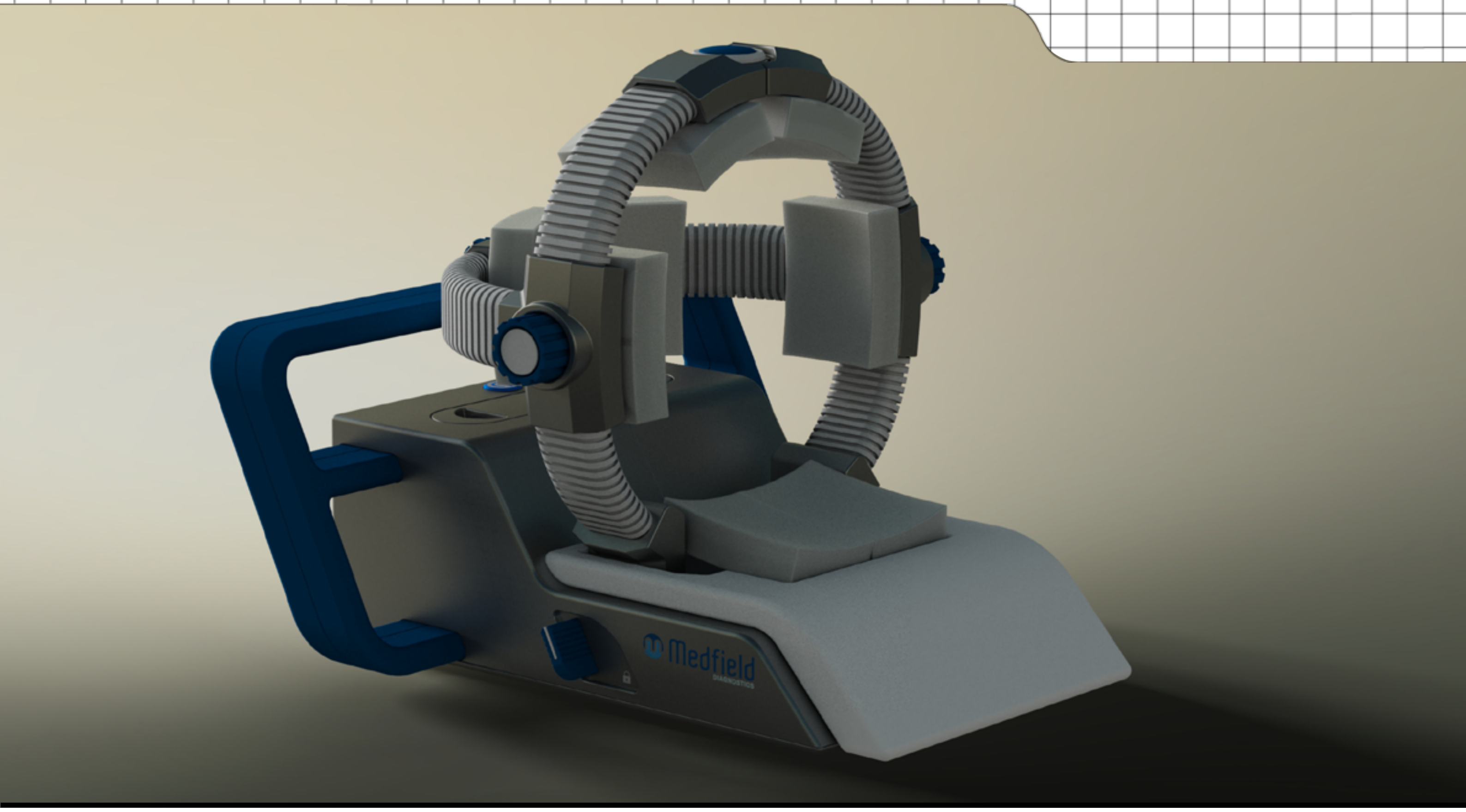
CHALMERS



Development of a stroke diagnostic device

With focus on usability and visual brand identity

Master of Science Thesis in the Master Degree Program, Industrial Design Engineering

SAMUEL LUNDE

TOBIAS OLSSON

CHALMERS UNIVERSITY OF TECHNOLOGY
Gothenburg, Sweden 2014

Department of Product- and Production Development
Division of Design & Human Factors

Master of Science Thesis PPUX05

Development of stroke diagnostic device
Master of Science Thesis in the Master Degree Program, Industrial Design Engineering

Chalmers University of Technology
SE-412 96 Goteborg, Sweden
Telefon +46(0) 31-772 1000

Cover photo: Olsson/Lunde
Print: Repro Service Chalmers

Master of Science Thesis

Development of a stroke diagnostic device

Samuel Lunde
Tobias Olsson

SUPERVISOR: Johan Heinerud, Stefan Kidborg, Stefan Candefjord
EXAMINER: Ralf Rosenberg

CHALMERS UNIVERSITY OF TECHNOLOGY
Gothenborg, Sweden 2014

Department of Product- and Production Development
Division of Design & Human Factors

Abstract

Stroke is the second most common cause of death worldwide. In Sweden alone it costs billions of SEK yearly in addition to the human suffering it causes. Medfield Diagnostics are currently developing a stroke detection device which will reduce the time to treatment for stroke patients, thus reducing suffering and cost. This master thesis focuses on the further development of this stroke detection device in terms of usability and expression in order for it to be used by paramedics within and outside of the ambulance.

The development of the stroke diagnostics device has been an iterative process following an industrial design engineering process. It started with a thorough background study of stroke, stroke treatment and anthropometric data. This was followed by user studies where several paramedics from different counties and other stakeholders were interviewed and observed in order to explore the needs set by the user and the environment where the device should be used. Four concepts were generated and evaluated from a use perspective by revisits to the paramedics and from a technical perspective by the staff at Medfield Diagnostics. The final concept was refined in a form study, function tested with mock-ups and visualized by a final CAD model.

The final concept is designed to work for a vast majority of the Swedish population in terms of anthropometrics. It consists of eight antennas placed on the head that are adjusted to the patient with three adjustments wheels and is constructed with consideration to the manufacturing. The product expression is that of a robust and professional medical device which reflects Medfield Diagnostics' brand values. It has clearly marked interaction areas which enable an intuitive usage and the large and sturdy handle makes it easy to handle and carry. The product has been designed to work in any of the rough environments where the paramedics operate and considerations have been taken in order to fit it into an ambulance.

The result of this thesis is an intuitive product which if implemented into ambulances has the potential to save both lives and costs for the healthcare by reducing the time to treatment for stroke patients. The thesis also works as a guideline for the design of future Medfield Diagnostics products in terms of brand expression.

Keywords: *Industrial Design Engineering, Prehospital Stroke Diagnostics, Product development, Stroke, Ambulance Equipment, Brand Identity*

Acknowledgments

We appreciate all the help and input we have received during this project and we are thankful to everyone who has dedicated time and effort to help us. We would like to thank the ambulance personnel in Karlstad for enthusiastically answering our questions and letting us visit their garage. Thanks to the paramedics at the Gothenburg ambulance garage who let us follow them during a day's work.

We would like to thank Olof Bergström at the Säve ambulance helicopter for showing us how prehospital care is done from a helicopter as well as giving us a lot of input about medical devices and Linnea Dreijjer for showing us around the Kungälv hospital and explaining how stroke patients are attended. Thanks to Sandra Carlsson and Miriam Kåveryd Holmström at Sahlgrenska hospital for showing us Medfield Diagnostics' existing equipment and to Hans-Allan Martinsson at Nilsson Special Vehicles for giving us a lot of input and feedback about placing medical devices in ambulances as well as showing us how ambulances are built.

We would like to thank Medfield Diagnostics for giving us the opportunity to do this master thesis in collaboration with them and also for all the support they have given us during the duration of this project. A special thanks to Stefan Kidborg and Stefan Candefjord for all the feedback and support they have given us.

We would also like to thank our supervisor Johan Heinerud and examiner Ralf Rosenberg at Chalmers for all the feedback and support throughout this master thesis.

A final thank goes out to Ajdin Hrnjica for putting a lot of time and effort into proofreading this report.

Samuel Lunde

Tobias Olsson

Contents

Terminology

Ischemic Stroke: Stroke caused by a blockage

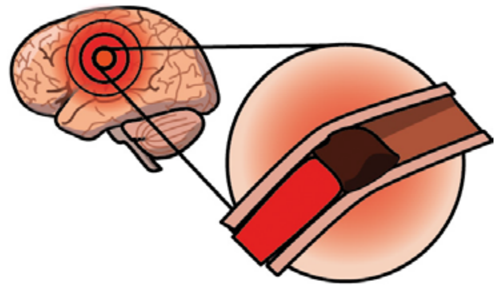


Figure 1-Ischemic stroke

in a blood vessel.

Hemorrhagic Stroke: Stroke caused by a

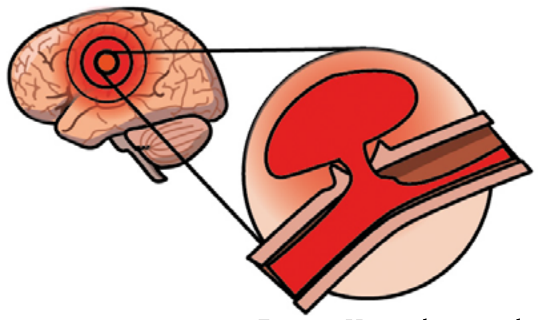


Figure 2-Hemorrhagic stroke

ruptured blood vessel.

Thrombosis: Formation of a blood clot in the heart or in a blood vessel.

Thrombolytic treatment: Treatment for a stroke patient who suffers from a blood clot. A clot buster is injected into the patient to dissolve the clot.

Telemedicine: Telemedicine can be seen as "the practice of health care delivery through the use of advanced communication technologies, computers, video instrumentation, and medical devices to exchange information and to deliver services that overcome the barriers of distance, time, and socio-cultural differences" (Yadin, 2004).

ECG: Electrocardiography is a "Recording of the moment-to-moment electromotive forces of the heart as projected onto various sites on the body's surface, delineated as a scalar function of time." (Karolinska Institutet University Library, 1998)

SDD: Stroke Diagnostic Device, name used to identify the future product this project will result in.

Strokefinder R10: Medfield Diagnostics' current device used in clinical trials.

PSAP: Public Service Answering Point, in Sweden equivalent to SOS Alarm.

CT: Computer Tomography is a medical examination that involves a computer-aided construction of slice images. (Nationalencyklopedin, 2014)

LP 15: Is an abbreviation for Lifepak 15, a combined heart monitor and defibrillator produced by the company Physio Control.

1 Introduction

Background

Stroke is according to Fassbender (2013) the most frequent cause of permanent disability in adults and according to Donnan et al. (2008) the second most common cause of death, responsible for 9% of deaths worldwide. Around 1.9 million neurons and 14 billion synapses are potentially lost during each minute that a large vessel stroke goes untreated (Fassbender, 2013). Ghatnekar et al. (2004) concludes that the total cost during the whole lifetime for stroke victims would be around 12.3 billion SEK per year in Sweden (year 2000). The cost consists both of healthcare and social services as well as loss of production due to premature deaths and early retirement.

Reducing the time to treatment, Fassbender (2010) says, is a very important factor in reducing the amount of damage a patient suffers from a stroke. There are two different types of stroke, ischemic and hemorrhagic. Hemorrhagic stroke is caused by a bleeding whereas ischemic is caused by blockage of blood vessels in the brain. Ischemic stroke can be treated with intravenous thrombosis (injecting a clot buster into the blood vessel that dissolves the clot) (Fassbender, 2013).

In order to minimize the damage caused by stroke Walter et al. (2010) performed a study in Germany where special ambulances were equipped with a computer tomography (CT) scanner and medical personnel trained to diagnose and treat strokes. If a stroke was diagnosed as an ischemic stroke they could begin the treatment in the ambulance thereby minimizing the damage to the brain by minimizing time to treatment.

Medfield Diagnostics are developing a diagnostic instrument which is based on microwave technology. The microwave technology has been developed by researchers at Chalmers University of Technology in collaboration with Medfield Diagnostics and is patented to Medfield Diagnostics. The technology has potential to, amongst other things, detect if a stroke is caused by an internal bleeding (hemorrhagic stroke). This technology could work as a substitute/compliment for the specialized ambulances mentioned above when it is equipped in standard ambulances. Currently Medfield Diagnostics is working on finishing the first version of the commercial product after successful clinical trials with the Strokefinder R10 (see Figure 3).

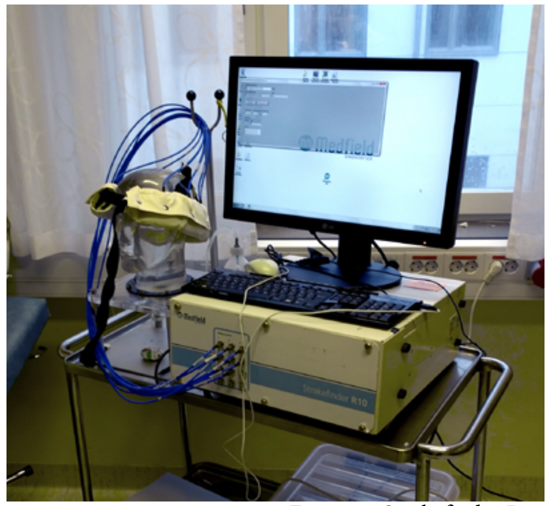


Figure 3- Strokefinder R10

Purpose

The purpose of this thesis is to improve the ease of use and reduce the learnability of the Strokefinder. It is also to adapt it to the mobility required for it to be used primarily in ambulances and secondarily emergency rooms, with main focus on the Swedish market.

Goals

The goal of this master's thesis is primarily

to further develop Medfield Diagnostics' equipment. The development should improve the existing product in terms of usability, improved functionality, and flexibility in order to enable use in ambulances.
A conceptual CAD-model of the product, (with specified measurement but without tolerances and draft angles) which should be possible to produce within the near future will be created.

Secondarily, a mapping of the product requirements and needs along with an exploration of the use areas and user scenarios of the product will be conducted. The visual brand identity of the product and company will also be incorporated.

Alongside this, but subordinate to the potentially lifesaving goals, regards to a sustainable development will be taken in order to create a product that is easy to repair and maintain in order to maximize the products lifetime. The product should be easy to disassemble for recycling and material combinations that are hard to recycle should be avoided.

Limitations

- The individual components within the product will not be modified
- The antennas will not be modified
- The sensors' position in relation to the head are fixed
- The product should fit adults

2 Theory

In this chapter the theories that have been used in the thesis are presented. It covers the areas; medical procedures, regulations, manufacturing techniques and anthropometry.

Stroke treatment

Today the general way a stroke is treated after the alarm comes to the PSAP (Public Service Answering Point) is as follows (PM-strokelarm, 2013, Appendix 01): An ambulance is dispatched, the ambulance personnel make a quick medical evaluation of the patient to try to determine if the patient has a stroke and the severity of it. If the stroke is deemed serious a so called Stroke alarm is called in to the emergency department so they are prepared for the patient. When the patient arrives to the hospital they are sent directly for a CT-scan. The results from the CT-scan together with blood samples taken and a NIHSS score (see appendix 01) determine if the patient should receive thrombolytic treatment or not. Thrombolytic treatments are not given if the stroke is caused by a bleeding.

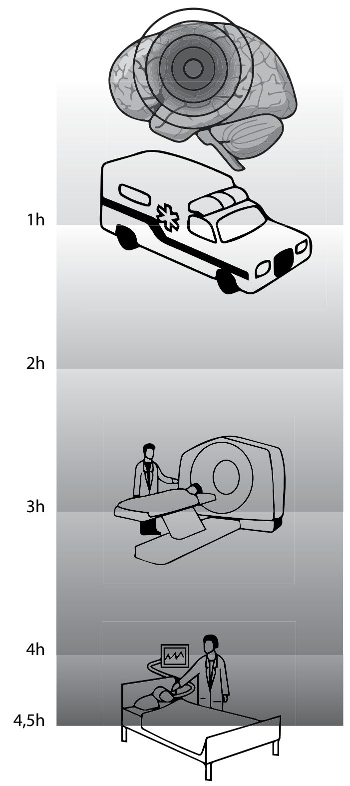


Figure 4-Stroke treatment procedure

Poljak et al. (2006) write that a licensed nurse may on certain indications administer drugs. This requires written directives from a physician in charge. (Poljak et al, 2006). From 2005 a nurse must be present in every ambulance in Sweden (Poljak et al., 2006).

Requirements, medical devices

The European standard SS-EN1789:2007 +A1:2010 specifies requirements which need fulfilling in order for medical equipment to be used in ambulances as well as situations outside of hospitals and clinics where the ambient conditions can differ from normal indoor conditions.

The equipment shall be securely and safely stowed to prevent damage and injury whilst the vehicle is in motion. For safety reasons the fixation should hold the device to withstand accelerations or decelerations of 10g in the longitudinal, transverse or vertical direction. The device should be designed for use in mobile situations and in field applications. It should be capable of use outside of the vehicle which means that it should be possible to carry by one person and have its own built in power supply (where relevant). The user interface of the medical device should be designed so that buttons, indicators controls and switches are easily accessible and visible. Standardized graphical and SI units are to be used where it is applicable.

The equipment should withstand the forces and ambient conditions which it might be subjected to in the ambulance and during outside use. This means that unless otherwise marked on the device; it should function:

- Through a temperature range from 0°C to 40°C

- For at least 20 min when placed in an environment at -5° after storage at room temperature (20°)
- When brought back to room temperature (20°) after storage in temperatures ranging from -30° to 70°.
- Liquid and humidity ingress shall comply with EN 60601-1 and with particular device standards of the EN 60601-2

The mechanical forces that a medical device should withstand are:

- Free fall test (EN 60068-2-32) from 0.75 meters on six different surfaces
- Vibrations test (EN 60068-2-29 test Eb) which consists of 1000 bumps with pulse duration of 6ms and a peak acceleration of 15g.

Afterwards the device shall function within tolerances specified by the manufacturer.

Branding

There are three important factors that define a brand according to Hestad (2013). The first is what the company wants to communicate e.g. a vision or a philosophy, Hestad (2013) calls this the brand story. The second is the mediator of the brand story, this can be the name or the logo but also the products. The third factor is the interpreter; the interpreter according to Hestad (2013) is the one that interprets the brand story from the mediating object e.g. the customer.

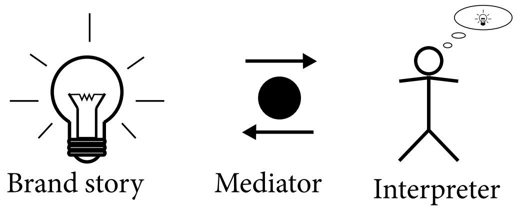


Figure 5-Brand identity according to Hestad

This is in accordance with Abbing (2010) who states that a brand is not the logo itself but what the logo symbolizes. Hestad (2013) suggests a method for communicating the brand message, where the company's core brand values together with its heritage are considered as the brand DNA. The role of the company's heritage differs. Newer companies do not have a lot of heritage to consider whilst older companies has a strong heritage that will affect the brand DNA (Hestad, 2013). The brand DNA is the core for the creation of a product's design and also what the company wants to communicate (brand story) (Hestad, 2013). The brand DNA is translated to design guidelines that use explicit and implicit design cues as means for communicating the DNA to the customer (Hestad, 2013).

Warell (2006) stresses the importance of the product as a carrier for the brand and consequently that it is important for the products to be in line with the brand message. Therefore one of the most important components of the brand identity is the product identity, and the visual aspect of the product is the key for building the identity through design (Warell, 2006).

Production techniques

Vacuum casting is a manufacturing technique used for low volume production of thermosetting polyurethane (PUR) plastics (Thompson, 2007). The method, Thompson (2007) continues, is used mainly as a prototyping method in many franchises including the medical industry but also in low series production. A silicone mold is created for the product which because of its flexibility can incorporate undercuts without increasing the number of parts (Thompson, 2007). The product can be of any size but a larger product will have a longer cycle time. Because the process is a low pressure process, Thompson (2007) explains, variations in wall thickness can be easily made. The silicone mold takes up to a day to create and can produce 20 to 30 cycles before a new one needs to be made.

Injection molding is a popular high volume production method for plastic products (Thompson, 2007). The method is used, Thompson (2007) continues, in every industry and the complexity of the possible geometrics is more an economic issue than a technical. The process is cheaper if the geometry is simple and more expensive the more complex the geometry gets (Thompson, 2007). The main cost of Injection molding comes from creating the mold itself whereas the labor cost is relatively small according to Thompson (2007). Injection molding can be done with almost any kind of thermoplastic materials and with some thermosets (Thompson 2007).

Anthropometric data

Anthropometric data consists of body measurement, for example size and shape, taken from a statistically significant sample of the population. The data is used to create products that are fitted for a large part, or specific part, of the population (Pheasant, 2003). In order to make sure that the product works for the target group (18 years and older, men and women) anthropometric measures regarding head circumference, width and breadth are needed. Head measurements were obtained from Hansen (2009) who uses data gathered from 18-65 years old Swedish men and women. According to Kraemer (2005) the changes in anthropometric data for older people are mainly decreased body length and limb length.

The traditional way of using anthropometric data is by selecting the highest and lowest value in the selected interval e.g. when designing a desk you may chose the 5th and 95th percentile of body height (Bohgard et al. 2009), thus covering 90 percent of the population. In practice this would mean that you create a desk suitable for people ranging from 156 cm to 191 cm tall (Hansen, 2009)

However, when you have two variables to consider this approach is not always optimal (Högberg, 2013). Then it is advisable to use a confidence ellipse instead. The confidence ellipse gives a better representation of bi variable data, especially if the variables are correlated to each other.

For the purpose of a headgear that will be used to diagnose stroke the interesting measurements are head width and breadth.

The confidence ellipses for head length and head width show that there is a low correlation between them (Antropometri.se, 2014). Hence, choosing the highest and lowest percentiles of the respective measurements is a good enough estimate.

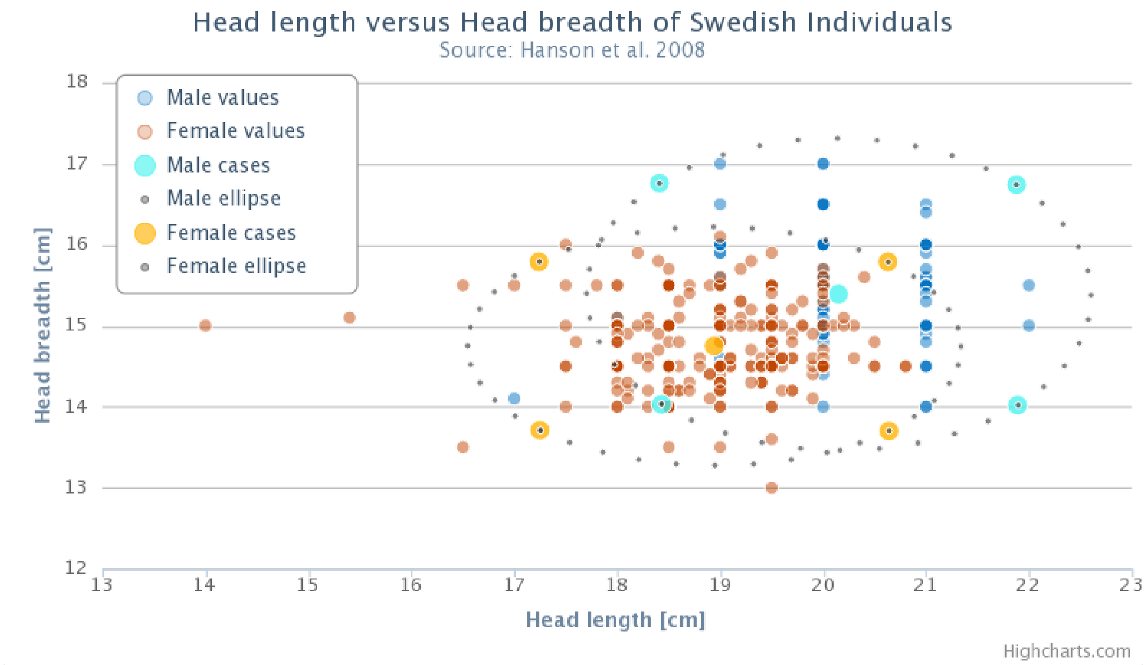


Figure 6-Confidence ellipses of head lenght vs breadth for swedish individuals (antopometri.se, 2014)

The first market for the SDD is Sweden, but on a longer perspective the market will expand to include other populations. From Hu (2007) anthropometric data on head sizes from a elderly Chinese population is gathered, Bradtmiller and Friess (2004) gives data on an American population. Figure 7 & 8 shows the difference between these two populations as well as the Swedish measurements from Hansen (2009).

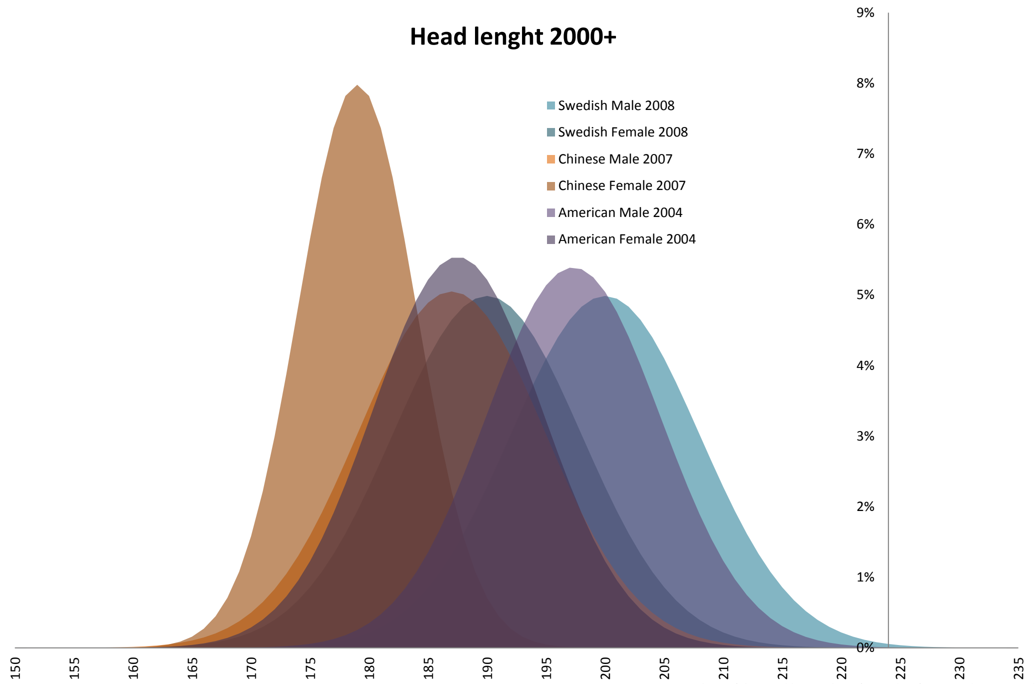


Figure 7-Graph of headlenght for differend populations

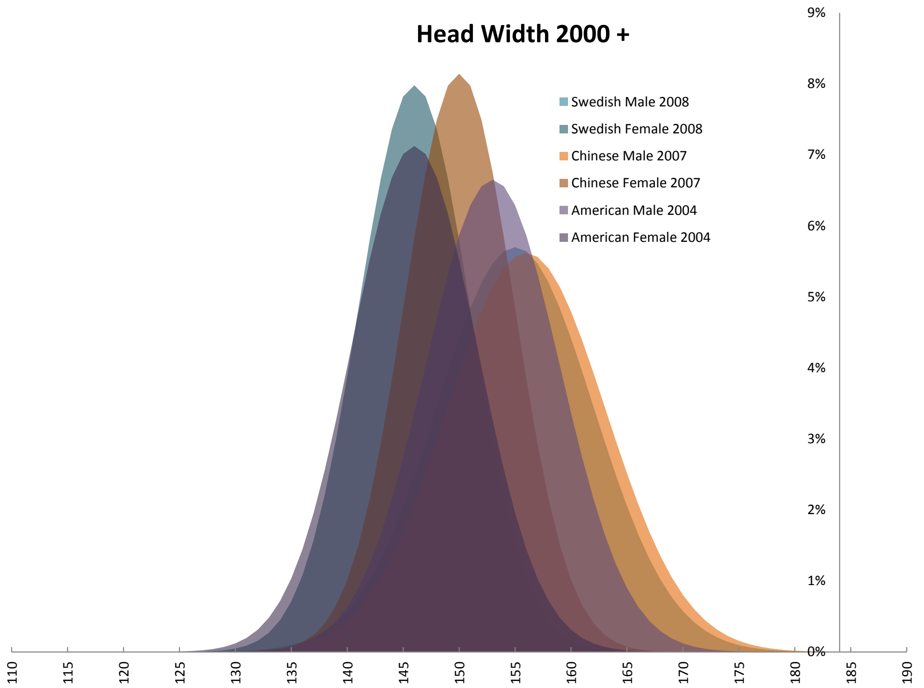


Figure 8-Graph of headwidth for differend populations

3 Methods

In this chapter the methods used throughout the thesis are presented. It consists of methods for research, analysis, ideation and visualization.

