	Principles of display design
43	The system interface should use the principle of multiple resources	Principles of display design
44	The system interface should provide predictive aiding	Principles of display design
45	Procedures for performing similar tasks shall be consistent.	NASA-STD-3001 10.1.3.8
46	System messages shall be specific and informative.	NASA-STD-3001 • 10.1.6.2
47	The system shall provide user interfaces that are efficient, e.g., with reduced training time, task time, errors, and frustration.	NASA-STD-3001 10.1.1.3
48	The system interfaces should provide means to promote physician-patient communication	P-E congruence (Interaction model)
49	The system may provide means to promote the patient's understanding of their's conditions	P-E congruence (Interaction model)
50	The system may provide means to promote collaboration between physicians	P-E congruence (Interaction)

The system may adjust to physicians different *preferences*		P-E congruence (Independence)
ERROR PREVENTION/ MITIGATION		
- Prevent		
50	System shall be capable of continuous and autonomous operation for no less than 2 hours.	A0 Conduct physical examination
51	The system shall be easy to clean.	A0 Conduct physical examination
52	The system shall have a germ-resistant surface.	A0 Conduct physical examination
53	The system may provide assistance to the physician to make an appropriate diagnosis.	A0 Conduct physical examination
54	The system interface should adapt to physician's workflow and do not interfere with it	P-E congruence
55	The system interface may facilitate the access to patient information	P-E congruence
56	- Detect	
57	The system shall provide feedback to the users with regards their actions and the consequences of them	
58	The system shall provide a means to inform the users when it is not working properly or needs calibration.	A0 Conduct physical examination
- Correct		
59	The system shall provide mechanisms to prevent or correct mistakes that may occur when using the system	A0 Conduct physical examination
60	The system should be designed for error. Plan every possible error that can be made and provide a recovery solution them allowing the user to recovery from any possible mistake.	User centered principle (Norman, 2002)
PLEASURE		
61	The system shall promote an *engaging* interaction with the user.	
62	The system should provide a *pleasurable experience* to the user while interacting with the product.	
63	The system may provide an emotion detection software	
64	The system may provide means to *promote* communication between physicians and patients	P-E congruence (Interaction model) - Jordan model

65	The system should not interrupt physicians when they are interacting with the patient or analyzing the patient information	
66	The system may provide means to prevent the physician from feeling incompetent or insecure (because not knowing how to use it)	
67	The system should be easy to carry around	Jordan / P-E congruence / Ergonomics
68	The system should feel good in the hand	Jordan / P-E congruence / Ergonomics
69	The system should fits well and comfortable against the face	Jordan /P-E congruence / Ergonomics
70	The system should confer high cultural status (physician-clinician	Interview
71	The system textures shall be comfortable to the user	P-E congruence / Human Factors
72	The system materials temperature shall be comfortable to the user	P-E congruence / Human Factors
73	The system may be fun to use	P-E congruence
74	The system may promote sociological pleasure	
75	The system should not interfere with patient-doctor relationship	P-E congruence /Jordan (Socio)
76	The system may promote patient-doctor relationship	P-E congruence /Jordan (Socio)
77	The system should give aesthetics pleasure	P-E congruence /Jordan (Ideo)

