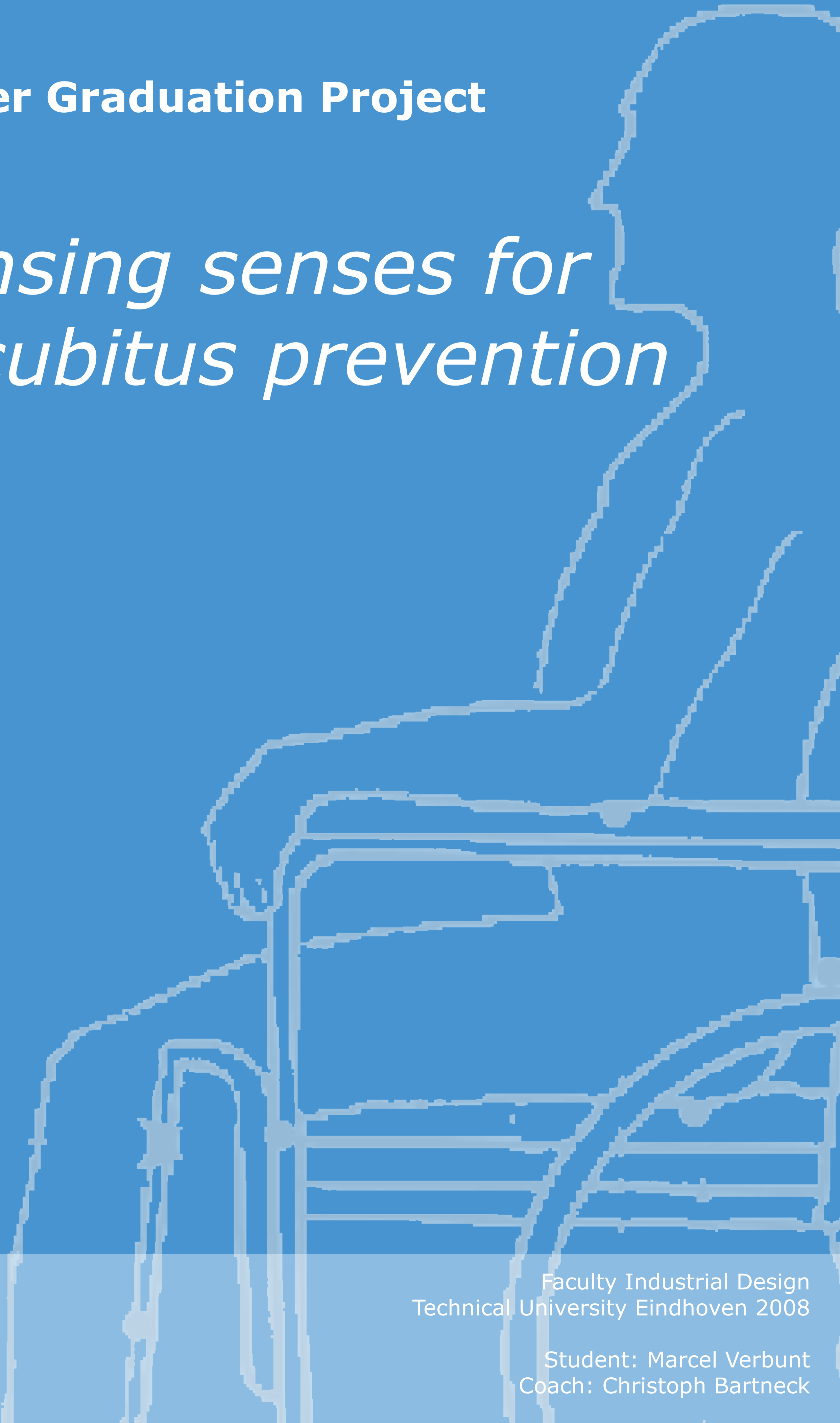
Master Graduation Project

Sensing senses for decubitus prevention



Faculty Industrial Design
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Preface

Healthcare is an interesting and grateful design area with many challenging problems to solve. As designer I like to work connected with people and I try to use my skills to contribute with the improvement of the quality of life. Although the medical world is already full of technical innovations there are many challenges left. With a change in healthcare patients become more autonomous and new products are needed.
With this report I describe the design process and development of a product which aims to decrease the risk on decubitus for people with a spinal cord injury (SCI). During the design process I experienced the complexity of the subject and the enthusiasm of a small group of people that is studying the subject. All these people have the same goal; decreasing the number of decubitus and improve the quality of life. I decided to dive into the deep and with the help of many experts I managed to breath. With the support from different fields I developed a new method for decubitus prevention based on the needs of the future. At the end I am proud to present my work which hopefully contributes to the prevention of decubitus and inspire others.

Involved in the project is Bos Medical, a company in which I found a client. I want to thank Wim Jalink and Danny Goossen who supported me and injected the project with their knowledge, energy, and motivation. Thanks for the trust and cooperation.
I also want to thank my coach Christoph Bartneck for coaching and all mental support during the past years. I want to thank you for the opportunity to be surprised, learn, be surprised again, laugh, and graduate coached by you.
I will not forget to thank the students and members of the staff that helped me during the moments that my own skills didn’t match the tasks for the project.

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1.1 Project goal

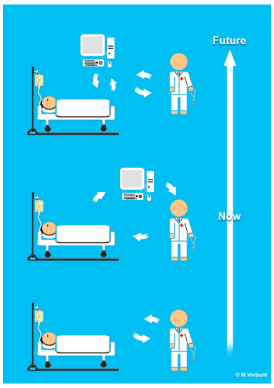


Figure 1.1
Vision definition healthcare

From ancient time people that experienced problems with their health approached a doctor for help. In that time medicine was a combination of physical techniques using various tools and holistic medicine using rituals and religious belief systems. Surgeons in that time used practically the same tools as Western doctors did only one hundred years ago.

Healthcare is changing and an important change is the autonomy and participation of the patient during the rehabilitation process. A patient wants to be involved more in the rehabilitation process [1] and this needs a change for products and systems that are used. Nowadays patients are highly dependent on the information from doctors and nurses while they rehabilitate in an healthcare centre. With the development of technologies the tools improve and enable doctors to monitor and heal the human body better then ever. The development of technologies also result into products (thermometer, insulin meter) that enable humans to monitor their body and gather information before approaching a doctor. In the future more products will be developed that enable humans to monitor their body. Therefore it is interesting to think about the role that doctors have now and will have in the future.

The new technologies also allow telemedicine, telemedicine is introduced to overcome distances between doctors and patients. The method currently enable doctors to manage chronic diseases as diabetes and heart problems from distance. The development of non-invasive sensors are very promising to monitor physiological functions and also daily activities and functions [2]. With new techniques products can be developed that monitor the human body not only in the static environment of the hospital but also at other more dynamic places. Within these scenarios the role of the doctor and the patient changes. The interaction partner of the medical system changes and therefore also the interface of the system has to change.

This project I want to use my knowledge to translate knowledge from experts and the information from the target group into a product that improves the ability for a person to prevent himself for decubitus.

A simple device and a good example of a device that extends the human ability of monitoring the body is the thermometer. The thermometer enables a person to

Figure 1.2 *products for 'home healthcare'*

monitor his body and display information that cannot be sensed (exactly) by the body itself. With the information from the device the user can decide if a doctor is needed. Nowadays you see more devices and tests enter the market that enable a person to monitor the body. To manage this information Google already introduced a tool to create a personal medical document 'Google Health'.

1.2 Problem Area

Pressure damage is common in many healthcare settings and affects all age groups. For every person that must spent a long time in a bed or chair increases the risks of decubitus ulcer. People with a spinal cord injury (SCI) are not able to sense the environment with the parts of the body that are cut off from the nervous system. Environmental aspects that cause irritation or pain are not detected and the body will not react by adopting the body or environment to the needs of the body. Signals as irritation and pain are elementary to prevent the human body to prevent from damage. 85% of the people with SCI experience damages that are directly related to the not sensing of signals that alert the human body for irritation or pain [3]. By not sensing irritation there is an increased risk on decubitus. "Decubitus is an area of localized damage to the skin and underlying tissue caused by pressure, shear, friction and or a combination of these" (European Pressure Ulcer Advisory Panel).
The aim of this project is to translate the measurements from different sensors (humidity, temperature, pressure, shear) into intuitive feedback for patients with SCI. The system measures the interaction from the body with the environment (wheelchair). The information from the sensors will be used to detect 'irritation'. With intuitive feedback the patient will be instructed to change posture. With a pre-study the current developments in research related to decubitus are studied. From the pre-study can be concluded that many different research groups are busy to find out what causes decubitus and how to prevent patients from decubitus. Roughly there are two main streams of research. One direction focuses on risk determination, which factors increase the risk on decubitus? The other direction studies the conditions of the tissue during the development of decubitus.
The market for products that focus on decubitus prevention is a passive market. Most of the products are for many years on the market and step by step re-developed. Most of the theories behind the products are based on a study from Reswick and Rogers [4]. A current study from Amit Gefen [5] shows that out of the box thinking is required for new and innovative prevention methods. With the development of new technologies and out of the box thinking a solution for one of the biggest issues of healthcare can be reduced.

1.3 Target group

The project focuses on young adults (18-40) with a lower SCI. Focused is on people that are able to control the upper part of their body. For this group is chosen because decubitus is an important aspect of their (in)dependency in daily life. Especially this group is in control to actively participate with decubitus prevention.
If a pressure sore develops a person's mobility decreases and this influences the social life of the person. With a pressure sore also medical treatment is needed what decreases the independency of a person. Because the awareness of decubitus is very important during the rehabilitation. Especially when this rehabilitation continuous outside the rehabilitation centre.

1.4 'Out of the box' prevention

Detection of irritation is an important aspect of decubitus prevention. Irritation is normally noticed by the person himself but for a person with a SCI it easily happens unnoticed.
Although different studies focus on the detection of irritation there is no idea about how to translate this information into valuable feedback for prevention. Most research approaches the problem from the medical point of view and not from the patient's point of view. This study tries to focus on the abilities of the user and create a new way of understanding the body. A new sensory system need to be designed and adapted to the abilities and needs of the user.

Figure 1.3 *sensing senses*

1.5 Bos Medical

Bos Medical is an innovative company that develops and produces products and knowledge for healthcare. The past years the company decided to develop with a strong focus on decubitus. Bos Medical exists out of two companies Bos Medirent and Bos Medical. The first company focuses on renting and distribution of products for healthcare institutes. With their knowledge and expertise on decubitus products are selected that fit the needs of each situation. The second company focuses on the development of new products and methods for decubitus prevention.

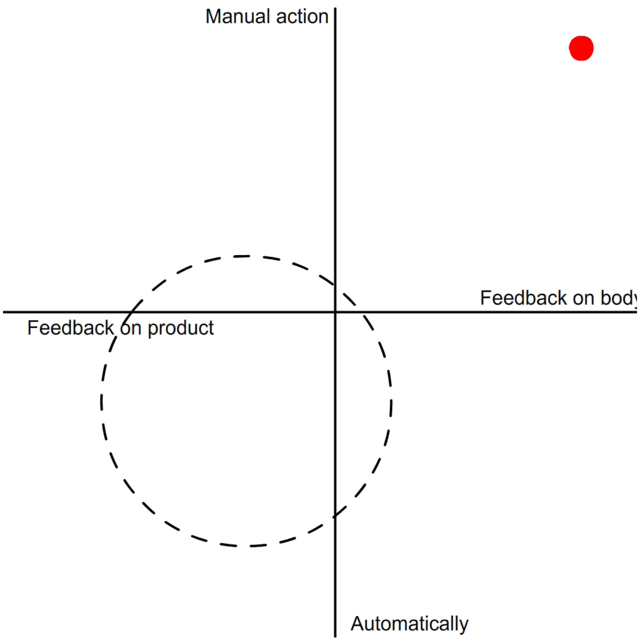


Figure1.4 *market*

Market decubitus prevention

When looking at the existing products used for decubitus prevention, can be concluded that the innovation is only focused on improving the existing products. In agreement with Bos Medical is decided to develop a product that approaches prevention from another direction. The limitation of the user is not taken over by a device but translated in a way that enables the user to solve the 'problem' himself.

2. Decubitus prevention

Introduction chapter

Both internal as external aspects influence the development of pressure sores. "For the Netherlands with a population of about 16 million the costs of the prevention and treatment of pressure sores is approximately 600 million euro per year what is more than 1 % of all costs of healthcare" [6]. The prevention of pressure sores is a highly cost-effective goal. Because of the costs it is interesting to focus on prevention of decubitus. A Dutch study reports that approximately 13% of patients in university hospitals had pressure ulcers, 23% exhibited them in general hospitals, 30% in nursing homes and 17% in home care [7].

There are different factors that can increase the risk on the development of decubitus. The factors can be divided into external and internal factors. This project primarily focuses on the effect of external factors.

Areas of interest for this project are decubitus, sensing physiological elements (pressure, shear, humidity, temperature), and the translation of the physiological elements into feedback for a person with SCI. With the involvement of different stakeholders in-depth knowledge is gathered from the different areas.