PD-method

The Product Development method followed in this thesis was divided into five phases where each phase represents a step towards the final product. The product development process however is not a straight line, iterations between the phases was therefore conducted.

The phases are: research, analysis, concept generation, concept evaluation and concept refinement.

Research

This is an important phase where information about users, user environment and opinions on the existing product was gathered. The research phase worked as the base for the analysis phase and delivered enough relevant information to create a good analysis.

Analysis

The information collected in the research phase was analyzed and structured in this phase. The goal with the analysis phase was to find the needs and requirements of the SDD, based on the findings in the research phase and to prioritize them. The results from the analysis then became the basis for further development of the product.

Concept generation

The results of the research and analysis phases became the corner stones for the idea and concept generation. The goal here was to create a large variety of different ideas and solutions. The solutions were then merged into complete concept solutions.

Concept evaluation

The concepts were in this phase to be evaluated against each other in order to decide which one to further develop. The decision was based on discussions with Medfield Diagnostics, clinical personnel and ambulance personnel as well as by using a decision matrix.

Concept refinement

The decision from the concept evaluation was the basis for further development and optimization of the concept. Form studies were done and descisions on a detail level were taken.

Final Product

The final version was visualized with a CAD-model and renderings as well as with a physical representation.

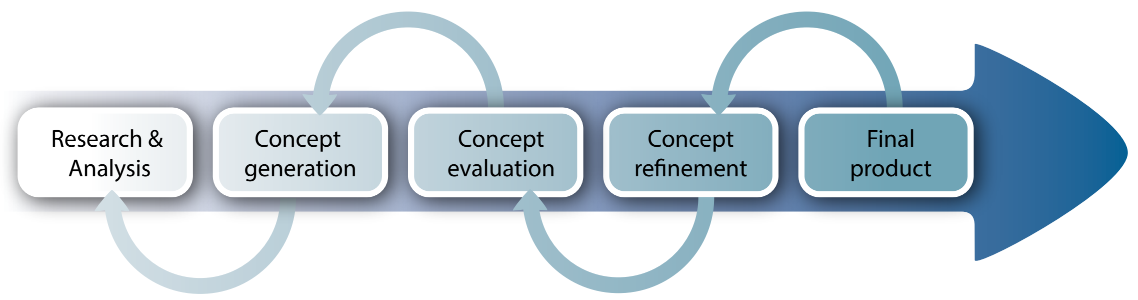


Figure 9-The product development process

Research

Observations

Observations are used as an objective method for gathering information regarding the use situation; they can be done either in the real environment or within a lab (Bohgard, 2009). The purpose is to get an understanding for the user environment and the user's behavior as well as information regarding how products are used, tasks are performed and problems that occur (Bohgard, 2009).

Interviews

According to Bligård (2011), interviews are a method for gathering information from individuals. Bligård (2011) writes that interviews make it possible to gather information regarding how the user thinks and reasons but also expectations, experience and opinions. Interviews can vary from structured to unstructured Bligård (2011) continues, where the structured interview consists of pre written questions and the unstructured interview discusses different subjects freely. In between the structured and unstructured interview lies the semi structured interview where the questions are prepared but are used as discussion basis (Bligård, 2011). The structured interview will generate more quantitative data whilst the unstructured will generate more qualitative data (Bligård, 2011). In this thesis the interviews will be semistructured in order to gather a both quantitative and qualitative result.

Literature study

Literature studies are a way of finding existing knowledge regarding a subject or area of research from existing sources of knowledge e.g. literature and databases (Bohgard, 2009).

Focus group

Focus groups according to Bohgard (2009) are group interviews or group discussions. The group consists of a moderator who leads the discussion and 6-10 participants. During the discussion mediating objects e.g. photos, products and models may be used to help the discussion (Bohgard, 2009). The positive effect of the group discussion is that the participants interact with each other around the posed questions and associate freely from the other participants' answers (Bohgard, 2009).

Analysis

Affinity diagram

Bergman and Klefsjö (2010) describe the affinity diagram (also called the KJ-method) as a method for organizing large amounts of data e.g. customer desires, ideas and opinions. The method should be performed in groups where the data is organized by associations rather than logical connections (Bergman & Klefsjö 2010).

Market analysis

A market analysis is according to Johannesson (2004) a way to find information about competing products and their benefits and drawbacks. It is also a way to discover possible and available technical solutions on the market (Johannesson, 2004). Information can be gathered from multiple sources such as competitor's web-pages, patents and exhibitions (Johannesson, 2004).

Since there are no competing products in the market, competing products will be seen as similar products that are used in the same environment (ambulances and emergency ward) in order to investigate their benefits and drawbacks. Ambulances of different models will also be part of the analysis since space and architecture differs between different models and this is an environment where the SDD should be used and primarily placed. This is done by observing and asking personnel, working with these products, about the different products' benefits and drawbacks when conducting interviews and observations.

Mood-board

Bligård (2011) writes that a mood-board is a collage of images that describes the expression, mood message feel etcetera of the product. The purpose of the mood-board is to communicate the thought behind the aesthetics of the product as well as function as a support during the ideation phase. When a mood-board mainly focuses on the expression of the product it is called an expression board (Bligård, 2011).

Ideation and visualization

Brainstorming

Brainstorming is a method for generating large amounts of ideas. it is performed in

a small group where the goal is to create as many ideas as possible that solve the problem definition (Österlin, 2007). It is important that the problem definition is formulated properly for a good result; formulated to narrowly and it will limit the range of ideas, on the other hand formulated too vague and it will cause the generated ideas to be vague (Cross, 2000). During the brainstorming session it is important to have a positive mindset and it is not allowed to criticize any ideas as the goal is to produce as many ideas as possible and not to evaluate how good they are (Österlin, 2007). The target is to find a couple of good ideas to work further with after the session.

Brain-sketching

Brain-sketching is similar to brainstorming but instead of working together with the ideas, each group member sketches on their own piece of paper instead of a collective larger piece of paper (Österlin, 2007). The method can be performed in two different ways; either the papers are shifted between the participants after set time intervals or presented by each participant who then continues on his or her own paper. Both are ways to make the participants gather inspiration and make associations from the other participants' ideas (Österlin, 2007).

Functional analysis

The aim of a function analysis is according to Österlin (2007) to figure out the main function, the part functions and support functions of a product. This is done in order to fully understand the reasons behind each part of a product. The main function should describe the overall functionality of the product (Österlin 2007).

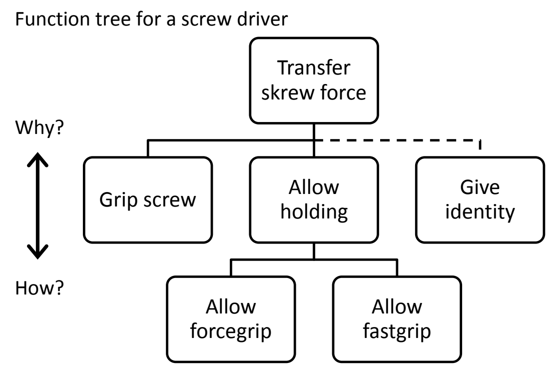


Figure 10-Example of a function tree

The part functions, Österlin (2007) writes, should describe how to achieve the main function and the support function is a function that isn't vital for the product to function but brings value. The functions should, Österlin (2007) continues, be described shortly with a verb and a substantive, e.g. "allow grip". It is also possible to add a function limitation e.g. "for diameters 8-20 mm". In a complex product, says Österlin (2007), the functions will form a hierarchy where each part function has its own part function and thus can be seen as a main function for those. When moving up in the tree, it answers why a function is needed and if you go down it tells you how a function should be achieved (Österlin 2007).

The function analysis enables the designer to take a step back and see what the actual function of each component is and how they together provide the overall functionality of the product (Österlin, 2007). This, Österlin (2007) concludes, minimizes the risk of locking to a particular solution too early in the process. By using a function analysis the focus is drawn away from potential solutions and instead centered around the actual functions. This creates greater freedom for the idea generation phase and is a good basis for a brainstorming session (Österlin, 2007).

Morphologic chart

The aim of the method according to Cross (2000) is to generate the complete set of possible design solutions for a product. First the aspects that need to be incorporated and that the product has to be capable of doing are listed(Cross, 2000). These aspects are gathered in a list placed in the left hand side of a matrix and then horizontally across the matrix, possible solutions (both new and existing) for achieving the different aspects are placed (Cross, 2000). In the next step these different sub-solutions (one from each horizontal row) are combined creating the complete set of possible design solutions (Cross, 2000).

Sketching, mock-ups and functional models

Sketching is one of the principal tools of the product designer. It is very useful for generating and communicating ideas in a relatively fast manner. Sketching enable the clients to stay involved in the design process, and get an overview (Eissen & Steur, 2011). Sketching is usually performed with pen and paper but can also be done digitally using computer software. The detailing of sketches vary from rough idea sketches on a napkin to complete near life representations depending on the purpose.

Mock-up models and functional models are another way of communicating ideas. Mock-ups tend to be a bit more basic than the functional models which in general are more advanced (Engelbrektsson, 2010). More than communicating ideas, models can be used to test and evaluate ideas and concepts in real life. Models can give answers to if a product will be ergonomic, if the design is good and if the function will work. The most basic modeling technique is called "Quick and dirty" and is a fast way of testing ideas using whatever material is available, for example duck tape and white board pens, to create a model.

Computer Aided Design (CAD)

CAD is a tool used to make digital 2D- or 3D-representations of products and features. Making 3D-models is a very helpful way to visualize the aesthetics, design, structure, interaction and interface of a product. The 3D-model enables the user to view the product from different angles without the need to construct a physical prototype (Johannesson, 2004). The 3D model may then be exported into a visualization software in order to generate realistic depictions of the product. The 3D-model may also be converted into a physical model through Rapid prototyping. This is a very fast way of creating a model in order to evaluate the concept (Johannesson, 2004).

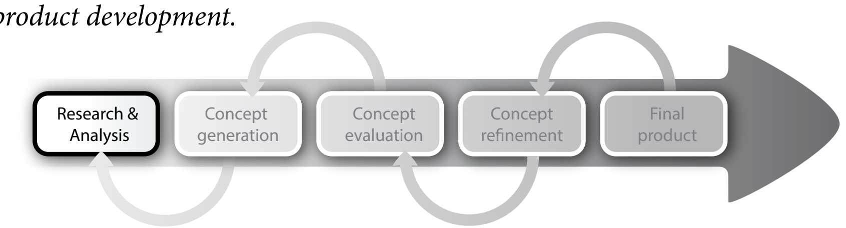
In this project Autodesk Catia V5 was used for the 3D model and Autodesk Showcase for the visualization.

Form development by order and meaning

Müller (2001) suggests a methodology for how to create product form based on ordering elements of the spatial features. Müller describes six dimensions that the elements can be ordered after by decreasing abstraction: *orientation, distribution, proportion, plasticity, construction*, and *materiality*. Each dimension consists of different elements that are ordered by different ordering features and articulating different spatial features. By using the different elements and ordering, going down the dimension levels of abstraction the form becomes more tangible and the sought articulation of the form can be created on each level.

4 Research and analysis

In this chapter the process and results of the user study are presented. In the end a product framework is presented which forms a basis for the future product development.



Process

User studies

During the research phase of this thesis work several user studies were conducted in order to gather as much and widespread data as possible. The studies were conducted as interviews and observations of the potential users of the SDD as well as in house interviews to grasp the technical aspects.

Technical aspects

A semi-structured interview with Fabian Wenger, technical product manager at Medfield Diagnostics, was performed. The purpose was to establish the basic technical specifications for the existing product such as; crucial parts, technical limitations, information flow, schematic view of the system as well as information regarding the development of the product. For a full description of questions and topics posed see appendix 02.

Paramedics at ambulance station

A focus group was performed with the personnel at Karlstad ambulance station. The purpose was to find out what requirements the paramedics would have on a SDD. A group of 13 paramedics including the Chief of ambulance was present. The focus group started with a short presentation of the SDD as it looks today, how it works and what the goal of this project is. Following that, the group was asked to give their opinions on the product, and how it should work. The group was also asked how similar (in terms of usage) products were used and what benefits and disadvantages they had.

After the focus group four of the paramedics partook in a deeper interview where they also demonstrated how the equipment was used and how they believed a SDD could come to best use. The interview took place in the ambulance garage where the ambulances as well as the equipment within were used as mediating objects. Four interviews were performed, all the subjects were ambulance nurses with a collective experience of 25 years, including the medically responsible nurse and a nurse with previous experience of thrombolytic treatment. The interviews were semi-structured since the goal was to find out as much as possible that may or may not be of use, but a few specific questions and general directions were focused upon. For a full description of questions and topics posed see appendix 03.

Emergency room

In order to gain knowledge about the procedures for stroke treatment at a hospital and how the whole system from the emergency call to when the patient receives treatment work a semi structured interview with an AT- doctor working at the emergency room at Kungälv Hospital was performed. While at Karlstad an observation was also performed together with a nurse working in the emergency room. The nurse showed different medical equipment used for diagnosis and monitoring of patients whilst describing the usage of the equipment and neck collars used for patients with suspected trauma to the spine. For a full description see appendix 04

Ambulance helicopter

A semi structured interview was performed with Olof Bergström, a specialized nurse working in the ambulance helicopter stationed at Säve airport. The purpose of the interview was to find out what requirements personnel working in the ambulance helicopter would have on a SDD, regulation demands for medical products in the helicopter and opinions on products similar to the SDD.

During the interview the helicopter and its equipment was used as a mediating object. For a full description of questions and topics posed see appendix 05.

Ambulance manufacturer

A semi structured interview was performed with Hans-Allan Martinson, sales representative of the ambulance department of Nilsson Special Vehicles. Nilsson Special Vehicles produce vehicles such as ambulances, limousines and funeral cars. The purpose of the interview was to find out what technical demands, limitations and possibilities there is in the ambulance for medical equipment, how new equipment is introduced into the ambulances and. Further it was investigated how the SDD would be placed and function inside the ambulance. During the interview Nilsson vehicles ambulances were used as mediating objects. For a full description of questions and topics posed see appendix 06.

Paramedics observation

A full day of observations was done with the paramedics at the ambulance and prehospital emergency department at Sahlgrenska University Hospital. The observations were done while shadowing two paramedics during their 11 hour work day in the ambulance. The observations were complemented with clarifying questions and a semi structured interview. The purpose of the observation was to get a good overview of how the paramedics work, what equipment they use and what attitude they have towards it.

Analysis

All the data from the research phase was sorted and analyzed with an affinity diagram, sorting the immense amount of information into large groups. The groups were then sorted into smaller groups depending on the topic the information was relating to. All this data together with the theory resulted in the product framework.

The product framework was sorted into three sub groups: Functions and features, Future Procedure and Product expression. Requests and requirements were sorted out from the information and was the basis for the Functions and features group and the requirements list. The future procedure was interpreted from the input of the different users during the research on how they would like the SDD to work, how they work with products similar to Strokefinder R10 today and what routines and regulations there are on how to treat stroke patients.

In order to communicate and create a basis for the future development regarding product expression an expression association web was created. The words in the expression association web originate from the results of the market analysis, the company's current brand identity and the results from the user studies. These inputs were sorted and analyzed into a basis for what the product expression should be. The product framework was the basis for the product development phases.

Results

Technical specification

As seen on the schedule in figure 11, the system consists of eight antennas which are connected to a switchboard. The switchboard is then connected to a VNA module (Vector Network Analyzer). These connections are made with coax-cables. The switchboard is also connected to the computer device through a usb cable. The VNA is connected to the power source. The data from the VNA is sent to a CPU through a usb cable. Eight antennas are preferred since most of the previous work can be applied and since eight antennas cover almost the whole head.

The computing capacity needed from the computer device is equal to that of a hand held device, such as a smart-phone or tablet.

The device takes seconds to power up and can be used as soon as the VNA has reached its functional temperature, which takes a few minutes. After a while the VNA reaches higher temperatures, thus requiring a heat sink to function properly.

The antennas have to be placed in a precise manner that can be repeated indifferent to head size and head shape. In theory the antennas should be as spreaded out as possible in order to get the best readings. Furthermore the antennas need to be placed as close to the skull as possible in order to prevent air from disturbing the readings. Since air is

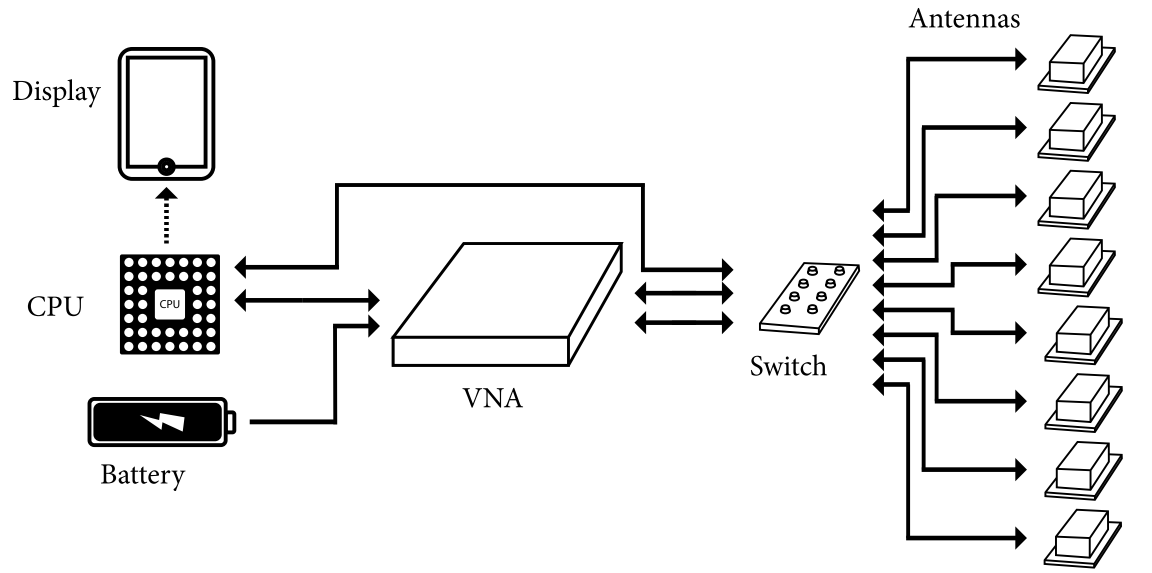


Figure 11-Component scedule for the SDD

particularly bad for the readings, a gel, fluid or similar may be used in order to fill out the space between the antennas and the skull. The antennas should preferably be placed in a symmetrical manner, i.e. the antennas should be placed so that each antenna on the right side has a counterpart on the left side. This is so that the SDD can determine on which brain half the stroke is located.

Today three sequential readings are made and the whole procedure takes about a minute and a half. A test scan is also made on a dummy before applying the equipment on the patient. In the future product the three sequential readings will only take around 30 seconds.

User studies

Emergency dispatch

During an emergency dispatch the ambulance and ambulance helicopter personnel work very calm and methodical. They rather walk fast from the vehicle to the emergency than run, this is because the time they win is very small and it is much easier to make mistakes when stressed. When the helicopter is called out for an emergency, an ambulance car is called out as well. Since there is only one helicopter in the region they need to prioritize which cases they send the helicopter to and they may be required somewhere else, therefore an ambulance car is also sent along.

Ambulance helicopters differ in model and staffing depending on which county they belong to. In Västra Götaland they have a very large helicopter (ca 5000 kg) because they operate in a large area and want to be able to travel from one edge of the county to the other without having to stop for refueling. They have two pilots, one anesthetics doctor and one specialized nurse. The helicopter is always on stand by and sometimes they are airborn the whole shift and only return for the shift change. In the Nordic countries the helicopters fly during nighttime, which is less common further south in Europe.

Figure 12-The helcopter at Säve airport

The ambulance cars also differ between counties and even within counties but the equipment within is quite similar. When transport from the emergency starts they call the triage at the emergency room to state what symptoms the patient has and at what time the estimate to arrive. They can also call a doctor for advice and ordinations regarding the patient. They use regular cellphones to contact the hospitals which can sometimes be problematic, for instance when operating in an area with poor coverage. When travelling by helicopter the speed, height and the distance between the cell masts can cause similar problems calling as well. If that is the case they have a satellite phone they can use instead. In difference to the ambulance cars however, the helicopter has a doctor onboard who can diagnose the patient, thus making the phone calls shorter and less vital.

Stroke procedures

The stroke procedures differ slightly between counties but in general the ambulance first a call to a suspected stroke case. When the ambulance personnel then arrive, they try to figure out what has happened and when the stroke occured. They then do a prehospital evaluation where they check the patient for awareness level, paresis, speech impediments and other stroke indicators (see appendix 01 and 07) as well as general patient information (name, age etc.). At this stage the procedures differ. The ambulance personnel in Värmland county also take six different blood samples at this stage whilst the personnel in Kungälv and Gothenburg don't take any. Personnel in Gothenburg think it is more reasonable that blood samples are taken at the hospital. The paramedics also try to find out what medications the patient is taking, either by asking the relatives, searching for it themselves or asking the hospital to look at their personal file. They are mainly looking for blood thinning medication.

If the stroke is confirmed and fulfills the criteria for it, a stroke alarm is actuated. The Ambulance personnel then drive the patient straight to the CT-scan at the hospital where they meet up with the medical personnel at the hospital and brief them about the case.

The CT-scan is performed, a procedure which takes around 10 minutes. The results from the CT-scan together with a more extensive physical evaluation of the patient, NIHSS (see appendix 01), and the results from the analyzed blood sample serve as a decision base for whether or not the patient should be treated with thrombolysis or monitored and referred to rehab.

Thrombolysis is a procedure which has a certain risk associated to it. Therefore the medical personnel are very meticulous when they examine the patient in order to set the right diagnosis before administrating the thrombolysis drug. It is never administered without a proper CT-scan. An unconscious patient will not receive thrombolysis, but it is uncommon that stroke patients are unconscious. Thrombolysis is administrated through a needle in the arm. The doctors in an ambulance helicopter are licensed to administer thrombolysis, but since there is no CT-scan in the helicopter, they don't.

Patients

In general the stroke patients are regarded by the paramedics as quite calm patients who are easy to handle. Even though they may be confused and frustrated because they for instance can't find the right words. Stroke patients can be notoriously anxious and want to move around when the ambulance personnel handle them. The patients may also be disabled and unable to sit up for themselves. On occasions the stroke may cause the patient to fall and this may require the paramedics to put on a neck brace if the patient got hit in the head. On some occasions the patient may be nauseous and need to vomit, partly because of the stroke but also because of the ambulance trip. When the ambulance personnel arrive, the stroke patients usually lie down, partly because they become groggy and partly because the PSAP recommends them to do so. Within the ambulance the stroke patients sit up or lie down dependent on each individual case.

Neck brace

A stroke patient may on occasion fall because of the stroke and is therefore in need of a neck brace. Neck braces are quite easy and quick to apply. There are a lot of different companies producing neck collars but they all look similar in some aspects. When a neck collar is applied it is "modified" so that it fits snugly between the angle of the cheek bone and the trapezius muscle. A neck collar always has a hole in the front to make it possible to check the pulse and one in the back to enable a spine examination.

Ambulances

Ambulances in Sweden are used for around 5 years before they are replaced by new ones. There are a few manufactures active on the Swedish market today. The largest of them is Nilsson Special Vehicles; they have around 50% of the Swedish market.


Figure 13- A commpnly used neck brace

Figure 14-Ambulance from Nilsson Special Vehicles

Ambulances are bought by the different counties and they decide what equipment they should be equipped with. Therefore the ambulances are in some sense custom made. It is not possible to change everything, but fixtures for different equipment and power outlets are typical things that are customized in the ambulances. The seats, stretcher, shelves are not possible to change due to safety demands. It is possible to get both 12v and 230v power outlets in the ambulance. In Nilsson Special Vehicles ambulances the 12v can be placed almost everywhere in the ambulances after the customers wishes. . The 230v however, are only possible to place on a few different locations. The power in the ambulance is supported by two car batteries, one supplies the car and one supplies the medial equipment. The ambulances are allowed to carry around 600kg including the passengers in it. This is according to Hans-Allan Martinsson at Nilsson Special Vehicles very similar for all ambulances used in Sweden. He suggested three different placements for the SDD; under the seat that is opposite to the paramedics seat in the back, on the rails on the side of the stretcher or in the shelves at the back. These positions suggested by Hans-Allan Martinsson are based on their ambulance model, but the market analysis and observations performed on other ambulance models suggests that these three positions could be possible on not only Nilsson Special Vehicles ambulances.

Each of these positions have benefits and drawbacks. If the SDD is placed in the compartment under the seat the benefit is that it is fairly easy to connect it to a power supply and charge the battery while it is in the ambulance. It is also possible for the paramedic to reach it when working with the patient during transport. Drawbacks for this position is that the paramedics need to go into the ambulance through the side door to get the SDD and based on the observations and market analysis this area is the one that differs most between different ambulances and manufacturers.


Figure 15-The compartment under the seat

Benefits with placing the SDD on the rail on the side is that it is easy to reach for the paramedics when sitting with the belt on in the back. it is also easy to connect it to a power outlet and when the paramedics take out the stretcher they can easily reach the SDD. Drawbacks are that it puts strict demands on the size of the SDD since it cannot extend beyond the indent in the side wall where the rail is placed (height 450mm, depth 220mm to 260mm). The rail is also a popular place to mount equipment and therefore competes for the space with other important equipment. It also needs a specialized fixture manufactured to be able to be mounted on the rail. Another drawback is that some vehicles like those in Västra Götaland don't have the railing at all.

Figure 16-The railing inside an ambulance

Placing the SDD in the shelves in the back of the ambulance has the benefit of not requiring any modifications on existing ambulances. Furthermore, it is easy to grab when reaching for the stretcher in the back. Drawbacks with this position is that the ambulances don't always have power outlets in the shelves and that it is impossible for the paramedics to reach the SDD from the seat they sit in when riding with the patient.