Appendix 3: Design models

First iteration

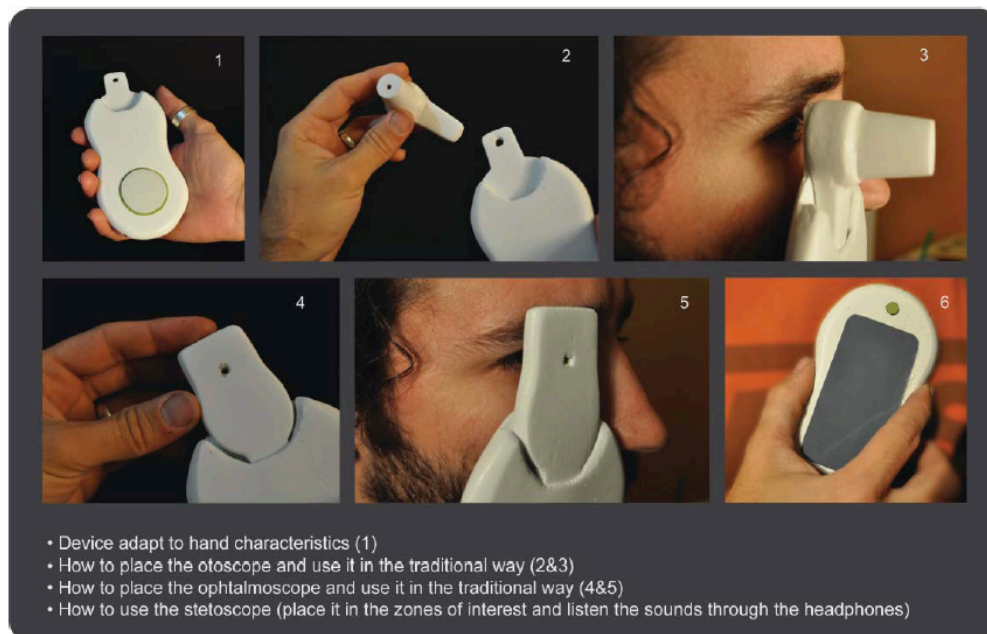


Figure A 5 Wooden model first iteration, description and use



Figure A 6 Wooden model Exchangeable instruments

Second configuration for the all-in-one medical device

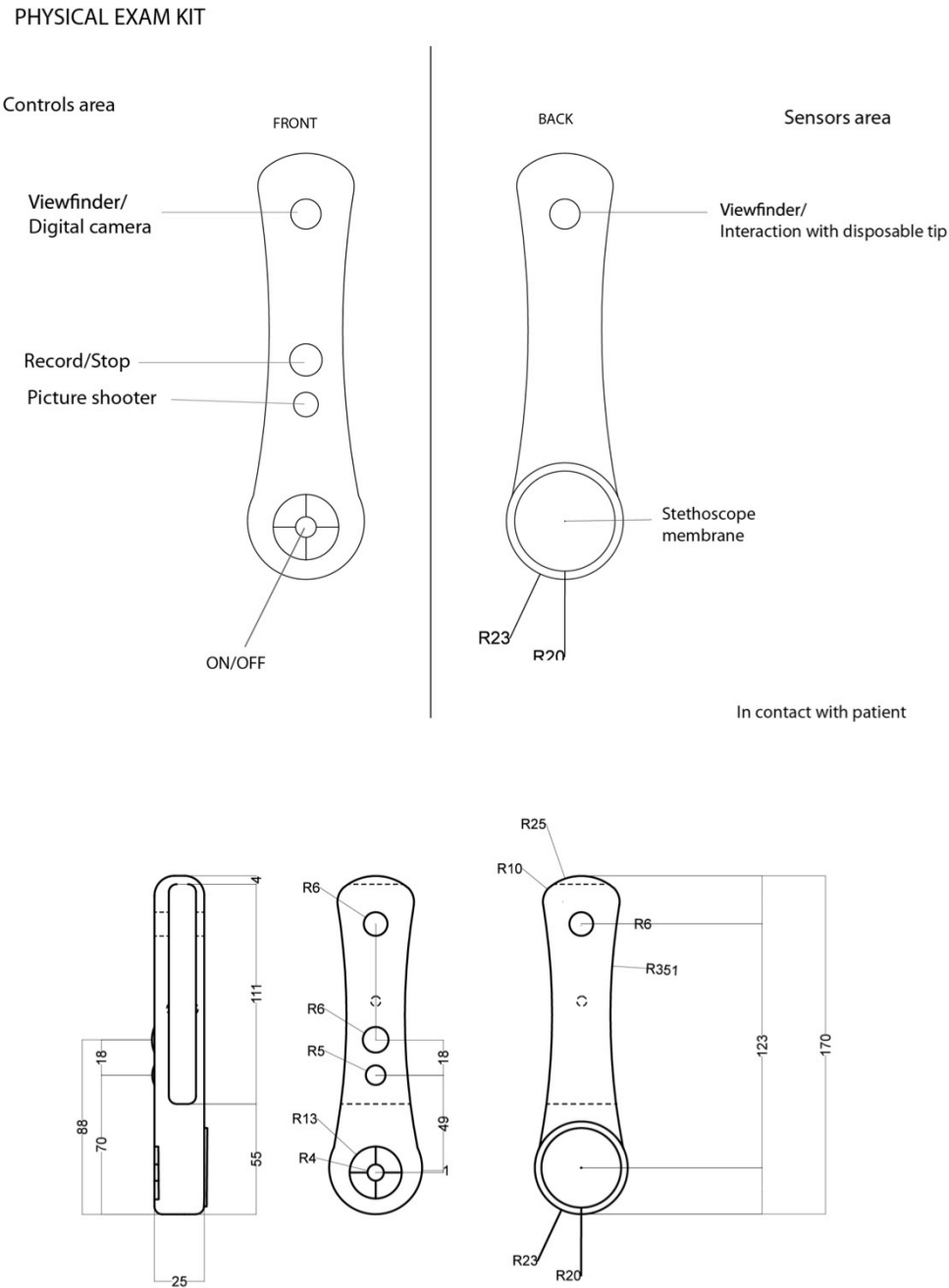


Figure A 7 Second iteration, description and dimensions



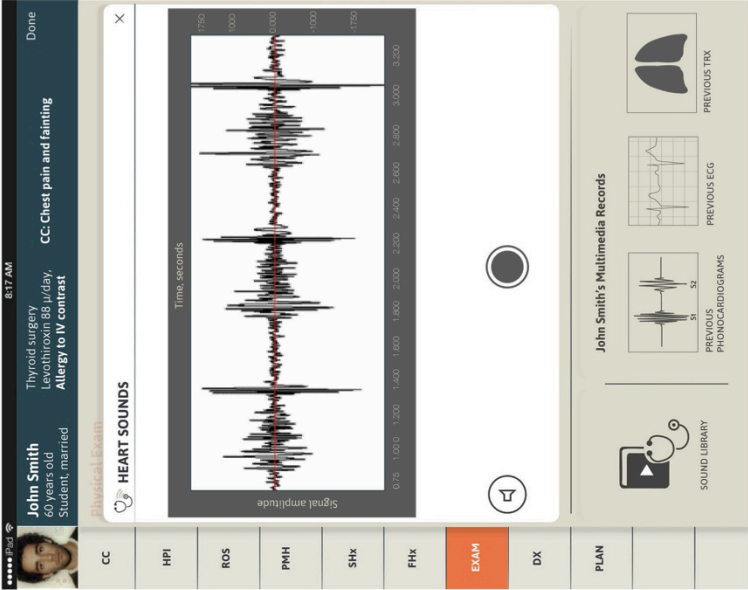
Figure A 9 Second configuration, 3D model (digitally modeled by Tylee Cairns, Lea Cavestany and Konstantin Brainich as part of their Senior Capstone project)

John Smith 60 years old Student, married		8:17 AM Thyroid surgery Levothyroxin 88 µ/day, Allergy to IV contrast		Done
Physical Exam				
CC	General:	Vital Signs:	Skin:	H E E N T:
	HPI			Neck:
	ROS			Lymph Nodes:
	PMH			Thorax & Lungs:
	SHx			Cardiovascular:
	FHx			JVP: Carotid Upstrokes: PVI: Rhythm: Frequency: S1: S2: S3: Murmurs:
	EXAM			
				Dx
				PLAN
				Breast:
				Abdomen:
				Genitalia:
				Neurological:

John Smith 60 years old Student, married		8:17 AM Thyroid surgery Levothyroxin 88 µ/day, Allergy to IV contrast		Done
Physical Exam				
CC	General:	Vital Signs:	Skin:	H E E N T:
	HPI			Neck:
	ROS			Lymph Nodes:
	PMH			Thorax & Lungs:
	SHx			Cardiovascular:
	FHx			Breast:
	EXAM			Abdomen:
				Genitalia:
				Neurological:
				Pelvic:
				Rectal:
				Extremities:
				Peripheral vascular:
				Musculoskeletal:
				Neurologic:

Figure A 10 Final GUI Screen examples 1

Heart sounds live from all-in-one device



Heart sounds saved at patient's record

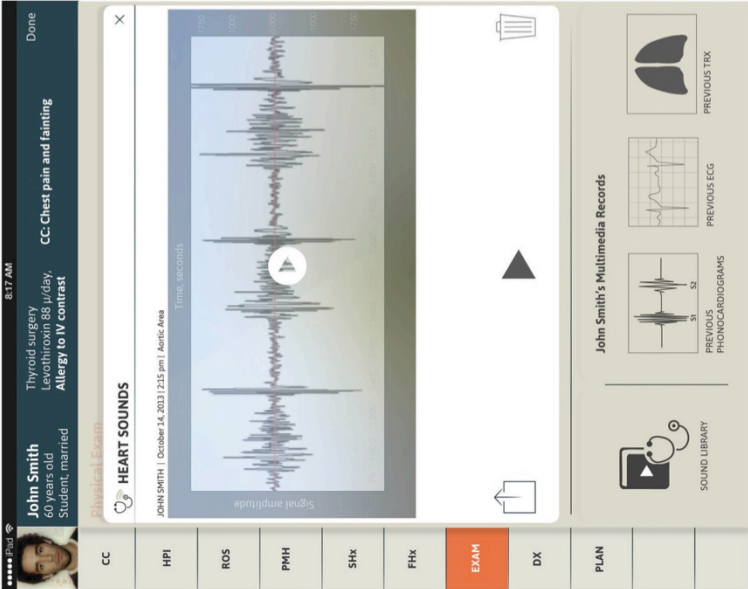


Figure A 11 Final GUI Screen example 2

Library examples of heart conditions

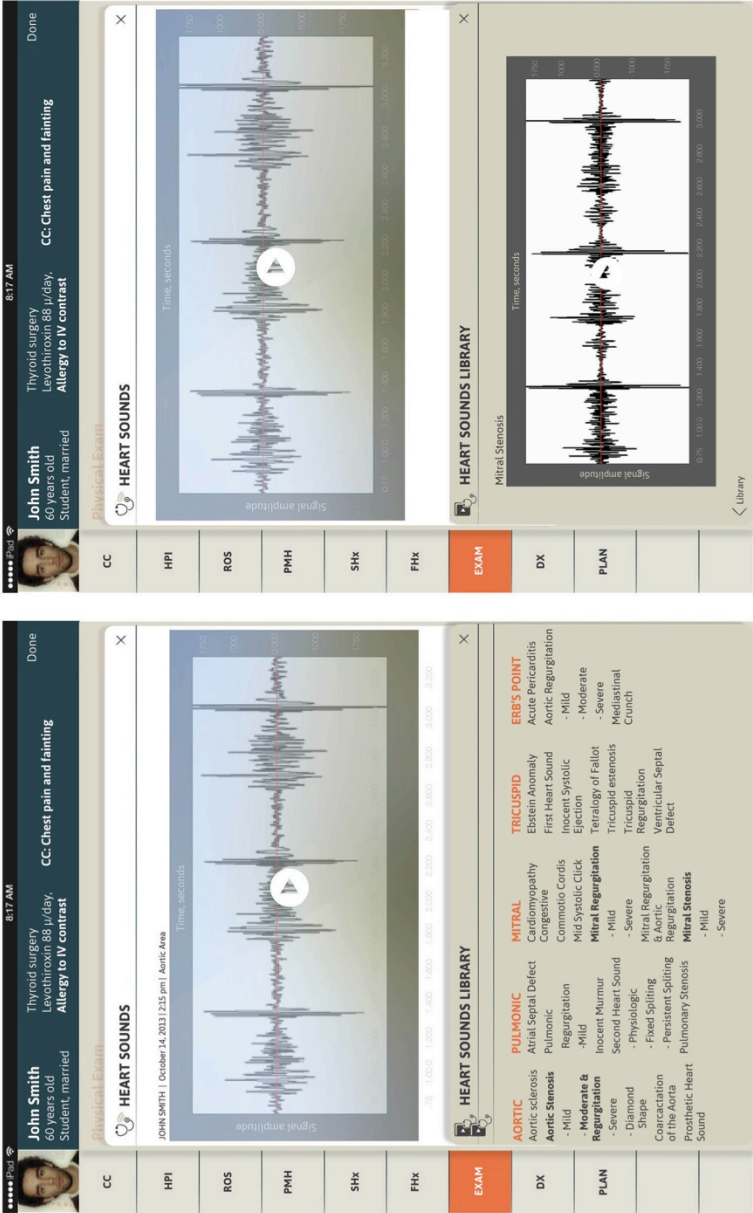
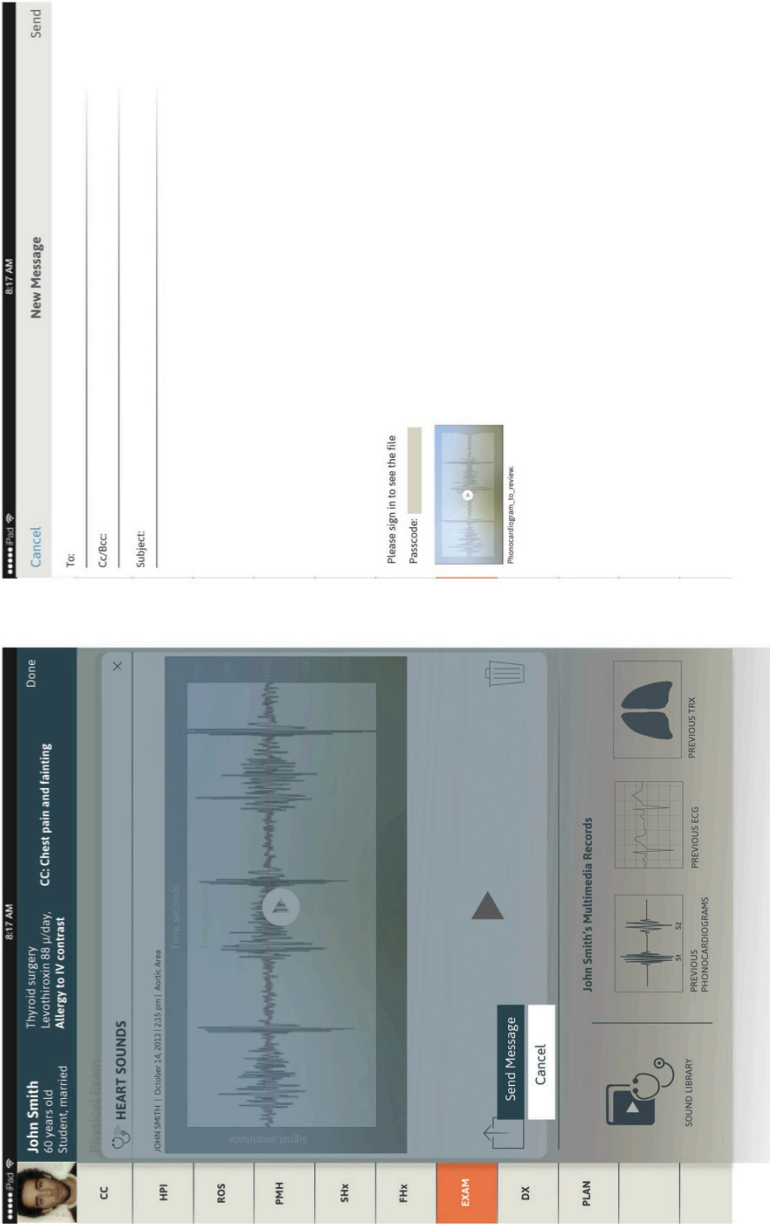
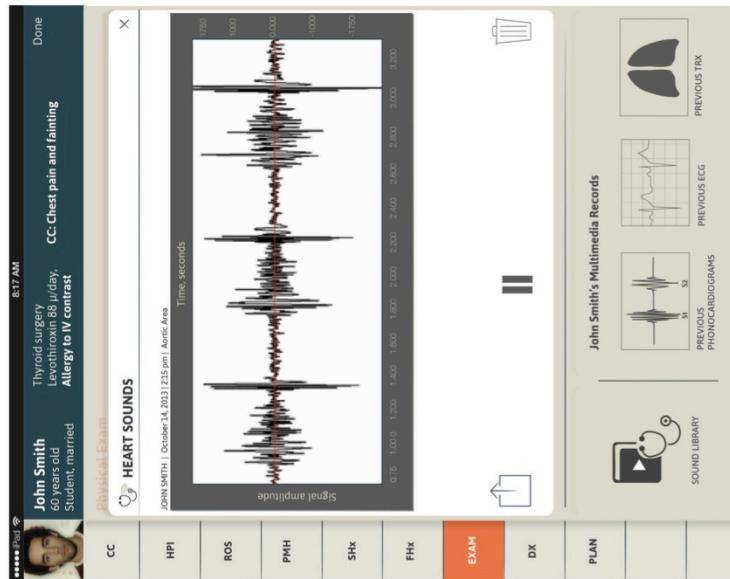


Figure A 12 Final GUI Screen example 3

Sharing heart sounds' file



Listening to heart sounds (phonocardiogram)



Deleting heart sounds

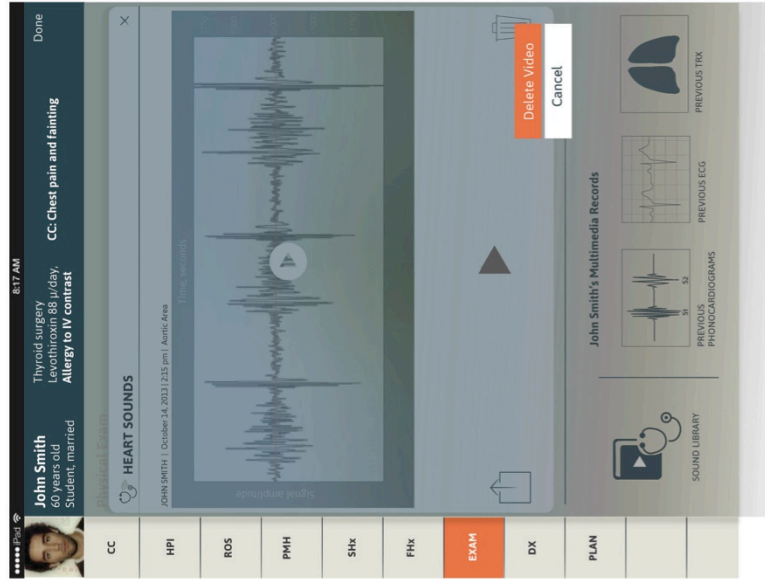


Figure A 14 Final GUI Screen example 5

Editing automatic recordings from heart sounds

John Smith
60 years old
Student, married

Thyroid surgery
Levothyroxin 88 µ/day,
Allergy to IV contrast

8:17 AM

Done

CC

HPI

ROS

PMH

SHx

Physical Exam

General:

Vital Signs:

Skin:

H E E N T:

Neck:

Lymph Nodes:

Thorax & Lungs:

Cardiovascular:

JVP:

Carotid U:

PMI:

Rhythm:

Frequency: 86

S1:

S2:

S3:

Murmurs:

Breast:

Abdomen:

Genitalia:

Neurological:

FX

EXAM

DX

PLAN

Done

CC: Chest pain and fainting

Regular
Normal
Narrowly split
Absent
A grade II/VI systolic ejection murmur at the left upper sternal border

Recordings saved at patient's records

John Smith
60 years old
Student, married

Thyroid surgery
Levothyroxin 88 µ/day,
Allergy to IV contrast

8:17 AM

Done

CC

HPI

ROS

PMH

SHx

Physical Exam

General:

Vital Signs:

Skin:

H E E N T:

Neck:

Lymph Nodes:

Thorax & Lungs:

Cardiovascular:

JVP:

Carotid U:

PMI:

Rhythm:

Frequency: 86

S1:

S2:

S3:

Murmurs:

Breast:

Abdomen:

Genitalia:

Neurological:

FX

EXAM

DX

PLAN

Done

CC: Chest pain and fainting

Regular
Normal
Narrowly split
Absent
A grade II/VI systolic ejection murmur at the left upper sternal border

Medical Records

New Patient

Name

Existing Patient

Name

Multimedia Library

Dermatologic pictures

Heart sounds

Lung sounds

Federico Cernuschi
29 years old (09/16/81)
Student
Married

PMH: Tirod surgery (2000)
Levothiroxine 150µ/day
Seasonal Allergies

[Go to Patient folder](#)

► **PMH:**

► **Chief complaint:**

▼ **Physical examination**

General :

Vital signs:

Skin:

Head, eyes, nose, throat:

Neck:

Lymph Nodes:

Thorax and Lungs:

Cardiovascular:

Breasts:

Abdomen:

Genitalia:

Rectal:

Extremities:

Peripheral vascular:

Musculoskeletal:

[Take pictures from skin lesions](#)

[Record lung sounds](#)

[Record heart sounds](#)

HOME [Back](#) [Home](#) [Settings](#) [Camera](#)

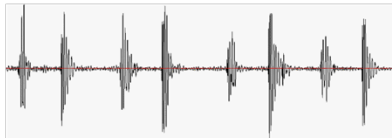
Federico Cernuschi
29 years old (09/16/81)
Student
Married

PMH: Tirod surgery (2000)
Levothiroxine 150µ/day
Seasonal Allergies

[Go to Patient folder](#)

HEART SOUNDS November 22th, 2010

Area: Pulmonic



[Previous](#) [Next](#) [Settings](#)

Do you want to delete Federico's Sound file?

[Yes](#) [No](#)

HOME [Back](#) [Home](#) [Settings](#) [Camera](#)

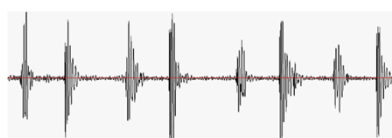
Federico Cernuschi
29 years old (09/16/81)
Student
Married

PMH: Tirod surgery (2000)
Levothiroxine 150µ/day
Seasonal Allergies

[Go to Patient folder](#)

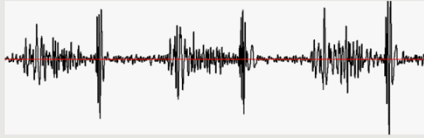
HEART SOUNDS November 22th, 2010

Area: Pulmonic



[Previous](#) [Next](#) [Settings](#)

Aortic valve stenosis



[Previous](#) [Next](#)

Sound Library

Aortic Stenosis Mitral Valve Prolapse Ventricular Septal Defect Mitral Stenosis
Early Aortic Stenosis Mitral Regurgitation Atrial Septal Defect
Late Aortic Stenosis Pulmonary Stenosis Aortic Regurgitation

HOME [Back](#) [Home](#) [Settings](#) [Camera](#)

Figure A 16 First iPad GUI iteration screen examples

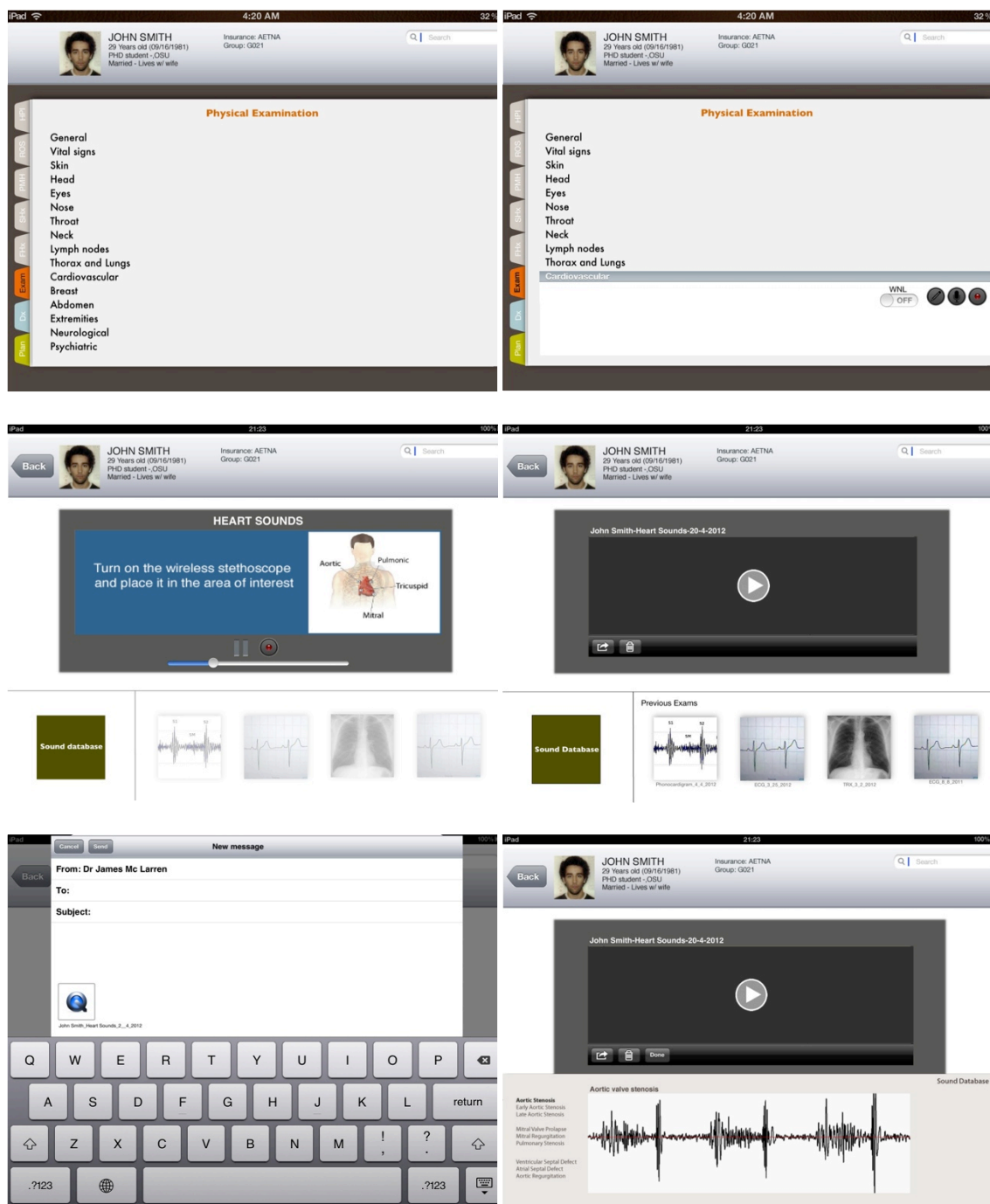


Figure A 17 Second iPad GUI iteration screen examples



Figure A 18 Functional prototype. Images courtesy of Tylee Cairns

Appendix 4: Informed Consent



CONSENT FORM

Project Title: Designing medical instruments to improve physicians' routine, communication with patients and adoption of new technologies: a human factors and person-environment congruence approach

Principal Investigator: Carmen D. Steggell, Ph.D.