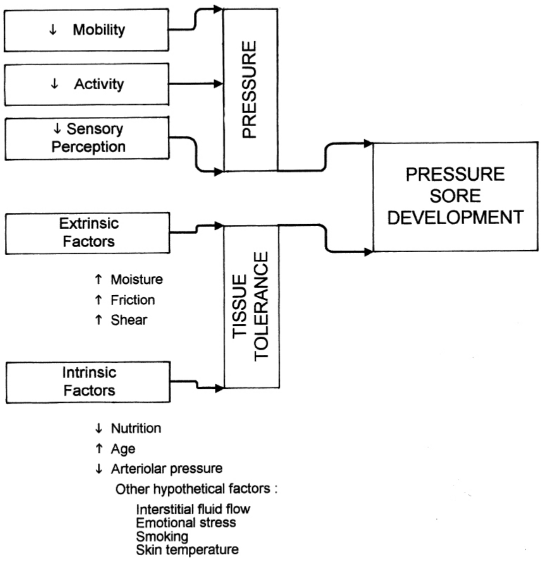


Figure 2.1 *Conceptual model by Braden & Bergstrom (1987)*

2.1 SCI and the risk on decubitus

Decubitus is widely recognized as serious complication for persons with SCI. Motor paralysis affect a person's ability to respond unconsciously to potential noxious stimuli, e.g. fidgeting while sitting or turning while asleep. Decubitus affects the quality of life of many people, both young and old.

The focus group for this project are the younger (age 18-40) people with SCI in a wheelchair. For this specific group decubitus is another important aspect of (in)dependency. To prevent the body from decubitus a person must be aware of the risk on decubitus and check the body regular on possible developments of decubitus. An important rule is that the skin 1 or 2 times a day is checked on redness at risk spots. If a red skin is detected the person has to immediately decrease pressure on the spot. If the skin is damaged a specialist must be contacted because from that

moment a wound can easily develop to the second stage.
A universal staging system for pressure ulcers is proposed by the National Pressure Ulcer Advisory Council (NPUAC) based on the depth and type of tissue damage:

• **Stage I:** Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.

• **Stage II:** Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister.

• **Stage III:** Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.

• **Stage IV:** Full thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar maybe present on some parts of the wound bed. Often includes undermining and tunneling.

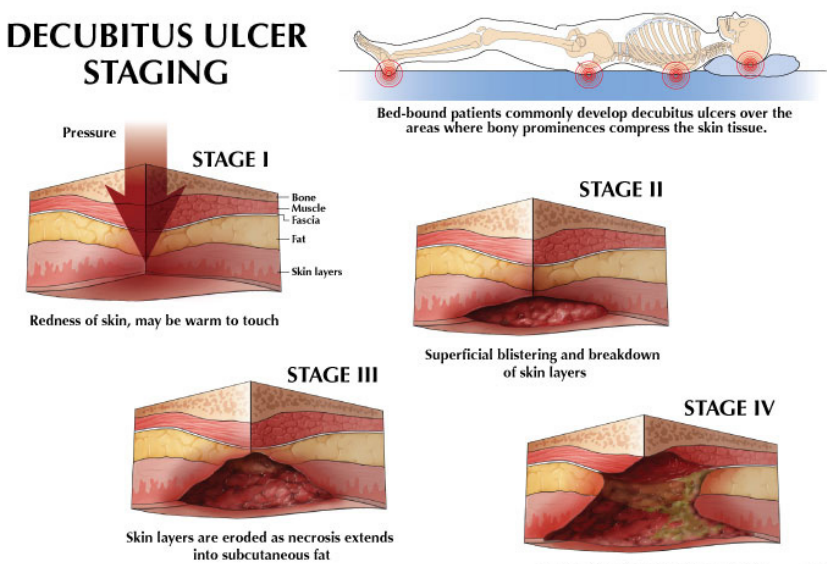


Figure 2,2 *four stages tissue damage source: Trialsight Medical Media*

A Dutch study [8] shows the increased risk on decubitus when a patient is discharged from the rehabilitation centre. The study shows an increased risk within the first 5 and after 19 years from the moment of discharging. After 19 years the age of the person is an important factor of the increased risk. For the first 5 years there are different reasons for the increase but one important aspect is the decrease of professional care and the process of learning to live with SCI. A patient has to learn to interact with the environment with limited senses. An early development of pressure sores can negatively affect the individual's psychological adjustment to life with SCI. Decubitus has a major effect on the mobility of the person because resting is the only way to heal the wounds. With the already limitation in mobility, because of the SCI, a second drawback not only affects the physical but also the mental state of the person.

2.2 Posture activity

Different experiments are executed to study the posture of a person in a wheelchair. A study [9] aimed to quantify the frequency and extent of postural changes during prolonged wheelchair sitting. Healthy volunteers provided basic information about posture changes while sitting. Studies [10,11] among people that are permanently using a wheelchair show less changes in posture. The results show that people without SCI change their posture at time intervals shorter than those recommended by the Agency for Health Care Policy and Research (AHPCR) for people in a wheelchair. A person without SCI changes their posture 9±6 minutes in the sagittal plane and every 6±2 minutes in the front plane. This movement is initiated (unconscious) by the body because of sensory input from the lower part of the body. A person with SCI doesn't get this input and moves much lesser.

At this moment different companies develop alternating pillows that actively move the surface under the bottom of a person. The advantage is that the alternating surface actively relieves the pressure at the bottom. The disadvantage is that the patient loses the control and awareness to manage his body. The problem for people with a SCI is that they cannot sense, not that they cannot move their body.

2.3 Methods for decubitus prevention

There are many products and procedures developed to prevent a patient from decubitus. As is shown with the Braden and Bergstrom model many different aspects are involved with decubitus. Because the many aspects each individual needs another prevention. A tool that is often used for risk determination is the Braden Scale [12]. With the Braden scale (appendix 2.3-A) the risk on decubitus can be predicted for each individual. If a person has an increased risk on decubitus.

A scale that is nowadays used by many Dutch healthcare institutes is the CBO list (appendix 2.3-B). One way of prevention is pressure distribution and avoiding pressure peaks of pressure on the body from a bed or chair. Different pillows and mattresses are developed to equally spread the weight of the body on a surface. Next to passive objects also products with an active function are developed to change the pressure from a surface on the body. A less developed aspect is the interaction from the patient with these products. Mostly a doctor or nurse decided which product to use and after installation the patient itself has to 'undergo' the interaction.

2.4 Pressure measurement and risk determination

Pressure distribution systems are widely used for the evaluation of weight supporting surfaces in shoes, chairs, beds, and prosthesis. Examples of studies show the irritation zones of the body part from the prosthesis. Pressure mapping technology has a positive impact on clinical decisions regarding the provision of pressure-reducing cushions. Measurement systems like FSA, Tekscan, or X Sensor enable a person to visualize the senses that can't be sensed because the SCI. The information that is gathered enables the patient to react on the environment and 'sense' the feedback from the environment on the body. The limitation of these systems is the complexity which is the result of the purpose of the systems, they are all developed for research.

Pressure measurement systems are often used at healthcare institutes as part of risk management. The systems provide information about pressure and weight distribution that is used to monitor a patient and select the right pillow for decubitus prevention (see appendix 2.5). With the outcome of the measurement and the 'factor comfort' a pillow is selected for decubitus prevention. There are different types of pillows (figure 2.3) and they all focus on three aspects; weight distribution (contact area), pressure relief (physical slow reaction), and comfort.

Because the measurement systems are primarily developed for gathering information for researchers, the gathered data isn't understandable as feedback for the patient. An expert is needed to translate the information and give advice about prevention methods. It is a problem that is part of a bigger problem in healthcare; information is captured by products and experts and isn't available and/or understandable for the patient.

Only few companies tried to develop a feedback system but without any success (figure 2.4) so far. The pressure alert is a good example of a product that shows the naivety of a company. The product measures pressure at only two spots (very limited input) and makes a noise when the pressure crosses a defined threshold. Although the product warns the user, and everyone that is near, it doesn't supply information about at which spot the pressure is too high and what to do when the pressure is above the threshold. Because it only measures two spots the user might neglect other areas when no alert is received.

At Bos Medical, a leading company in products for decubitus prevention, the FSA pressure mapping system is used to monitor patients, select and install pillows for prevention. With the FSA, a measurement system with 256 pressure sensors, it is possible to give a real-time visualization of the pressure from the body on a surface. The measurement gives detailed information about risk areas and the functionality of products that prevent the patient from decubitus. The disadvantage of the measurement is that it only visualizes the pressure at that moment with that specific posture. The measurement is just a 'snapshot'. For a better judgment all activities (watching television, reading, gaming, etc) need to be measured individually and over a longer time.

At this moment systems are developed that measure besides pressure also shear and a logical new step will be temperature, moisture and in the future inside pressure. For the patient it is important that these developments reach their needs. The main need for these patients is to monitor their own body without support from experts. To reach this the developers need to think from the user's point of view.

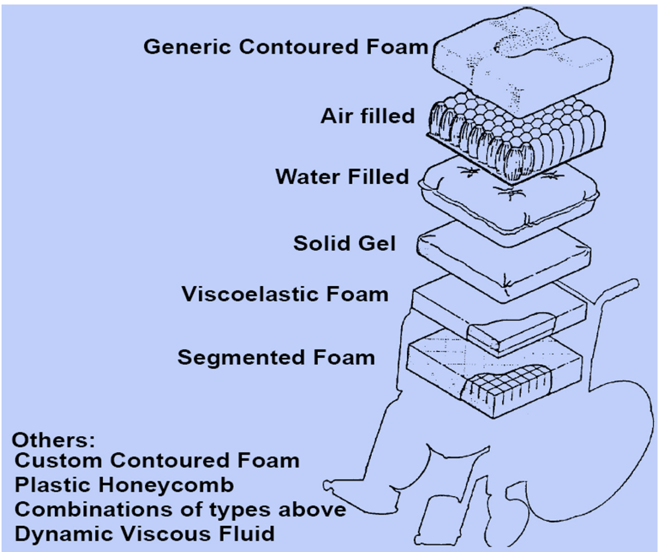


Figure 2.4 *Different types of pillows for decubitus prevention (Douglas A. Hobson1999)*

Figure 2.3 *this pressure alert is an example of a design that doesn't prevent a person for decubitus at all.*

2.5 Products to prevent decubitus

With the automation bed [13] researchers made in 1975 the first attempt to prevent patients in the hospital from decubitus. The bed automatically and periodically rotates a patient from side to side to prevent decubitus for people that sleep. Nowadays the automation bed is replaced by Air-fluidized beds which are an important and proven therapy for pressure sores. Patients rest on a bed of beadlike ceramic spherules through which filtered air is circulated, thereby simulating the mechanics of "fluid" movement. This bed is used in extreme cases where a wound is already developed. More often are used the alternating pressure mattresses. These mattresses alternate pressure on the body by changing the pressure of the different segments of the bed.

Products and systems designed for the decubitus market can roughly divided into 3 groups: products and systems that heal, detect, and prevent decubitus. Prevention is most interesting for several reasons. In the first place is this the moment to prevent a person from a long and painful rehabilitation. Second because a product for this group can help most patients. And third because at this stage most money can be saved which is therefore attractive for support from other stakeholders (government).

The market for products that prevent decubitus is not very innovative. Most of the innovation is focused on materials and the ideas behind the products didn't change the last decade. Most products focus on weight distribution and this without awareness

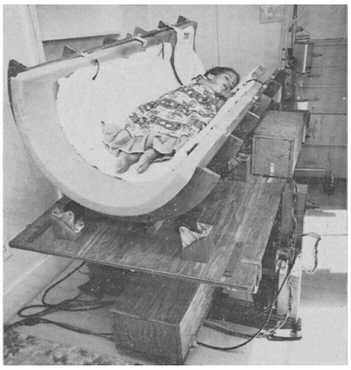


Figure 2.5 *products to prevent persons from decubitus, left the rotation bed with right from it the Air-fluidized bed*

of the user. Because the market is full of similar products it is difficult to chose the right product. The lack of understanding by the user and even nurses result in a product choice which increases the risk on decubitus.

From the many factors (figure 2.6) that influence the development of decubitus only a few can be influenced by the patient himself. These factors are interesting for decubitus prevention methods when the user is actively involved during the

prevention process. Involving the patient is very important because this improves the awareness and knowledge about the risks on decubitus.
Immobility is one of the greatest risk factors because it increases the periods of continuous pressure from the environment on the body. In close relation with immobility are four factors. The first and most obvious factor is pressure, this force that decreases the flow of oxygen which lead to cell destruction. Another factor is

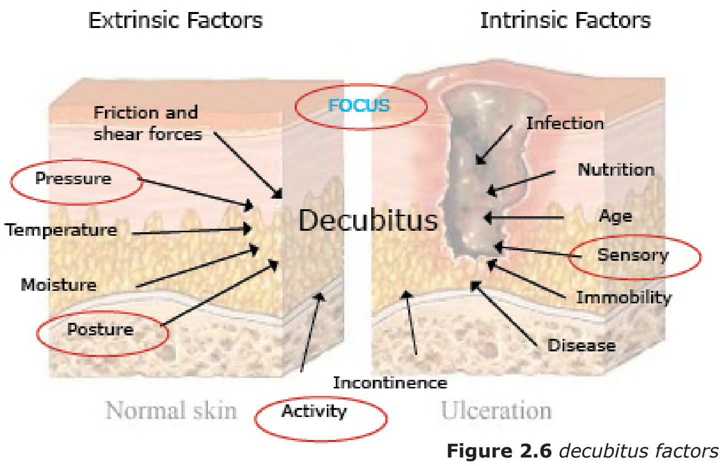


Figure 2.6 *decubitus factors*

the posture of a person. A good posture results into a good weight distribution and less risk on peak pressure. A third factor is activity, less activity increase periods of pressure. The forth factor is sense, without sense no detection of pain or irritation which are the first symptoms of decubitus. The close relation between the factors make it necessary keep in mind all these factors during the design process.