Figure 17-Back shelves of an ambulance

Fixed ambulance equipment

All the equipment in an ambulance must be fixed during transport because of traffic safety. In the case of a crash they should not be able to loosen and hurt someone in the ambulance. The equipment is placed in cupboards or, if they are to be used during transport, fixed on rails or other fixtures. Some equipment has special mountings e.g. the stretcher and the lp15. The lp15's mounting makes it easy to remove and bring out of the ambulance but it also fixates it during transport.

One difference between the ambulances and the helicopter is that there are no strict rules about fixating the equipment. Different helicopter types can bring different amount of equipment depending on size. In the VG region they have as mentioned earlier a large helicopter so they have the possibility to add more equipment if they would like to. However, when they add new equipment they usually also remove old equipment at the same time. In the helicopter used in VG they store the main part of their equipment in a compartment in the back of the helicopter which is only accessible from the outside. This as mentioned earlier will differ greatly from helicopter to helicopter as well as possible amount of equipment to bring.

Figure 18-Storage compartment of the Säve helicopter

The stretchers used in the ambulance cars differ from the ones used in the helicopter. The ones used in ambulance cars are larger, z-shaped and weigh circa 40 kg whilst the ones used in the helicopter are smaller, weighing around 15 kg and are flat. The stretcher used in the VG helicopter can be adjusted in the horizontal plane so that the doctor and nurse can get the best reach around the patient depending on the need of treatment.

Emergency equipment

When the ambulances in Karlstad reach an emergency they always bring their standard bag with them and often the stretcher as well. In the case of a suspected heart failure they also bring the LP15 and oxygen tubes, which bring up the carried weight per person to around 40kg. When they are going to a suspected stroke they bring their standard bag, stretcher and a kit for taking blood samples. Some

paramedics prefer to bring the bare necessities when they go to a patient and afterwards get back to the ambulance to bring for instance the stretcher. Especially if the patient is in a hard to reach area, for instance in an apartment without elevator or at the beach.

When the helicopter reaches an emergency the personnel only do procedures which improve the patient's outcome directly on the ground. Procedures that the patient does not directly benefit from are done when they are in the air because their main advantage is their speed.

Medtech in helicopters

For medical technology products to be allowed to be used in helicopters, the equipment needs to be approved for every individual helicopter model. There are companies that perform these tests for approving new equipment e.g. SAAB. First they test the single equipment and then they test it together with other equipment with the helicopter running. The main purpose is to test how different types of interference from the equipment affect other devices and the helicopter, but also vice versa. The main problem is electromagnetic radiation which can cause a lot of problem for the helicopter. The helicopter also creates a lot of electromagnetic radiation that can affect the equipment. On the Gotland ambulance helicopter they had problems where a respirator in the ambulance scampered due to the electromagnetic radiation from the helicopter. A lot of the requirements may be avoided however, if the SDD is shut off inside of the helicopter.

On board computer

Both the ambulances and the ambulance helicopters are equipped with a computer. It runs windows XP and can be fitted with different programs e.g. in Karlstad they have a program for patient journals and in Säve it works a lot like a GPS. The computer used in the ambulances in Karlstad and in the helicopter is called Paratus and is developed by SAAB. It has the possibility to transfer data both by satellite and by 3G.

Telemedicine

Telemedicine is widely used during critical heart conditions. The LP15 gives the possibility to send an ECG directly to an emergency room or a specialized heart ward, where a doctor can look at it and give the ambulance help by prescribing drugs and treatments. This increases the patient's chances since treatment can be administered directly in the ambulance after the doctor's ordination. The doctors and nurses receiving the patient at the hospital also get more information about the patient's condition and are therefore more prepared. The ambulance personnel in Karlstad were very positive about this type of telemedicine and had only positive experiences of it.

HMI problems

When looking at medical products the Lucas heart compressor is a product that excels in usability. For Lucas the instructions are clearly shown and done step by step in a logical order. When unpacking the bag and assembling the Lucas, the parts appear in the order they are needed. Operating it is done in three sequential steps which are easy to follow.

Figure 19-Lucas heart compressor

Sunlight can be a problem when working with a screen due to reflections but in the LP15 they solved this by having a mode where the screen switches to darker colors. To be able to work during night, the ambulance cars are lit from within, as is the helicopter but with a green light. The helicopter personnel said that it is better to make the SDD intuitive and fast than to minimize the size and weight. The ambulance personnel however want it so be as small as possible in order to save space.

Portability

The interviewees all confirm that there is a wish for the SDD to be portable. The paramedics would prefer it since there is more space and the nurses can collaborate when applying the equipment. The helicopter nurse generalized it so that if a procedure will improve the outlook for the patient it is done outside of the helicopter. For example if the patient has an abdominal trauma the ultrasound will be done within the helicopter since it is more important to get the patient to the hospital. Battery dependent portable equipment is generally charged within the ambulance with some exceptions, e.g. the ultrasound equipment for helicopters is only charged when the helicopter is grounded.

Cables

Cables should be kept to a minimum. In general the paramedics complained about the amount of cables they had to handle and how the cables often got tangled and broke. The LP15 has a lot of cables that get tangled and this is a problem since they use the equipment on a daily basis. Some of the cables also has weak attachments which cause them to rip.

Figure 20-LP15

Adjustment

The Strokefinder R10's major benefit in adjustment is that it only needs to be adjusted in one place which makes it simple to attach to the head.

Other variant of products that the interviewees have tested include a headband that requires a more precise placement of the sensors. The placement is determined from the placement of the temple, the bump in the back head and the middle of the forehead. This enables a more precise placement but it takes quite a long time to place the headband. The headband also has a screw to adjust the overall size of the headband. For the nurses this is very convenient but it also increased the risk of tighten too tight. Headbands which have to be adjusted in the back of the head are inconvenient for the nurses since the patients often are in a semi sitting or laid down position. One product that the paramedics in particular liked was the disposable breath-cap, partly because it is disposable and partly because it is very quick to adjust.

Reliability

The reliability of the equipment is important for the nurses. They need to be able to rely on it to work, in terms of having a robust product that can withstand the everyday usage of emergency equipment. This includes free falls, temperatures down to -30°C (due to winter and wide open ambulance doors), humidity and generally rough treatment. It also needs to be reliable in terms of knowing that they have used the equipment correctly, "it is important that the equipment is functional, I'd rather have a larger product that is easy to handle and impossible to misuse" (Olof Bergström, Säve ambulance helicopter). The SDD should be simple, have few error sources and give feedback. The research nurses also agree with the importance of feedback and that the design of a SDD should minimize possible error sources and the risk of misuse.

Disinfecting / Cleaning

Cleaning is very important. A product must withstand cleaning against multi resistant bacteria and viruses as well as blood stains and vomit. For instance bands that can be cleaned with alcoholic gel are better than cotton bands which can't. All equipment in the emergency room is cleaned with alcohol on a daily basis and if it for example gets splattered with blood it is cleaned directly afterwards. Some equipment e.g. the ultrasound in the helicopter is cleaned with disinfection tissues. Parts that are in contact with patients are usually replaceable and changed between patients. For product that aren't invasive, cleaning and disinfecting is sufficient.

Container

The container that holds the SDD should be easy to open, but safe enough to not open unwantedly e.g. when running with it. It should also be robust and rugged since it is handled roughly from time to time. The container should allow for a logical and structured storage of the equipment, like for instance the bag for the Lucas heart compressor.
Hygiene is also important for the container since it is in contact with the instruments. The ambulance nurse gave examples of different fabrics which support this, for instance Pax Plan and Pax techno which are rugged and

water repellent and therefore easy to clean. Condura is another rugged more esthetically pleasing material in use; this however is very hard to clean.

Maintenance

The prescribed maintenance procedures from the manufacturer are followed regarding maintenance of equipment. Both at the ambulance garage in Karlstad and Gothenburg but also at the helicopter base in Säve. They have a schedule of when the equipment needs to be checked and calibrated. The LP15 does an automatic calibration at a set time every 24 hours but it also needs to be manually checked by the personnel at specified time intervals. In the ambulance garages they do a quick function test of their equipment at the start of each shift if they have time and aren't called to an emergency. They all preferred to do as little maintenance and calibrations as possible. The important thing is that the equipment works and that they can rely on it to work properly when used.

Requested procedure

The ambulance personnel would like to be able to use the SDD both inside the ambulance and outside. They also want the possibility to use it during transport to save time, but since they already do a preliminary diagnose before leaving the emergency site, and if the SDD is fast to use, they would probably use it on the spot before leaving. The helicopter personnel stated that they would probably use it outside the helicopter since it improves the patient's odds and the results would also help them take the patient to the best hospital. Overall they all want the procedure to be as fast as possible since each minute is important during a stroke. The ambulance personnel stated that it would be possible to start up the SDD before traveling to the emergency if needed in order to save time at the emergency site.

Process for the existing product

When the research nurses perform readings for the clinical study with the Strokefinder R10, they follow the same procedure every time. First they start the equipment which needs some time to to warm up, then they perform a test scan on a test head. The test scan shows that the antennas and the connection to the main unit are working.

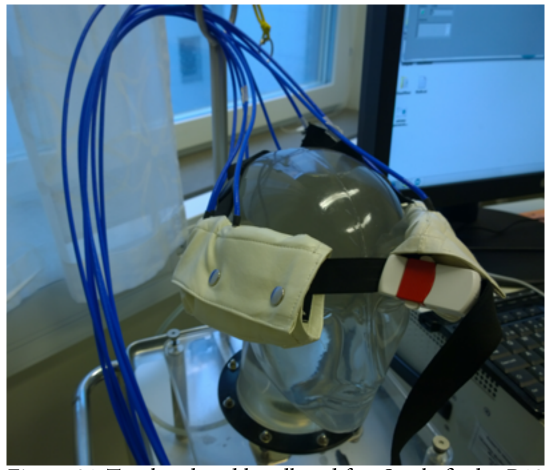


Figure 21-Test head and headband for Strokefinder R10

After that they mount the headgear onto the patient's head. The patient lies in a semi raised position to make it easier for the nurse to work. They first place it in the back of the head and then adjust and tighten it so that the antennas are placed correctly on the head. The nurses state that it is important to be able to get visual feedback that the antennas are placed correctly. It is also important that they are held against the head in such a manner that it doesn't move during the measuring.

Product framework

The results from the research and analysis together with the theory have resulted in a list of demands and requests for the SDD. The full list can be viewed in Appendix 08. The most important features and functions which need to be considered for the future development are presented below. The product expression sub chapter presents what the SDD should communicate and express based on the results from the research and analysis. The future procedure is the suggested work flow for the SDD based on the limitations in the technical equipment and the input from the medical personnel.

Features and functions

Below, the most important features and functions from the demand and requirement list are presented.

- Enable adjustments of the antennas with regard to differences in head size and shape. The SDD must fit 95% of the population with a goal to make it fit 99,9% of the population.
- Minimize the air between the antennas and the patients head. Air gaps reduce the exactness of the measurements

made by the SDD and the goal is to place the antennas so that there is as little air gap as possible.

- The antennas need to be fixated during scan in order to minimize errors in the measurements. If the antennas change position during a scan this will affect the results negatively, but the patients comfort also needs to be considered in this case.
- The SDD should work both inside and outside the ambulance vehicle. This means that the SDD should be able to be used on the patient whilst lying on the stretcher but also in other situations when it is used outside the ambulance e.g. patients bed, floor and on the ground. It also means that the SDD need a power supply to work where there are no power outlets.
- It should be able to be transported in the ambulance. This means it must follow the regulations of SS-EN 1789 which includes demands on safety, working in a large temperature span, withstanding the forces in an ambulance etc.
- The SDD should be able to be carried by one person outside the ambulance. It should be easy for the ambulance personnel to transport the SDD between the ambulance and the patient. It should also withstand the forces it may be subjected to during transport and use.
- The interaction with the SDD should be intuitive and logical for the users. It should not be possible to apply or use it wrongly and the users should be confident that they have used it correctly. It should also be fast and efficient when used due to the fact that every second counts and the SDD should not prolong the time it takes to get treatment.

Requested procedure

The ambulance personnel receive an alarm of a possible stroke and drive to the emergency. When they arrive they grab the SDD and other needed equipment from the back of the ambulance. Arriving at the patient's home, the first paramedic talks to the patient, evaluates with a ModiNIHSS (see appendix 01) and takes blood samples. The second starts up the SDD and places and adjust the SDD on the patient's head. The patient is lying down e.g. a bed, sofa or on the floor. The patient is "scanned" and the results are sent to a specialist physician by 3G or satellite together with the ModiNIHSS score. They put the patient on the stretcher, bring the patient to the ambulance and load her/him in. The physician calls the ambulance, he/she have concluded that it is a stroke and that is caused by a clog. The physician prescribes that thrombolytic treatment should be started. The paramedic that rides with the patient prepares and begins the treatment during the transport to the hospital.

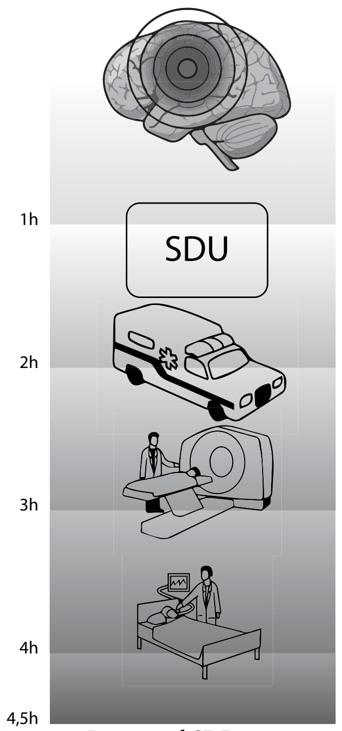


Figure 22-Requested SDD treatment procedure

An alternative scenario would be if the patient doesn't get the stroke at home. Then they would load the patient into the ambulance and there perform the initial diagnose, take blood samples and "scan" the patient with the SDD. The rest would be identical with the initial scenario.

Product expression

The expression board created represents the values of the Medfield Diagnostics brand. It also represents what the SDD should communicate to the users, both caregivers and patients. The expressions were generated into six word clouds. Later on representations with illustrations were created to accompany the clouds. The larger words in the word clouds represent the main values and the smaller represent supportive values to further emphasize the expression. The SDD is a professional and precise tool for analyzing stroke. It shall be a high-tech and seamless solution to a common medical issue. The SDD is also to be user friendly and understandable to use for the paramedics using it. Even though it is a high-tech professional tool it is used in an environment where stress is a vital aspect. The patients shall feel the SDD to be inviting and safe, and the paramedics and doctors shall be able to rely on it. It shouldn't break or produce false data. Finally, the SDD is a hygienic medical equipment and should express cleanliness.

From the word clouds, six pictures were chosen to represent the expressions. The can-phones represent *user friendliness* and *simplicity*, the metal ring and ropes represent *reliability* and *roubustness*, the blue flow of ones and zeros represent *high-tech*. On the bottom row the microscope expresses *professionalism* and *preciseness*, the clean desk represent *hygienic* and finally the lifebuoy on the beach represent *welcoming* and *safe*.

Figure 23-Expressions of the SDD

Discussion

In the research phase the purpose was to find as much information about users and their demands and requirements as possible. In order to get a wide perspective on the usage of the SDD not only ambulances and ambulance personnel were included in the research phase but also emergency room and ambulance helicopter personnel were interviewed and observed.

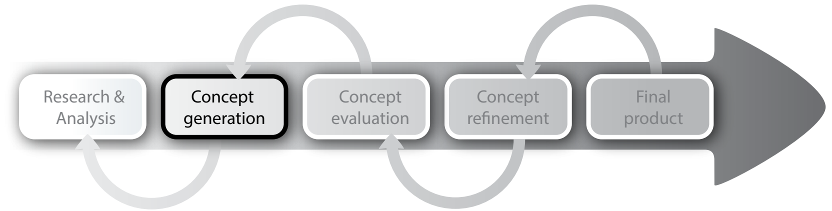
This in combination with visits to an ambulance manufacturer and the research nurses using the Strokefinder R10 have given a good and valid basis for the product framework.

Questions regarding patients and their behavior have been posed during the interviews and observations, but no questions have been posed directly to patients. This is because their behavior in general and during a stroke have been described sufficiently by the medical personnel in the research. Another reason is that the operator is the primary user of the SDD and not the patient. However the patient's experience and comfort during use will not be neglected in the future product.

During the interviews, focus groups and observations the LP15 (or equivalent) has been a mediating object for the discussion. This, since it is a medical product that is used for diagnosis inside and outside of the ambulance and because it communicates with the hospital in a way similar to what is intended for the SDD. This has been a very good tactic since both positive and negative aspects of the LP15 are very good input for the SDD. Another benefit has been that the interviewees could relate to the SDD and how they would want it to work. But it is important to critically analyze the information to find what is applicable for the SDD and what only relates to the LP15.

5 Concept development

In this chapter the product framework was utilized for concept development. The chapter consists of the process and results of the concept development.



Process

Functions

The first phase of the concept generation was to create a function tree in order to come up with the most important functions of the SDD. These were then placed on one axis in the morphological matrix. The goal was to come up with as many different ways to solve these functions as possible. This was conducted with both brainstorming and brain-sketching. The ideas were then entered in to a morphological matrix, and the entries in the morphological matrix were combined to create different ideas for the product.

Ideation

In order to create more ideas and to get external input, an idea generation workshop was conducted together with other students of the Industrial Design Engineering Master. During the workshop brainstorming and brain-sketching was conducted around several functions such as, but not exclusively: different ways of adjusting the antennas and how to protect the sensitive equipment in a rough environment (see Appendix 09 for a full description of the workshop topics and procedures). During this phase the function of placing the antennas on the head and to easily adjust them so that they fit different patients was regarded as a high priority. The reason for this is that it is crutial that the entire area of the antennas are in full contact with the head in order to get a valid reading.

All the ideas from the idea generation sessions were then sorted and analyzed leading to unrealistic ideas being scrapped. With regard to the main goal of creating a product that was easy for ambulance personnel to use in and out of an ambulance, three structural categories were created. They are based on how to package all the different components in different ways, which creates different ways on how the product is handled and used.

After the structural categories were decided they were developed further with sketching, brainstorming and mock-ups. The purpose of building simple mock-ups of the structures was both to test the plausibility of them but also to get more information on size and geometry. During the testing it became evident that structure category B was not creating any special benefits compared to structures A and C and was therefore scrapped. Simultaneously different concepts on how to adjust the antennas against the head were developed. The first step was to investigate other products on the market that in some sense are adjusted against the head and to find what solutions are used in other applications to find useful technical principles. The second step was to brainstorm and investigate other possible technical principles for adjusting the antennas and pushing them against the head. The found technical principles were further developed by building simple mockups to test the function of the concept. From the results the technical principles which were regarded as functional were combined together with the two concept lines of the component arrangement into different concepts. These concepts were further developed with sketches and simple mockups with focus to make sure that all concepts would function and would be able to be implemented in an ambulance.

Results

Functions

The function tree with the elementary functions which the SDD needs to fulfill, see figure 25.

Ideation

The workshop resulted in a wide span of possible solutions for the SDD as shown in figure 24. And from this larger span of solutions a few were sorted out to be worked further with.

The results of the workshop became a ground to start from when further brainstorming and sketching was done. This resulted in more and improved ideas and solutions as seen in figure 26

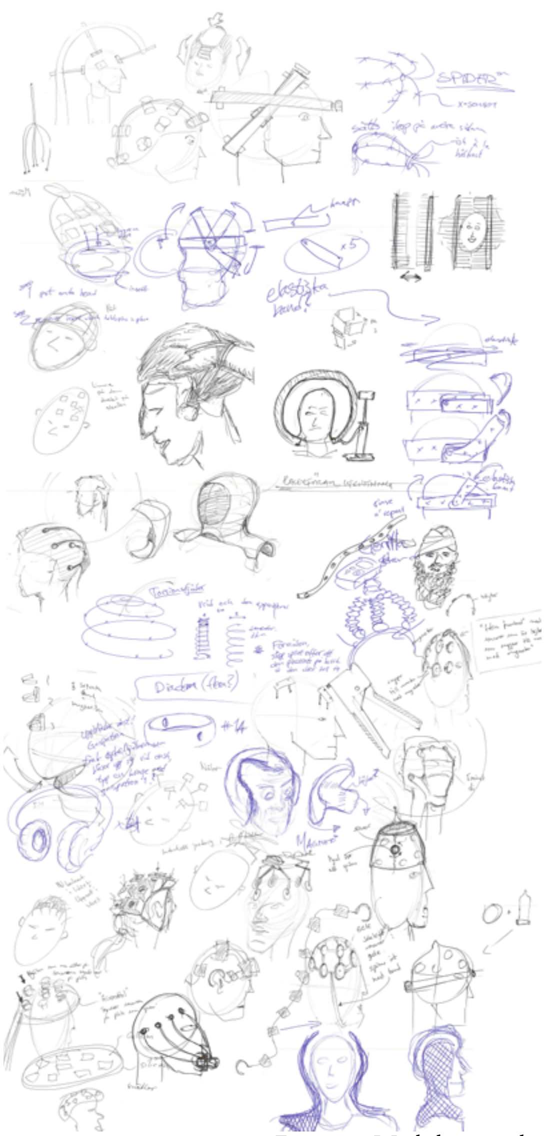


Figure 24-Workshop results

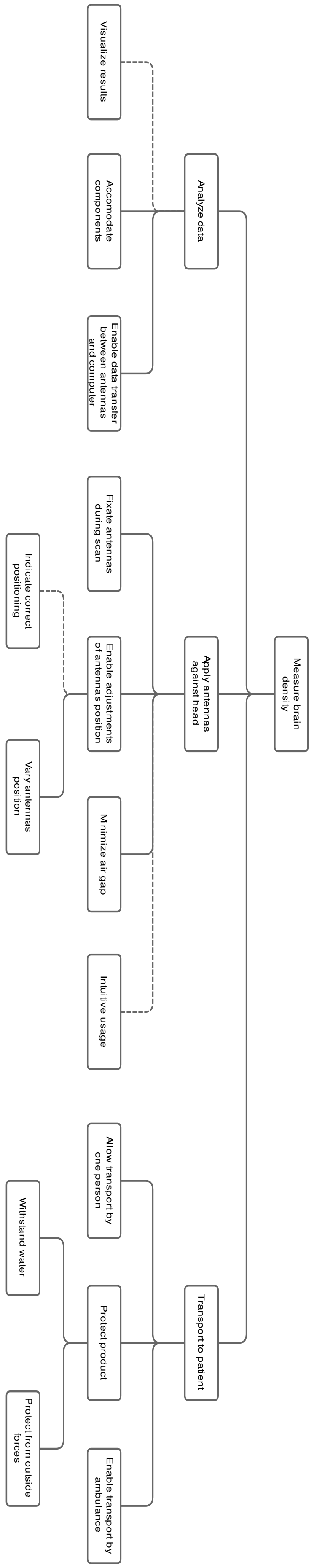


Figure 25-Function tree

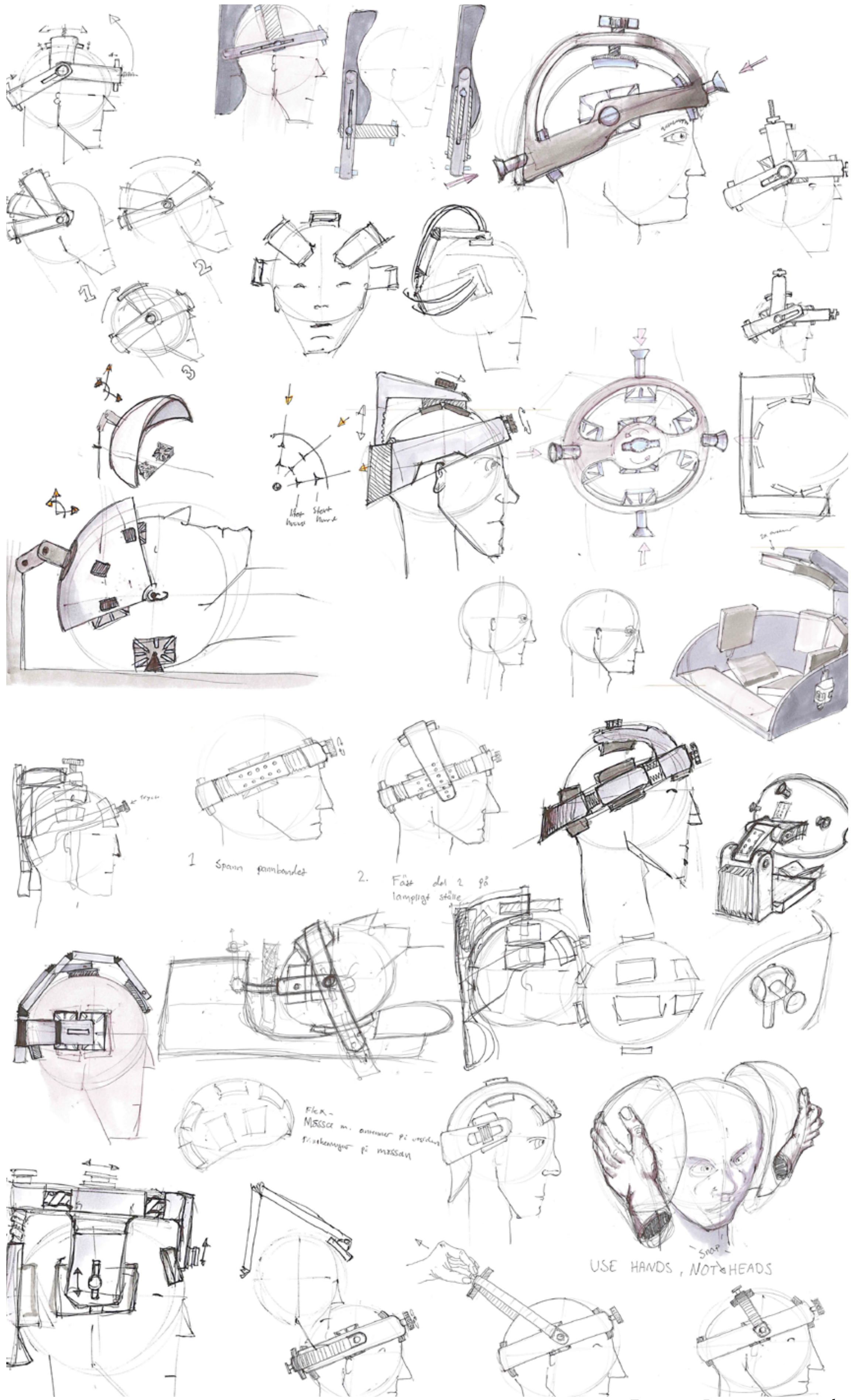


Figure 26-Brainstormin results

The concepts were sorted into three structural categories, A, B and C where A is a category where all the components are placed within a single casing. This creates a single packed solution (see picture A) where the patient has to lie down in order to be scanned. The B category splits up the components into two parts where the VNA, switch and antennas are placed on the head and a separate casing holds the batteries, CPU and other components (see picture B). This creates a solution where the patient could be in a semi-upright to laid down position. Category C also has two separate casings but the VNA is not placed on the head, which makes it possible to measure in an upright position (see picture C).
Mock up components were made in order to get a sense of how big the product would actually become.