Student Researcher: Silvina de Brum, B.S.

WHAT IS THE PURPOSE OF THIS FORM?

This form contains information you will need to help you decide whether to be in this study or not. Please read the form carefully and ask the study team member(s) questions about anything that is not clear.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to develop and evaluate a design concept for a physical examination kit. The kit consists of a multifunctional instrument, with the functionality of a stethoscope, ophthalmoscope, otoscope and dermatologic camera. The graphic user interface of an iPad application will provide the link between the instrument and the EMR. The kit will be developed as part of a comprehensive health care toolkit and will be tested using non-functional mockups.

This study is being conducted by a student for the completion of Silvina de Brum's Master's thesis.

Up to 25 participants may be invited to take part in this study.

WHY AM I BEING INVITED TO TAKE PART IN THIS STUDY?

This is a case study with clinicians who conduct physical examinations as their daily routine. In order to develop medical equipment that accounts for the characteristics and needs of clinicians, it is essential to hear about your experience with devices during the development stage. As a medical clinician, you have a unique perspective that will provide a valuable contribution to the development of a new medical technology.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

If you agree to be part of this study, you will be asked to participate in activities that involve getting to know a new medical device, interacting with a non functional prototype, and then completing a written questionnaire and a verbal interview. The study will be scheduled at your convenience and will take place either at Oregon State University or at a nearby location of your choice. The procedure will take about an hour.

Recordings: An audio recording will be made during your visit. You should not enroll to participate in this study if you do not want your opinions to be audio recorded.

Oregon State University

IRB Study # 5757

Expiration Date 08/13/2014

Page 1 of 3

Observers / notetakers: Researchers will observe and take notes of your reactions and comments while you interact with the prototype. You should not enroll to participate in this study if you do not want to be observed or have your reactions or comments to be paper recorded during this study.

WHAT ARE THE RISKS AND POSSIBLE DISCOMFORTS OF THIS STUDY?

Risks are minimal; you may find it uncomfortable or embarrassing to interact with a non-functional prototype or to talk about their experience with it. This study is focused on the device, not the ability of each participant to interact with it. Although every precaution will be taken to prevent that the information you share will not be identified with you personally, there is a chance that we could accidentally disclose information that identifies you. The security and confidentiality of information collected online cannot be guaranteed. Confidentiality will be kept to the extent permitted by the technology being used. Information collected online can be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses.

WHAT ARE THE BENEFITS OF THIS STUDY?

This study is not designed to benefit you directly.

WILL I BE PAID FOR BEING IN THIS STUDY?

You will not be paid for being in this research study, but you will receive a gift card to a local store.

WHO WILL SEE THE INFORMATION I GIVE?

The information you provide during this research study will be kept confidential to the extent permitted by law. Research records will be stored securely and only researchers will have access to the records. Federal regulatory agencies and the Oregon State University Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

If the results of this project are published, your identity will not be made public. Tape recordings will be transcribed and excerpts may be published. Every precaution will be taken that the information you share will not be identified with you personally.

To help ensure confidentiality, your name will not be associated with any information that you provide. Each record will be identified with a number, but numbers will not be associated with names. To facilitate analysis, data will be stored in password-protected electronic files whose access is restricted to the researchers.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Participation in this study is voluntary. If you decide to participate, you are free to withdraw at any time without penalty. You will not be treated differently if you decide to stop taking part in the study. If you choose to withdraw from this project before it ends, the researchers may keep information collected about you and this information may be included in study reports.

Optional questions: Every question that you are going to be asked is optional. You are free to skip any questions that you would prefer not to answer.

WHO DO I CONTACT IF I HAVE QUESTIONS?

If you have any questions about this research project, please contact:

Carmen D. Steggell, Principal Investigator
 328 Milam Hall
 Oregon State University
 Corvallis, OR 97331
 Phone: 541.737.0995
 Email: carmen.steggell@oregonstate.edu

If you have questions about your rights or welfare as a participant, please contact the Oregon State University Institutional Review Board (IRB) Office, at (541) 737-8008 or by email at IRB@oregonstate.edu

WHAT DOES MY SIGNATURE ON THIS CONSENT FORM MEAN?

Your signature indicates that this study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Do not sign after the expiration date: 08/13/2014

Participant's Name (printed): _____

 (Signature of Participant)

 (Date)

 (Signature of Person Obtaining Consent)

 (Date)

Appendix 5: Case study

System Usability Score.

Extracted from Brooke, 1996

System Usability Scale

© Digital Equipment Corporation, 1986.

	Strongly disagree						Strongly agree
1. I think that I would like to use this system frequently	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	1	2	3	4	5		
2. I found the system unnecessarily complex	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	1	2	3	4	5		
3. I thought the system was easy to use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	1	2	3	4	5		
4. I think that I would need the support of a technical person to be able to use this system	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	1	2	3	4	5		
5. I found the various functions in this system were well integrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	1	2	3	4	5		
6. I thought there was too much inconsistency in this system	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	1	2	3	4	5		
7. I would imagine that most people would learn to use this system very quickly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	1	2	3	4	5		
8. I found the system very cumbersome to use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	1	2	3	4	5		
9. I felt very confident using the system	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	1	2	3	4	5		
10. I needed to learn a lot of things before I could get going with this system	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	1	2	3	4	5		

Pleasure With Products

Extracted from Jordan, 2002.

PLEASURE WITH PRODUCTS (GENERAL INDEX)

1. I feel stimulated when using this product

0	1	2	3	4
Strongly disagree		Neutral		Strongly agree

2. I feel entertained when using this product

0	1	2	3	4
Strongly disagree		Neutral		Strongly agree

3. I feel attached to this product

0	1	2	3	4
Strongly disagree		Neutral		Strongly agree

4. Having this product gives me a sense of freedom

0	1	2	3	4
Strongly disagree		Neutral		Strongly agree

5. I feel excited when using this product

0	1	2	3	4
Strongly disagree		Neutral		Strongly agree

6. This product gives me satisfaction

0	1	2	3	4
Strongly disagree		Neutral		Strongly agree

7. I can rely on this product

0	1	2	3	4
Strongly disagree		Neutral		Strongly agree

8. I would miss this product if I no longer had it

0	1	2	3	4
Strongly disagree		Neutral		Strongly agree

9. I have confidence in this product

0	1	2	3	4
Strongly disagree		Neutral		Strongly agree

10. I am proud of this product

0	1	2	3	4
Strongly disagree		Neutral		Strongly agree

11. I enjoy having this product

0	1	2	3	4
Strongly disagree		Neutral		Strongly agree

12. Using this product helps me feel relaxed

0	1	2	3	4
Strongly disagree		Neutral		Strongly agree

13. This product makes me feel enthusiastic

0	1	2	3	4
Strongly disagree		Neutral		Strongly agree

14. I feel that I should look after this product

0	1	2	3	4
Strongly disagree		Neutral		Strongly agree

Overall Pleasure Rating

--

Figure 4.2 Pre-prepared questionnaire for quantification of product pleasurable
Source: Questionnaire designed by Patrick Jordan, Philips Corporate Design (1996).

Scenario

You are examining a young patient who is complaining of chest pain, fainting upon exertion, shortness of breath; fatigue, especially during times of increased activity, chest pain and heart palpitations. After completing anamnesis, you decide to conduct a cardiologic exam to evaluate if the patient has a murmur that could be compatible with the diagnosis of aortic stenosis.