Healthcare 'being in control' (Figure 2.7)

To improve healthcare, products are needed that empower the patient. An important change in healthcare is that patients want to be 'in control', they want to know when, why, and how things happen. Understanding the rehabilitation process is an important aspect that has to be taken into account when designing for healthcare. In the first place understandable products are needed. And for this project it means that the product enables the user to monitor the body.
Many healthcare products are developed from a practical industrial point of view. Without the important user feedback products enter the market that don't match the skills of the patient. Instead that the product enables the patient to improve his life the product becomes another obstacle. With the development of products from the patient's viewpoint usability problems can be detected and eliminated.
Important is that the role of the doctor will change (figure 2.7). When a patient interacts with a product a specialist is needed to support this interaction. At this moment the specialist is actively involved but in the future this will become more passive.

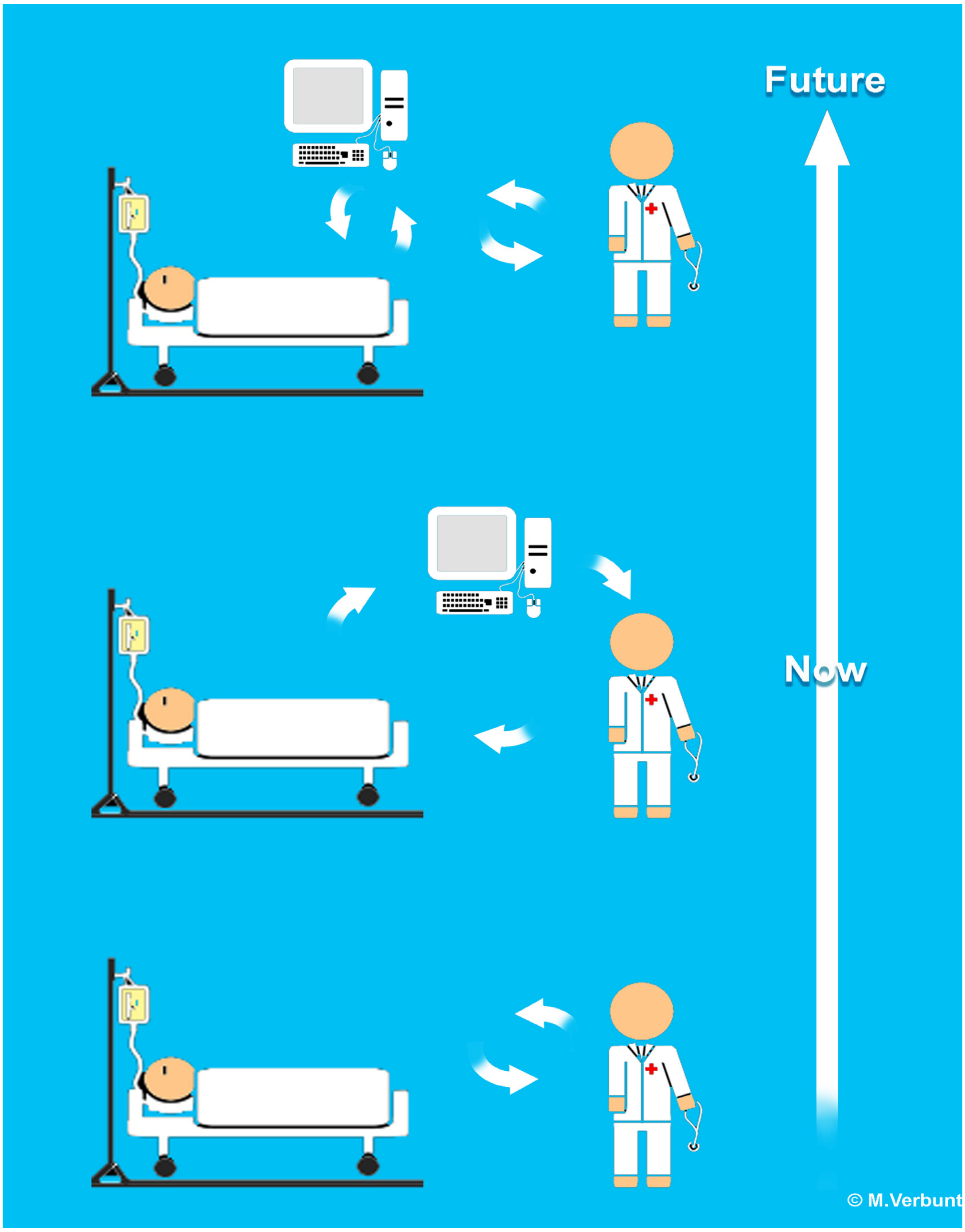


Figure 2.7 *Vision definition healthcare*

2.6 Introduction user studies

As input for the design process it is important to have a good understanding of the target group. To gather the information three areas are explored. The output of the studies will be used as guideline for the design process.
To get a good understanding about the influence of decubitus during rehabilitation a meeting is organized with Jos Bloemen from Stichting Revalidatie Limburg (SRL). Jos Bloemen is a nursing researcher and expert on problems during rehabilitation from SCI. The expertise from the expert is used to find out what are important aspects for prevention methods. Another direction which is tried to gather information from the target group are blogs. Many blogs are created by people with SCI. On most blogs people write very detailed and emotional stories about the rehabilitation and difficulties in life. The blogs are used to understand emotional and private aspects that are related to decubitus prevention. The third direction that is used for information is the target group. Via doctor H. Bongers from SRL patients are contacted that fit in the profile of the target group. With an interview detailed information is gathered about the influence of decubitus during daily life.

2.6.1 Visit SRL

For the project it is important to understand the future environment of the product. With the expertise of a nursing researcher the rehabilitation process is discussed. After the project is presented a tour is given to explain the prevention methods within the context of the rehabilitation centre. There is a strong focus on decubitus prevention and all methods and products for prevention are discussed. Besides the objects (mattresses, pillows) also exercises and knowledge are taught to the patient. Because the body cannot sense the risk on decubitus other skills need to be developed to 'sense' the risk. Awareness is very important for the patient especially outside the rehabilitation centre. At the rehabilitation centre awareness is developed with therapy. When the rehabilitation is finished and the patient re-enters his life decubitus isn't the main point of interest. The past shows that only after experiencing decubitus the patient is aware of the problem. But even after this the awareness decreases after a while.
The visit showed the importance of support during and also after rehabilitation. When people finish rehabilitation the support stops and knowledge for prevention must be developed further by the patient. Because decubitus is one of the many new aspects of the daily life of a person with SCI it isn't remarkable that many cases of decubitus occur the first year after rehabilitation.

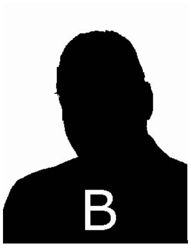
2.6.2 Interview target group

With interviews is tried to find an answer on the question: "What is the influence of decubitus during daily life for people with SCI?". To answer this question people with a lower SCI that experienced decubitus during rehabilitation are contacted.
A profile is created to select people that fit the requirements of the target group. With this profile questions are constructed for the interview (appendix 2.6.2).
Doctor Bongers from SRL agreed to select a number of persons that fit the profile and who were willing to cooperate with an interview. The interview discusses the influence of decubitus during the rehabilitation and during daily life. With the questions as guideline discussion were taken within the home environment. The discussions took about 1 hour. Because people were in their home environment they could support their stories with demonstrations. It enabled participants to show their equipment, their prevention methods, and also their daily activities as; driving a car, handcrafts, doing exercises, and transfers.

Profile: The participants for the interview are selected from a database from SRL. All people that participated were born without a SCI. They were all young adults when they got injured, and they all experienced the effect of decubitus during and after their rehabilitation at SRL. This group of people experienced all aspects of decubitus and the importance of prevention. Another important element is that they all know the difference between a life without and with a SCI. The all had/have to develop an awareness of decubitus.

User A: For this person it is important to live independent, with his wheelchair and car he is able to go where and whenever he wants. Because of his hobby, craftwork, he moves a lot during the day. This activity results in an active posture which is good for avoiding peak pressures over time.
With several exercises and different products he prevents himself from decubitus. Both his bed as his wheelchair are equipped with specific mattresses. In the middle of the room stands a 'home trainer' that is designed to move the legs automatically to stimulate these. During the conversation he presents proudly he self-made tool which enables him to stand up by himself.
The risk on decubitus and the prevention of it became a factor of live and this person is aware of the risks and also on the consequences of decubitus. He often repeated that it is important to be aware for

situations that increase the risk on decubitus. Even in a hospital or rehabilitation centre it is necessary to actively attend the nurses on materials and products that prevent them for decubitus.
" the only person I trust with decubitus prevention is myself"



User B: For this person the prevention of decubitus is an important aspect of his life. A few years ago he could go when and wherever he wanted. After he lost his leg as the consequence of decubitus he sold his car and minimized all risks on decubitus. He optimized his wheelchair, the mattresses, and pillows. More then ever he started to minimize every risk on decubitus and became actively involved in selecting products to prevent him from decubitus.
He joined studies on decubitus and used his experiences to inform nurses and doctors. This person takes every chance to minimize the chances on decubitus and selects products as his pillow, mattress, and wheelchair with precision.
"It would be a pleasure if I hadn't to think all the time about the risk on decubitus."

User C: This person lives by the day regarding the prevention of decubitus. He wants to enjoy his live as much as possible and doesn't want to spend time on thinking or preventing decubitus. The products that prevent this person for decubitus are prescribed by specialists. The only criteria he uses selecting products for prevention is comfort.
To prevent himself for decubitus he has to lay every day on his belly to relief his back and bottom from pressure.
"The care related to my spinal cord injury takes already to much time"

Important for all persons that were interviewed is their independency. Another important aspect is awareness during the daily life about the risk on decubitus. As one of the participants said when he was asked if he would like to want a system which could show him the risk on decubitus; "So much valuable time of my day is taken by the spinal cord injury that I won't waste more time". Another participant said; "If there would be a product which could ensure me that my pressure distribution is good I wouldn't have to think all the time about it".
The participants that were interviewed can be divided into two groups.

The notation laggards and innovators that is used by marketers (Rogers, 1971) to divide target groups for new products can also be used to divide the participants. Where one participant tried every new product to improve the prevention of decubitus and even actively joined that process of testing another participant trusted the products he used for the past years. One participant even created his own products to improve his daily life (picture 2.7).

Figure 2.7 *participant A with the by himself created 'stand-up'*

2.6.3 Blogs

Blogs are used by many different people for different objectives. Interesting of blogs is that it's an easy access to people's experiences. Blogs enable people to share experiences and opinions with others.

For this project blogs are used because it provides good access to personal stories of people with SCI. It is a medium which enable people with SCI to share experiences and meet people to discuss experiences. Detailed stories are written and the difficulties SCI entails are explained. With the stories it is possible as designer to have a imaginary walk-through with the first ideas.

The blogs give good insight information into the situation and specific problems. Mostly there are also different needs described by the target group. With a forum connected to the blog it is possible to find answers on specific questions.

From the blogs it was possible to understand the problem from the user's point of view. The stories explained the complexity of the situation. Although a forum enabled a conversation it is difficult to answer in-depth questions on-line.

Figure 2.8 *blog Steve*

3. Concept creation

Introduction chapter

The development of decubitus is the result of different factors and therefore the problem can be approached from different angles. It is remarkable that despite the size of the problem only a few prevention methods are developed. There is a strong focus on the adaptation of the environment (pillows and mattresses) and less attention is paid to the adaptation of the user. It is also remarkable that different user groups use the same products for decubitus prevention while they have different needs.

Because decubitus is a complex problem it requires a good understanding before a concept can be developed. At the other hand a good understanding may limit the creativity at the early phase of the design process. For this project is chosen for an iterative design process that starts at the first week of the project. Linear with the background study the idea generation started. For each new session new background information is used as input for the idea generation. The concepts are discussed with experts on the subject and the results are used as input for a new cycle. The documented ideas are regularly reviewed with new information and some elements are used as input for new sessions.

When the background study is finished different concepts are developed. After the concepts are presented and discussed with the client the idea phase is finished. From that point in the project the divergent thinking is changed into convergent thinking to work out one concept and develop a prototype. With the prototype the concept can be tested and validated by experts and its future users.