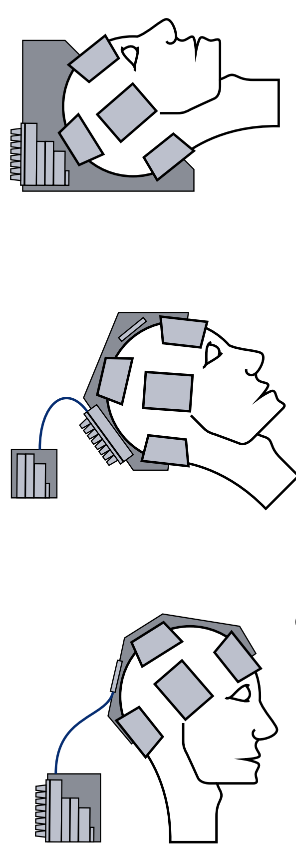


Figure 27-The three structual categories

When the components were taken into consideration it was determined that category B did not provide any unique advantages in comparison to working further with A and C. B would not provide an all in one solution like line A, neither would it be as easy to apply as line C. Thus category B was discarded.

Technical principles

The idea generation resulted in two main technical principles for adjusting the antennas in order to fit different head sizes.

Screw adjustment

Screw adjustment is a common solution to adjust for example bicycle helmets and surgical headlamps to different sizes. Its main principle is a cog wheel that when rotated increases or decreases the circumference.

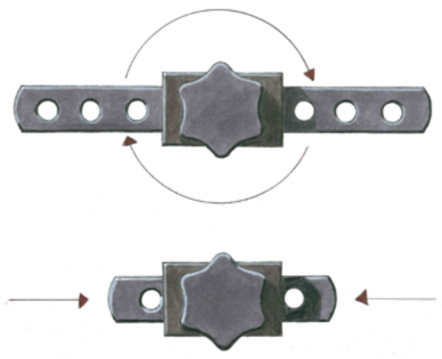


Figure 28-Screw adjustment

Dampening piston

The dampening piston principle consists of a two-part rod were the smaller part slides into the larger part with a spring in between. The idea is that the piston is pushed down in a perpendicular angle against the head. The rod is held in place by a snap lock. The front end that the antenna is mounted on is pushed into the larger bit so that the spring brings a constant force pushing the antenna against the head.

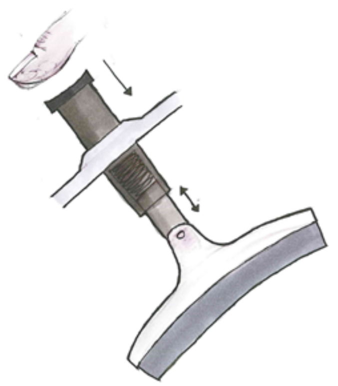


Figure 29-Dampening piston

Concepts

Concept: Headband

The Headband is based on the concept line C with the two-part solution. One part consists of the antennas and the switch. This is placed on the patient's head with a cable that sends the readings from the antennas to the second part in which the batteries, VNA etc. are placed. The antennas are adjusted using screw adjustments on the sides of the head. These increase or decrease the circumference of the headgear to make it possible to fit different head sizes while also pushing the antennas against the head. The top antennas are also adjusted by changing the circumference of the semicircle going vertically across the top of the head.

Procedure:

When measuring a patient with the Headband the following procedure applies: First the headgear part is lifted out of the transport package. The headgear is placed on the head of the patient that is in an upright or semi upright position. The screws on the side are adjusted equally so that the antennas in the back and front are placed correctly and with sufficient force against the head. The maneuver also fixates the headgear against the head. When the headgear is fixed it is possible to adjust the top screw bringing the four center antennas against the head without pushing the headgear of.

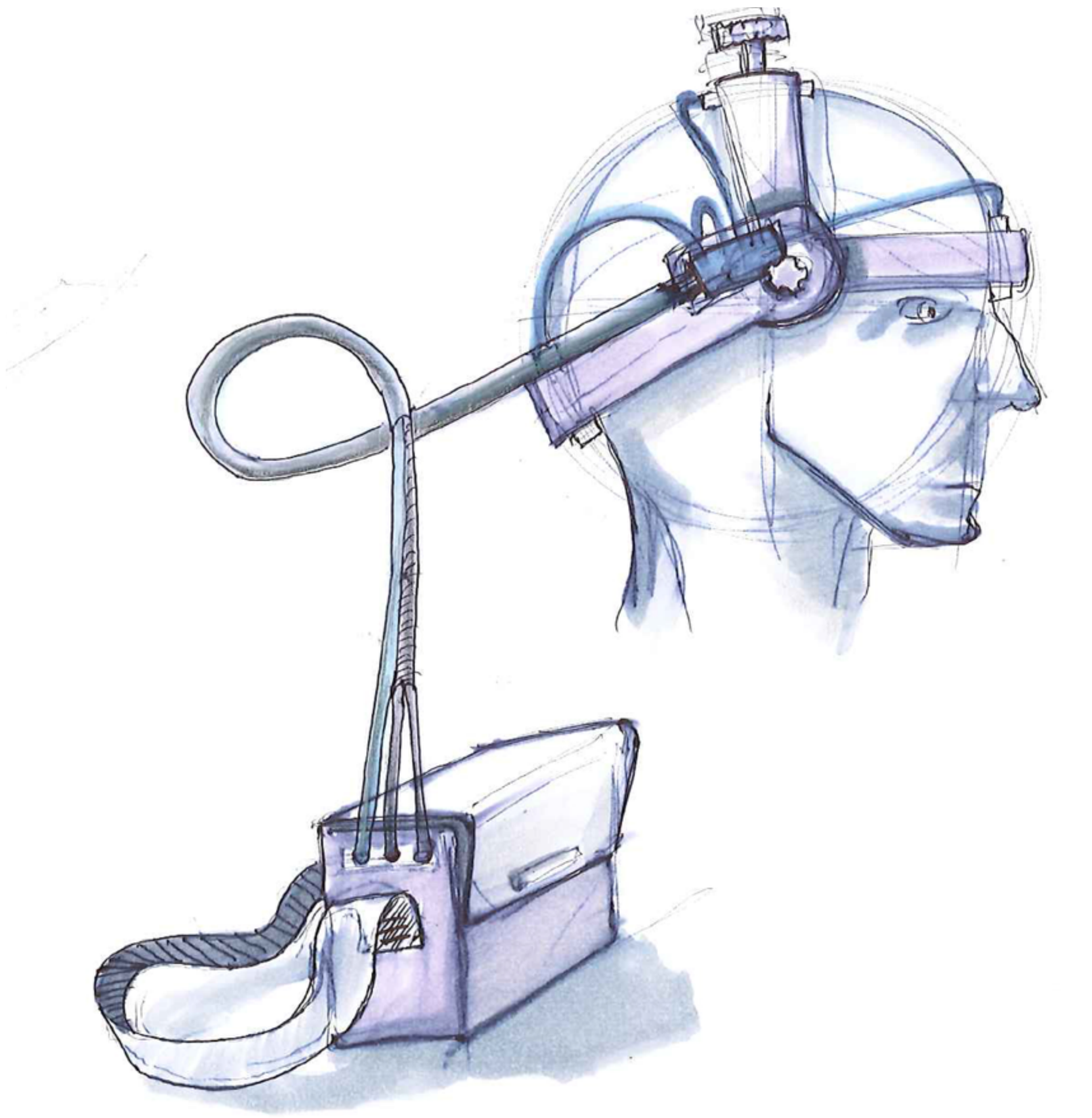


Figure 30-Headband concept

Concept: Safety belt

The Safety belt concept uses the same idea as the Headband concept with a screw to make adjustment for the size differences and to push the antennas against the head. The difference is that all components in the Safety belt are in one part. The front and top antennas are connected to the "headband" which is adjustable in angle and in the horizontal axis, while the back antennas are in a fixated position.

Procedure:

Using the Safety belt for measuring a patient the following procedure applies: First the protective casing is removed. Then the concept is placed on a horizontal flat surface. The patient's head is placed on the two back antennas and the headgear part is moved over the patient's head. The antennas are adjusted by the two screws on the side so they are pushing down on the head and then the top antennas are adjusted so they also push down on the patient's head.

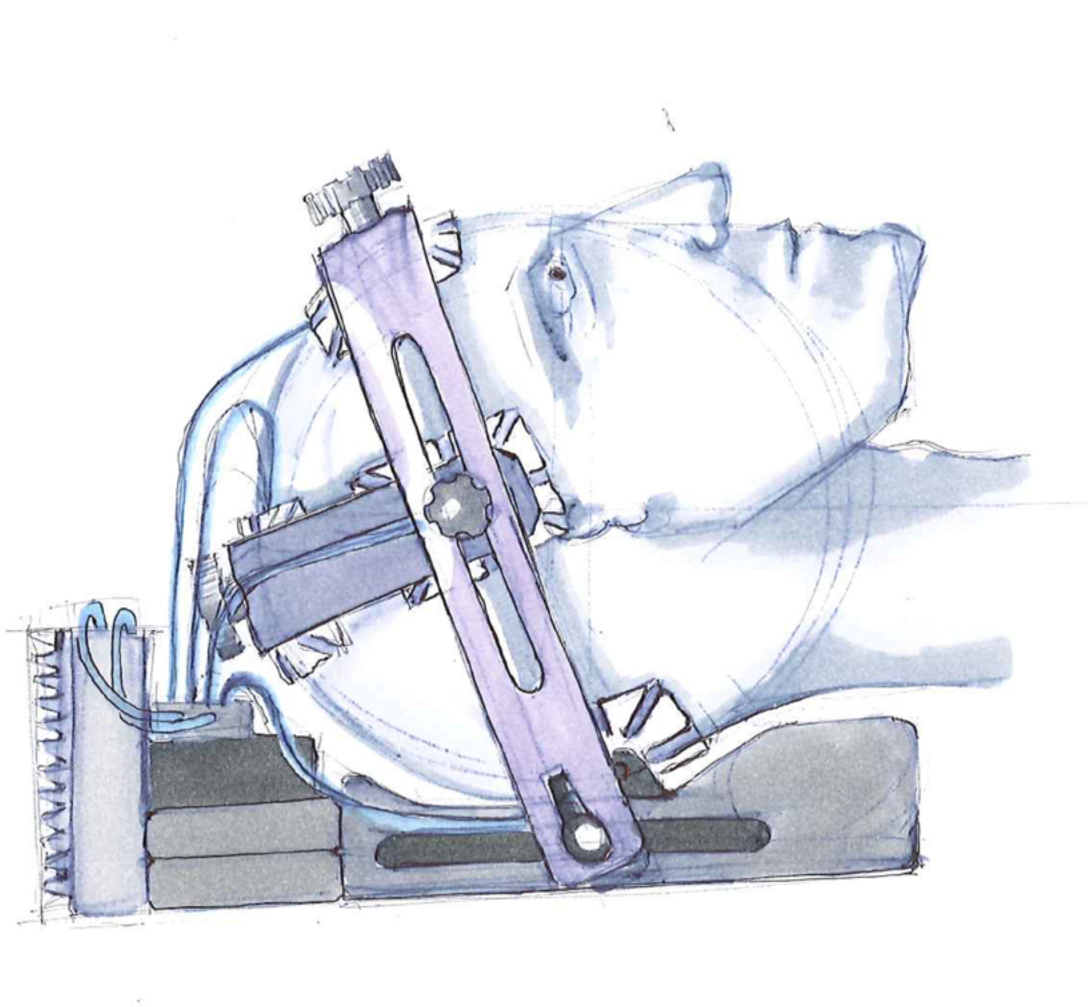


Figure 31-Safety belt concept

Concept: Helmet

The Helmet has in similarity with the Headband concept two parts; the head gear, with antennas and the switch which, is connected to the second part where the VNA, batteries etc. are. The antennas are connected to "rods" that have a spring function built in them. The rods are movable in one axis making it possible to move them towards or away from the patient's head. This makes it possible to adjust for different sizes and the spring function creates a constant pressure forcing the antennas to the head.

Procedure:

The following procedure applies when using the Helmet for measuring on a patient: First the headgear part is lifted out of the transport package. The headgear is placed on the head of the patient that is in an upright or semi upright position. Then the top rod is adjusted so that all antennas are placed in a correct position around the head, then the antennas around the head are adjusted pairwise (back and front antennas, left and right side antennas) so that the antennas are pushed against the head. The last step is to push down the top antennas a bit more in order to apply pressure against the head.

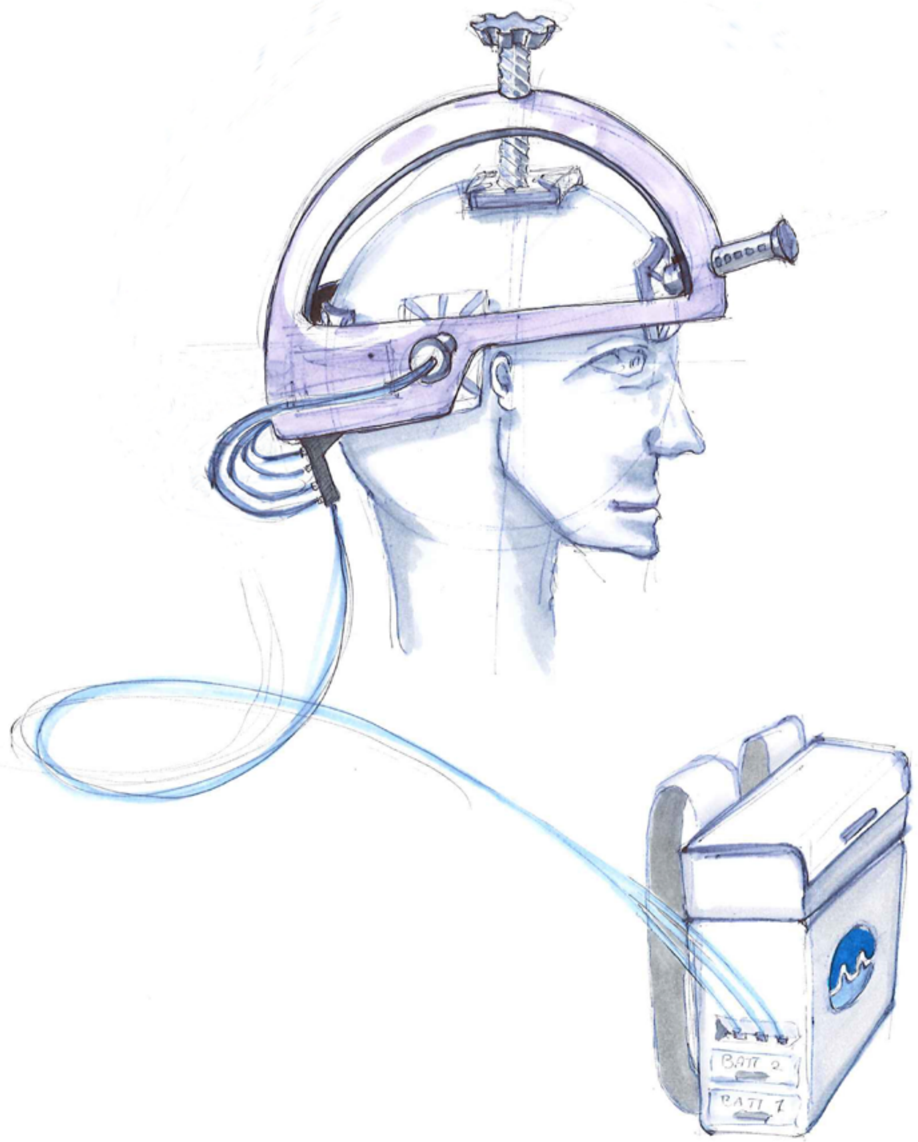


Figure 32-Helmet concept

Concept: Parabole

The Parabole concept uses the same rods as in the Helmet concept but here they are attached on to a parabolic surface. The parabolic surface makes it possible in similarity with the Helmet to move the antennas in direction against the head. The parabolic shape and the angle of the rod adjustments make it possible to get the same antenna positioning relative to the head for all head sizes.

Procedure:

Using the Parabole for measuring a patient the following procedure applies: First the protective casing is removed. Then the concept is placed on a horizontal flat surface. The patients head is placed on the two back antennas and "the parabola" is lowered and locked into position over the patients head using the ears as guidelines. The antennas are then pushed against the head.

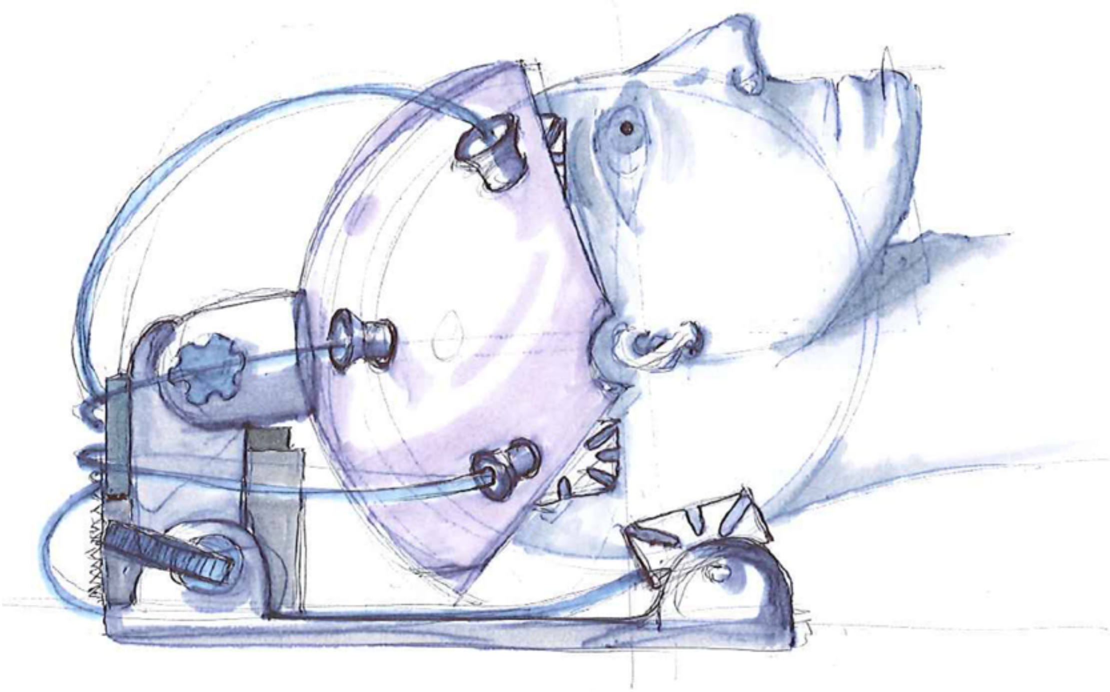


Figure 33-Parabole concept

Carrying bag suggestion

Carrying bag is an extra concept or idea on how the SDD could be protected during transport in the ambulance and by hand. Depending on if the SDD is in one part (Safety belt and Parabole) or two parts (Headband and Helmet) the inside will differ. If the SDD is in one part it will be placed inside the "bag" and brought out when used.

The two-part solutions will be integrated in the "bag" where the VNA, batteries etc. will be fastened in the bag and only the headgear part will be taken out and mounted on the patient. The headgear will be placed on a "dummy head" inside the "bag" when transported which makes it easy for the paramedics to start and calibrate the SDD before use. The carrying bag has a modular function were different modules can be fastened to the bag so that the paramedics can modify the bag for what they want to bring e.g kit for taking blood samples or checklist and procedure descriptions.

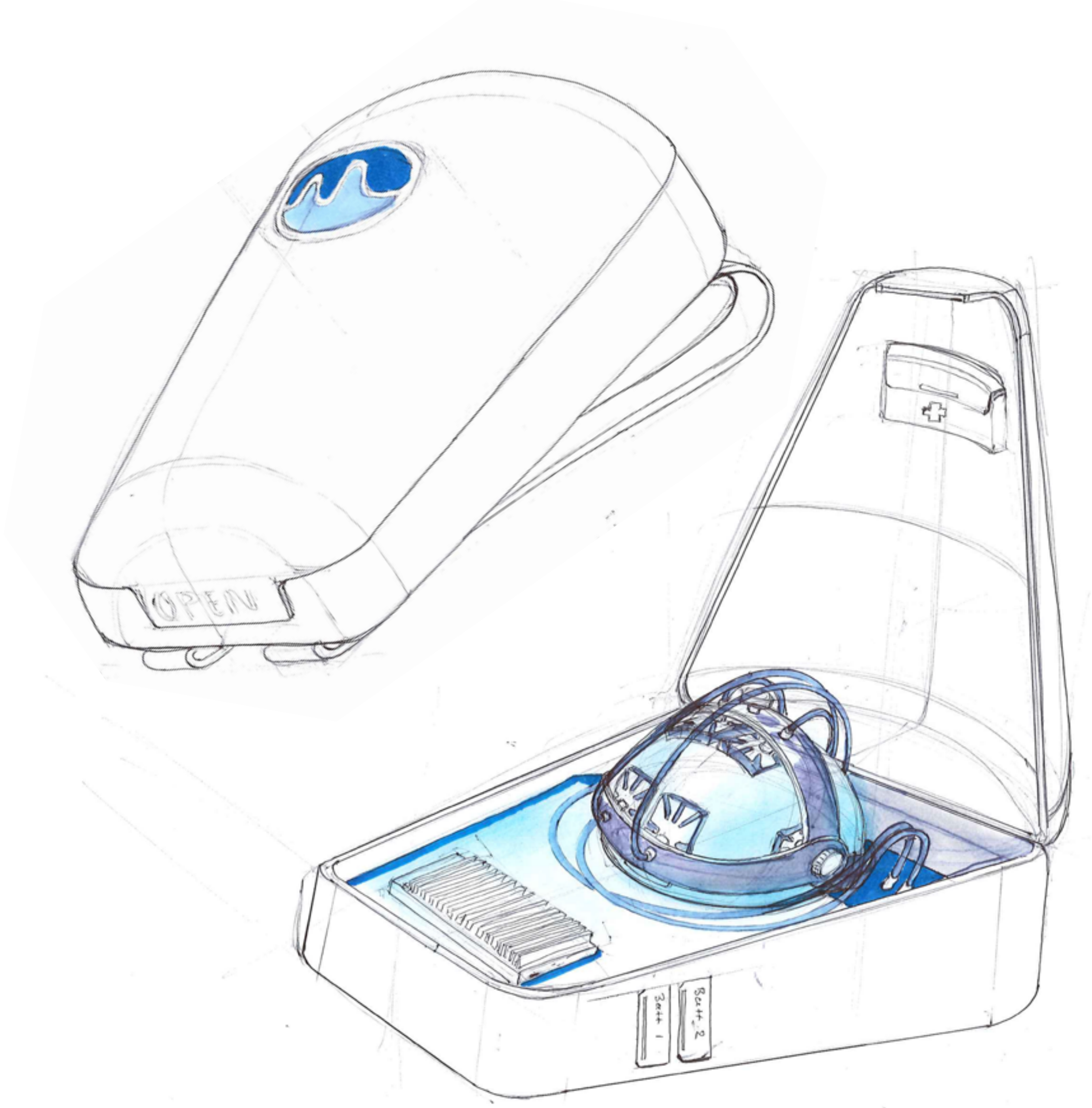


Figure 34-Carrying bag suggestion

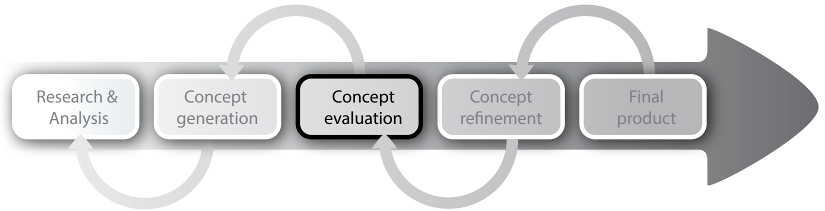
Discussion

During the concept generation phase the use of mock-ups has been a crucial part of the developing process. Since the product needs to be able to fit a large part of the population there is a large span in the head measurements. The mock-ups have been very important during the concept generation to give a quick visualization of size, proportion and especially how much the antennas need to be adjusted. The size and proportion are very important to be able to evaluate how it would be for the paramedics to carry and use in the ambulance.

Early in the concept generation phase a decision was taken together with the company to not continue further with solutions using mechanical arms to adjust and fixate the antennas against the head. The reason was that parallel to the master thesis the company has two projects developing two concepts using mechanical arms to adjust the antennas. These two projects have been running longer than this master thesis and to develop another idea using arms would therefore be a waste of time since these two projects are ahead in this area. The focus has consequently been on creating concepts with other ways of adjusting the antennas instead, which will be more beneficial for the company in the long run.

6 Concept evaluation

In this chapter the process and results of the product evaluation are presented. The chapter ends with the choosing of which concept to further refine.



Process

User feedback

Since the paramedics are the main users of the SDD their opinions about the conceps were important in the selection of which to work further on.

Paramedics in Gothenburg

During a visit to the ambulance and pre hospital emergency department at Sahlgrenska university hospital the four concepts were shown and discussed by two paramedics. This was done to get feedback from the users in order to select which concept that should be worked further on.

Paramedics in Karlstad

A second visit to the ambulance garage in Karlstad was also performed. The concepts were shown and presented to three paramedics. They discussed and came with feedback on each concept with main focus on handling inside and outside of the ambulance. In the end they choose which of the four concepts they liked the best.

Pros and cons list

A pros and cons list was created for the four concepts in order to analyze and communicate each concept's strengths and weaknesses. The list is based on the feedback received from the paramedics in both Gothenburg and Karlstad. The Carrying bag concept was not included in the list since it is not one of the four main concepts but instead a compliment to the concepts.

Stakeholder feedback

In order to take a decision on what concept to move forward with and further developed all concepts were presented to the company. First the concepts were shown and explained in the aspect of technical principles and how the product would be used in live situations. Mock-ups of the technical principles were also showed. Feedback from the paramedics on the concepts was presented as well as the pros and cons for each concept. Then all the concepts were discussed and the concept the company wanted to see further developed was decided.

Results

User feedback

Paramedics in Gothenburg

The two paramedics differed slightly when they described which concept they liked best. The first paramedics spontaneous reaction was to chose the Safety belt concept since it enables the paramedics to always place the head in a straight position and get clear instructions so that they can operate in exactly the same way each time. He saw a problem with the side stability however, but disregarded it with the comment that they can always stabilize it with rolled up blankets. The second paramedic on the other hand preferred the Headband concept because the stroke patients are notoriously anxious and move their head around to see what happens. It is also hard to get through to the patients to ask them to sit still. She therefore thought that a helmet solution which follows the patient's movements rather than restricts them would be better. They thought that it didn't really matter if the Helmet and Parabole concept had three or six dampening pistons as long as the fixation process is easy. They didn't think that it would be traumatic for the patient if they tightened a headband around the head with the motivation that they already stick needles into the patient, and a headband is considerably less intrusive.

Paramedics in Karlstad

The three paramedics thought that all four concepts would work in and outside the ambulance. The screw adjustment was seen as the simplest and easiest way to adjust for different head sizes. The Concepts Headband and Helmet are better with regard to that patients can be restless and the risk for the patients needing to vomit. For the two other concepts Safety belt and Parabole were the patient is fixed, a movement from the patient can potentially ruin the scan and it could be dangerous if the patient should vomit since they can't turn to the sides. For the Headband and Helmet concept the paramedics wanted the possibility to be able to disconnect the cables when mounting it on the patients head and reconnect them when it is properly mounted. They were afraid that the cables could be in the way for them and possible tangle. The carrying bag concept was appreciated especially the possibility to add different modules. They wanted to be able to bring equipment for blood samples, thrombolytic treatments and room for procedure descriptions e.g NIHSS. In the end they chose the concept Headband as the one they liked the most.