Physician: Conduct cardiac auscultation in one area

1. Check on the iPad application, ensure that you are on the patient's file
2. Select physical examination section
3. Place the iPad somewhere near you
4. Ask the patient to sit or lie on the examination table
5. Using the all-in-one instrument, listen and record the patient's heart sounds
 - a. Turn on device
 - b. Plug headsets to the device
 - c. Place the device at cardiac area of interest
 - d. Listen to heart sounds
 - e. Record heart sound
 - f. Stop recording
6. On the iPad application,
 - a. Review the sound at the screen
 - b. Compare it with the sound database
 - c. In order to obtain a second opinion about the characteristics of this sound, send the file to a specialist and request advice

Questionnaire

The purpose of this questionnaire is to gather information about your experience with the instruments with which you have interacted today (all-in-one instrument and iPad application). This questionnaire consists of 32 questions and a checklist. It will take about 15 minutes to complete. Please respond to the questions that apply to you. Once you are finished hand this questionnaire to the interviewer. Your responses are anonymous.

Personal information

1. What is your job title or profession?

2. Which of the following best describe the environment in which you are currently working? (Mark all that apply)
 - a. Hospital
 - b. Clinic
 - c. Private Practice
 - d. Other_____
3. How long have you been working in the medical field?
 - a) 15 years or more
 - b) 6 to 14 years
 - c) 0 to 5 years
4. What is your gender?
 - a) Male
 - b) Female
5. What was your age at your last birthday?
 - a) 21 - 29
 - b) 30 - 39
 - c) 40 - 49
 - d) 50 - 59
 - e) 60 or older
6. In a typical week, how many days do you use a smart phone and/or electronic tablet at least once?
 - 0) Never
 - 1) 1- 3 days a week
 - 2) 4-6 days a week
 - 4) Every day
7. How strongly do you agree or disagree with the following statement?
“Technology can improve medicine and health care systems”
 - 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree

Please comment on this statement.

Experience with the System

The following questions are related to your experience with the system (all-in-one device and iPad application). To answer them please imagine that the system is fully functional and already in the market.

8. I think I would like to use this system frequently
 - 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
9. I found the system unnecessarily complex
 - 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
10. I think the system would be easy to use
 - 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
11. I think I would need the support of a technical person to be able to use this system
 - 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
12. I found that various functions in this system are well integrated
 - 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
13. I thought the system was too inconsistent
 - 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
14. I would imagine that most people would learn to use this system very quickly

- 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
15. I found the system to be very cumbersome to use
- 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
16. I would feel confident using the system
- 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
17. I would need to learn a lot of things before I could get going with this system
- 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
18. I like the look and feel of this system
- 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
19. I would feel stimulated when using this system
- 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
20. I would feel entertained when using this system
- 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
21. I would feel attached when using this system
- 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree

- 5) Strongly agree
- 22. Having this system will give me a sense of freedom
 - 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
- 23. I would feel exited when using this system
 - 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
- 24. This system would give me satisfaction
 - 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
- 25. I would be able to rely on this system
 - 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
- 26. I would miss the system if I no longer had it
 - 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
- 27. I will have confidence in this system
 - 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
- 28. I will be proud of this system
 - 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
- 29. I will enjoy having this system
 - 1) Strongly disagree

- 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
30. Using this system will help me being relaxed
- 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
31. This system will make me feel enthusiastic
- 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree
32. I feel that I will have to look after this system
- 1) Strongly disagree
 - 2) Disagree
 - 3) Neither agree or disagree
 - 4) Agree
 - 5) Strongly agree

System Attributes Checklist

The following statements are related to characteristics of the system, please mark your level of agreement or disagreement with them. To answer them, please imagine that the system is fully functional and already in the market. Level of agreement:

- 1 = Strongly disagree,
- 2 = Disagree,
- 3 = Neither agree or disagree,
- 4 = Agree,
- 5 = Strongly agree

	System	Level of agreement
33.	The system is portable	1 2 3 4 5
34.	The system can be comfortably carried	1 2 3 4 5
35.	The system feels good in the hand	1 2 3 4 5
36.	The system has useful functions	1 2 3 4 5
37.	The system is easy to clean	1 2 3 4 5
38.	The system is resistant to impacts and droppings	1 2 3 4 5
39.	The system is safe to use (does not provide physical or other harm to the users)	1 2 3 4 5
40.	The system is easy to navigate	1 2 3 4 5
41.	The system could be used without requiring written	1 2 3 4 5

	instructions	
42.	The system's displays are useful to understand how to use the system	1 2 3 4 5
43.	The system displays provides information from the patient that is useful to achieve the correct diagnosis	1 2 3 4 5
44.	The system's displays are clearly visible	1 2 3 4 5
45.	The system's displays are legible	1 2 3 4 5
46.	The system's display presents information in a consistent manner	1 2 3 4 5
47.	Using this system would enhance my social image	1 2 3 4 5
48.	I would feel proud if other see me with this system	1 2 3 4 5
49.	Having this system makes me feel better about myself	1 2 3 4 5

Interview Guide

1. What kind of instruments do you currently use to conduct the physical examination? (Analog instruments, digital instruments, both)
2. How does this system compare with what you use now? (Same/better/worse)

3. In what ways do you think that this system would affect the medical encounter process? (Saving data, retrieving, analyzing it, compare it with previous exams)?
4. Did you experience any issue when using the system?
 - a. Could you please tell me more about this?
5. After you learn how to use this system. Do you think it would affect your daily routine?
 - a. In what ways?
6. Do you think this system would affect your relationship with your patients?
7. Do you think that this system would affect communication with your patients?
8. What functionalities provided by the system would be useful? What functionalities would not be useful? What else could be included?
9. Would you buy this system if it were on the market?
10. Would you recommend this system to your colleagues?
11. What do you like the least about this system?
12. What do you like the most of this system?

Appendix 6: Test results

Table A 4 Responses to System Usability Scale Modified from Tullis, T., & Albert, W. (2008b)

Question	Min Value	Max Value	Mean	Standard Deviation	Total Responses
I think I would like to use this system frequently	1	3	2.0	0.8	7
I found the system unnecessarily complex	3	4	3.9	0.4	7
I think the system would be easy to use	2	3	2.1	0.4	7
I think I would need the support of a technical person to be able to use this system	2	5	3.4	1.1	7
I found that various functions in this system are well integrated	2	3	2.1	0.4	7
I thought the system was too inconsistent	3	5	3.9	0.7	7
I would imagine that most people would learn to use this system very quickly	1	3	2.0	0.6	7
I found the system to be very cumbersome to use	1	4	3.4	1.1	7
I would feel confident using the system	2	3	2.1	0.4	7
I would need to learn a lot of things before I could get going with this system	4	5	4.3	0.5	7

Statements in bold are positively stated, high means are expected. The other ones, not bold, are negatively stated, small means indicates positive results.