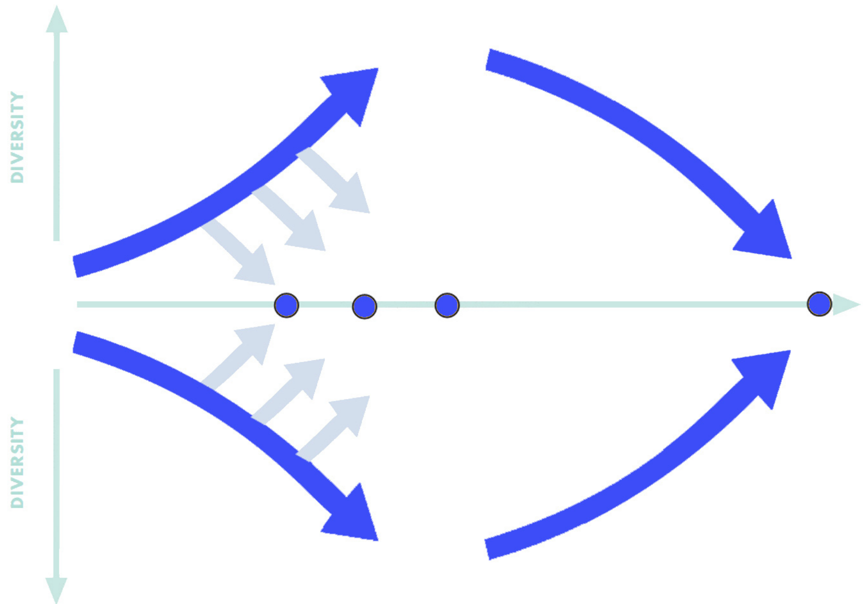


Figure 3.1 *Process concept development*

3.1 Idea generation

From the many ideas at the start of the project there are two good to explain more detailed (figure 3.2). One idea focuses on the detection of decubitus. The first stage of decubitus is a red spot on the skin that fails to disappear once the pressure from the area is relieved. To prevent such a spot from developing further the body needs to be inspected twice a day. For people with SCI it is difficult to check at all places of the body and often a mirror is used or someone else is asked to check the body. An idea to simplify the process is the 'Spotter'. With this device the user can press the 'Spotter' on the skin to detect red spots. By pressing the object and relief it after a given time the object scans the skin. When an irritation is detected the object informs the user.

Another idea is the 'I-plaster'. This plaster contains sensors that alert a person when a physiological aspect (moist, temperature, and pressure) around the skin is harmful. The plaster could change colour or attent the user with an audio alert. Later was found a thesis from the faculty of biomedical engineering Eindhoven with a similar idea based on tissue changes. A student developed a plaster which reacts on fluids from the skin. With the plaster it is possible to detect the early stages of decubitus.

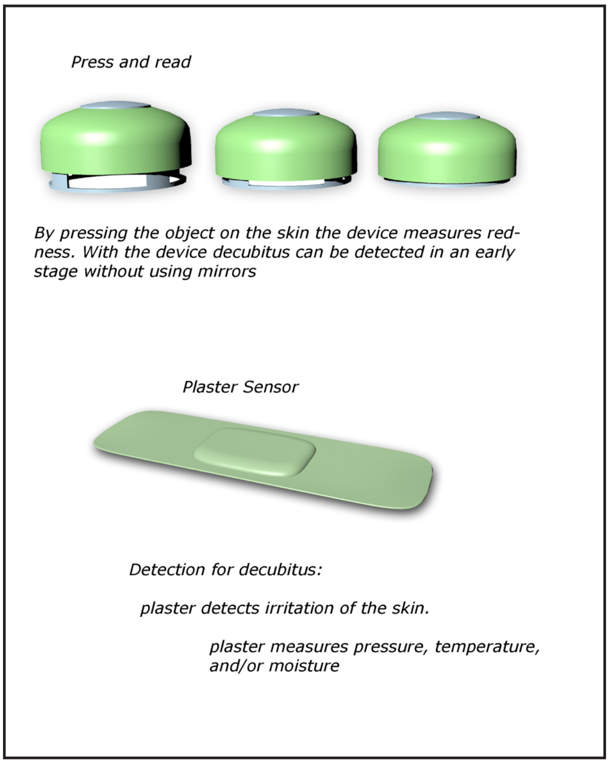


Figure 3.2 *the ideas 'spotter and 'I-plaster'*

Both ideas focus on the development of decubitus and alert the user when it is actually too late. From the three product segments (prevention, detection, and healing) most of the ideas, that were generated at the start of the project, did focus on detection. Reflecting back on the idea generation the detection of decubitus, which symptoms are easy to understand, is a logical starting point. For the development of ideas for prevention more in depth knowledge about the development of decubitus is needed. For different reasons it is more interesting to focus on prevention. The second idea generation was mainly focused on the development of the problem.
The focus of the second session was avoiding harmful situations. The idea generation was focused on the environment and mainly on the wheelchair. Different ideas (figure 3.3) are developed that focus on the interaction between the user and the wheelchair. The next step was to change the focus from the wheelchair to the patient. With this change new opportunities arose and ideas could be generated that did better fit the needs of the user.
The ideas generated during the different settings are discussed with experts within the field of decubitus. Three of them are worked out and one of them is chosen for further development.

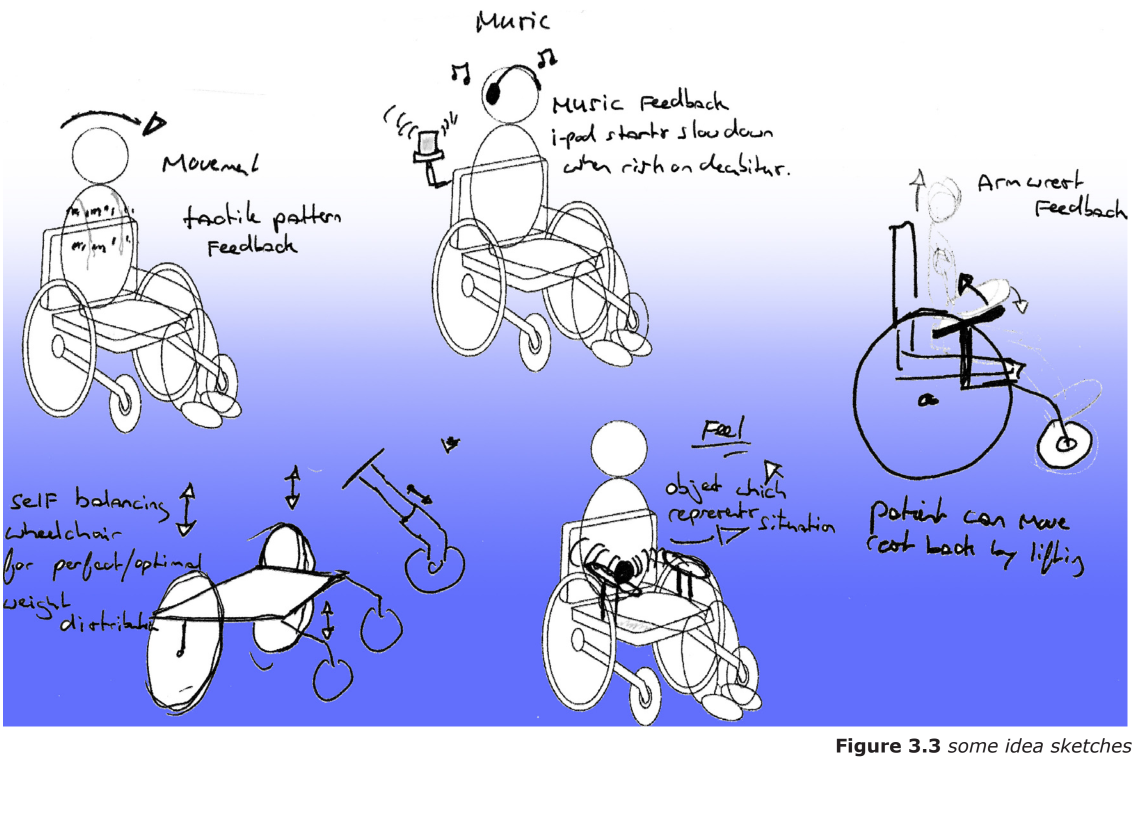


Figure 3.3 *some idea sketches*

3.2 Three Concepts

The three concepts that are presented to Bos Medical focus on the influence of immobility and low activity on decubitus development. The user's posture is a key element and close related to the activity. Findings suggest that people with SCI have maximum pressures that are higher than nondisabled subjects [14]. These maximum pressure are measured for nine typically postures assumed by wheelchair users. Because peak pressures are the start of cell damage this is a moment where prevention can make a difference. The study also showed that maximum pressures can be reduced by postural changes. Alternations to sitting postures enable the skin to relief from pressures and decrease the maximum pressures with 9 to 38 percent. Together with a study which found that people with SCI move less frequent than normals [9] make it very important to focus on both posture and activity. With an active posture the tissue is frequently relieved from peak pressures.

Because the market for decubitus prevention is very conventional there is chosen to work with only a few restrictions. Discussions with Bos Medical were used to adjust the concepts to the future vision. An important element is the user's involvement during the prevention. The product must become an extension of the body and improve the quality of life. To support the goals requirements are defined that guide the concept development.

- Direct (intuitive) feedback for monitoring body
- Integration of system in wheelchair/user
- System may not limit user in daily activities
- Feedback from the system is only noticeable for the user

A) Seating history

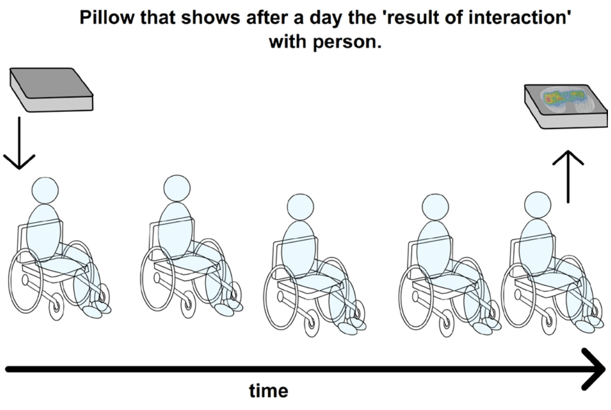


Figure 3.4 *Seating history*

For a person with SCI it is difficult to control his posture. The lack of feedback make it impossible to improve his posture for a optimal weight distribution and frequent pressure relief. The current prevention product support the weight distribution but don't inform the user about possible improvements. With a pillow that can store data it would be possible to visually represent a 'day of sitting'. The history of the interaction between

body and seating surface make it possible to detect possible risk areas. The feedback not only enables a specialist to adapt the wheelchair cushion, but also the user. With some instruction the user can easily adapt his filled cushion.
The disadvantage is that the time between cause and effect is much shorter than a day. With the daily feedback the user can adapt his posture but it is much better to do this more frequently. Another aspect is the moment of feedback, it is much better to involve the user at the moment itself than afterwards. If the user is attended at the moment itself he will learn faster.

B) Watch it

'Watch it' alerts the user at the moment of risk. With different pressure sensors the weight distribution of the body is analyzed. When there is a risk on decubitus a visualization guides the user to change his posture. The visualization can be played on a small screen that is integrated in the wheelchair or a wearable device. The concept works as a training wheel that passively supports the user. With the information the user needs to participate actively. A disadvantage is the communication between system and user at the moment of risk. How to attend the user? Visual feedback needs a continuous attention from the user. With a subtle light signal or sound the user could be attended. The main disadvantage of both mediums is the lack of privacy. Other people around can also detect the private information. Although the system alerts the user for a harmful situation the user will always be in control and have the ability to ignore. This is important because in some situations the user will have to use a specific posture. Especially in these situations the user doesn't want to share the information from his body with the environment. A solution could be a watch that alerts the user with tactile feedback, on a little screen the user can watch the supporting feedback.

Figure 3.5 *watch it*

C) Sensing senses

The third concept focuses on a new method of sensing lost senses. With sensors and actuators feedback information is transferred from one part of the body to another

part of the body. With integrated (pressure) sensors clothing becomes an active second 'skin'. With this skin irritation that causes decubitus can be detected. Actuators are used to communicate the information at a part of the body that isn't affected by the SCI.
With the integration of sensors into clothing the user becomes much more independent. Instead that the environment needs to be prepared for decubitus prevention the user is prepared. The integration of sensors and actuators also secures the privacy that is related to the information.
The concept includes many challenging elements that are at the start of a broad market introduction. Intelligent textiles are commercially available for only a few years and the integration into clothing is mainly focused on sports. The development of tactile feedback is at the start of a broader implementation and primary used for experimental models.

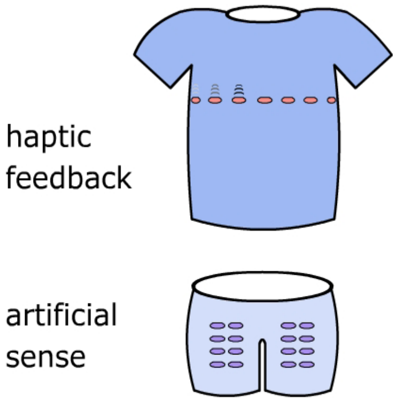


Figure 3.6 *Sensing senses*

Concept choice

The first concept (A) involves the user actively but the moment of involvement doesn't match with the moment of risk. The cushion mirrors the interaction with the body and becomes a representation of the body. A strong element of the concept is that the product visually confronts the user with his own behavior. The other two concepts include many similarities but differ in the way of interacting with the user. Concept C is a huge step in an unknown area for decubitus prevention and therefore very interesting. Both for the client as the project most challenges are offered by concept C.
For Bos Medical it is interesting to explore another method for decubitus prevention. The user involvement and the active prevention method are new for company as for the market. The integration of technology into clothing and the development of tactile feedback are very interesting design challenges.

Note:

It is important to realize that decubitus is the result of many different factors that all influence the development. Therefore it is always necessary to approach the prevention from different directions. The concept that will be developed will always be used in combination with other methods.

4. Concept development

Introduction chapter

The goal of the project is to decrease the risk on seating acquired pressure ulcers. The concept that is chosen for further development focuses on postural feedback that alerts the user for peak pressures and instructs how to avoid these. During the development of the concept there is a strong focus on privacy, intimacy, and intuition. The development of the prototype exists out of two elements. One element is the input the other element the output. The input measures different physiological states and the result of the measurement is translated into an output. The output will be created with multiple actuators. For the development of both the input as the output two areas are important to explore. One area is the development of tactile feedback and the second area is the integration of technology into clothing.