Pros and cons

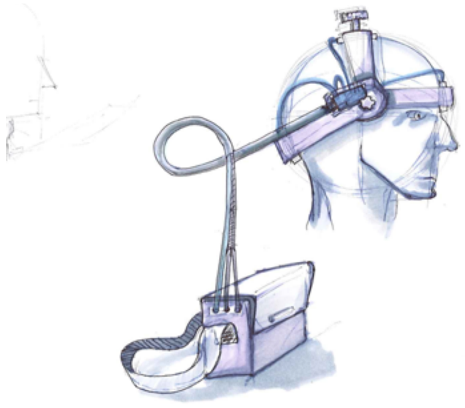


Figure 35-Headband concept

The Headband

Pros

- The patient can move during a session without interfering with the relative positions of the antennas
- The screws give the paramedic better control over the adjustment
- It is a well known adjustment technique

Cons

- The cables may cause interferences
- The cable attachments are a weak spot

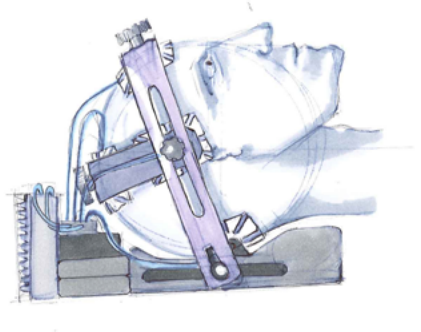


Figure 36-Safety belt concept

The Safety belt

Pros

- The patient can lie down on the baseplate
- The screws give the paramedics better control over the adjustment
- It is a well known adjustment technique
- The cables can be encased

Cons

- It is large and a bit clumsy
- The patient has limited moveability

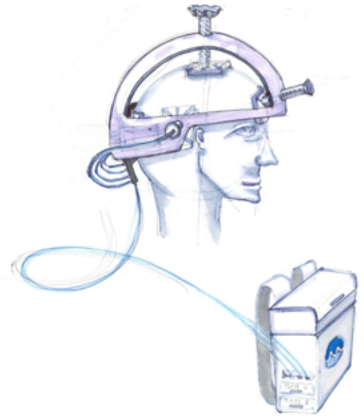


Figure 37-Helmet concept

The Helmet

Pros

- The patient can move during a session without interfering with the relative positions of the antennas
- The helmet can be robustly built

Cons

- The cables may cause interferences
- The cable attachments are a weak spot
- It will become large
- There are many handling sequences before it is attached properly

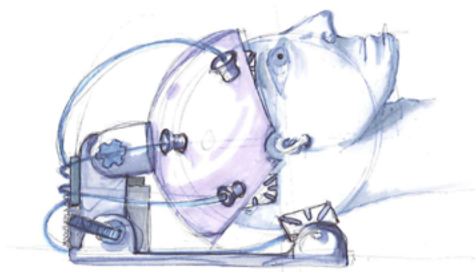


Figure 38-Parabole concept

The Parabole

Pros

- The patient can lie down on the baseplate
- The paramedics only need to adjust the Parabole to fit one measurement (I.E. the ears)
- The cables can be encased

Cons

- It is large and a bit clumsy
- The patient has limited moveability

Stakeholder feedback

The company opinion was that the screw adjustment was a simple and functional solution, with the large benefit that it exists in other products today and can therefore be bought as a part ready for use. The dampening rod principle was seen as more complicated and the fact that it probably needs to be specifically manufactured for the company was also a disadvantage. The two-part solutions were seen as interesting especially since they had gotten good feedback from the paramedics, even though some problems with the two-part solutions were recognized. The main problem was with the cables. Partly since the length of the cables affects the data collection and the two-part solutions will have longer cables than the one-part solutions. But also because when these types of cables bend the resistance in the cables changes and this also affects the results. Therefore a two-part solution with two long cables that will bend freely and differently would affect the precision of the results much more than a one-part solution where the cable lengths are shorter and the bending is more controlled.

The decision taken from the meeting with the company was to continue to further develop the concept safety belt. The reason was both due to the problems that long cables bring in the form of lowered precision of the measurements but also due to the the screw adjustments' simplicity. The fact that the product the company is working on to be released soon is an all in one solution, weighed in as well. By continuing working on that track it is more beneficial for the company since ideas and solutions can be transferred more easily between the concepts. It was also decided that the casing that the product should be carried in should have a low prioritization and that focus should be on the development of the SDD for the remainder of the project. The problem with patients being nauseous and vomiting as well as not being able to be still was regarded as something that is important to take into account and if possible, implement a feature that would either enable the paramedics too quickly release the patient or enable some flexibility for the patient if he/she needs to vomit.

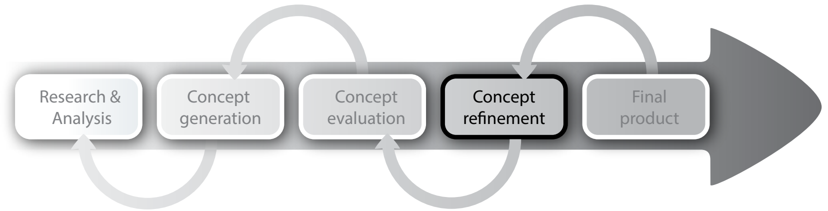
Discussion

The two-part solutions were preferred by most of the paramedics whilst the one-part solutions were the stakeholder's favorite. This was as mentioned because of the technical aspects and in this case they were given priority over the paramedics' opinions. This could be seen as conflicting since it in some sense reduces the usability on behalf of a technical issue. But in the end it comes down to patient security, and if the solution needs to be in one part in order for the readings to be the best they can, then the technical aspect must be prioritized. It could also be justified with the paramedics' attitude that all of the concepts probably would work; they simply had their personal favorites. Hence the Safety belt was choosen.

The decision to work with a one-part solution at this stage also meant that the development of the carrying solution was put on ice. The focus from here on was to develop the actual product itself and a carrying solution was left for future work.

7 Concept refinement

In this chapter the process and result of the concept refinement are presented.



Procedure

Mock-ups

In order to determine the dimensions needed in the final product mock-ups were built.
First a neck support with antennas was built. This was built so that the height of the neck antennas could be adjusted in order to determine which height the antennas can be placed on without being uncomfortable for the patients. This was tested by letting five people of different length and head size (ranging from tall and large to short and small) test different height placements of the neck antennas. The participants got to test five different heights of the neck antennas measured from the surface they were laying on to the lowest point of the top of the antennas. The five different heights that where tested ranged from 65 mm to 150 mm with even steps in between. The different heights were tested randomly to avoid biased test subjects. For each height the test subjects were asked how the position felt, if it was uncomfortable, if they could breathe easily and if they thought that they would manage to lay in that position for two minutes. The estimated time for the sequence of the three scans is 30 seconds but since it will take some time adjusting the SDD it is likely that the patient will be lying in the SDD for around a minute, so if the test person believes that two minutes wouldn't be a problem the position will probably be ok for most patients for one minute.

To test the functionality of the antenna adjustment and the dimensions needed for the antennas to work on different head sizes, a mock-up model with functional adjustments of the two headbands was constructed. The model combined with the neck support mock-up was used to investigate dimensions and test different functions. The placement

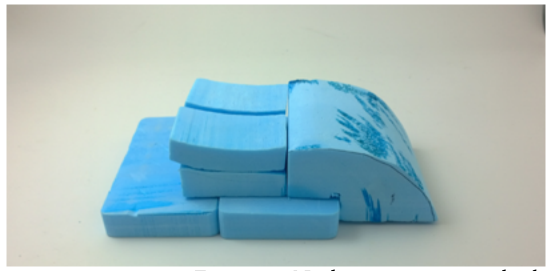


Figure 39-Neck support 65 mm high


Figure 40-Neck support 85 mm high


Figure 41-Neck support 100 mm high

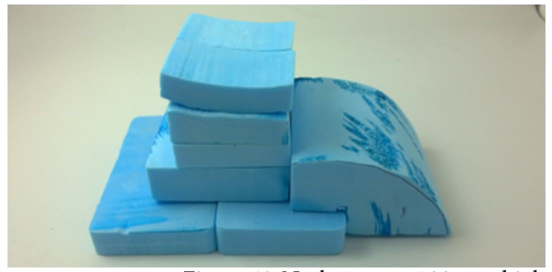


Figure 42-Neck support 120 mm high


Figure 43-Neck support 150 mm high

of the patient on the neck antennas and the adjustment of the headband was, among other things, tested with the models.

Further investigations of the component placement were also made using the same mock-up and dummy components in order to try out different set-ups. The aim for this was to acquire all the necessary dimensions for further design work and modelling as well as fixing the architecture. This was then used as a base to explore the form and expression of the product. In total six different component placements were created and then evaluated by the technical product manager at Medfield Diagnostics Fabian Wenger with regard to the technical perspective.

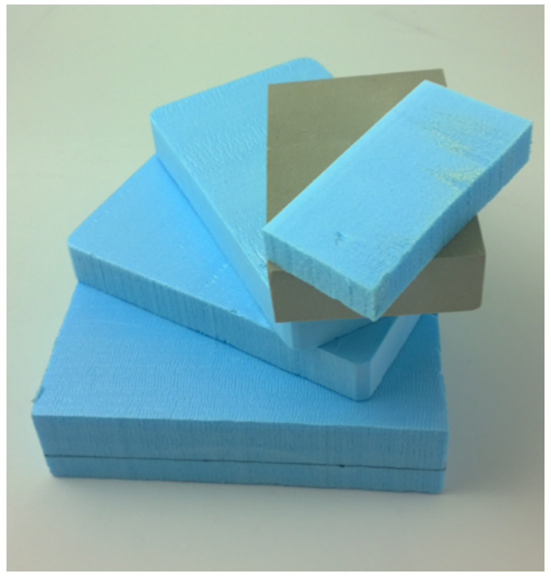


Figure 44-Dummy components in polystyrene

After the components were fixed and the critical dimensions of the SDD were set, the handling was tested. Since the product would weigh almost five kilograms the handling of the product became an ergonomic issue. A paramedic should be able to carry and adjust the SDD effortlessly and single handedly. Therefore a small usability study was conducted. During the study five different handle combinations were tested with a dummy product weighing approximately five kilograms. The handles were tested by five students from the Industrial design engineering program at Chalmers university, all with different hand sizes and strengths ranging from large to small. The aim was to decide the best handle from a usability perspective.

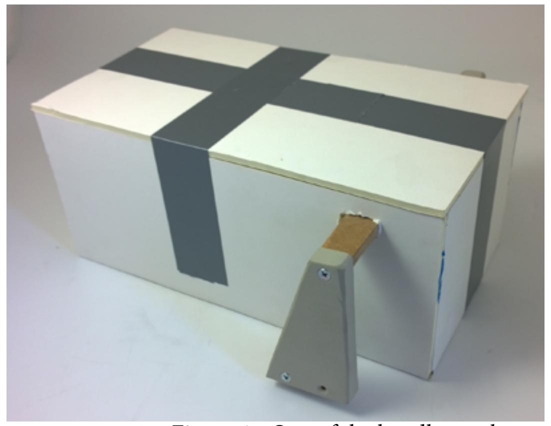


Figure 45-One of the handle mock-ups

Expression

The expressions previously generated were specified in order to get concrete design guidelines to follow. Each of the sought expressions was translated into more tangible form elements to use to create the expression.

The form of the SDD was developed through several steps. At each step a lot of different form variations were generated with the help of Müllers (2001) form dimensions. A large amount of form variations were achieved and out of this three ideas were chosen to further develop. The chosen forms were further developed by creating new form variations which differed less from each other. From this second iteration three form ideas were once again chosen to work further with. The chosen forms were those who best portrayed the sought expressions. They were visualized with CAD to be able to view the form in all angels with proper dimensions and with the base and headgear integrated as intended. This enabled the form concepts to be visually evaluated.

After the evaluation an overall form design was decided upon from the form concepts. This was done by mixing form elements from the three separate forms into one final form. Next step was to decide upon the details of the form such as buttons, split lines, handles and materials. The goal with the design of buttons and other parts that are to be interacted with are to create clearly marked manipulation areas. This was based on the specified design guidelines created to help visualize the sought expressions of the SDD. The design of the buttons and the interaction areas was created by first sketching the different ideas, then modeling them in CATIA and finaly altering the 3D models in several steps to refine the design. An extensive form study was done on the handles in order to generate a handle which would express the right values. Sketches and eight different cad models were produced and together with the results from the usability study a final handle was selected.

Results

Mock ups

The results from the test of optimum height for the neck antennas showed that the maximum height before it became uncomfortable differed depending on the test subject. It seemed that taller test subjects could manage a higher placement of the neck antennas without feeling discomfort. Since the SDD needs to work on the whole population the highest position of the antennas that all of the test subjects stated as comfortable was chosen as the maximum height. The maximum height that the neck antennas can be placed in relation to the surface the patient will be laying on will be 140mm. However all test subjects stated that they didn't see it as a big issue to withstand the discomfort from the antennas in two minutes, independent of the height.

The mock-up showed that when the head was placed in the rig and the bands were tightened, the headbands had a tendency to rotate backwards, causing the head to fall out. This was corrected by a simple lock at the rotating axis which should be applied when the patient is in place. When a lock function was added the mock-up proved to be working as intended, see figure 46.

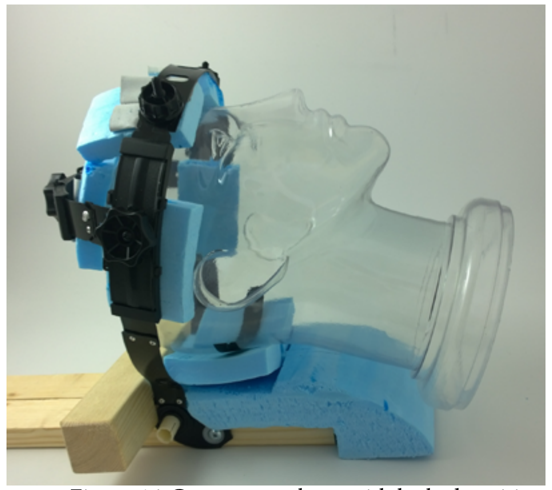


Figure 46-Concept mock-up with locked position

The mock up also showed that the headband could be placed in an upright position when placing the patient. and when fastening, the headband needed to be tilted around 20 degrees forward. Thus the components could be placed closer behind the head since the headband didn't need to tilt backwards.

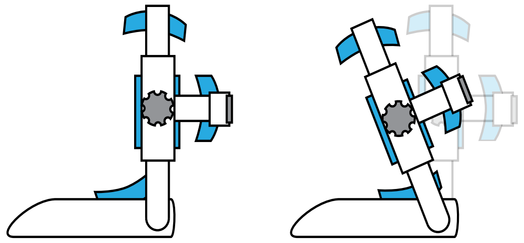


Figure 47-Tilting necessary in the concept

The evaluation of different set-ups for the components resulted in that configuration A and B were chosen by the technical product manager. The reason was that since the metal in the components affect the readings from the antennas a symmetric placement is better. With a symmetric placement the left and right placed antennas are equally affected by the metal in the components and therefore it is easier to remove the noise created by the metal.

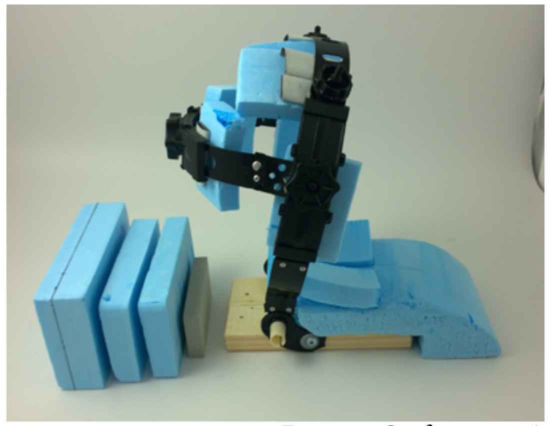


Figure 48-Configuration A

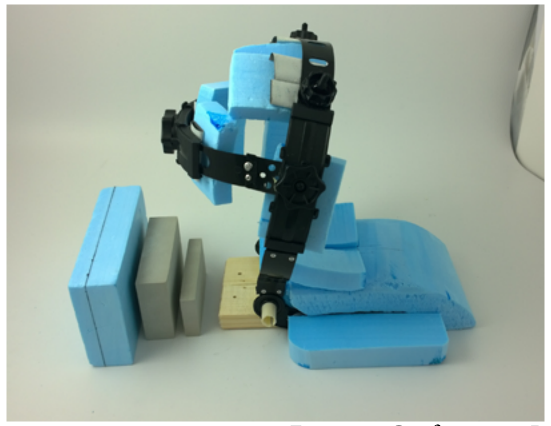


Figure 49-Configuration B

A change from two batteries to one battery was done due to that one battery provides sufficient power and by removing one the weight was reduced by 0.5 kgs. With this, configuration A was chosen since placing the battery in the back instead of under the neck support makes it easier to reach and change the battery.

The handling test showed that SDD was quite hard to carry and to place correctly because of the weight. To ease the hardship with the handling a handle in the rear of the SDD is needed. The test also showed that a handle would make it easier for the user to lift and place the SDD correctly under the patient's head, especially if one of the operator's hands are occupied by lifting the patient's head.

From the five handles tested (see appendix 10 for the full test) a handle which goes around and on top of the base unit was chosen (see figure 50). This handle was selected because it showed a huge advantage in sliding and carrying the product, mainly when a person tries to operate the product singel handedly. From a carrying perspective the handle gave the user a freedom to carry the product in several different ways. When sliding the product under the patient's head it was discovered that a handle which gave the possibility to push in the center of the product was much easier to handle than simply placing two handles on the side.

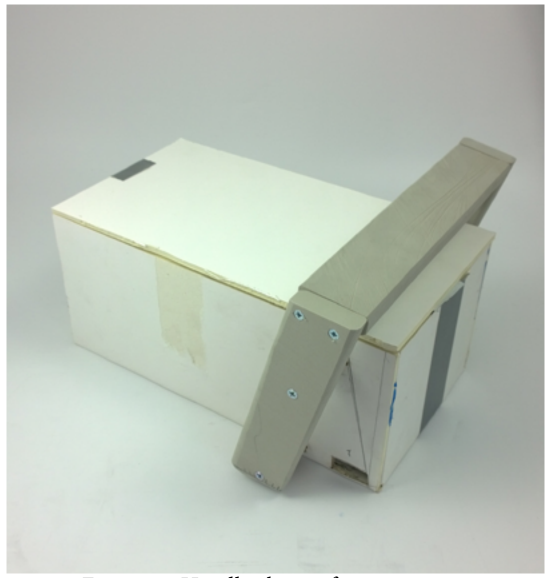


Figure 50-Handle chosen from a use perspective

Expression

The expressions were concretized as follows:

Figure 51-Hygenic

Hygienic, as in smooth surfaces and no hard-to-reach areas.

Figure 52-High tech

High tech, as in hig gloss surfaces, lights, sharp edges and hard surfaces.

Figure 53-Welcoming

Welcoming, as in soft radius, calm colours smooth surfaces and a soft headrest.

Figure 54-User friendly

User friendly, as in a logical and sequential usage process, as well as gripable and clearly marked manipulation areas.

Figure 55-Reliable and robust

Reliable, as in quality materials.

Robust, as in grouped, homogenous, dense and no "loose" parts.

Figure 56-Professional and precice

Professional, as in few but matchin colours, preferably grayscale plus a complimentary colour.

Precice, as in distinct splitlines, sharp edges and distinct material shifts.

With the expressions as a base the form development proceeded as shown In figure 57. First a wide span of ideas was sketched. From the idea span three types were selected for further exploration. The first one (A) was chosen for its preciseness, sharp corners and sharp edges that together gave a professional and exact expression. The middle one (B) was chosen for quite the opposite reason; its curvy and natural forms gave a soft and welcoming expression. And the last one (C) was selected because it is very grouped and dense which gave a robust and reliable expression.

These three forms were then explored on a more detailed level to further emphasize their expressions. One each of these was chosen for construction in CAD where the headband was added as well, in order to show the full complexity of the productand and create a more accurate selection.

The general shape of the first form (A) was decided as a base to work further on. The handles from the other two forms (B) and (C) were mixed together in eight differnt ways and attatched to the form (A). The eight different handle forms can be seen in figure 58. together with the usability aspects previously mentioned a final handle was selected.

At this stage the production techniques were also taken into account in order for fastenings and split lines to be placed at the correct location as well as to make sure that all parts were possible to produce. The production techniques considered were vacuum casting and injection molding. The first is more suitable in an initial stage where the production volume is small, and the later in a stage where the production volume has increased.

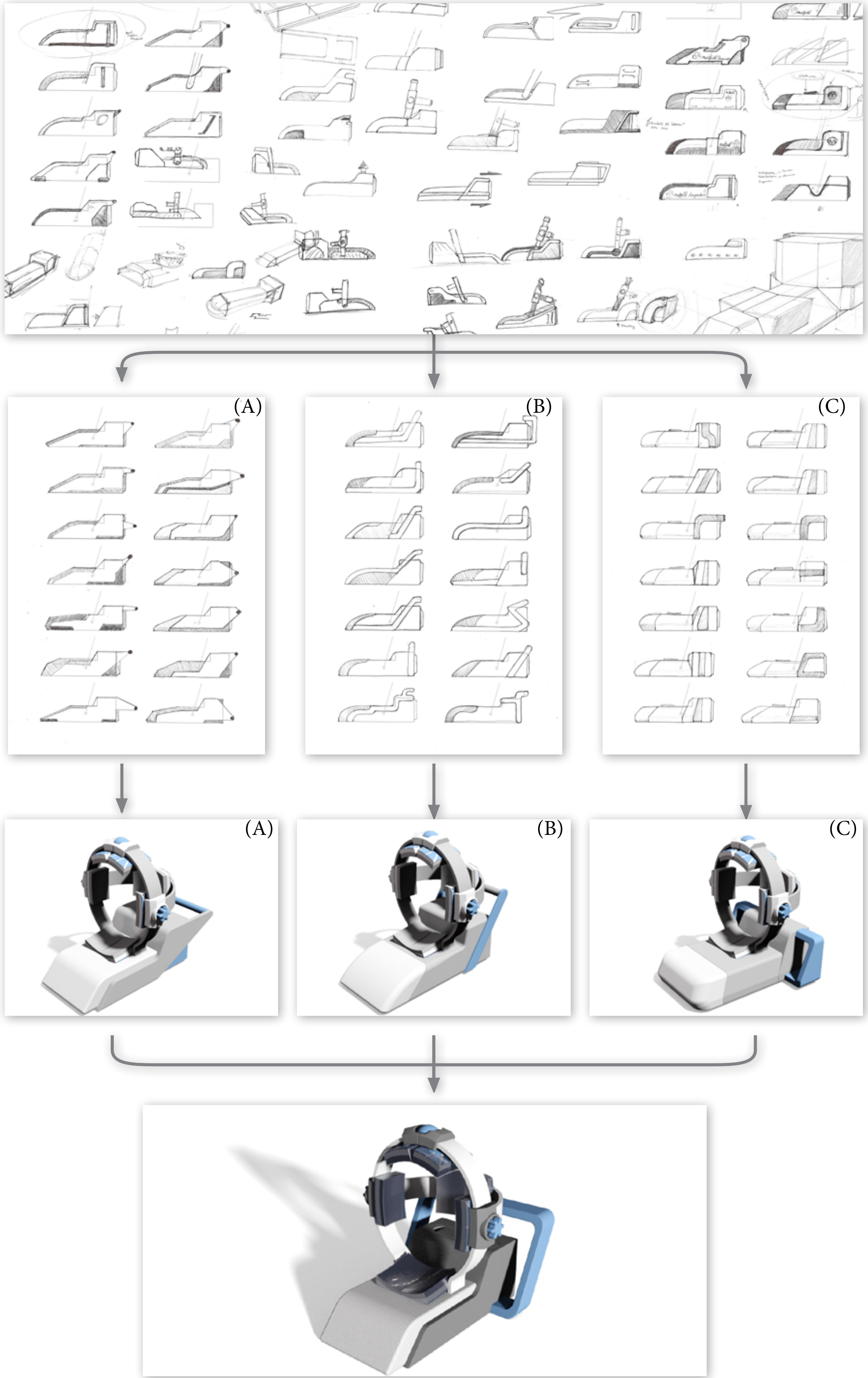


Figure 57-The Form development process

Figure 58-Eight handle designs

Discussion

All the studies done in this chapter have been done in a very hands on manner. The tests have had quite few participants and they have been using quick mock-ups as models. To get more statistically viable results more participants would be needed but for the purpose of these studies we believe that the tests have been sufficient. The number of participants has been low but the span which they represent has been wide. And by doing these quick tests the product development process has been drastically faster than it would hane been otherwise.

Building mock-ups is also a great way to make a problem tangible. When doing sketches and constructing cad-models it is possible to lose track of reality but when a model is constructed it becomes much more concrete.

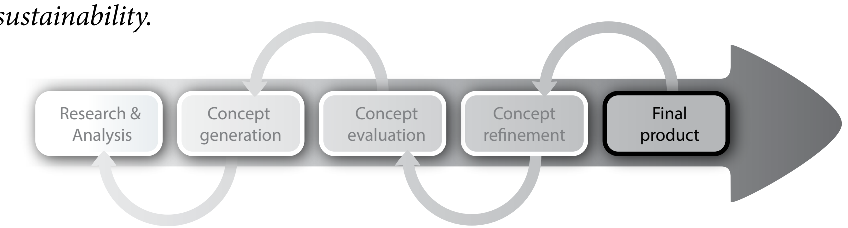
The concretization of the expression-board became very useful for conveying the expression to others. The concretization is our interpretation of which features generate the sought expressions. It can be debated and expanded but works perfectly fine at its current state.

There are however some conflicting features in the expressions. Welcoming with round and soft features conflicts with precise and high-tech which requires sharper edges and hard surfaces. This has been the topic of a wide discussion and in the end a compromize has been the goal. It is important to keep both the welcoming aspect for the patient but also to keep the professional and percise expression for the paramedics to be able to rely on it.

When doing the form study it became apparent that small details such as radius and surface roughness are very important for the overall expression of the product. That is why the sketching phase of the form interpolation was kept relatively short and CAD models were produced. CAD is much more efficient when it comes to altering those parameters.

8 Final product

In this chapter the final result of the thesis is presented. The chapter describes the final product, usage, expression, construction, manufacturing and sustainability.



The SDD is a product that with microwave technology detects if a stroke is caused by a clot or bleeding. It is developed for usage by paramedics in and outside an ambulance in order to allow the correct treatment as fast as possible to minimize the damages for the patient. The SDD is designed so that it works on 99% of the population. It consists of eight antennas that are placed on the patient's head and adjusted with three adjustment wheels. The product is controlled from a tablet that wirelessly communicates with the SDD. The product consists of two large parts; the headgear were all the antennas except the neck antennas are mounted and the base were all technical equipment needed are placed e.g battery and CPU.