Table A 5 Responses to requirements checklist

#	Question	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree	Total Responses	Mean
1	The system is portable	0	0	0	3	4	7	4.6
2	The system can be comfortably carried	0	0	0	3	4	7	4.6
3	The system feels good in the hand	0	1	0	1	5	7	4.4
4	The system has useful functions	0	0	1	2	4	7	4.4
5	The system is easy to clean	0	0	2	4	1	7	3.9
6	The system is resistant to impacts and droppings	0	0	5	1	1	7	3.4
7	The system is safe to use (does not provide physical or other harm to the users)	0	0	0	5	2	7	4.3
8	The system is easy to navigate	0	0	1	5	1	7	4.0
9	The system could be used without requiring written instructions	0	2	1	3	1	7	3.4
10	The system's displays are useful to understand how to use the system	0	1	0	6	0	7	3.7
11	The system displays provides information from the patient that is useful to achieve the correct diagnosis	0	0	1	3	3	7	4.3
12	The system's displays are clearly visible	0	0	0	4	3	7	4.4
13	The system's displays are legible	0	0	0	6	1	7	3.6
14	The system's display presents information in a consistent manner	0	0	3	4	0	7	3.0
15	Using this system would enhance my social image	0	1	5	1	0	7	3.0
16	I would feel proud if other see me with this system	0	1	5	1	0	7	3.0
17	Having this system makes me feel better about myself	0	2	3	2	0	7	3.71
18	I like the look and feel of this system	0	1	1	2	3	7	3.3

Table A 6 Responses to pleasure with product questionnaire[illegible]

Table A 7 Responses to qualitative interview

	Participant #1	Participant #2	Participant #3	Participant #4	Participant #5	Participant #6	Participant #7
Most Useful functionalities	Camera (E,Ea,S) Stethoscope	Camera (S) Record automatically to EMR Heart sound library	Built-in camera (S) Store and access files in EMR	Record Compare & evaluate Patient education Consulting	Record files and data to EMR Document and compare murmurs (same child)	Record files to EMR Share files	Camera (S)
Least Useful functionalities	Diagnostic aid	Thermometer	Thermometer			Thermometer	Thermometer
Heart sounds recording		++	-	++	++	++	-
Lung sounds recording				+		++	
Temperature recording		--	--			--	--
Camera (eyes)	+		-	+			--
Camera (ears)	+	++					
Camera (skin)	+	++	++			++	++
Save files to patient EMR		++	++	++	++	++	0
Document Evaluate evolution of conditions		++ H,S,E ++	+	++ ++	++H ++	++ H	++ S +
Categorization aid	--H	++	--	++			-
Share information	-			++			
Seek feedback	-			++			
Unified functions	-	++	++		++	++	++

Most common themes related to features and their perceived usefulness. ++ refers to strongly positive, + positive, - negative – strongly negative.

Qualitative Interview Analysis

Table A 8 Frequently occurring responses related to the system functionalities.

	Themes - Features	Magnitude	n	Representative comment
Most useful features	Built in camera	Strongly positive	6	"In terms of camera I would be really exited about" ¹
	Record directly to EMR	Strongly positive	5	"The fact that it could translate to the EMR would be really helpful " ⁵
	Documentation	Strongly positive	5	"It would be great for documentation. Sometimes is really hard to describe what an ear looked like" ⁴ I would say the one thing I like the most is probably the ability to digitize all that information to be able to share it and see it later." ⁶ "I had a patient who had kind of a pimple or an abscess on his elbow. He had been seen by another provider four days earlier and I'm just looking at her note trying to imagine what it looked like and then now I'm seeing it later and I'm trying to think, [how it looked like] " ²
	Compare and evaluate (Within same patient)	Strongly positive	4	"that would help me be able to compare patients, someone comes in next week and I'm kind of relying on what I wrote, what I thought they sounds like last week and what I wrote in their chart to describe it where I could kind of listen" ⁴ "about 80 percent of kids are going to have a heart murmur at some point. And so a lot of times I'll say, "Oh, they have a heart murmur." It'd be helpful for that next doctor to say, "You know, maybe -- I wonder if this is the same one," and sort of be able to go back and look at that and see if it was the same one would be nice." ⁵
		Positive	1	
		Negative	2	
	Compare and evaluate (with Databases)	Strongly positive	3	" You could feel more confident. This is just a murmur" ² "Practicing physicians don't need help in diagnostic skills in the physical exam to the extent that they're going to record something and then come back to it later and sort things out." ¹
Negative		2		
Strongly Negative		1		
Share information with specialists	Strongly positive	2	"I'm hearing something and I want somebody else to listen and they're too busy, or I'm in a rural area, so I can just have them listen to the recording and we can talk about it." ⁴ I think it would be really useful" "Oftentimes it would be really cool in an academic setting, again, sharing the physical exam when you don't have access to bring that in." ⁶	
Least Useful features	Thermometer	Strongly negative	4	"You know, if you're envisioning this as something for physicians we don't use temperature a lot. That's usually our medical assistant or nurse that's doing that." ⁶

Table A 9 Frequently occurring responses related to usability

Themes	Magnitude	n	Representative comment
Ease of use	Strongly +	5	“I could see where you could go really crazy if it is really that easy” ² “I could foresee it being a very easy device to use” ⁶ “Seems easy to use and well thought out” ⁴
Easy to use -	Headphones -	2	“I like the headphones because a lot of times, especially in my world there's sometimes three or four kids in the room and there's lots of noises going on. So if you can have just the ear buds in or earplugs in you can kind of track everything out of there.” ⁵ “But then again, that would be something that could potentially get lost, or tangled, I guess. It'd have to be thick enough, not just like your headsets or earphones; it would have to be something thick enough that when it gets grabbed it's not going to snap or break or anything like that, or get caught around a kid.” ⁵ “you are having to put on headphones and then connect the headphones; that may be one drawback that I can see with this” ⁶ Stethoscope would be the biggest adjustment ⁵
Easy to use -	No carrying mechanism	4	“We do not use lab coats so we would just have to put it around our necks or something”
Easy to learn	Positive	1	“ I do not think it would take time to learn...It wouldn't be any difference from using a ophthalmoscope, otoscope or stethoscope really, they just look different”
Easy to learn -	Labeling -	1	“A bit more well-labeled the two buttons to switch because the learning curve initially could be a pain”
Difficulty to make mistakes	Negative	2	“Not pediatric friendly (Kids could accidentally push buttons)” ⁵ “People with bigger hands just pushing the incorrect button adjacent to whichever you are trying to push” ⁷
Efficiency +	Neutral	1	“It would be the same” ³
	Positive	2	
Efficiency – (Ipad interaction Increase time)	Neutral	1	“ I wonder about faster? Efficient?” ⁵
	Negative	1	
	Strong -	1	“If you are a researcher that [evaluate evolution of conditions by seeing pictures of different visits] makes perfect sense. If you are a practicing physician, it's a luxury of time you don't have” ¹
Satisfaction Buy	Trial period	3	“I'd wait and see how it works [before buy it]” ³
	Strong +	3	“I would definitely buy it” ⁴
	Conditional	1	“if it did the things I'm imagining it could do, absolutely” ¹
	Buy depending on cost	5	“I'd be really curious to know what the price point would be”
Overall satisfaction	Positive	4	“It's a unique concept,...it combines all the elements that I would like to have” ⁶
	Neutral	1	
	Negative	1	“I am pleasantly surprised” ² “the most part it seems to me is simply replace several instruments with one. That doesn't really do much for me.” “I need to use it, understand cost and maintenance before recommend it” ³
Satisfaction Recommend	Recommend	5	
	Neutral	2	

Table A 10 Frequently occurring responses related to the system pleasurability.