Tactile feedback is a design element that is commonly used for human-computer interfaces. It is one of the many interaction mediums with specific properties that fit the terms natural and private feedback. Because artificial touch is not commonly integrated in daily life (except the vibration of a mobile pone) the designed feedback needs to be intuitive or learned by the user. A study about vibrotactile feedback [15] identifies two types of vibro-feedback; impulse and continuous feedback. Impulse refers to ballistic interaction as knocking. Continuous feedback refers to contact over a longer period of time. Where impulse feedback could be used to link to information it is interesting to find out how vibration feedback itself can contain information, information containing feedback.

Another challenge is the integration of the prevention method into clothing or an object that can be attached to the user's clothing or equipment. The speed of the integration of technology into clothing is increasing. Especially the integration into sportswear is booming business and stimulates the development. Also within the area of healthcare the development of so called intelligent textiles is starting.

	Feedback which links to information	Information containing feedback
Direct feedback (On Body)	Vibration, temperature	Vibration pattern
Indirect feedback (Outside Body)	Audio, Visual	Visual, Audio
	Impulse feedback	Continuous feedback

Figure 4.1 *Feedback and information*

4.1 Smart textiles and design for healthcare

With the fast development of different technologies clothing becomes an interesting partner for the integration of sensors and actuators. Clothing as second layer of the human body create new opportunities for healthcare related products and systems. With the integration of sensors and actuators into clothing smart textiles enable a doctor (and patient) to monitor a body without disturbing and uncomfortable hardware.

At this moment the development of smart textiles is at a starting point with high expectations from different markets as: leisure, sport, and healthcare. Projects as EASYTEX and Clothing Area Network [16] explore scenarios of the future and inspire for new applications. Another example is TNO that shows the possibilities of physiological measurements with the presentation of the intelligent firefighters garment.

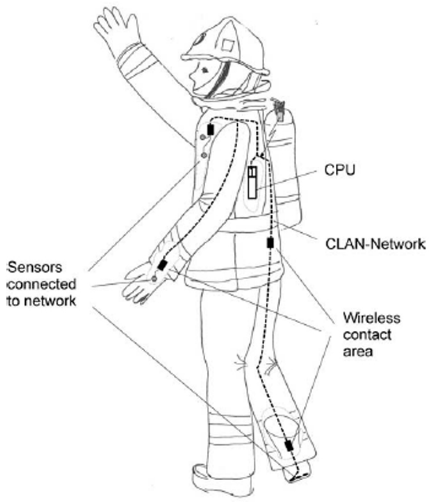


Figure 4.2 *Concept fire-figther's gear*

For the prevention of decubitus it would be very interesting to monitor the pressure, temperature, and humidity of the skin. For people with SCI, the lack of sensory input disables the body to react on influences from the environment. With the implementation of sensors it will be possible to 'sense' the environment and react on it. The shape of the body influences the pressure measurement and it would be much better to shape the measurement around the human tissue. Clothing is a medium that separates the environment from the human tissue. Underwear is the first layer and has direct interaction with the skin, the middle layers function as isolation and the outer layers as protection and appearance. Especially the clothes that have direct and continuous contact with the body can be used to integrate sensor for monitoring physiological parameters as humidity, pressure and temperature.

With the integration of sensors in textile constructions it will be possible to design clothing that actively monitors the body and the interaction with the environment. With the information it will also be possible to protect the body from the environment. At this moment the development is in its starting phase but more products with intelligent textiles enter the market. Next to sport and leisure wear also garments for the healthcare sector can profit from innovative clothing.

To integrate electronic components into clothing the components should be designed in a functional, unobtrusive, robust, small and inexpensive way. Especially the requirement unobtrusive is important because a physical obtrusive design (rough, sharp) could improve the risk on pressure sores. The sensor must be designed in a way that its physical condition doesn't have a negative affect on; pressure, shear or other physiological conditions.

The development of smart textiles seems to support the vision described in chapter one. Clothing with technologies that monitor the body increase the freedom of movement for the patient. The development also includes a new role of the doctor. The doctor as supervisor of the interaction between device and body instead of the mediator between device and body.

From different studies and experiments several technological textile solutions are designed to measure physiological elements. The textile spacer is designed to measure the pressure on a surface. Two conductive layers separated by a spacer (textile with a physical resistance) are connected when the pressure on the surface is higher than the physical resistance of the spacer. Another sensor that is created with textiles is a moisture sensor. The sensor is woven with conductive yarn and exists out of three layers. The two outer yarns are connected with a power supply and the middle layer is a 'normal' yarn. When the humidity increases the resistance of the middle layer decreases and this difference is translated into humidity. A third sensor that is interesting for decubitus prevention is a hybrid textile that measures temperature. The voltage drop of a copper wire is measured and the extracted resistance relates to the temperature. The sensors in combination with chips create smart textiles.

Important for decubitus prevention is comfort of clothing. It is important to integrate the sensors in a way that they don't increase the irritation while

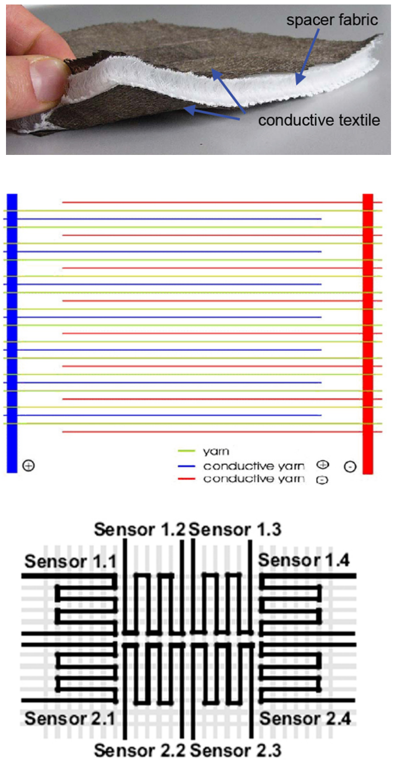


Figure 4.3 *clothing sensors*

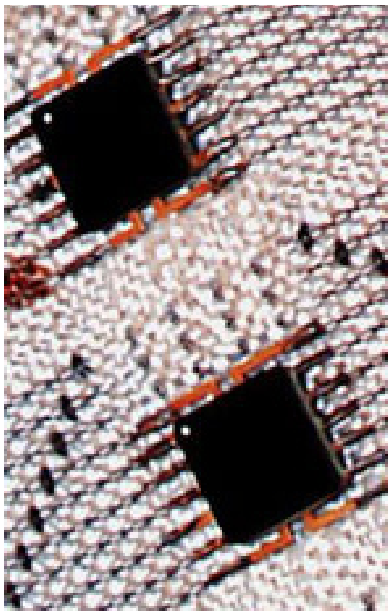


Figure 4.4 *integrated chip*

measuring.
Besides the integration of technology into fabrics, it is also important to be aware of different needs and restrictions related to clothing: aesthetics, functionality, and availability. "Clothing should enhance an individual's self esteem and be attractive to both the wearer and others. It should also be comfortable and appropriate for any physical requirements. In addition it should be easily available for reasonable price." [17]. Although the main task is to develop a prevention method the requirements will be kept in mind for further development.

4.2 Tactile feedback

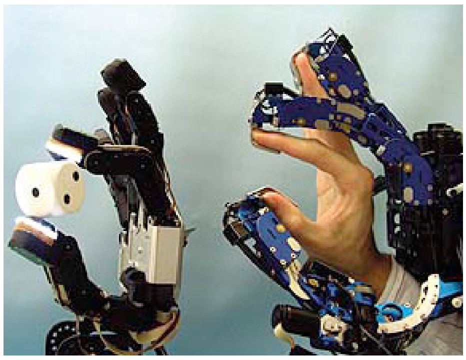


Figure 4.5 *Haptic interaction*

Tactile feedback in human computer interaction often is an interaction between a sensor, actuator, and the user. Both sensing as actuating, from both the system as the user, take place at the same area. In the case of a person with a SCI the area of sensing and actuating are interconnected. This interconnection is unnatural and therefore difficult to substitute. As inspiration and guidance for the design of the feedback a study [18, 19] from Karon MacLean is used. The study explains how haptic feedback can be used to best effect in interactive applications. Touch is a unique way of interaction and includes many different information properties. In most cases the user actively explores the environment and starts a haptic interaction with the object. For this project an interaction partner (tactile feedback) is proposed to replace the real interaction partner (seating surface). In comparison with the examples from the study this set up make it difficult for the user to explore the interaction partner.

4.2.1 Model for multi-sensory interaction

User

When designing for people with a spinal cord injury it is necessary to focus on possibilities but also on possible limitations. It is also important to focus on privacy issues because the feedback includes information about the body (information that is normally processed within the body). Another important aspect is the level of attention, does the user need to pay attention to the device all the time or only at specific moments.


Figure 4.6 *User*

During the concept development three types of feedback are defined: support, demand, and play. Support feedback naturally supports the user with feedback. This method can be compared with training-wheels. Demand feedback forces the user to obey to the information that is given. An example of this type of feedback is an airbag. The third type of feedback is play. This method presents the feedback in a playful way.

An example that could be used for this project is the game 'Hit The Mole'. This could be played by changing pressure patterns to relieve pressure.
Feedback mediums as light and sound are difficult to protect from other people's perception. Because the part of the body that has continuous contact with the environment (wheelchair) is cut off from the nervous system tactile feedback is difficult to integrate within the wheelchair.
The goal is to design feedback that supplies suggestive guidance and is integrated into the natural environment of the user. Tactile feedback is used to communicate the information from the real interaction area to an artificial interaction area. This artificial area is the upper part of the body that isn't affected by the SCI. The feedback may not disturb the user during daily activities and therefore the user is always in control.

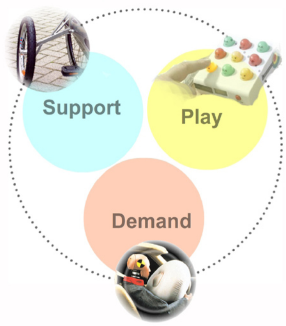


Figure 4.7 *3 types of feedback*

Environment

The model of multi-sensory interaction is mostly used for virtual environments. Usually a CAD model functions as environment. For people with SCI the environment is the place where the body (without the ability to sense) interacts with the world (in this case the wheelchair). An interesting factor of this environment is the level of irritation. As described in previous chapters different factors influence the irritation. For this concept it is important to detect peak pressures.


Figure 4.8 *Environment*

Physical Interface

The physical interface is every object that accepts input from and provide output to the user for the sensory modalities. With a pressure measurement device the interaction of the body with the wheelchair is monitored. Force Sensing Array (FSA) is a system that is normally used for the selection of decubitus prevention cushions. With the system it is possible to visualize pressure distribution. The input that is gathered for the supporting feedback are peak pressures. When a peak pressure is located the system translates this into


Figure 4.9 *Actuator*

supporting feedback to guide the user in a position that avoids peak pressures. Because the user cannot sense with the part of the body where the irritation takes place this information is translated by multiple actuators. The actuators communicate with different tactile patterns to inform the user about harmful situations. With the information the user is able to avoid these. The modality that is selected are multiple vibration units that are located on the upper part of the body.

Interaction Model

With the interaction model the relation between user and environment (wheelchair) is defined. The user interacts with the prevention device within an environment where already different types of information are around. This information is communicated over different mediums (audio, visual, and tactile). The physical interface interferes (with only tactile information) the existing information to guide the user to a new posture. The feedback is created with information from a measurement device. This measurement device detects peak pressures and translates this information into tactile direction patterns that instruct the user to change his posture. When the measurement device detects a peak pressure it measures the location and starts a feedback pattern in the opposite direction. With this principle at a later stadium other factors (shear, deep tissue pressures) of irritation can be implemented.
Because the use of tactile feedback is at its starting phase different experimental models are developed. From different experiments the method will be selected to communicate the information from the measurement device.

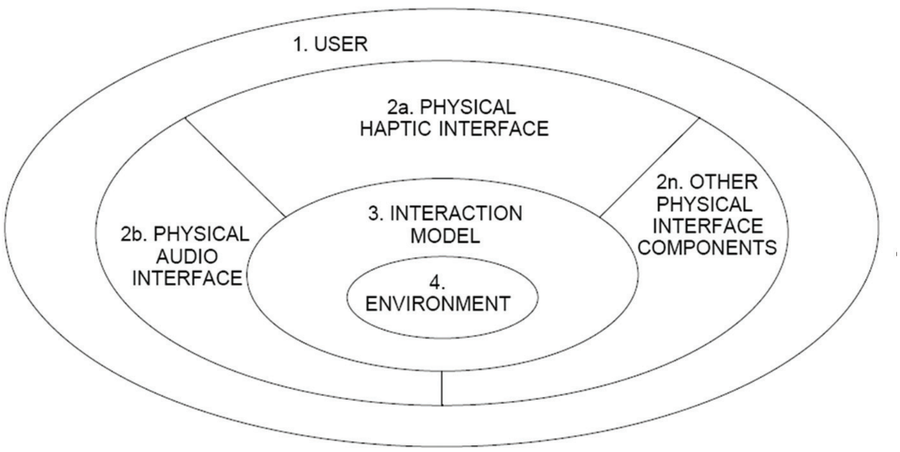


Figure 4.10
Model for multi-sensory interaction

4.2.2 Experimental models tactile feedback

There are only a few products on the market that use tactile information as interaction medium. The product that is best known is the cell-phone. The vibration function alerts the user for a call or a message. Another example is the tactile feedback integrated into game consoles. This feedback is used to intensify the user's gaming experience. The difference between those two tactile interactions is that the first feedback message refers to information while the second feedback message itself contains the information. For the tactile feedback that is designed for decubitus prevention the feedback that contains information is most appropriate.