Figure 59-The SDD

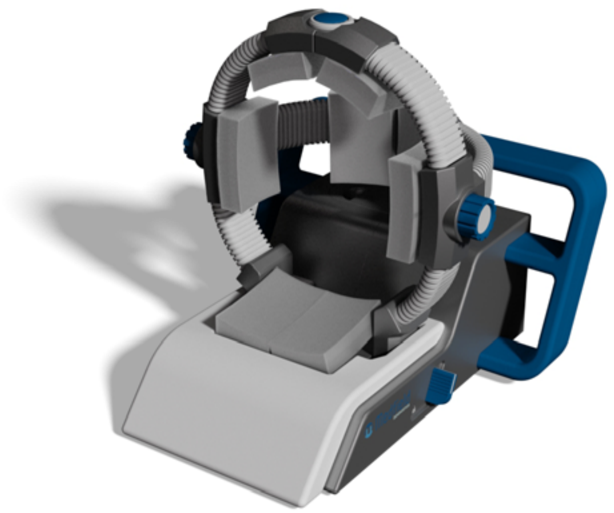


Figure 60-SDD perspective view

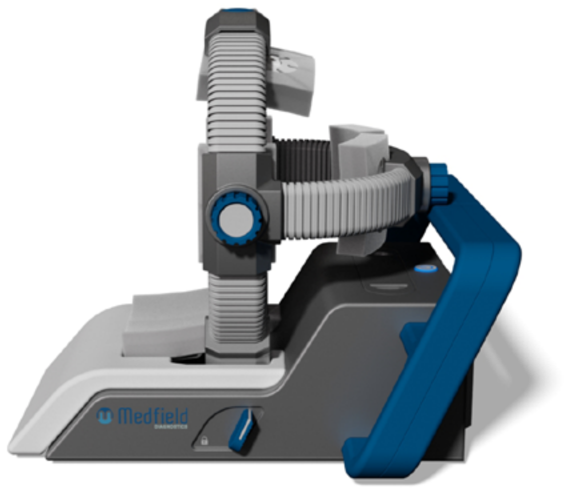


Figure 61-SDD side view

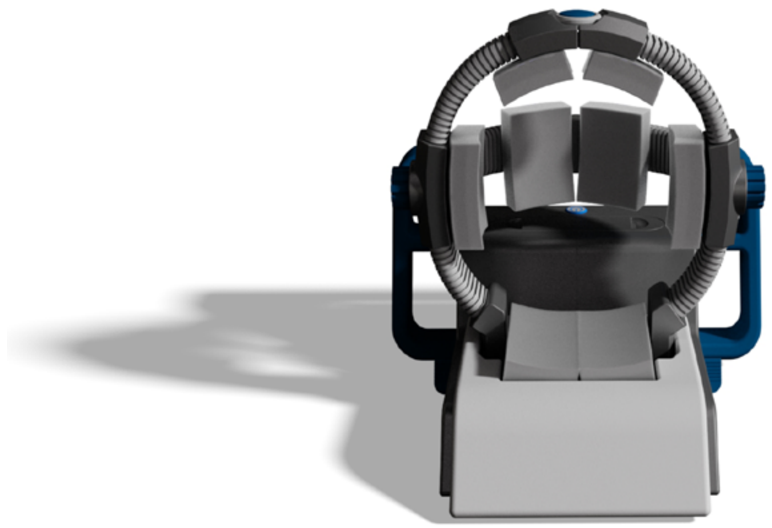
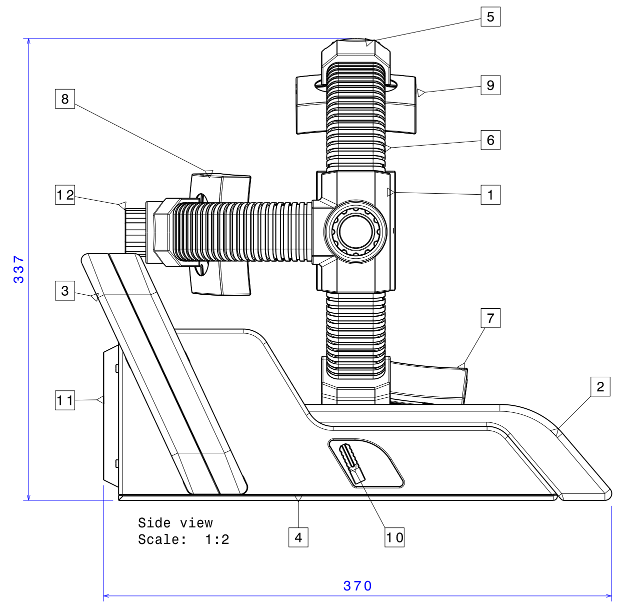


Figure 62-SDD front view



Outside components of the SDU

Number	Name
1	Headband intersection
2	Cushion
3	Handle
4	Base
5	Release button
6	Elastic tubing
7	Neck antennas
8	Top antennas
9	Forehead antennas
10	Locking button
11	Cooling fins
12	Adjustment wheels

Figure 63-Schematic view

Construction

Parts and functions of parts

The SDD consists of two main parts, the headgear and the base. The headgear, which is the part that is placed over the patient's head when measuring, has six of the eight antennas connected to it. It has three adjustment wheels that adjust the position of the antennas so that they are pushed against the head. The adjustment wheels placed on the sides adjuststhe main circumference of the headgear. Having two wheels instead of one enables a quick release button to be placed on top of the SDD. It also allows the antennas to be adjusted symmetrically so that the distances in between always are in relation to each other. Lastly it makes the construction of the mecanism easier since each wheel only has to have an adjustment span of eight centimeters instead of one wheel with sixteen.

The third adjustment wheel in the back adjusts the circumference of the semicircle, adjusting the two top antennas. Between the adjustment wheels there are elastic tubings that cover the cables as well as flex in relation to the adjustment of the circumference. The headgear can be tilted in the length direction of the SDD to make it easy to move the patient in and out of the SDD.

Component placement

In the base the rest of the needed components are placed; CPU, switch, VNA and battery. The headgear is connected to the base by

Figure 64-Component placement on bottom plate

an axis inside the base which allows for the headgear to be tilted. The tilt is locked in place by the buttons on the side in order to keep the headgear in position when the wheels are adjusted.The neck antennas are mounted on the base, in between the headgear ends. To make it more comfortable for the patient a cushion covers the area where the patient's neck rests. The cushion is removeable and made out of galon in order for it to be easily cleaned.

The handles are placed on the back of the base. They makes it easy for the paramedics to carry the product and adjust it when placing it under the patient's head with one hand. To keep the VNA sufficiently cool, there is a heat sink placed at the back of the base as well.

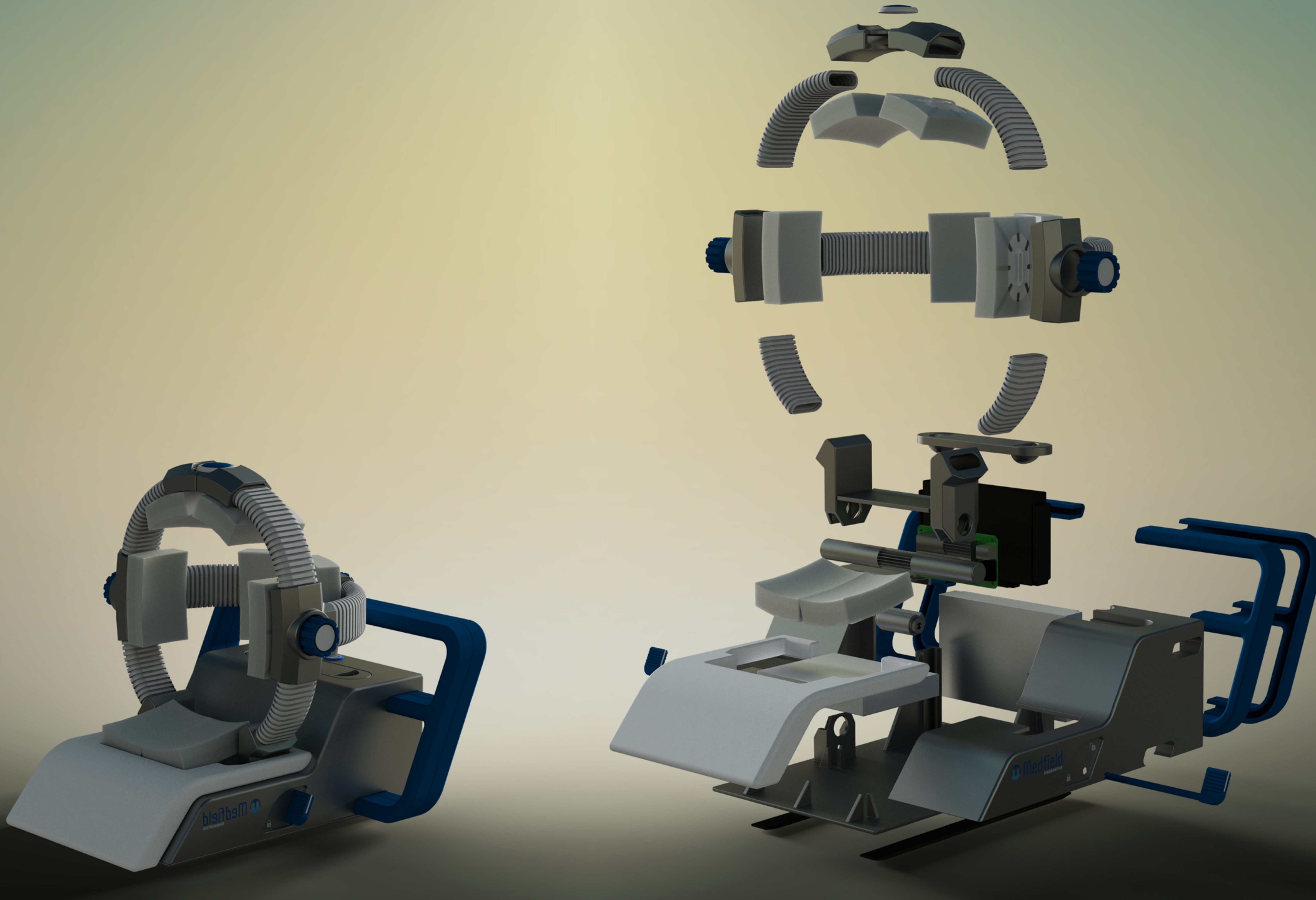


Figure 65-Exploded view of the SDD

Usage

Points of interaction and functions

The SDD has several points of interaction which are all designed to make it easy for the user to to handle the SDD. This has been done using clear shapes, positions and colors for the different interaction points. All the interaction points except the on/off button have a connection to the manual handling and adjustment of the parts in the SDD. The rest of the interaction for initiating the scan of the patient, presenting results and sending them to a physician is done on the tablet interface which is not within the scope of this project.

The adjustment wheels on the headgear that adjust the size of the headgear when rotated, are all sized and shaped in order to enable a good grip and make it easy to adjust for all users.

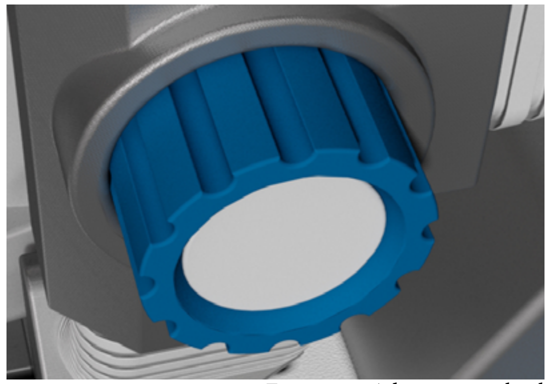


Figure 66- Adjustment wheel

The locking switches on both sides of the base that locks the headgear in a chosen position are connected to each other. Therefore it is enough to turn one of the switches to lock or unlock the headgear. This is so that the user can easily reach the switch regardless of which side of the SDD he/she is placed. This is especially important if the SDD is used inside an ambulance since the stretcher is usually placed against one of the sides, making it harder to reach the side facing the wall. The shape of the buttons are designed so that it is easy to grab and turn in order to lock or unlock.

The round button on the top is a quick release. When pushed it disconnects the two sides of the headgear to make it possible to quickly pull out a patient if he/she for example acutely needs to womit.

Figure 67- Locking switch, unlocked

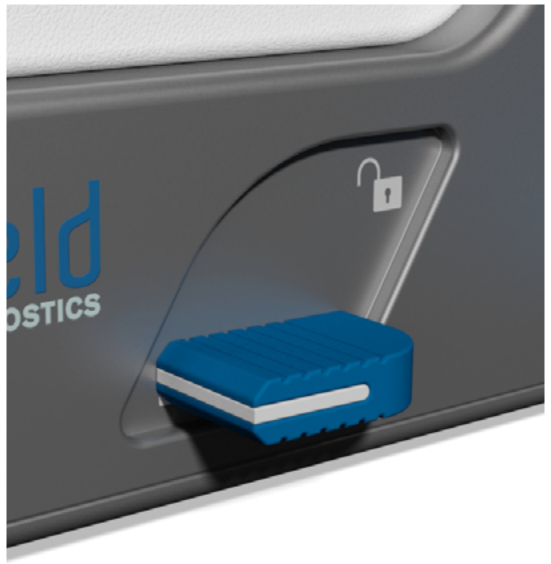


Figure 68- Locking switch, locked

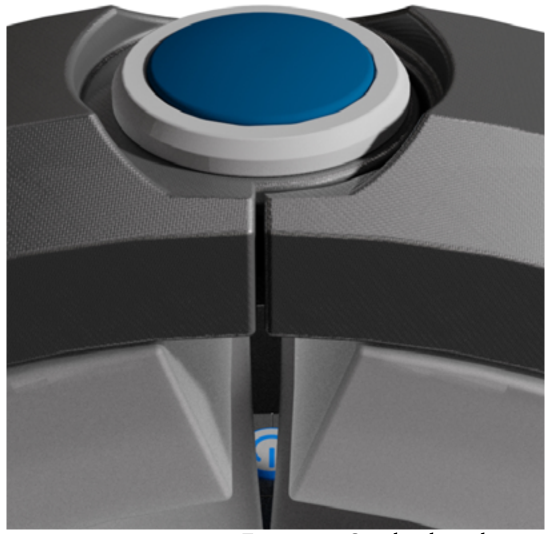


Figure 69- Quick release button

The handles are designed so that the product is easy to carry, but also easy to handle when placing under the patient's head. Usually the paramedics are working in pairs so that the one handling the SDD can use both hands moving it in position whilst the other lifts the patient's head. It is nevertheless designed so that one person can easily use only one hand to move and adjust it while using the other hand to lift the head of the patient. In a scenario where the other paramedic is occupied with something else it is possible for one person to use the SDD single handedly.

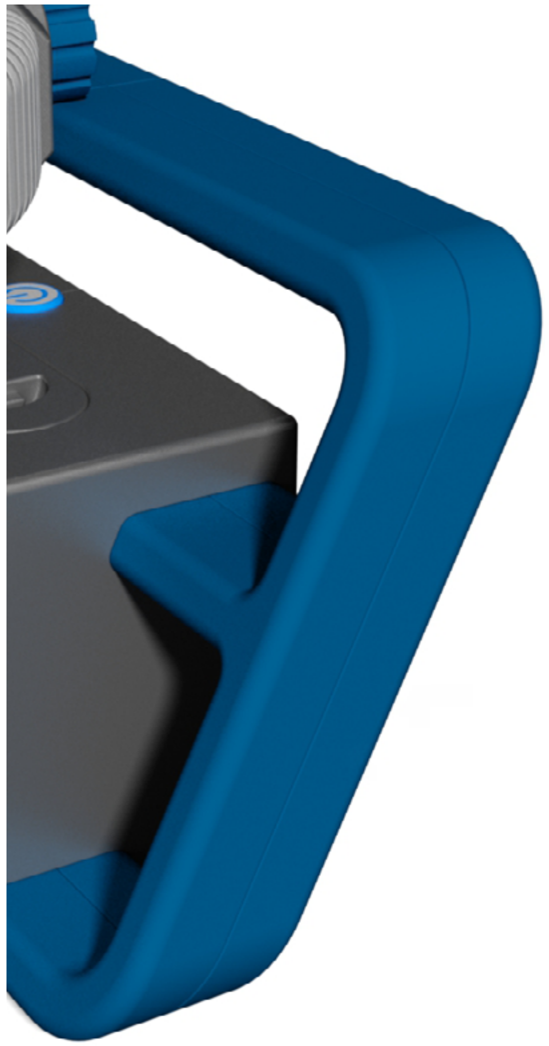


Figure 70- SDD handle

Under the handle on the base is the on/off button. It is a membrane type off button that has a circle around it which emits light when the product is on, making it easy to recognize that the SDD is on. The rest of the interactions needed for measuring e.g initiating calibration and starting the measurements, are done on the tablet.

Figure 71- On/Off button, turned off

Figure 72- On/Off button, turned on

The battery hatch placed in front of the handle is easily opened by pushing the two buttons together and lifting the hatch. Then it is just a matter of pulling out the battery and changing it with a freshly charged one when needed. The battery level is checked from the tablet.

Figure 73-Battery hatch

All the buttons have as mentioned earlier been designed to be easy to grip and use from both sides. In order to make it easy to recognise the buttons and areas that are to be interacted with, they are colored in the same blue color. The colour creates a contrast against the other colors making it very easy to see the different points of interaction. This is especially helpful since the SDD is not something that is used daily by the user. The paramedics can easily recognise the different interaction points which minimizes the risk for missing one step of the procedure or for handling the product in an incorrect way.

There is one exception in the color scheme and that is the battery hatch buttons that are not colored in blue. This is because the battery hatch is not interacted with during regular use and therefore it can be confusing to have them in the same color as the parts that are needed to be interacted with to use it correctly.

Use scenario

This is a descriptioin of how the SDD should be used and handled in a scenario of a stroke emergency.

- First the ambulance personnel receive an alarm of a possible stroke and drive to the emergency.
- When they arrive they grab the SDD and other needed equipment from the back of the ambulance.
- Arriving at the patient's home, the first paramedic talks to the patient, evaluates him or her with a ModiNIHSS list and collects blood samples.
- The second paramedic starts up the SDD and initiates the calibration sequence from the tablet.
- When the calibration is complete the patient (who is lying down), has their head and upper body lifted a bit by the paramedic.
- The SDD is slid under the patient's head and is adjusted so that the neck antennas are correctly placed in the neck when the patient is lowered down.
- The second step is to bring the "headgear" forward so that the forehead antennas are correctly placed, when this is done the angle of the headgear is locked by the button on of the sides of the SDD.
- Then the forehead antennas and the lower side antennas are moved towards the head by adjusting the two wheels on the side of the headgear simultaneously. To make sure that the head is "straight upwards" and that the two wheels are adjusted equally there is a marker on the top of the headgear that should be aimed at the center of the nasal bone.
- When the forehead and side antennas are placed correctly on the head, the top two antennas are moved towards the head by adjusting the wheel on the back of the headgear.
- The last step is to initiate the "scan" from the tablet. The scan takes approximately 30 seconds.
- The results are sent through the tablet together with the ModiNIHSS score to a specialist for evaluation of the results.
- The paramedics put the patient on the stretcher, bring the patient to the ambulance and load her/him in.
- The physician calls the paramedics as soon as the results have been evaluated.
- If the specialist physician has concluded that it is a stroke and that it is caused by a clog, then thrombolytic treatment could be started by the paramedics as soon as possible.

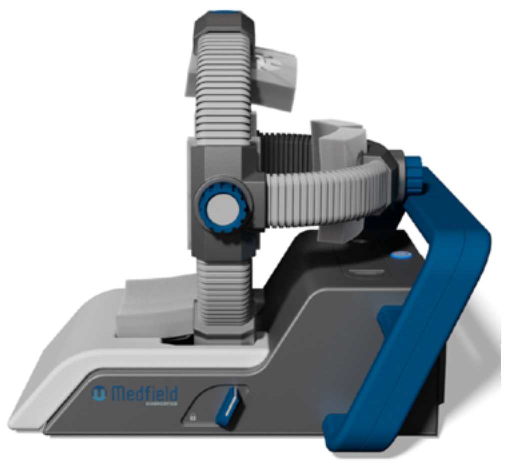


Figure 74-SDD sideview, upright position

Figure 75- SDD sideview, downwards position

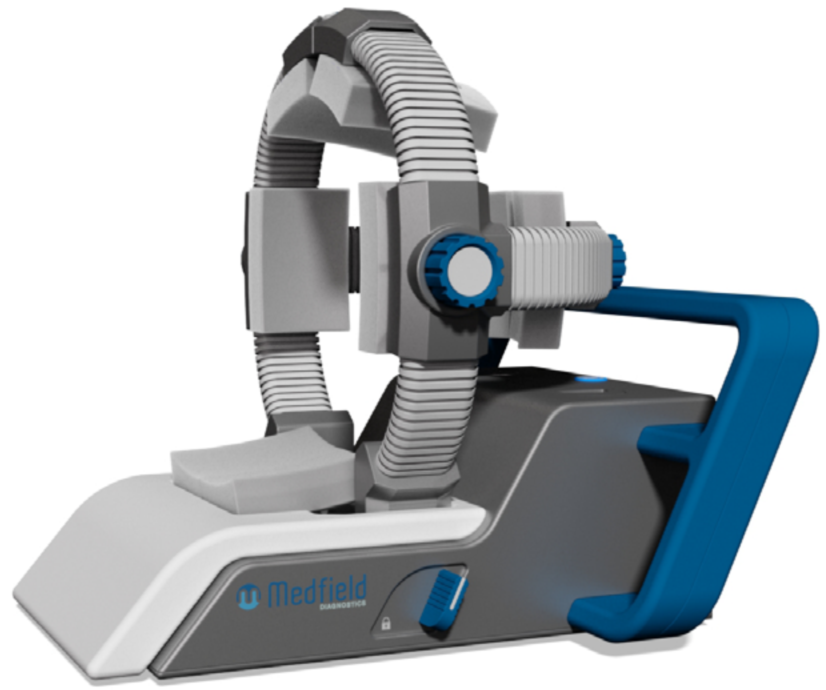


Figure 76 - SDD

Expression

The SDD should be experienced as; *user friendly, high tech, reliable, robust, welcoming, professional, precise* and *hygienic.* This is created with the use of appropriate shapes and colors. The expressions that the SDD communicates create the visual brand identity for the product. The way the product uses form and coloring to communicate the brand story could be used as guidelines for all upcoming products and in that way create a common visual brand identity for Medfield Diagnostics.

The expression of user friendly is created by the easy to grip buttons and the clear visibility of the interaction points. It is further emphasized by the large handle that enables the user to grip and handle the SDD in many different ways. All interaction points are colored in a distinctive blue color to further distinguish them from the rest of the SDD.

The base has a quite simple form with a large contact area to the surface it is standing on. The base is slightly wider than the cushion, creating a stable expression. The wide handle further emphasizes a robust and reliable expression in the sense that it creates a protective frame for the SDD. The headband is constructed with wide proportions in order for it to look as stable and reliable as the base.

From the front, the SDD composed by the soft white cushion and the white antennas. This generates a more welcoming appearance with soft edges and radiuses. From the back the SDD has sharper edges and a more precise appearance in order to give the expression of a high-tech professional device. The softer welcoming front will be what the patient experiences and the more professional harder back will be a part of the paramedics impression. The adjustment wheels and button on the headband create a compliment to the clean design of the headband and base, leading to an interesting but not too complicated overall look. The wheels are designed to enhance the precise feeling.

The white wipeable cushion also enhances the hygienic expression because it shows that it can be removed and cleaned separately. This also makes it easier to clean the rest of the SDD since there are very few hard to reach areas. The color scheme also conveys a very clinical feeling adapted for the paramedic environment.

Manufacturing and Materials

The three parts of the base are manufactured initially by vacuum forming a thermoset plastic. This gives the company the possibility to start out with producing lower series without having to invest in expensive tools. Later on if the production volume increases these parts should be produced in a thermoplastic material through injection molding. The handle is produced in the same manner but with blue coloring granulates added to the plastic.

By using standard components as far as possible the cost will be reduced. Components such as the membrane switch, the adjustment wheels and the release button should be able to be found as standard components where only the visible areas need to be custom made. For example for the adjustment wheels only the grip that the user interacts with needs to be custom made. These parts can be made using the same manufacturing techniques and materials as mentioned earlier.

During the assembly, all electrical components are mounted onto the bottom plate together with the headband. Then the handles are mounted on each of the two base casings. Finally the base and handles are put together on top of the bottom plate, encasing all the electronics.

Sustainability

The SDD could have a huge sustainability impact on the social level. For every minute the SDD shortens treatment time a lot of personal suffering is reduced. On top of that, on a socio-economical level the counties save money on rehabilitation which could be put to use elsewhere.

The environmental impact that comes from the manufacturing differs depending on manufacturing method. With vacuum casting the impact will be higher per produced unit because it will be produced in a thermoset plastic and therefore can't be recycled. With injection molding the environmental impact will be less since it can be produced in a thermoplastic and is thereby recyclable to some extent. The construction of the SDD makes it easy to upgrade parts or change parts that are broken, enabling a long lifetime for the product. The construction of the product also generates an easy disassembly so that materials can be sorted and parts reused at the end of the product life.

9 Evaluation and discussion

In this chapter the process and result of the thesis are discussed.

Process

The different parts of the process in this thesis have been discussed more in detail after each chapter. Here follows a discussion on the overall work.

Before starting the project a process for how to conduct the product development project was decided together with a time plan for how long each part of the process should take. This has been very beneficial since it made sure that each part was finalized within set time and therefore the project moved along and each part was thoroughly worked through.

Throughout this project the group has been located at the companys office. This has made the product development process a lot easier. One reason being the easiness of sharing information with the company. Questions were answered quickly and feedback on the work was received instantly all through the project.

Changing technology

Since the company is working with another concept simultaneously, there have been a lot of changes regarding the technical components in this project. Especially which parts that need to be in the final product. This has put special demands on this project group to be adaptable for changes. This created new demands but also new possibilities for the product and it has been a challenge during the course of the project. It has also been a very good experience since technology evolves fast and it is important to learn to be agile and quick to adapt for changes in technology in order to be able to benefit from them. This challenge has been handled very well in the project, one reason being a very close collaboration with the company and another one being that key decisions were taken at the right time. The risks are that since things are changing, decisions might be pushed forward which could delaay the product development process or instead decisions could be taken too early, therefore missing opportunities of new and better technology.

Final result

The goal of this master thesis was to further develop Medfield's diagnostic equipment for stroke detection. The development was conducted to improve the existing product in terms of usability, improved functionality, and flexibility in order to enable use in ambulances. The development was also set to incorporate a clear visual brand indentity into the product. The final product is easy to use by one paramedic, both inside and outside of an ambulance. The fact that it is possible to use in an ambulance was confirmed already in the concept phase by paramedics. That it is possible to use by one paramedic has been tested using mockups to ensure that the SDD can be operated single handedly. In comparison to the existing product this is a large improvement in both functionality and flexibility. In terms of usability, the SDD has an intuitive and easy sequence for placing the patient and mounting the antennas on the head. It is also easier to see if the antennas are placed correctly with the indicator on the top of the headgear and the increased visibility of each antenna. It is important that the program in the tablet which controls the SDD is designed with the same focus in order for the whole system to have a high usability.

Although the paramedics stated that it should be fully possible to use the SDD in and outside the ambulance the SDD still needs to fulfill the demands from the standard SS-EN1789.

These have been taken into consideration during the product development but it has not been tested accordingly. This needs to be done in order to guarantee that the SDD is fulfilling all demands tand can be allowed to be used in an ambulance.

Expression

The SDD has been designed to both reflect what the company stands for and to fit into the form language of other medical equipment. The design of the SDD is a good basis for the company's visual brand identity that can be used in other products in order to create a good brand recognition for the company. One sensitive part of achieving the expression of the SDD is the final finish of the produced product. For example in order to convey robustness and reliable it is crucial that the assembly of the product is done with low tolerances and with high quality. There can not be for example parts that feels loose or that the adjustment wheels need to be turned a little before they actually starts to adjust the headgear.