	Themes	Magnitude	n	Representative comment
Physio-logical	Easy to hold	Positive	4	"It's easy to hold" ⁵
Physio-logical	Small dimensions	Negative	1	"The handle 's just not really long enough..." ⁷
Physio-logical -	Comfortably carried	Negative Neutral	4	"But that's not to say it'd be hard to carry around" ⁶ "I'm not really good at remembering things unless it's attached to my body when I walk out of the room, so like pens; I always had to stick them in my pony tail because I'll forget things and my stethoscope is around my neck. If I don't have those things attached to my body I'll forget." ⁵
Ideo-logical	Unified (multifunctional) Concept	Strongly positive	7	"It's a unique concept,...it combines all the elements that I would like to have" ⁶ "just one thing in my hand" ³ "It would be handier" ⁷ It would be great, I would have one thing in my hand" "Is much nicer to have one thing instead of multiple equipments on you" ⁷
	Design	Positive	4	"I like the design" ⁵
	iPad as technology	Negative	4	"the least would probably be just the technology piece, using the iPad and having to interact with the iPad." ⁴
Psycho-Logical+	User confidence	Positive	1	"You could feel more confident. This is just a murmur" ²
Psycho-logical+	Pleasure of use	Strong positive	4	"I could see where you could go really crazy if it is really that easy" ²
		Strong negative	1	
	Useful functions		5 +	"It's a unique concept,...it combines all the elements that I would like to have" ⁶
Socio – logical	Patient communication and education	Strongly positive	4	"I was thinking about is really the potential to share that information with them because once they experience it, whether they hear it or see it in whatever sense it becomes more real for them. If we can say your heart, this is what a normal heart sounds like and this is what yours does. I think it will provide that experience to them that will kind of solidify their knowledge and experience." ⁶
	Communication with other doctors	Share information Discuss cases	3	"Yesterday I saw a guy who had kind of a pimple or an abscess on his elbow. He had been seen by another provider four days earlier and I'm just looking at her note trying to imagine what it looked like and then now I'm seeing it later and I'm trying to think, " ² "It would be really useful, if I want somebody else to listen, or if I am in a rural area I can just have them to listen the recording and we can talk about it" ⁴

Learning	Positive	1	“I like the most is probably the ability to digitize all that information to be able to share it and see it later.it would be really cool in an academic setting, again, sharing the physical exam when you don't have access to bring that in.” ⁷
	Negative	1	
Status-	Strong	1	“You would loose the prestige as a doctor to have the stethoscope around the neck”
Distracter for kids	negative Negative	1	
			“this is totally pediatric minded, lots of times if the kid's not cooperative I give him the ophthalmoscope to hold while I listen to them. It would be harder to do that so I'd have to find another distracter, other than a medical device.” ⁵

Table A 11 Device interference with clinician's relationship with patient or workflow

Area	Themes - Features	Theme Magnitude	n	Representative comment
Affect patient relationship	Disruption	Initial disruption	2	"I think initially using it you'd be putting a lot of focus on using this... the whole technology piece. So that could take away from really paying attention to those subtle signs." ⁴
		Explain what it is	2	"Probably at the beginning you would have to explain" ²
		Disruption after learning period	7	"It would probably become second hand" ² "I don't think it would because we use tools to examine patients all the time and I don't think it really affects the relationship." ³
		It could	1	"It looks like it would not get in the way" ¹ "It could, because is technology"
	Improve Communication	Understanding of condition	4	"I was thinking about is really the potential to share that information with them because once they experience it, whether they hear it or see it in whatever sense it becomes more real for them. If we can say your heart, this is what a normal heart sounds like and this is what yours does. I think it will provide that experience to them that will kind of solidify their knowledge and experience." ⁶
		Understanding evolution	2	"This is what your asthma sounds like last two weeks ago and now you're doing so much better. Listen, now you sound like this," ⁴
		Positive	1	"kind of show them how things have progressed." ⁶
	Improve relationship	Depending on patient's perceptions of technology	1	"It probably will depend on the patient, how much they -- if they like this piece of technology involved. "Especially working with students because they want to know their providers are on the cutting edge of technology. When I have my laptop often students say, "Wow, you have a touch screen? That is so cool." I think it makes them feel like you're not some dumb dinosaur who doesn't know what they're doing. So yeah, it might be helpful." ⁴
		Age group perceptions	1	
		Improve perception of clinician	1	
Affect workflow	Adjustment	Adjustment to new routine	3	
		Like any tool	1	"it would be easy, it wouldn't be any different from the otoscope, ophthalmoscope and stethoscope" ⁵
	Time	Speed things up	5	"It would save me time" ¹
		Strongly positive (easy)	1	
	Time	Increase time	3	"It could because it's technology" ⁴ "I wouldn't play with the iPad while I am with the patient" ³ "Doesn't fit my routine" ¹
		Slightly negative (interacting with technology)	1	
		Negative		

Table A 12 Frequent responses related to user suggestions

Suggestion	n	Representative comment
Record Physical exam in real time into the EMR	3	"If it can give me the ability to record my physical exam ...and that changes depending on what I am looking at, wow that's great"
Voice recognition	3	"You can dictate part of your note"
Screen display (high quality)	2	"This needs to be electronic; it needs to be a camera with a screen" ¹ Would there be an ability to -- like in a digital camera you have the ability to immediately see the picture that you just took -- if I'm taking a picture of something or recording or something I want to make sure that it is of good quality, so that would just be offered on --? ⁶
Diagnostic aid	1	"It's the kind of diagnostic tools that are more useful, have to do with -- not so much the physical exam but developing a list of differential diagnoses and then" ⁶
Treatment and test suggestion	1	"Determining what test to order, that's when is good to have information in your fingertips" ³
Tonometer	1	"calculated intraocular pressure if you suspect glaucoma"
Tympanometer	1	"to measure ear pressure in your tympanic membrane"
Measure dimensions of skin lesions	1	"you could potentially, using a ruler, along the skin or let's say it has the ability to measure distance." ⁶
Echocardiogram	1	

Table A 13 Themes related to clinicians' needs and characteristics

Needs and characteristics	Theme	n	Representative quote
Time -	Reduced time per patient	3	“more and more time is everything; it's really crazy” ¹ “If you're a practicing physician it's a luxury of time that you don't have” ²
	Typing time	3	“most physicians hate going back to the computer and typing away at notes” ⁶
Cost - Instruments used Records findings	Concern	2	“I'd be really curious to know what the price point would be”
	Analog	7	
	After exam	4	“I try to keep the computer out of it.” ¹ “Now when I do a physical I'm not interacting with the computer at all” ² “Usually I try and do most of it during the visit, especially like the history as they're telling me....then sometimes I'll finish the other stuff after they've gone.” ⁵
Accuracy	Recalling details -	4	“maybe most of the physical exam's normal but there's just a few abnormalities you really want to make sure you remember. this always comes to me... "Was I looking at the left leg or the right leg?" ² Obviously you can't remember everything, or it gets hazy, or was it that patient or that patient?” And the problem when you're doing physical exam is you don't have the computer in your hand.” ²
Eye exam expertise	Lack of training & equipment	1	“We are not really good doing eye exams because of the equipment and lack of training”
Diagnostic aid during physical exam	Not needed Needed	4	“Now when I do a physical I'm not interacting with the computer at all... Then I have to come back later ... Because what happens is I do my physical exam then I talk to my patient, counsel them, order the prescriptions, then you're looking at, "Oh, I'm five minutes behind, I've got a patient waiting.. you don't do the physical exam until maybe my lunch hour when I'm done seeing patients and I'm having to remember details....was it the right leg or the left leg”
Sound quality	Negative	1	“ I have a little concern about the sound quality” ¹
Battery quality	Negative	4	“ The battery just died, so that's why I wonder how good the battery is going to be” ²
Maintenance	Negative	2	How much it needs to be maintained? Does it need constantly upgrades? ³
Break concern	Negative	1	
Stolen / Loose concern	Negative	5	“I'd be afraid I'd put it down and someone would grab it or it would fall off or something like that, whereas the stuff I have now it goes in its holders and my stethoscope goes around my neck”

Needs and characteristics	Theme	n	Representative quote
Wear Coats	Strongly -	4	“Hospital 90% of the physicians are wearing white coats, but in an outpatient setting you hardly see that anymore” ⁶
Temperature cording	Strongly -	2	“Temperature -- the nurse always does that” ⁷
Difficulty to explain a patient their conditions	Negative	2	“Sometimes I try giving my stethoscope and seeing if they can hear it but they can't.” ⁵