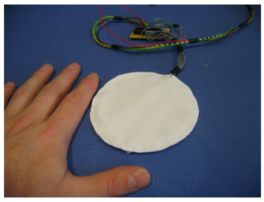


Figure 4.11 *Model A*

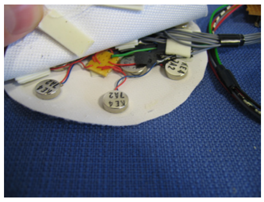


Figure 4.12 *Model A*

Tactile feedback that contains information is most interesting because it is most similar in comparison with touch. Another reason is that with information containing feedback the user doesn't have to link the incoming information with earlier developed knowledge. With an experiment is explored how vibration motors can be used to communicate different types of feedback. Two tactile models are designed to test the influence of distance and frequency for the perception of tactile feedback.

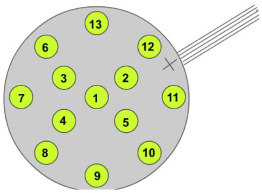


Figure 4.13 *Model A*

Model A is a patch with a diameter of 10cm that contains 13 vibration motors. The distance between the vibration motors is +/- 2cm. Model A explored the neck, back, arm and belly. The patch is designed as dynamic vibration unit. The patch is programmed with 5 different patterns. When it is possible to identify 5 different patterns in theory two patches are able to communicate 25 messages.

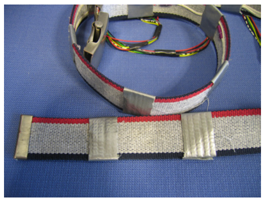


Figure 4.14 *Model B*

Model B is a belt of 100cm that contains 13 vibration motors that are placed 8cm from each other. With the belt it is possible to communicate pulses and linear patterns. Model B is explored at the larger parts of the body (arm, chest, back).

Figure 4.15 *Model B*

For both models the MOT-10 is used. The vibration motor with a diameter of 10 mm and a height of 3mm is integrated into textile. The weight of the motor is 1 gram and it works on 3 Volt, 70mA.

With both models is tested if it is possible to perceive different patterns. Also is explored the experience of the feedback.

Although some parts of the body were more sensitive than other

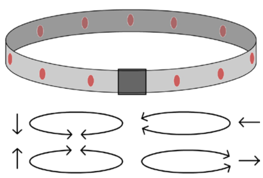


Figure 4.16 *Model B*

parts it was not possible to recognize different patterns with model B. It seemed that the skin was too sensitive for the frequency of the motors. With model A it was easier to recognize different patterns. The 'walk' of the motors was good to perceive. Both models were perceived unpleasant when they were placed on sensitive areas as the neck and wrist.
The exploration showed that when vibration motors are placed close together the skin cannot sense individual motors. Also different patterns are difficult to identify. When multiple sensors are placed over a longer distance, and act by turns, it is possible to sense individual motors and the direction of a movement.
The use of haptic feedback as interaction medium is a new experience for most users and therefore needs time to learn. The first experiments with haptic feedback indicate that the learning curve increases after short-time practice [20].

4.3 Prototype 1.0

Simulating caressing (figure 4.18) is the starting point for the development of feedack for decubitus prevention. The introduction describes a study that identifies two types of vibro-feedback: impulse and continuous. Continuous feedback appears more common and refers to situations where contact remains over time. Because the feedback is designed as a supporting tool the goal is to design a continuous feedback that is perceived natural an intuitive.

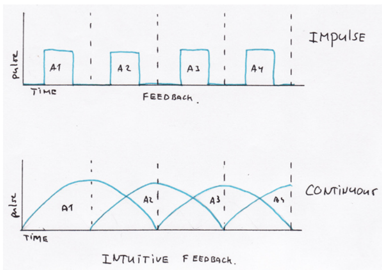


Figure 4.17 *impulse and continuous feedback*

During the exploration linear movement is perceived with thirteen vibration motors. Single pulses (figure 4.17) that were activated over time and distance communicated different movements. Because a delay and distance between the pulses it was difficult to perceive a connection between to pulses. By decreasing the delay between two pulses or overlapping pulses the relation becomes more clear.

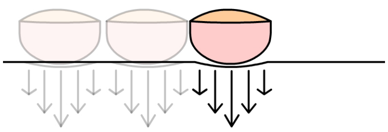


Figure 4.17 *feedback pattern caress*

Prototype 1.0 included twelve vibration motors that were controlled with a microcontroller. Because technical limitations only six of the vibration motors were able to communicate with different frequencies.

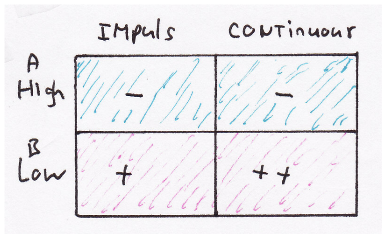


Figure 4.19 *Vibration variation*

The perception of prototype 1.0 was better than the exploration model. The decreased time between two individual motors results into an improved perception of movement and its direction. With the information from prototype 1.0 a new version is developed for testing.

4.4 Feedback device

For a validation of the tactile feedback a new prototype is developed. The knowledge from smart textiles and the explorations of the two models is combined. With the integration of conductive yarns is tried to improve the flexibility of the device. With the addition of technical components in combination with software the capabilities of the vibration motors is improved.

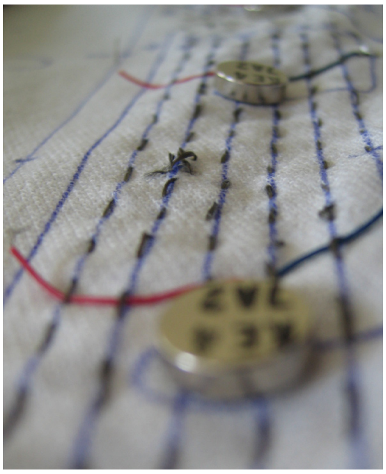


Figure 4.20 *Conductive yarn*

During the development of the prototype different failures occurred. Noise created by the vibration motors effected both the microcontroller as the led-driver. Another problem was the power supply for different components. To stabilize the prototype another led-driver is added and the power supply is divided. To minimize the risk on noise the conductive yarn is replaced with traditional wires.

Explanation

The feedback device is placed around the upper part of the body. With sixteen vibration motors there are sixteen possible starting points to communicate a direction. For the prevention of decubitus 8 starting points are interesting for posture feedback [22]. These 8 starting points refer to 8 defined commonly used postures. The nine posture (neutral) is not defined with this model. This because as standard prevention method 'lifting' is used. With lifting the user lifts his body which enables the cushion to shape and his body to relief from pressure. The message for lifting will be defined in a later stadium of the design process.

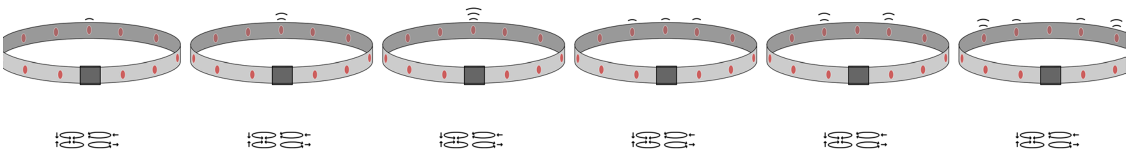


Figure 4.21 *Visualization forward vibration pattern*

To communicate a recommendation for a posture change a motor start vibrating followed by 5 other motors at each side. Each motor starts with intensity 0 and increases this to 16 before it fades out (figure 4.20). When the intensity is at its maximum the next motor starts.

Technical specification

The final prototype that is developed for the validation exists out of sixteen vibration motors. With these sixteen motors it is possible to start from eight different points a tactile vibration pattern. The sixteen vibration motors are controlled with two led-drivers that each control eight vibration motors. Both led-drivers are controlled with an Arduino microcontroller (appendix 4.4) that communicate different feedback patterns. The frequency, time, and delay between two pulses can be varied.

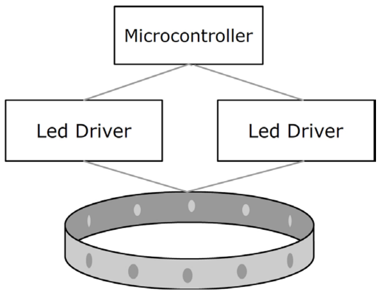


Figure 4.22 *Lay out*

As led-driver is used two MAX7313 that through I2C with the Arduino. The 16 I/O ports enable the Arduino to individually control each motor. Because the vibration motors develop some noise two led-drivers are used to avoid problems.

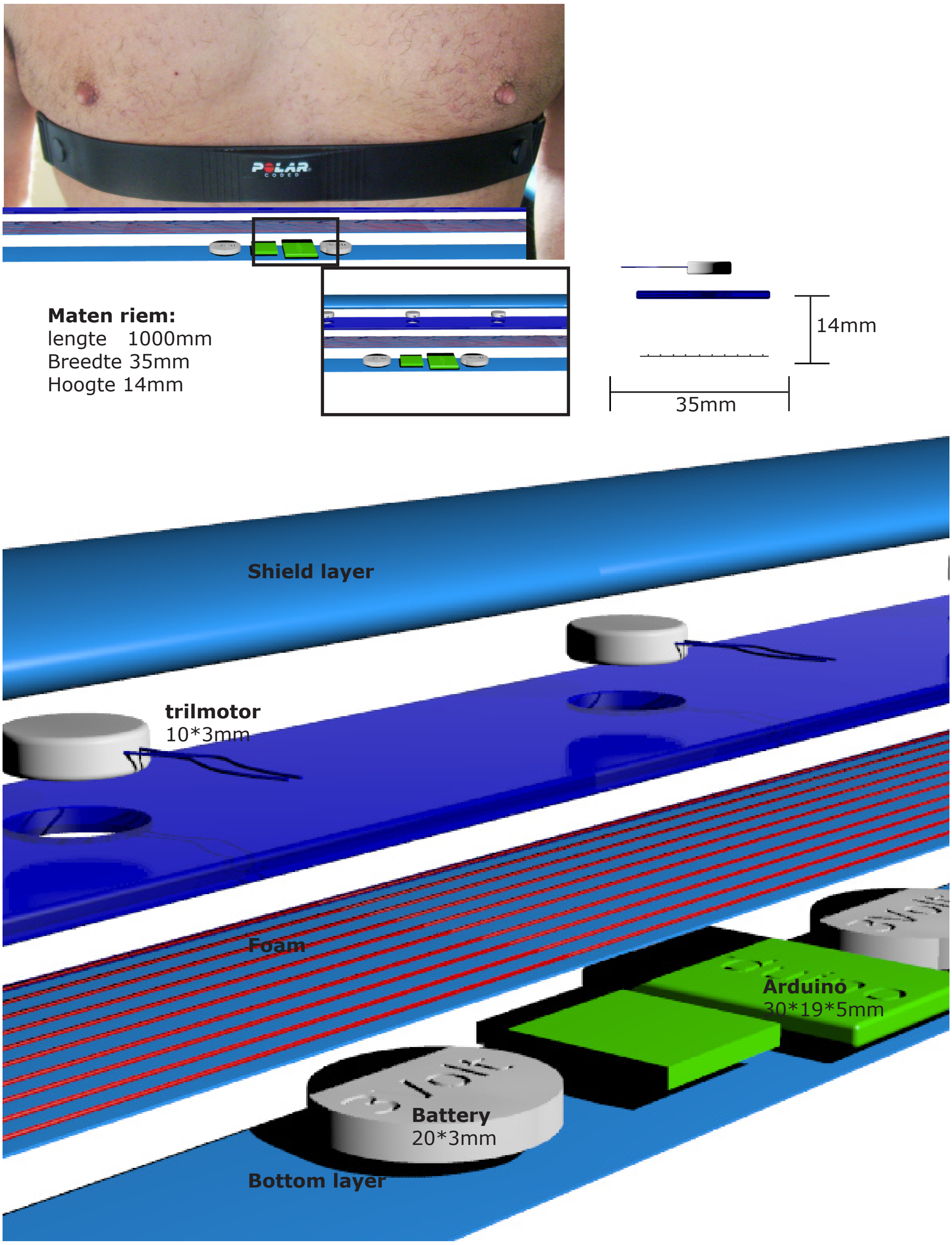


Figure 4.23 *Lay out feedback decive*

4.5 Measurement device

To monitor the interaction between wheelchair and user sensors are needed that can sense pressure. There are a range of pressure measurement systems that are used for different medical applications. Systems as Tekscan, X Sensor and FSA work with a similar principle and can all used as pressure monitoring for decubitus prevention. The system that is used for this project is FSA seating assessment from Vista Medical Canada. In contrast with Tekscan and X ray this system doesn't allow access to its software for research. With the software it is possible to change the configuration and calibrate the sensors. Without the protocol it isn't possible to use the software from FSA. To use the system as input for the feedback system it was necessary to develop software that reads the sensors. Before the development of the software started the communication between the FSA and the computer is analyzed (appendix 4.5). With the results from the analysis it is possible to read the sensors with the Arduino microcontroller.