Sustainability

The decision of manufacturing technique will change the environmental impact of the SDD and from that perspective using injection molding with a thermoplastic is the best choice for manufacturing the main plastic components. But since the SDD, at least in the beginning will be a low volume product injection molding will increase the price of the product due to the fact that initiating cost for injection molding is very high in comparison. This could lead to a higher price which could make it harder for buyers to afford it and lessen the amount of SDDs in ambulances and therefore the amount of people helped. On the other hand, even if injection molding is chosen the production cost for the plastic parts will still be a small percentage of the total cost since the internal electrical components are very expensive.

In conclusion , the final result is considered to fulfill the set goals of the project with one exception. The SDD needs to be tested to make sure it complies with the regulations for medical products in ambulances.

10 Future work

The chapter contains a description of areas to work further on.

Solution for carrying the SDD

A carrying solution for the SDD needs to be developed in order for it to be able to be used in and outside of the of the ambulance. The concept Carrying bag presented in chapter 4 is a good start for the development. The system with different add-on modules for the bag was something the ambulance personnel really liked when it was shown for them. This should therefore be something for the company to take into consideration when developing carrying solutions for their products. It is also important to consider the test head that is needed for the startup calibration when designing the carrying solution. The dummy needs to be easy to store in the carrying solution so that it is easy for the paramedics to reach the dummy and simple to put it back. If this is not fulfilled the dummy head will become an irritation for the users and there is a risk that it will be forgotten at the emergency site.

Cable mountings

Since the focus has not been on the internal construction, the only thing that has been taken into consideration is that it works and that there is room for all the components. This needs to be further developed and tested, especially how the cables are mounted in the headband. Because of the movement of the antennas the cable placing and mounting is an important factor for the functionality. It is also important that the cables do not bend too much since it affects the results from the measurements.

Manufacturing and materials

Further investigation of what materials and manufacturing techniques that should be used needs to be done. Due to the main focus of the project, material selection and manufacturing techniques have not been deeply investigated in this project. Therefore there could be a need for minor fixes of the form of the product depending on what manufacturing techniques are to be used. It is important that the material that is chosen in the end allows for narrow tolerances and a professional looking surface structure since that impacts greatly on the visual expression of the SDD.

Antenna design

One thing that was discovered during the project was the possible need to further develop the form of the antennas. Today the antennas all have the same shape and curvature but since the head's shape and curvature differ on different parts of the head, this might need some consideration. It could in other words be beneficial to alter the shape and curvature of the antennas according to their placement. For instance the antennas on the sides should perhaps be flatter than those in the back of the head.

Test against standards

The SS-EN1789 regulates what the SDD should withstand in terms of forces to be able to be used in an ambulance. This needs to be tested with a prototype in order to make sure that all demands are fulfilled. Especially the mechanical forces such as vibrations and a drop test is probably necessary in order to make sure that the SDD complies with the standard.

References

Literature

Abbing, E R., (2010) Brand-driven innovation. Lausanne, Switzerland: AVA Publishing SA.

Bergman, B., Klefsjö, B. (2011) Quality – from Customer Needs to Customer Satisfaction. 3rd edition. Lund: Studentlitteratur AB.

Bligård, L-O., (2011) Utvecklingsprocessen ur ett människa-maskinperspektiv, Chalmers University of Technology

Bohgard, M. et.al. (2009) Work and Technology on human terms, Stockholm: Prevent

Cross, N (2000). Engineering Design Methods - Strategies for Product Design (3rd Edition). Chichester: John Wiley & Sons

Donnan, G.A., Fisher, M., Macleod, M. & Davis, S.M. 2008, "Stroke", The Lancet, vol. 371, no. 9624, pp. 1612.

Eissen, K., Steur, R., (2011) Sketching the basics. Amsterdam: BIS Publishers

Engelbrektsson, P. (2010), Course compendia for the course "MMT015: Produktutveckling: behov och krav". For Teknisk Design, Chalmers University of Technology.

Fassbender, K., Balucani, C., Walter, S., Levine, S. R., Haass, A., Grotta, J., (2013) Streamlining of prehospital stroke management: the golden hour, The Lancet Neurology, Vol. 12, no. 6, pp 585-596

Ghatnekar, O., Persson, U., Glader, E., Terént, A., (2004), Cost of stroke in Sweden: an incidence estimate, International Journal of Technology Assessment in Health Care, vol. 20, no. 3, pp. 375-380.

Hanson, L., Sperling, L., Gard, G., Ipsen, S., Olivares Vergara, C., (2009), Swedish anthropometrics for product and workplace design, Applied Ergonomics, vol. 40, no. 4, pp. 797-806.

Hedstad, M., (2013) Branding and Product Design: an integrated perspective. Fanham, England: Gower Publishing Limited

Högberg, D. (2013), Lecture in Design for all, for Teknisk Design, Chalmers University of Technology (2013-09-27).

Johannesson, H., Persson, J. and Pettersson, D. (2004). Produktutveckling: effektiva metoder för konstruktion och design. (1st edition) Stockholm: Liber.

Kroemer, K. H. E., (2006) Extra-ordinary' Ergonomics. CRC Press, Santa monica

Müller, W., (2001) Order and Meaning in Design. Utrecht : Lemma

Pheasant, S., (2003) Bodyspace. (2nd edition) Boca Raton:Taylor & Francis Group.

Poljak, A., Tveith, J. & Ragneskog, H., (2006) Omvårdnad i ambulans – den första länken i vårdkedjan. Vård i Norden, vol. 26, no. 1, pp. 48-51

Thompson, R., (2007). Manufacturing processes for design professionals. London: Thames & Hudson ltd.

Walter, S., Kostpopoulos, P., Haass, A., Helwig, S., Keller, I., Licina, T., Schlechtriemen, T., Roth, C., Papanagiotou, P., Zimmer, A., Viera, J., Vierra, J., Körner, H., Schmidt, K., Romann, M., Alexandrou, M., Yilmaz, U., Grunwald, I., Kubulus, D., Lesmeister, M., Ziegeler, S., Pattar, A., Golinski, M., Liu, Y., Volk, T., Bertsch, T., Reith, W., Fassbender, K., (2010), "Bringing the hospital to the patient: first treatment of stroke patients at the emergency site", PloS one, vol. 5, no. 10, pp. e13758.

Warell, A (2006). Identity recognition in product design: An approach for design management. Proceedings of the 13th International Product Development Management Conference. Milan: Politecnico di Milano. June 11-13.

David, Y., (2004), Telemedicine, in Academic Press, , pp. 484-487.

Österlin, K. (2007) Design i fokus för produktutveckling. Vol. 2:1. Malmö: Liber AB.

Web pages

antropometri.se (2011) http://antropometri.se (2014-01-03)

Karolinska Institutet University Library (1998) http://mesh.kib.ki.se/swemesh/show.swemeshtree.cfm?Mesh_No=E01.370.370.380.240 (2014-02-10)

Ne.se (2014) http://www.ne.se/lang/datortomografi, Nationalencyklopedin (2014-05-26.)

Appendix

01- Stroke PM
02- Frågor teknisk specifikation
03- Frågor Karlstad
04- Frågor Kungälv
05- Frågor Säve
06- Frågor Laholm
07- Checklista stroke
08- Kravlista
09- Workshop
10- Handtag

Kungälvs sjukhus

PM – Strokelarm

VÄSTRA GÖTALANDSREGIONEN

Före behandling i hemmet och ambulansen

- SOS alarm och ambulanssjukvårdarna bedömer om kriterier för Strokelarm är uppfyllda
- mNIHSS – bilaga 6
- Triagering enligt RETTS
- Pat transporteras till CT lab på Kungälvs sjukhus via akuten, där id-band sättes
- Om pat kommer med ambulanshelikopter transportert direkt till rtg via personalingången
- PVK sättes i ambulansen, grön nål. Om det inte går sättes den på rtg av ambulanspersonal
- Höjd huvudända ca 30 grader
- P-glukos kontrolleras i ambulansen
- Ringer-Acetat 100-200 ml/timme ges (ej om bltr > 220/120)
- Syrgas ges
- Antiemetika vid behov – Inj Dridol 2,5 mg/ml, 0,4 ml = 1 mg iv
- Ambulansen ringer ssk på AKM Kungälvs sjukhus
- Personuppgifter tas fram (om identitet ej är känd tilldelas reservnr)
- Uppgift om:
  - symtom
  - debuttid
  - sidolokalisation
  - om patienten står på Waran
  - beräknad ankomsttid till sjukhus
  - telefonnumret till ambulansen
- Dessa data används av medicinjouren för att skriva en CT remiss "Strokelarm"

Insjuknande på sjukhus - patient eller besökare

Vid strokelarm på inneliggande patient, tillkallar avd ssk medjouren, som skyndsamt går till berörd avdelning, och gör en första bedömning. Om strokemisstanke finns, ringer med jouren koordinatorn på akuten, tel 98387, som i sin tur aktiverar larmkedjan. Avdelningens personal transporterar patienten till CT lab, där medjouren och stroke ssk möter upp. Avdelningen har dessförinnan tagit akuta strokeprover vid behov (om inte adekvata prover nyligen är tagna), och satt grön PVK.

Före behandling på sjukhus

- Ssk på akuten aktiverar larmkedjan och ringer/meddelar:
  - Medicinjouren 98524
  - CT lab mån-fre kl 07-18 98717; lör-sön kl 07-18 98718; mån-sön kl 18-07 98726
  - Strokessk strokeenheten 98536/ 93536/ 98496
  - IVA 98662/ 98661/ 98599/ 98127/ 43448
  - Akuten meddelar CT lab omedelbart. CT lab ringer in rtg jouren om denne befinner sig i hemmet. Övriga i larmkedjan meddelas när ambulansen ankommit till sjukhuset
- Ambulanssjukvårdarna transporterar patienten direkt till CT lab på röntgen

Carl Henrik C:u Kaatz 2012-04-28 Sidan 1 av 12

- Strokeprover tas på akuten och lämnas direkt till lab (endast om pat står på Waran)
- Medicinjouren skriver rtg remiss "Strokelarm" CT hjärna + CT angio. Remissen ska innehålla uppgifter om symtom, debuttid och sidolokalisation baserat på uppgifter från ambulansen. Finns ett aktuellt S-kreatinin ska det också anges.
- Medicinjour och stroke ssk går till CT lab och möter ambulansen
- Ambulanssjukvårdarna rapporterar kortfattat pat till stroke ssk, medicinjour samt rtg ssk
- CT hjärna + CT angio utföres
- Patienten placeras på bårvagn
- Medicinjouren gör status enligt NIHSS.
- Medicinjouren kompletterar anamnes – Checklista stroketrombolys
- CT bilderna bedöms
  - radiologiska kontraindikationer mot trombolys
  - angiografiska tecken på ockluderad a cerebri media
  - angiografiska tecken på ockluderad a basilaris
- Om NIHSS ≥ 14 poäng vid vänstersidig hemisfärskada och ≥ 11 poäng vid högersidig hemisfärskada kan endovaskulär behandling komma ifråga. Basilarisocklusion motiverar också kontakt med SU. Patienter med kontraindikation mot trombolys i form av ökad blödningsrisk, t ex nyopererade patienter, kan bli aktuella för endovaskulär behandling eftersom blödningsrisken är betydligt mindre för denna behandling. Tidsfönstret för endovaskulär behandling är längre än för iv trombolys; inom karotiscirkulationen upp till 6 timmar och vid basilarisocklusion upp till 12 timmar.
- Om trombolys beslutas, ringer medicinjouren IVA och informerar
- Blodtryck kontrolleras. Trandate 1-2 ml ges av stroke ssk iv om bltr >185/110
- Stroke ssk samt medicinjouren transporterar patienten till IVA
- Om ej trombolys, beslutar medicinjouren vart patienten ska flyttas - strokeenheten, annan vårdavdelning, IVA eller AKM för fördjupad diagnostik

Under behandling på IVA

- Akuta strokeprover tas, Hb, TPK, Na, K, Krea, PK, APTT, CRP, P-Glukos.
- PVK, två infarter
- Bolusdos Actilyse ges
- Blodtryck kontrolleras och vid blodtryck > 185/110 ges Trandate 2ml = 10 mg iv.
- Infusion Actilyse ges baserat på kroppsvikt. Infusionstid en timme
- IVA övervakning under de två första timmarna
- Kontroll av RLS, puls och bltr var 15:e minut
- NIHSS kontroll av medicinjouren efter två timmar
- Om trombolysen inte haft effekt och kvarstående höga poäng, kontakt med trombolysjouren Sahlgrenska, för ställningstagande till endovaskulär behandling
- Om inga komplikationer tillstöter överförs pat till strokeenheten

Efter behandling på strokeenheten

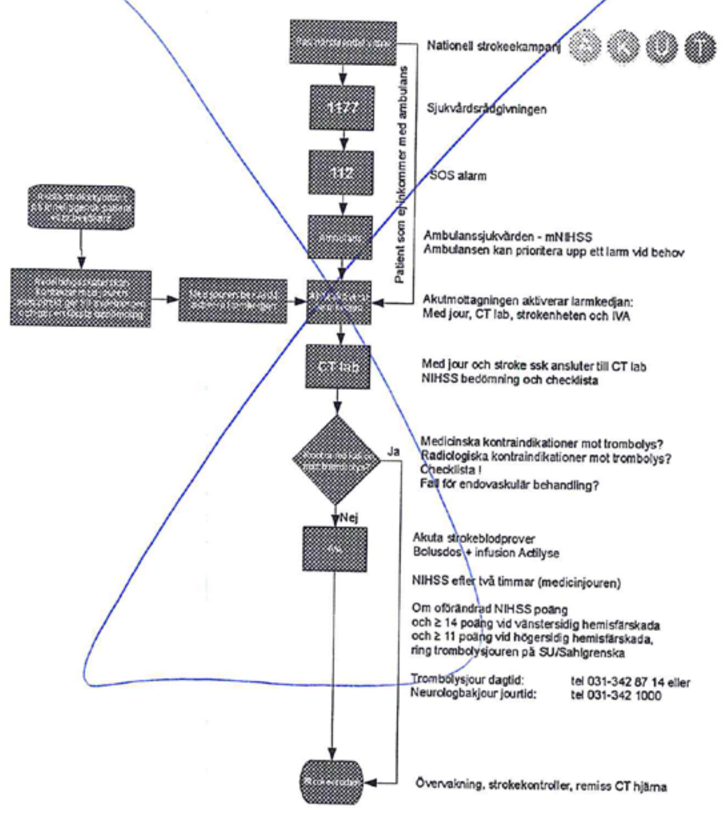
- Sedvanliga strokekontroller enligt ordinarie rutin för nyinlagda strokepatienter.
- Eventuellt inkomstprover och EKG om trombolys ej varit aktuellt (Hb, TPK, Na, K, Krea, PK, APTT, CRP, P-Glukos, S-lipider). Hb kontrolleras dagligen dag 1-3 och vid behov.
- Mobilisering tidigast 2 timmar efter avslutad behandling på grund av fallrisk med mera. Pat får komma upp på toalettbesök etc. Vid eventuell nytillkommen blåspares sättes KAD med tunn silikonkateter.
- Avdelningsläkare eller medicinjour skriver remiss för CT hjärna kontroll som bör göras 24-36 tim efter behandlingsstart

Sidan 2 av 12

Flödesschema

Tid är hjärna

Varje minut dör 1,9 miljoner hjärnceller vid ischemisk stroke



Sidan 3 av 12

Bilaga 1

Basala data

Pat id

Pers.nr: Plats för etikett

Namn:

- **Insjuknandetid** (alternativt senast kända tidpunkt när patienten var i sitt habitualtillstånd) **Klockan:__:__Datum:** ....
- **Anamnes och status** tydande på akut stroke ☐Ja ☐Nej
- **Kontraindikationer** mot trombolys ☐Nej ☐Ja
- NIHSS vid inkomsten: ....poäng
om >25 poäng så är det kontraindicerat med intravenös trombolys, överväg trombektomi ☐≤ 25 ☐> 25
- **CT hjärna** – kontraindikationer ☐Nej ☐Ja
Undersökningen utförd, **Klockan:__:__**
- **Patient (eller anhörig) samtycker** till behandling
Om ej beslutsmässig gäller förmodat samtycke ☐Ja ☐Nej
- **Symtomduration <4,5 timmar** vid behandlingsstart: ☐Ja ☐Nej
- **Trombolysbehandling skall ges** ☐Ja ☐Nej
- **Ansvarig läkare** ....
- Bolusdos ges **Klockan__:__**
- Infusion påbörjas **Klockan__:__**
- NIHSS 2 timmar efter påbörjad trombolysbehandling ....poäng
- Kontroll-CT 24-36 timmar efter insjuknandet beställd ☐Ja ☐Nej
- Kontroll-CT utförd **Klockan__:__Datum:** ....
- NIHSS 24 timmar efter påbörjad behandling: ....poäng

Sidan 4 av 12

Bilaga 2

Checklista stroketrombolys

Indikationer

- □ Uppfyller kriterierna för hjärninfarkt
- □ Ålder >18 år (>80 år individuell bedömning)
- □ Symtomdebut ≤ 4,5 tim till insatt trombolys
- □ Neuroradiologi har uteslutit intrakraniella kontraindikationer (blödning, omfattande infarkt, masseffekt, expansivitet)
- □ Pat skall ge samtycke till beh. Om ej beslutsmässig förutsätts samtycke

Kontraindikationer

- □ Mycket ringa symtom eller betydande symtomregress (dvs liten sannolikhet för kvarstående handikapp även utan beh)
- □ Mycket uttalade strokesymtom (NIHSS>25p, motsvarande omfattande infarkt med stor blödningsrisk vid beh)
- □ Medvetandesänkning (RLS>2)
- □ Klar misstanke på/tecken till annan diff. diagnos än ischemisk stroke (pares pga hypo-eller hyperglykemi, P-glukos <3mM, >22 mM, krampanfall med postiktal pares, subaraknoidalblödning)
- □ Klar misstanke på septisk embolisering/endokardit
- □ Tidigare genomgången *spontan* intracerebral blödning
- □ Stroke, intrakraniell operation eller svårt skalltrauma < 3mån tidigare
- □ Känt, obehandlat AVM eller aneurysm intrakraniellt
- □ Pågående beh med antikoagulantia (Waran INR ≥1,7, fulldos heparin el liknande APTT >48s, Pradaxa) PK
- □ Gastrointestinal- eller urinvägsblödning < 3 veckor tidigare
- □ Större operation senaste 2 veckorna
- □ Artärpunktion eller annan punktion på ickekompressibelt ställe < 1vecka
- □ Känd, okorrigerad blödningsrubbning. TPK <100. Annan ökad blödningsrisk, pågående blödning
- □ Blodtryck ≥185/110 trots akutbeh med i.v. medicinering

Bilaga 3

NIHSS

Pat id

Pers.nr: Plats för etikett

Namn:

Testtyp	Poängbedömning	Före beh	2 tim	24 tim	7 dagar
1 a. Medvetandegrad Enligt RLS-85	0. Vaken och alert (RLS 1) 1. Slö, men kontaktbar vid lätt stimulering (RLS 2) 2. Mycket slö, kräver upprepade eller smärtsamma stimuli för kontaktbarhet eller för att följa uppmaning (RLS 3) 3. Coma. Patienten okontaktbar. Reflex- eller automatiska rörelser (RLS 4-8)				
1 b. Orientering Fråga om nuvarande månad och patientens ålder, ge inga ledtrådar – initialt svar gäller !	0. Två rätt 1. Ett rätt. Ges även om intuberad/dysartri/annan språksvårigh. 2. Inget rätt. Ges om afasi eller coma.				
1 c. Förståelse Ge kommando (visa inte): Slut ögonen ! Knyt handen ! (icke paretiska sidan) Om afatisk patient utföra pantomim	0. Två rätt 1. Ett rätt 2. Inget rätt				
2. Ögonmotorik/ögonställning Observera först ögonställningen, testa sedan ögonrörelserna åt hö och vä sida. Om patienten inte lyder uppmaning, pröva Doll's eye-manöver	0. U. a. 1. Partiell blickpares (dev conjugée) som kan övervinnas viljemässigt eller med Doll's eye. Perifer ögonmuskelpares. 2. Komplett blickpares (dev conjugée) som ej kan övervinnas				
3. Synfält Använd konfrontationstest, t.ex. fingerräkning, eller genom att föra handen "hot/ulit" mot pats öga. Om pat är blind på ett öga, kontrollera det friska ögat.	0. U. a 1. Partiell hemianopsi. Visuellt neglect vid bimanuell konfront 2. Komplett hemianopsi 3. Blind bilateralt, oavsett orsak (inkl kortikal blindhet)				
4. Facialispares Medvetandesänkt eller afatisk patient testas genom att skatta reaktionen på smärtsamt stimuli.	0. U. a 1. Partiell central facialispares (utslätad nasolabialfåra, asymmetri vid leende) 2. Komplett central facialispares 3. Perifer facialispares				
5. Pares i arm Pat i liggande. Lyft armarna 45°. Be pat hålla kvar i 10 sek. Testa icke-paretisk sida först! Amputation eller kontraktur ger 0 poäng.	0. Håller kvar i 10 sekunder 1. Sjunker inom <10 sek men når ej till sängen 2. Faller till sängen inom <10 sek men visst motstånd mot grav. 3. Armen faller omedelbart, men kan röras mot underlaget 4. Ingen rörlighet i armen	Hö / Vä	Hö / Vä	Hö / Vä	Hö / Vä
6. Pares i ben Pat i liggande. Rakt benlyft till 30°. Be pat hålla kvar 5 sek. Testa ickeparetisk sida först! Amputation eller kontraktur ger 0 poäng.	0. Håller kvar i 5 sekunder 1. Sjunker inom <5 sek men når ej till sängen 2. Faller till sängen inom <5 sek men visst motstånd mot grav. 3. Benet faller omedelbart, men kan röras mot underlaget 4. Ingen rörlighet i benet	Hö / Vä	Hö / Vä	Hö / Vä	Hö / Vä
7. Ataxi Testas med finger-näs och knä-häl. Avser endast cerebellär symtomatologi. Hemipares, apraxi, amputation etc. ger 0 poäng	0. U. a. Används också om pares 1. Ataxi i en extremitet 2. Ataxi i två extremiteter				
8. Sensibilitet (smärta) Testas med nål. Avser endast dysfunktion pga stroke. Medvetandesänkt eller afatisk pat skattas med smärtsamt stimuli. Coma ger 2 poäng.	0. U. a 1. Lätt-måttlig nedsättning. Ändrad känselupplevelse men medveten om att berörs 2. Svår eller total nedsättning, omedveten om beröring. Pat med hjärnstamsstroke och bilateral nedsättning				
9. Språk/kommunikation Be pat beskriva bilden, namnge föremålen och läsa meningarna.	0. U. a. 1. Lätt – måttlig afasi. Svårigheter namnge, parafasier, etc 2. Svår afasi, fragmentarisk, ja o nej 3. Stum, global afasi				
10. Dysartri Be pat läsa ord från listan, tala inte om varför! Intuberad pat ges 0 poäng	0. U. a 1. Lätt dysartri, sluddrar på några ord eller är svårförståelig 2. Svår dysartri, oförståeligt tal eller mutistisk				
11. Neglect (utsläckning) A: Utgå från tidigare testresultat. B: Be pat blunda, berör samtidigt hö o vä sida. Om uttalad hemianopsi och/eller afasi men normal hudstim.reaktion ges 0 poäng.	0. U. a. 1. En modalitet nedsatt 2. Båda modaliteterna nedsatta eller svår ensidig utsläckning för en modalitet. Känner inte igen sin egen hand				
SUMMA:					

5

Bilaga 3 forts

Patienten läser orden i samband med skattning av uppgift 9, språk:

Du kan

Jordnära

Jag kom hem från arbetet

Nära bordet i vardagsrummet

De hörde honom tala på radion igår kväll

Patienten läser orden i samband med skattning av uppgift 10, dysartri:

MAMMA

TIPP-TOPP

FEMTIO-FEMTIO

TACK

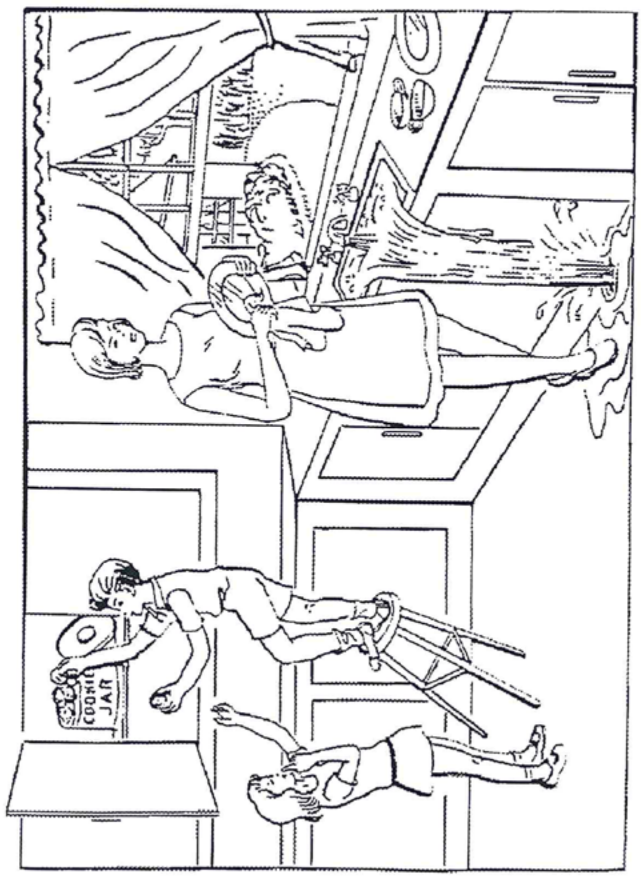
KRUSBÄR

BASKETSPELARE

Bilaga 3 forts

Figur A används i samband med skattning av uppgift 9 och 11, språk och sensoriskt neglekt.

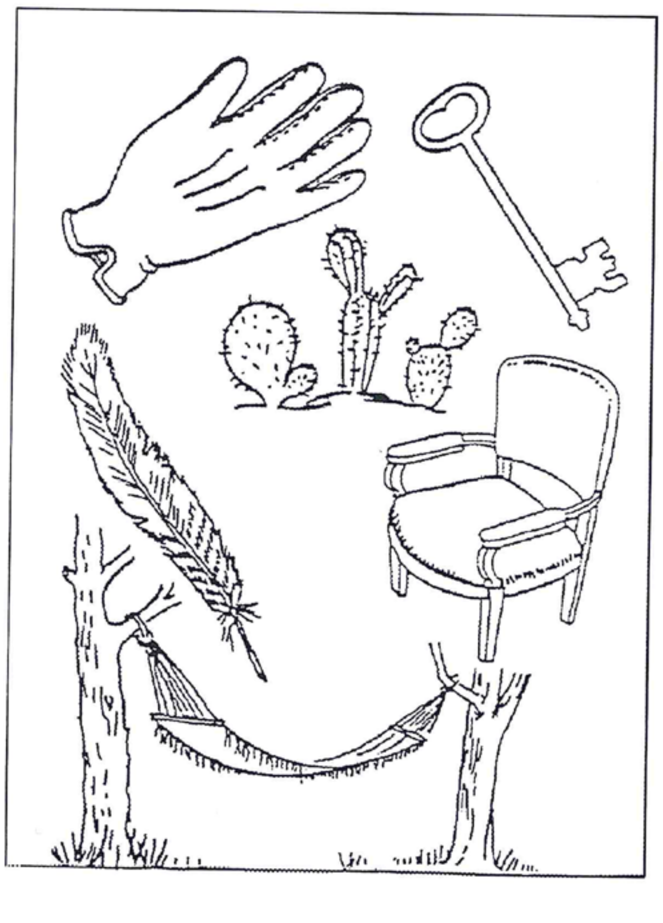
Figur A



Bilaga 3 forts

Figur B används i samband med bedömning av uppgift 9, språk.

Figur B



Bilaga 4

Akut CT-hjärna

Pat id

Pers.nr: Plats för etikett

Namn:

Undersökningstid: Klockan __:__ Datum: ....

Resultat

Helt normalt!	☐Ja	☐Nej
Äldre infarktförändringar?	☐Ja	☐Nej
Synlig färsk infarkt?	☐Ja	☐Nej
Masseffekt?	☐Ja	☐Nej
Ödem?	☐Ja	☐Nej
Tidiga infarkttecken?	☐Ja	☐Nej
Hyperdenst mediatecken?	☐Ja	☐Nej
Proximal a. cerebri mediainfarkt åtkomlig för neuroradiologisk intervention synlig på CT angio?	☐Ja	☐Nej

Område:	☐ MCA – a. cerebri media	☐dx	☐sin
	☐ ACA – a. cerebri anterior	☐dx	☐sin
	☐ PCA – a. cerebri posterior	☐dx	☐sin
	☐ BA/VA – a. basilaris/vertebralis	☐dx	☐sin

Kontraindikationer mot trombolys

Blödning?	☐Ja	☐Nej
Tecken till utbredd infarcering?	☐Ja	☐Nej
Överskjutning av medellinjen?	☐Ja	☐Nej
Expansivitet (TC, AVM, abscess)?	☐Ja	☐Nej

Ansvarig radiolog: ....

Bedömning gjord: Klockan __:__ Datum: ....

Bilaga 5

Actilysedosering

Bolusdosen ges som intravenös injektion under 1-2 min
Resten ges som infusion under 1 timme

Notera tiden för
1. start av bolus: __:__
2. start av infusion: __:__
3. avslutad infusion: __:__

Dosen skall vara 0.9 mg/kg, dock max 90 mg. Färdigspädd lösning har konc 1 mg/ml

Vikt (kg)	Totaldos tPA (1mg/ml) i ml	Bolusdos (=10%) i ml	Infusionstakt (ml/tim)	Förpackningar (mg)
40	36	4	32	50
42	38	4	34	50
44	40	4	36	50
46	41	4	37	50
48	43	4	39	50
50	45	5	40	50
52	47	5	42	50
54	49	5	44	50
56	50	5	45	50
58	52	5	47	50+10
60	54	5	49	50+10
62	56	6	50	50+10
64	58	6	52	50+10
66	59	6	53	50+10
68	61	6	55	50+20
70	63	6	57	50+20
72	65	7	58	50+20
74	67	7	60	50+20
76	68	7	61	50+20
78	70	7	63	50+50
80	72	7	65	50+50
82	74	7	67	50+50
84	76	8	68	50+50
86	77	8	69	50+50
88	79	8	71	50+50
90	81	8	73	50+50
92	83	8	75	50+50
94	85	9	76	50+50
96	86	9	77	50+50
98	88	9	79	50+50
100	90	9	81	50+50

Bilaga 6

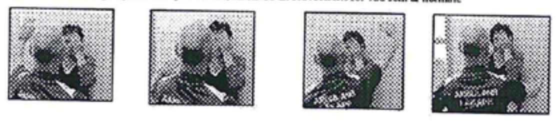
ModifNIHSS för prehospital bedömning av patient med misstänkt stroke

Personnummer: Namn:	Datum: Poängbedömning	AMB Klockan:		VÅRDAVD Klockan:	
Orientering Fråga om nuvarande månad och patientens ålder	0 Båda rätt. 1 Ett rätt. 2 Inget rätt (även afasi eller coma).				
Förståelse Ge kommando: Slut ögonen! Knyt handen! (icke paretiska sidan)	0 Båda rätt. 1 Ett rätt. 2 Inget rätt				
Ögonmotorik / ögonställning Observera först ögonställningen. Testa sedan ögonrörelserna	0 U.a. 1 Pat tittar från sjuka sidan, men vid stimulering kan pat få över blicken åt andra sidan. 2 Pat tittar från sjuka sidan och kan inte få över blicken åt andra sidan.				
Synfält Testa ett öga i taget. Använd "fingervifting", se illustration nedan. *)	0 U.a. 1 Påverkat synfält åt ena sidan.				
Pares i arm Pat skall ligga. Lyft armarna ca 45 grader. Be pat hålla kvar i 10 sek. Testa icke paretisk sida först. Poäng avser sämsta sidan.	0 Håller kvar i 10 sek. 1 Sjunker inom 10 sek, men ej hela vägen till underlaget. 2 Sjunker mot underlaget inom 10 sek, men med visst motstånd. 3 Faller omedelbart, men kan röras mot underlaget. 4 Ingen rörlighet i armen.	HÖ	VÄ	HÖ	VÄ
Pares i ben Pat skall ligga. Raka benlyft ca 30 grader. Be pat hålla kvar i 5 sek. Testa icke paretisk sida först. Poäng avser sämsta sidan.	0 Håller kvar i 5 sek. 1 Sjunker inom 5 sek, men ej hela vägen till underlaget. 2 Sjunker mot underlaget, men med visst motstånd. 3 Faller omedelbart, men kan röras mot underlaget. 4 Ingen rörlighet i benet.	HÖ	VÄ	HÖ	VÄ
Känsel Testa med beröring eller trubbigt stift på handrygg och fotrygg	0 U.a. 1 Nedsatt känsel.				
Språk / kommunikation	0 U.a. 1 Lätt till måttlig dysfasi. Svårt att hitta ord eller uttrycka sig. 2 Svår afasi, svarar i stort sett bara "ja" och "nej" 3 Stum, total afasi				
	Total poängsumma:				

Undersökningsmomenten görs i tur och ordning, med patienten liggande. Varje delmoment testas så gott det går med hänsyn till patientens förmåga att medverka. Sedvanlig Triage enligt METTS skall alltid göras först. Om pat har svårt att förstå givna instruktioner, försök att instruera patienten med ditt kroppsspråk.

- 0-1 poäng tyder på mycket lindrig stroke som normalt ej är aktuell för strokelarm
- 2-5 poäng tyder på måttlig stroke. Strokelarma om inte kontraindikationer enligt strokelarm-listan föreligger.
- 6-19 poäng tyder på allvarlig stroke. Strokelarma om mindre än 8 timmar gått sedan insjuknandet om det inte framkommer att patienten har en uttalad demenssjukdom.

*) Testa ett öga i taget. Be patienten titta på din näsa. Börja med att röra fingrarna i periferin av synfältet, flytta sedan handen successivt in mot centrum tills patienten ser fingrarna. Testa uppe-nere-vänster-höger. Testa sedan med andra ögat förtäckt. Om du själv tittar på patientens näsa under testningen testar du ditt eget synfält som jämförelse, du får då en bra referens för vad som är normalt.



02- Frågor teknisk specifikation

Frågor teknisk specifikation

1. Positionering av antenner:
    i. Hur många är de?
    ii. Hur nära måste de sitta huvudet?
    iii. Hur måste de placeras i förhållande till huvudet?
    iv. Hur viktig är placeringen i förhållande mellan antennerna?
2. Hur sker kommunikation mellan antennerna till datorn interface?
    i. Systembild av informationsflödet?
    ii. Vilka olika möjligheter finns för att överföra informationen till datorn?
    iii. Wifi?
3. Vilka är de ingående komponenter?
    i. Hur många är de?
    ii. Vilka är de?
    iii. Hur stora är de olika komponenterna?
    iv. Hur tunga?
    v. Vilka komponenter måste sitta vid antennerna och vilka kan placeras längre bort (datorn)?
    vi. Finns det komponenter som kan flyttas runt eller måste placeras som det gör nu?
    vii. Vilka komponenter kan ha förändrats/bytts ut till nästa version?
4. Vilket kylbehov finns?
5. Hur mycket kraft behövs för att driva den?
    i. Är batteridrift möjlig?
    ii. I sådana fall vilken typ av batteri och hur stort är ett sådant ungefär?
    iii. Kan man tänka sig större/mindre för att köra helt på batteridrift/ knappt alls
6. Hur funkar det med standby/sätta på apparaten?
    i. Måste apparaten värma up?
    ii. Start-up tid?
7. Hur lång tid tar en komplett mätning/mätningar?

03- Frågor Karlstad

Frågor ambulanspersonal Karlstad

Övergripande frågor som vi vill ha svar på med undersökningarna:

Hur används liknande avancerad utrustning idag i ambulanser?

Vad tycker de är bra/ dåligt med dem?

Hur ser systemet för strokepatienter ut idag? (Kommunikation, diagnos, behandling)

Hur skall den nya produkten passa in i systemet?

1. Hur arbetar ni när ni får en trolig strokepatient?
    i. Hur arbetar ni från att ni får ett larm till att ni kommer till akuten?
    ii. Hur kommunicerar ni med akutmottagningen eller andra avdelningar?
2. Hur hanterar ni t.ex. hjärtmonitor och dylik utrustning som används ibland?
    i. Vad är bra och dåligt med befintlig utrustning?
    ii. Hur ser strömförsörjning till apparater ut?
    iii. Används batterier och hur hanteras dem i sådana fall?
    iv. Uppstartssekvenser och rutinkontroll av olika medicintekniska produkter?
3. Hur skulle ni tänkas arbeta med en sådan diagnostikutrustning?
4. Hur skulle ni vilja förvara den?
5. Hur ser utrymmeskraven ut?
6. Telemedicin, hur fungerar det i dagsläget?
    i. Vilka produkter har ni?
7. Hur ser båren ut och hur används den?
    i. Hur placeras patienten?
8. Hur använder ni nackkragen?
    i. Är nackkragen lätt att applicera?
    ii. Finns det olika modeller och skiljer sig märkena åt?
9. Vilken utbildningsnivå har ambulanspersonal?
    i. Kompetens kontra tillstånd att göra?

04- Frågor Kungälv

Frågor akutmottagning Kungälv

Övergripande frågor som vi vill ha svar på med undersökningarna:

Hur ser systemet för strokepatienter ut idag? (Kommunikation,diagnos,behandling)

Hur skall den nya produkten passa in i systemet?

Akutmottagning

1. Hur arbetar man med stroke idag?
   i. Hur ser flödet/systemet ut?
2. Hur vanligt är telemedicin?
   i. Används det?
   ii. Av vilka?
   iii. Hur ofta?
   iv. Hur fungerar det?
3. Vilken utbildningsnivå har ambulanspersonal/akutpersonal?
   i. Kompetens kontra tillstånd att göra?
4. Hur ser kommunikationen mellan sjukhus, ambulans och patient ut, från det att larmet kommer in?
5. Hur förbereder man när en patient ska komma in?
6. Har personer med stroke andra komplikationer när de kommer in?
   i. Skador från tex fall pga stroken
   ii. Stroken är följd av tex operation
7. Hur förvaras och hanteras annan portabel utrustning?
   i. Bra och dåliga exempel?
8. Rengöring av aparater, hur sker det?

Observera

- Hur vill man mäta? (sängliggande etc,)
- När/ i vilket läge vill man mäta (i triaget, före, efter)
- Vart vill man mäta? (finns det plats där?)

05- Frågor Säve

Frågor till Ambulanshelikopter

Övergripande frågor som vi vill ha svar på med undersökningarna:

Hur används liknande avancerad utrustning idag i ambulanser?
Vad tycker de är bra/ dåligt med dem?
Hur ser systemet för strokepatienter ut idag? (Kommunikation, diagnos, behandling)
Hur skall den nya produkten passa in i systemet?

1. Vad är skillnaden mellan ambulanshelikoptern och ambulansen?
   i. Arbetsätt?
   ii. Uppdrag?
   iii. Utrustning?

2. Hur arbetar ni när ni får en trolig strokepatient?
   i. Hur arbetar ni från att ni får ett larm till att ni kommer till akuten?
   ii. Hur kommunicerar ni med akutmottagningen eller andra avdelningar?

3. Vilken utbildningsnivå har ambulanshelikopterpersonal?
   i. Kompetens kontra tillstånd att göra?
   ii. Hur mycket görs innan ni kommer till CT scan (hur mycket beslutsunderlag, blodprover etc.)
   iii. Tas besluten i ambulanshelikoptern eller sker någon typ av telediagnostik?

4. Hur skulle ni tänkas arbeta med en sådan diagnostikutrustning?
   i. Vart skulle ni diagnostisera (ute eller i helikoptern)
   ii. Ligger patienten på en bår eller vill man diagnostisera innan? Sitter de i helikoptern eller är de alltid på bår?

5. Hur skulle ni vilja förvara den?

6. Utrustas helikoptrar från fall till fall eller finns allting alltid med?
   i. Skulle denna alltid finnas med?

7. Hur ser utrymmeskraven ut?
   i. Är utrustningsvikten ett stort problem?

8. Hur hanterar ni t.ex. hjärtmonitor och dylik utrustning som används ibland?
   i. Vad är bra och dåligt med befintlig utrustning?
   ii. Hur ser strömförsörjning till apparater ut?
   iii. Används batterier och hur hanteras dem i sådana fall?
   iv. Uppstartssekvenser och rutinkontroll av olika medicintekniska produkter?

06- Frågor Laholm

Frågor till Nilsson Special Vehicles

1. Vem/vad avgör vad som ska in i ambulansen?
2. Hur mycket kan ambulanspersonalen variera placering och utrustning efter leverans av er?
3. Vart kan man inte sätta saker i ambulansen?
4. Hur fungerar det med strömförsörjning av produkter? Vad kan man få ut? Hur fungerar det när ambulansen är avstängd?
5. Kan man styra utrustning ifrån framsätet, t.ex. stänga av och sätta på?
6. Hur skiljer sig utrustning och inredning mellan olika beställare?
7. Vad har man för möjligheter för att fästa utrustning? Vilka olika sätt, möjligheter begränsningar? Hur testar man att fästen och utrustning klarar av 10g (SS-EN 1789:2007+A1:2010)?
8. Hur ser trenderna ut?
9. Hur ser skillnaderna ut mellan olika storlekar av ambulanser? Väljer man att ha mindre mängd utrustning i mindre typer av ambulanser?

07- Checklista stroke

Landstinget i Värmland

Dokumenttyp	Ansvarig verksamhet	Revision	Antal sidor
Checklista	Ambulansverksamheten	4	2
Dokumentägare	**Fastställare**	**Giltig fr.o.m.**	**Giltig t.o.m.**
Eric Rinstad	Torbjörn Nyvall	2013-05-20	2016-05-20

Rädda hjärnan - Ambulanssjukvården

Gäller för: Ambulanssjukvården

Patientnamn	Personnummer	Symtomdebut kl	Mobil till ambulans

Patienter med stroke har ibland svårigheter att själva lämna anamnes. Det är därför oerhört viktigt att medicinjouren kan få kontakt med **den/de** som lämnat anamnesuppgifterna.

Anamnes från

patient ❑

annan ❑
namn:________________________

tfn/mobil:________________________

Syftet med checklistan är att ta ställning till om patienten är aktuell för trombolysbehandling.

1. Gå igenom indikationer och kontraindikationer och ringa in svaret.
2. Kontakta akutmottagningen på aktuellt akutsjukhus för utfärdande av Rädda Hjärnan larm om svaret är **"Ja"** på alla indikationer och **"Nej"** på alla kontraindikationer sid. 2. Uppge aktuellt **mobiltelefonnummer** till ambulansen.
3. I möjligaste mån tar medicinjour kontakt med ambulanspersonal för komplettering av anamnesuppgifter. Transportera patienten – **prio 1** – till närmaste akutsjukhus.

Indikationer

Patienten skall vara ≥18 år	Ja	Nej
Symtom som vid stroke, något av nedanstående - ensidig svaghet i arm och/eller ben - talsvårigheter	Ja	Nej
Kan komma till akutmottagningen vid Centralsjukhuset, Arvika eller Torsby inom 4 timmar från känd tidpunkt för symtomdebut.	Ja	Nej

Titel	Revision	Giltig t.o.m.
Rädda hjärnan - Ambulanssjukvården	4	2016-05-20

1 (2)

Kontraindikation

Allvarlig sjukdom (ex, avancerad cancersjukdom, grav demens) eller uttalad funktionsnedsättning	Ja	Nej
Kramper vid insjuknandet	Ja	Nej
Medvetslös (RLS 4 eller mer)	Ja	Nej
Waran-behandling *	Ja	Nej

*OBS! Patient med strokesymtom och samtidig behandling med Waran, Pradaxa, Xarelto, Eliquis som innebär risk för blödning - handlägg patienten fortsatt som en Rädda hjärnan patient och transportera som prio 1 till sjukhus.

Åtgärder

1. Mät blodtryck i båda armarna, puls, örontemp (om temperatur > 37,5 ^{0}C rapportera detta till medicin jour) och SpO_2, ge syrgas om <95 %.
2. Sätt PVK grovlek 1,1 i båda armarna
3. Ansvarig sjuksköterska kontrollerar patientens identitet och sätter på id-band. Sjuksköterskan tar blodprover venöst: Hb, LPK TPK, PK, APTT, Blodgruppering, Elstatus, CRP, Trop-T. (Totalt 3 st lila rör, 2 st gröna rör, 1 st blått rör).
4. Lägg rören i påsen som märkts med patientens id – förslut sedan påsen. Meddela akuten vilka prover som tagits för framtagande av etiketter.
5. Ge sakta 1000 ml Ringeracetat i.v.
6. Ta P-glukos, om hypoglykemi - ge glukos. Ta EKG - om det finns möjlighet (**får ej fördröja transport**). Taget EKG skickas till MUSE.
7. Vid ankomst till akuten märker sjuksköterskan som tagit blodproven upp rören med framtagna etiketter och skriv under blodgruppering.
8. Ambulansens personal transporterar patienten direkt till CT lab där patienten avlämnas, rapport ges till ansvarig läkare/sjuksköterska som övertar ansvaret för patienten.

Underskrift ansvarig sjuksköterska________________________

Utarbetad av: Eric Rinstad, Wolmer Edqvist, Lena Emanuelsson, Johan Sanner

OBS! Detta dokument är en journalhandling som skall följa patienten

Titel	Revision	Giltig t.o.m.
Rädda hjärnan - Ambulanssjukvården	4	2016-05-20

2 (2)

08- Kravlista

Group	Demand	Type	Explanation
1.Safety			
1.1	Fixated during transport	Demand	The fixation shall hold the device to withstand accelerations or decelerations of 10g in the longitudinal, transverse or vertical direction.
2.Mobility			
2.1	Be able to be transported and used in a ambulance	Demand	Scope of the project
2.2	Be able to be used in mobile situations and in field applications	Demand	In accordance with SS-EN 1789:2007 See 2.2.1-2.2.3
2.2.1	Be capable of use outside the vehicle	Demand	
2.2.2	Be possible to be carried by one person	Demand	
2.2.3	Have its own built in power supply	Demand	
2.3	Be able to be transported with an ambulance helicopter	Request	Outside of the project scope but would be beneficial if possible
2.4	Easy to transport by one person	Request	See 2.4.1-2.4.2
2.4.1	Minimize volume	Request	In order to save space in emergency vehicles and make it easier to carry
2.4.2	Minimize weight	Request	In order to minimize weight in emergency and make it easier to carry
2.5	Incorporate other portable instruments needed for stroke diagnosis	Request	E.g. Material to take blood samples in order to make it easier for the emergency personel
3.Outside influence			
3.1	Waterproof	Demand	The device shall comply with EN 60601-1 and with particular device standards of the series EN 60601-2 where applicable regarding demands on humidity and liquid ingress.
3.2	Shall work in by SS-EN 1789:2007 defined temperature interval	Demand	See 3.2.1-3.2.3
3.2.1	Work after storage in temperatures ranging from -30°C to 70°C	Demand	Unless otherwise marked on the device, the device shall function as described in 3.2.2 and 3.2.3 when brought back to room temperature (20°C) after storage in temperatures ranging from -30°C to 70°C.
3.2.2	Shall function in the temperature intervall from 0°C to 40°C	Demand	Unless otherwise marked on the device, the device shall function throughout the temperature range from 0°C to 40°.
3.2.3	It shall work in a -5°C environment for 20 min	Demand	Unless otherwise marked on the device, the device shall function for at least 20 min when placed in an environment at -5°C after storage in room temperature.

4.Usbility			
4.1	Buttons, switches, indicators and controls shall be easily accessible and visible.	Demand	In accordance with SS-EN 1789:2007
4.2	SI units and standardized graphical symbols where applicable shall be used.	Demand	In accordance with SS-EN 1789:2007
4.3	Visible interface during daylight, night and strong sunlight	Request	The SDU will be used in all possible lighting conditions
4.4	Intuitive set-up	Demand	It shall not be possible to do it wrong
4.5	Quick set-up	Request	The procedure shall be as fast as possible
5.Calibrations			
5.1	Easy and intuitive calibrations	Request	Minimize the work burden for the responsible personnel
5.2	Quick calibration	Request	Minimize the work burden for the responsible personnel
6.Reliability			
6.1	Minimize error sources	Demand	See 6.1.1-6.1.3
6.1.1	Give feedback if correctly placed	Demand	
6.1.2	Give feedback if functioning	Demand	
6.1.3	Give feedback if wrong	Demand	
6.2	Be able to be dropped	Demand	Medical devices which are taken out of holders and/or carried by hand shall be submitted to the free fall test, and shall then function within the tolerances specified by the manufacturer. Free fall according to EN 60068-2-32: Height of fall: 0,75m, 1 fall on each of six different surfaces
7.Outer sheltering			
7.1	Protect the device during transport in vehicle	Demand	The SDU shall be unaffected by the outer forces affecting it during transport
7.2	Protect the device during transport by hand	Demand	The SDU shall be unaffected by the outer forces affecting it during normal transport by hand
7.3	Sheltering should withstand rough handling	Demand	It is used in a tough environment
7.4	Sheltering should withstand water and other liquids	Demand	the SDU are to be used outside and the sheltering will come in contact with e.g. water, mud and snow
7.5	Enable easy access to the SDU	Demand	The Sdu are supposed to be used in emergencies and therefore easy access is important for a swift process
7.6	Enable a logical and structured storage	Demand	To make it easier for the emergency personal to work with the SDU and minimize misshaps
7.7	Enable varied fastenings	Demand	So that the SDU can be used in different types of emergency vehicles
8.Cleaning of product and outer shelter			
8.1	Easy to clean	Demand	Easy-to-clean materials in areas where cleaning is nesscesery
8.2	Withstand disinfection procedures	Demand	Shall withstand normal cleaning procedures with alcohol and "antivirus" substance
8.3	Withstand blood and vomit	Demand	There is a risk for blood and vomit splatter on the SDU
9.Adjustment			
9.1	Enable easy adjustment	Request	It should be eaasy to adjust the SDU for diffrent head sizes
9.2	Enable simple adjustment	Request	It should not be complicated to make adjustments for diffrent headsizes
9.3	Minimize the time to adjust the SDU for correct fit	Request	The SDU are to be used in an emergency situation where every minute counts
9.4	Enable correct placement on the head	Demand	The antennas position are crucial for the results
9.5	Fit 95 percent of the Swedish population	Demand	See 9.6.1-9.6.2
9.5.1	Fit head lengths from 175,9mm to 215,4mm	Demand	5 percentile women 95 percentile men
9.5.2	Fit head widths from 139,2mm to 164,8mm	Demand	5 percentile women 95 percentile men
9.6	Fit 99,9 percent of the Swedish population	Request	See 9.7.1-9.7.2
9.6.1	Fit head lengths from 164,0mm to 227,5mm	Request	0,1 percentile women 99,9 percentile men
9.6.2	Fit head widths from 131,9mm to 174,3mm	Request	0,1 percentile women 99,9 percentile men
10.Misc			
10.1	Enable patients to vomit		
10.2	Possible to use togheter with a stretcher	Demand	The SDU should be usable when the patient is siting or lying on a stretcher
11.Environment			
11.1	Easy to repair and maintain	Demand	
11.2	Able to disasemble	Demand	
11.3	avoid unrecyclable material combinations	Request	
12.Visual identity			
12.1	The SDU should comply with the company core values	Demand	
13. Antennas			
13.1	There should be eight antennas	Demand	Changing the number of antennas would come at a great expense
13.2	mirrored placement of antennas	Demand/request	The antennas should be equally placed on both the right and left side if the head in order to detect which side the
13.3	Antennas should fit close to the head	Demand	Air between the antennas and the head affect the results negatively

09- Workshop

Brainstorming Workshop

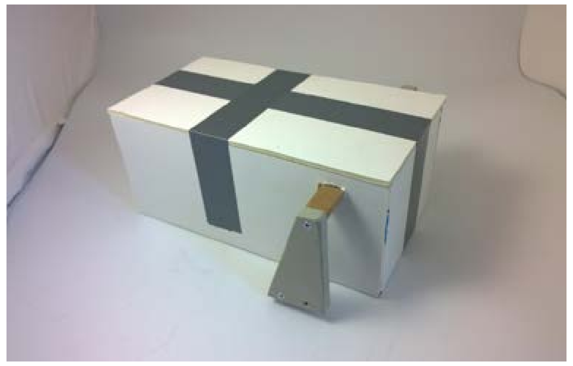
The brainstorming workshop was performed in two sessions (with a half hour break in between). The first session was a brainstorming session where the participants were presented with a quite loosely defined problem. This was deliberate in order to get a wide range of ideas, too much information and limitations could narrow the range of ideas the group will come up with. The problem definition that the participants were to find solutions to was: “How can you place 8 antennas on heads of different sizes and so that the antennas will be fixed during at least a 3min interval.” During the session all the participants presented one or more ideas that they had come up with every two minutes. This was done in order for the participants to get inspiration from the others participants and use this to create new and more novel ideas. The ideas were presented in text and with simple drawings. This session took approximately 30 min.

In the second session the procedure was different from the first session, the participants were the same but here each of the participants has a piece of paper with a more specific problem written on it. The topics were presented to the group so that everybody understood the topic before start of the session. They got three minutes to sketch ideas on the specific topics and then all sent their paper to the right and got a new paper from the participant on the left with a new topic. This was performed five times so that all participants had worked on all five topics. Then another round was performed were the participants only got 1,5 minutes with each problem to encourage them to work fast and not to think the ideas through too much but instead let their fantasy and creativity flow.

10- Handltag

Handle 1

-the backwards tilt made it harder to carry and adjust since the angle was in the “wrong” direction one handed adjustmen was also troublesome



Handle 2

-easier to use because or the straight front edge, one handed adjustmen was still troublesome though

Handle 3

-the backwards tilt made it hard to carry and adjust. the handle was too small and felt unreliable. one handed adjustmen was still troublesome

Handle 4

- Very easy to adjust with one hand since it is possible to han-dle it from the center. Easy to carry

Handle 5

-Better angle for adjustment and carrying, easier to use and carry than handle 1-3, however not as easy as handle 4

CHALMERS UNIVERSITY OF TECHNOLOGY
SE 412 96 Gothenburg, Sweden
Phone: + 46 (0)31 772 10 00
Web: www.tekniskdesign.se