The Arduino microcontroller reads the values of the sensors and processes these into matrices that are send to Arduino microcontroller (figure 4.17). Because the short memory of the Arduino is too small for the data send by the FSA for the prototype Microsoft Visual Basic is used to monitor the seating surface and control the feedback belt.

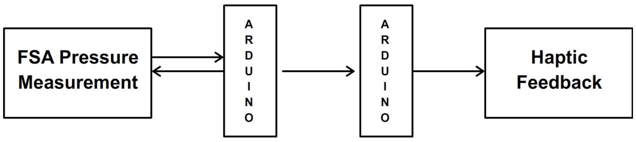


Figure 4.17 *communication*

Most important for this system and same time most difficult for risk determination; how much pressure at what time is harmful? With the current knowledge it is not possible to define a clear threshold. Known is that static postures and peak pressures are harmful. During the expert validation in chapter 5 the method for detecting irritation is discussed.

With Visual Basic the 256 pressure sensors are read and divided into nine sections. For each section is measured if a certain value crosses the threshold (30 mmHg). With a timer is measured often the threshold is crossed during a set time (20 during 25 seconds with 4 readings a second). When 20 readings during 25 seconds are above 33mmHg the system

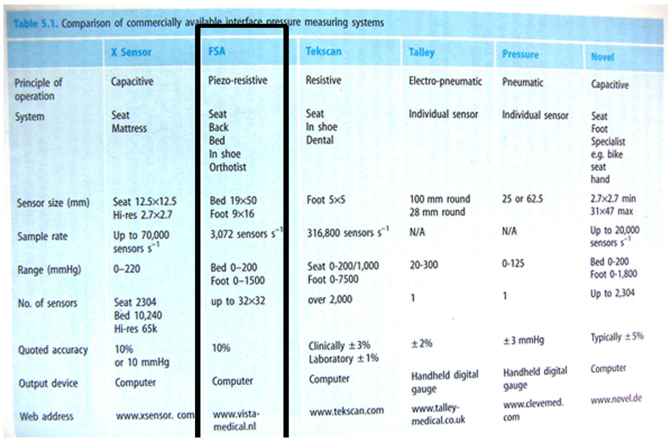


Table 5.1. Comparison of commercially available interface pressure measuring systems

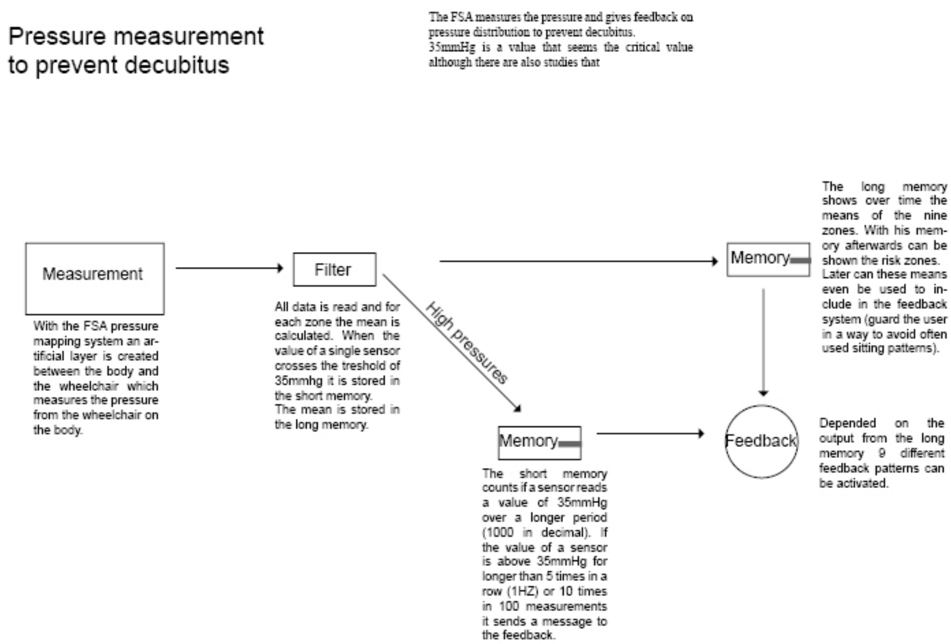
	X Sensor	FSA	Tekscan	Talley	Pressure	Novel
Principle of operation	Capacitive	Piezo-resistive	Resistive	Electro-pneumatic	Pneumatic	Capacitive
System	Seat Mattress	Seat Back Bed In shoe Orthotist	Seat In shoe Dental	Individual sensor	Individual sensor	Seat Foot Specialist e.g. bike seat hand
Sensor size (mm)	Seat 12.5×12.5 Hi-res 2.7×2.7	Bed 19×50 Foot 9×16	Foot 5×5	100 mm round 28 mm round	25 or 62.5	2.7×2.7 min 31×47 max
Sample rate	Up to 70,000 sensors s^{-1}	3,072 sensors s^{-1}	316,800 sensors s^{-1}	N/A	N/A	Up to 20,000 sensors s^{-1}
Range (mmHg)	0–220	Bed 0–200 Foot 0–1500	Seat 0-200/1,000 Foot 0-7500	20-300	0-125	Bed 0-200 Foot 0-1,800
No. of sensors	Seat 2304 Bed 10,240 Hi-res 65k	up to 32×32	over 2,000	1	1	Up to 2,304
Quoted accuracy	10% or 10 mmHg	10%	Clinically ±3% Laboratory ±1%	±2%	±3 mmHg	Typically ±5%
Output device	Computer	Computer	Computer	Handheld digital gauge	Handheld digital gauge	Computer
Web address	www.xsensor. com	www.vista-medical.nl	www.tekscan.com	www.talley-medical.co.uk	www.clevemed. com	www.novel.de

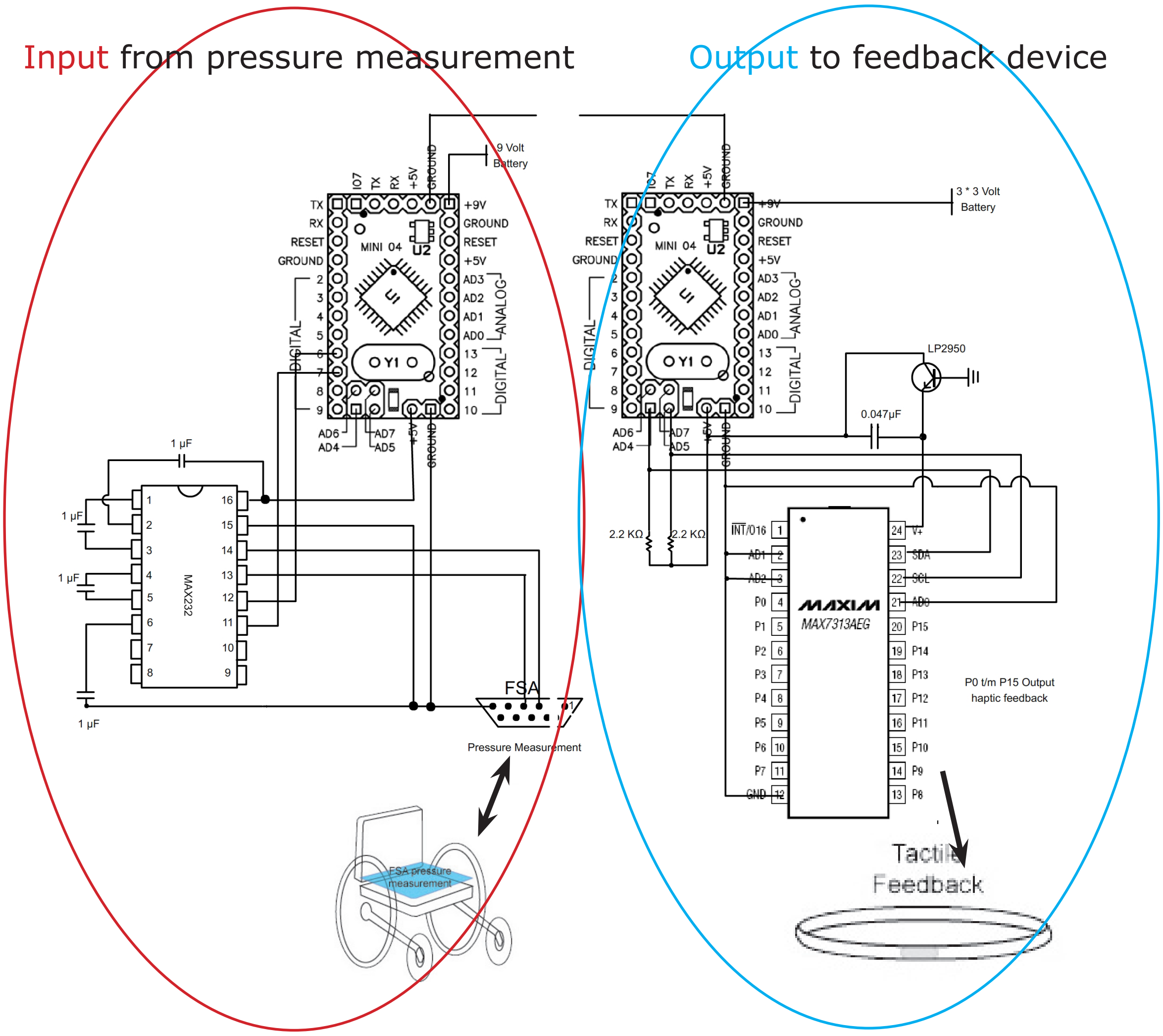
Figure 4.16 comparison measurement systems [x]

will activate a vibration pattern that will guide the user into a new posture.
Because each person has a unique anatomy the segmentation of nine measurement zones need to be adaptable. The adaptation must ensure that there is a symmetric measurement of the seating surface. Also the time and threshold needs to be adaptable because the condition of the patient affects the sensitivity of decubitus.

Future vision

The reason that the FSA is used and not a piece of underwear, as proposed during the concept development, is that there are too many limitations. Although in theory textile sensors are developed for detecting different physiological elements it is practically not possible to integrate them into underwear. The use of a measurement as the FSA has as main disadvantage the limited flexibility. At the moment the measurement is integrated into a piece of underwear the user can monitor his body on every surface. Therefore it is very interesting to find out what are the minimum numbers of sensors needed for prevention and is it possible to only focus on posture?




Input from pressure measurement
Output to feedback device
9 Volt Battery
3 * 3 Volt Battery
MINI 04
U2
Y1
TX
RX
RESET
GROUND
+9V
+5V
AD0
AD1
AD2
AD3
AD4
AD5
AD6
AD7
IO7
DIGITAL
ANALOG
1 µF
MAX232
FSA
Pressure Measurement
FSA pressure measurement
LP2950
0.047µF
2.2 KΩ
MAX7313AEG
P0 t/m P15 Output haptic feedback
Tactile Feedback

5. Validation

Introduction chapter

With a quantitative study the efficiency of the feedback is evaluated. This study is an abstraction of the project and only focuses on the designed feedback. The results of the test not only support the project with valuable feedback but the outcome is also relevant for other tactile applications. With the test is evaluated if the feedback is understandable, sufficient, and how tactile feedback works in comparison with audio feedback.

With a qualitative study the product is validated by experts and its future users. Through scenarios different properties of the system are discussed. With the outcome of the validation it is possible to optimize the system for further (clinical) testing.

The results of both studies are not only interesting for the design process, it is also interesting for the client of the project. Where the expertise of the experts enable the designer to fine-tune the design, the validation of the user already delivers insights about the user's interaction and expectations of the product.

5.1 Validation with experts and future users

Validation experts

The expert validation is not only used to validate the prototype but also to check through a scenario how the product fits within the big picture of decubitus prevention. For the validation experts with different backgrounds in decubitus are asked to give feedback. The goal is to validate the concept with experts on decubitus prevention. The client Bos Medical and its two partners in product development will also validate aspects that are related to the development of the product.

Bos Medical works in close collaboration with two companies that are involved during innovation processes. One is an external Industrial Designer and the other a production and development company for medical applications (Unitron). With a walkthrough the three stakeholders are introduced to the project and the developed product.

The validation consisted out of three parts; 1. the developed prototype, 2. the future development, and 3. the market position of the product.

1. The developed prevention method involves the user during the prevention. By involving the user the awareness improves which is a very strong point. The developed prototype is based on two factors of decubitus: peak pressures and posture. It is interesting to study the relation between both factors. If there is a possibility to eliminate pressure, would it be possible to monitor decubitus prevention with only posture information, and how much (extra) effort will this take for the user? Because

the system might be less accurate a broader tolerance is needed that might result in more (unnecessary) posture changes. At the other hand is it interesting to look if other causes of irritation as; moisture, temperature, shear, and deep tissue pressure can contribute without compensating on the usability. Another subject was the possibility of pre-programmed posture support which helps the user to increase his activity. Also for this solution the user will need to participate more active.
2. The future development of the product is another interesting part of the project. Thinking about further development is important for development of the product at a later moment. Little changes at the early phase will prevent big changes at a later phase. Important key points are: comfort, weight, integration into clothing, power supply, adaptation to different body seizes. Although it is not necessary to take all these point into account for the first prototype it needs attention for the future vision of the project. Besides the key points also the bigger picture of the development is discussed. For medical products it is necessary to built a support from different stakeholders. The first start is made with a quantitative test that focuses on the tactile feedback the second step is to start clinical testing. Only with the support of a clinical test it is possible to introduce the product on the market.
3. The product is developed for the prevention of decubitus. With the product it is possible to avoid harmful situations and therefore the development of decubitus. During the validation the product is placed at different stages of decubitus and showed opportunities for involvement with rehabilitation sessions. Because for people with decubitus it is important to be aware of harmful postures this target group could also be focused on.
With the feedback device specific spots could be relieved from pressures. Because posture is not only important for decubitus prevention but also for other aspects of a spinal cord injury the tactile feedback might be interesting for other objectives.
A second feedback moment is organized with an expert on identifying risks on decubitus and methods for early detection. From the faculty Biomedical Engineering at the Technical University Eindhoven dr. ir. Cees Oomens gave his opinion about the prevention method. An interesting moment for the project because the input for the feedback is difficult to define.
For the prevention method the definition of irritation is used as input for the feedback, when does the user need feedback for change posture? Irritation is caused by many different aspects and it is therefore difficult to define. Because not all details about decubitus development are known it is also difficult to define a threshold. At the other hand is it not always necessary to have all information for decreasing the risk on decubitus. It must be said that most products for decubitus prevention that are currently on the market are all based on the curve from 1976. And although this

information is outdated most products help to decrease decubitus.
At this moment it is still difficult to define a critical moment of danger. Recent work [21] improved the curve of Reswick and Rogers (1976) and support the project with some guidelines. Interesting from this study is that in comparison with other

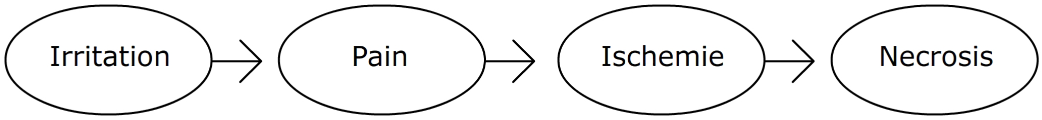


Figure 5.1 *Cell death development*

curves it shows a threshold for very short periods (figure 5.2). The study shows that peak pressures (>225mmHg) damage human tissue. From the study can also be concluded that long periods of relative low pressure (75mmHg) are also harmful for the risk on decubitus. This supports the studies that focus on the importance of posture changes and moments of pressure relief (lifting). Another study done by Joyce Black delivered some more specific information. With different categories thresholds are described that can be used as irritation guidelines.
From the discussion with Cees Oomens can be concluded that the prevention method is very interesting and especially in the broader picture of decubitus prevention. Connecting this work with their research show promising starting points for new

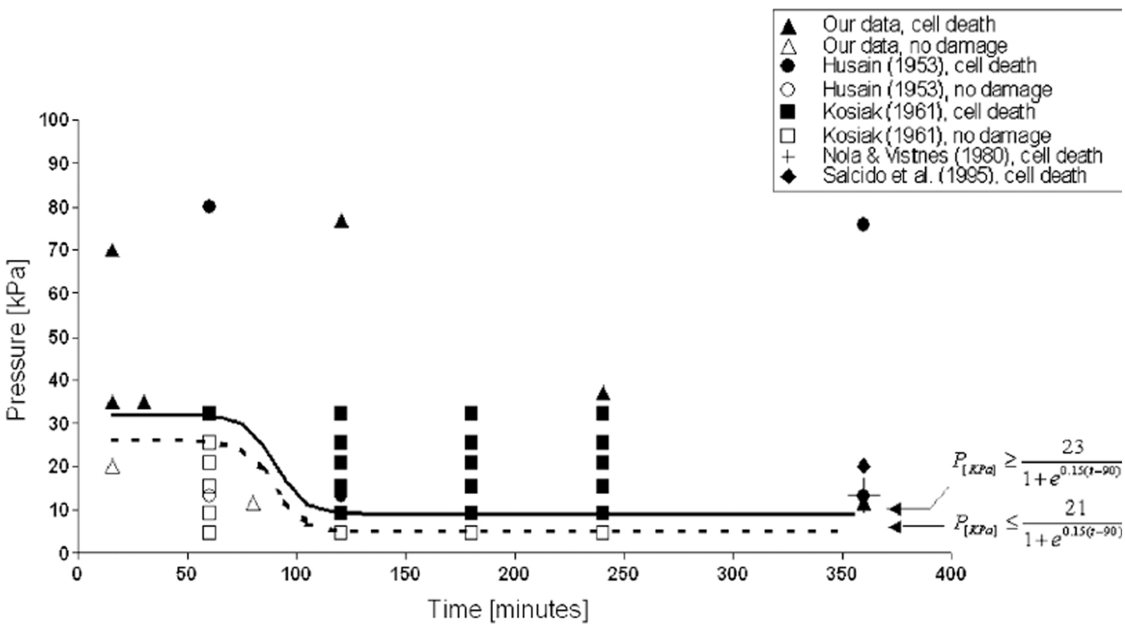
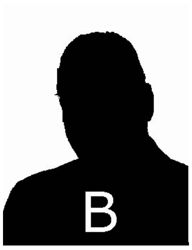


Figure 5.2 *Pressure-time cell death treshold for straited muscle of albino rats, E. Linder-Ganz et al. (2006)*

prevention methods. The current way of measuring, irritation (peak pressures), is limited but acceptable. It is difficult with the current knowledge to define clear pressure-risk categories. Because the method of preventing is relevant new findings on irritation can be easily adapted within the prevention method. The ability to improve the posture activity is promising because this has a major influence on development of decubitus. Also for this factor it is difficult to define a threshold or scheme that defines the 'right' posture activity.

Validation future users



To validate the product by its future user the prevention method is demonstrated to one of the persons that was also involved in the user studies (user B). The person is a type of user that actively cooperates with new prevention methods. During the validation the measurement tool is explained and the feedback device is demonstrated. With the computer different patterns were communicated that were well understood by the participant. After the demonstration the method is discussed with the user. The validation resulted in many practical questions:
Can I change the strength of the vibration signal, Can I charge the batteries, Is it water resistant, what if the belt rotates do I still get the right feedback, What does it cost, can I change the size, what if I don't feel the signal the first time, what if I don't want to change posture?
The answers of those questions are very important for the development of this prototype into a prototype for clinical testing. Although there are no real rules for introducing a new medical product into the decubitus market a product will only be accepted after clinical tests. For such a test a prototype needs to be developed that answers all the questions above.
Besides the questions the participant was very enthusiastic about the idea that he didn't need to think about the risk on decubitus with the product. Where this comment might seem a compliment it also emphasis the importance of the working of it and the abilities of the method compared to the other factors that influence the risk on decubitus.

5.2 Validation feedback

Posture is an important aspect that is related to decubitus development for people with a spinal cord injury [22]. A recent study [9] shows that because of missing information from the body immobilized people change their posture less frequently. Relieving pressure is important for preventing decubitus. By training patients to change their posture frequently is tried to minimize the risk on decubitus. To support patients during the rehabilitation a tactile support is designed that guides and stimulates posture changes.

That tactile feedback is an interesting medium for new interactions, is supported with the many studies and design projects that focus on tactile interaction possibilities. It seems that sense of touch is an overlooked and underutilized sensory modality that has great potential. This new medium is explored because more and more information is approaching the user and while doing this they are crossing each other's paths. Tactile interaction might result in new opportunities that enable interactions that minimize distraction from other information mediums (visual, audio). If tactile feedback can compete in efficiency and usability with other mediums (like visual and audio) is explored but the results of the first studies are promising.

A pilot study at Brunel University, UK [23] indicates that tactile interfaces are used successfully and may offer advantages over auditory interfaces for visual impaired people. Because visual impaired people rely on auditory information from the environment tactile feedback for navigation is a good alternative. The advantages of tactile feedback for visual impaired people is studied for specific situations and may also be useful in other situations and for other user groups. Another area where is experimented with tactile feedback is the automotive industry [24]. The study measured reaction times with different feedback mediums for collision warnings. The results show that tactile feedback is a good competitor for audio feedback.

Especially when a user needs his visual and/or auditory skills for other activities, tactile feedback seems to be an effective 'new' feedback medium.

For this study about posture feedback for people with a SCI tactile feedback is proposed as feedback medium. Tactile feedback is explored to design an intimate and natural interaction between patient and feedback system. Because the feedback is given during daily activities tactile feedback might better fit the abilities of perception from the user than audio or visual feedback. Another element is that tactile feedback seems more subtle and therefore more natural and private in providing information about the human body. Tactile feedback offers the advantage that no attention has to be paid at moments that no information is supplied and the information is only accessible for the user and not for other people around.

An experiment is set up to compare the effectiveness of tactile feedback with audio feedback for postural guidance. There are several ways to test the effectiveness of tactile feedback and four possibilities are discussed below.

1. One way of testing is the comparison between the use of impulse versus continuous feedback. New for this system is that it doesn't work with impulse feedback but with continuous feedback. Instead of a single vibration a movement of vibrations stroke the user. With this type of feedback the user not only gets information about a specific location but also about a specific direction (also the speed of the movement could be used to give information). Because the use of tactile feedback itself is still new this test would be more interesting as a follow up study. The results of the test are only meaningful if tactile feedback itself is more explored.

2. Another possible experiment is the comparison of effectiveness between tactile and visual feedback. The disadvantage of visual feedback is that the user needs to pay attention to gather information. For receiving tactile feedback the user doesn't need to pay attention till the moment of interaction.

3. An experiment which seems most interesting for the project is an experiment which compares tactile with audio feedback. This because these two feedback mediums are most identical and would be both appropriate for posture feedback. There are different ways of comparing the two feedback mediums. One way of testing is designing an exact audio copy of the tactile feedback. The belt that can start a vibration pattern from 8 different locations is compared with an audio set up with 8 speakers around the subject. Both feedback mediums could be used as input for changing posture.

4. The same test can be done with audio feedback that contains the information within the message itself. Instead that the information is included within the direction where the signal is coming from the audio feedback will use the words; left, right, back, etc.

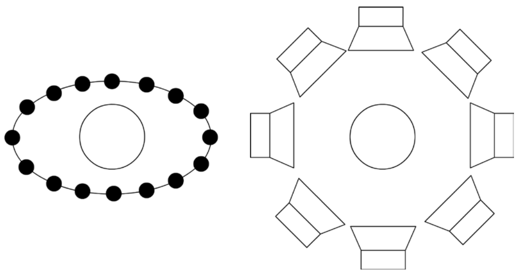


Figure 5.3 *Option 3: Eight speakers (left) versus sixteen vibration motors integrated in a belt.*

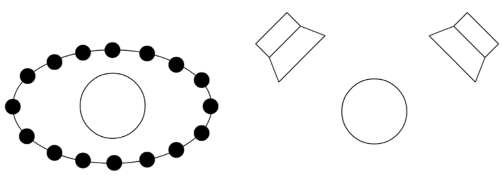


Figure 5.4 *Option 4: Two speakers with spoken text (left) versus sixteen vibration motors integrated in a belt.*

Both option 3 and 4 are appropriate for gathering information for the development of tactile feedback. Although option 3 is a good comparison, I think that option 4 is more representative because this way of audio feedback is already known by participants. The set up with 8 audio speakers is a direct copy of the vibration feedback but more unrealistic because this information supply is also new for the user.
Another important aspect for the experiment is the setting in which the both mediums are compared. Because tactile feedback often will be designed as 'second' information source, with which I mean that it will be used while other mediums as audio and visuals are already around, it might be good to test within an environment where other mediums (visual) are.

5.3 Experiment

Goal

The goal of the experiment is to test the effectiveness of tactile feedback in comparison with audio feedback. The set-up that is proposed for the experiment is a test which compares spoken audio with (continuous) tactile feedback. The tactile feedback is designed as posture feedback for wheelchair users with a SCI.

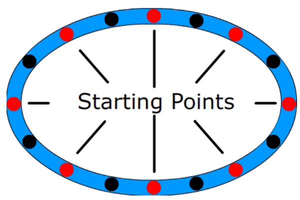


Figure 5.5 *Tactile feedback belt*

Participants

For the experiment 26 volunteers (22 men, 4 woman) from the department Industrial Design are recruited. None of them are involved in the study or join related studies. Participants ranged in age from 21 to 27 years, with an average of 24 years. 12 participants will be exposed to tactile feedback and 14 of them are exposed to audio feedback.

Set Up

The audio feedback exists out of four spoken messages (forward, backward, left, right) and are communicated with a headphone to the participant. The messages are spoken by a male computer voice. When receiving the audio feedback the user has to move his body into the direction that is spoken by the voice out of the speakers.
The tactile feedback is given with a belt that contains 16 vibration units that start from a specific point with vibrating (four starting points in total). The different patterns must stimulate and guide the user to change his posture within the line of the pattern. When the user receives the tactile information he has to move in line

with the direction of the vibration pattern. The belt that provides the tactile feedback is placed around the torso. The belt is worn under the outer layer over lightweight underwear.
During the experiment is measured if the participant moves the right direction and the time it takes to react. After the experiment a questionnaire (appendix) collects qualitative data about both feedback mediums.
For a good interaction between product and user the product needs to integrate itself into the environment. Because tactile feedback is often used in environments where other information is around it is necessary to test the product within an environment that is comparable with its future context. Because audio and tactile information is used during the experiment only visual information can be used as 'artificial noise' for the experiment. The artificial noise is created with a short cartoon without audio. The participant takes place in front of the screen, in a chair that can detect different postures.
During the test the participant receives posture changes and with a system is measured the time and posture change.

Measurement system

The chair contains 28 pressure sensors and is designed by Rick v.d Westelaken [25]. During the experiment the chair is used to detect the posture-change of the participant. The chair and both feedback systems (tactile and audio) are controlled

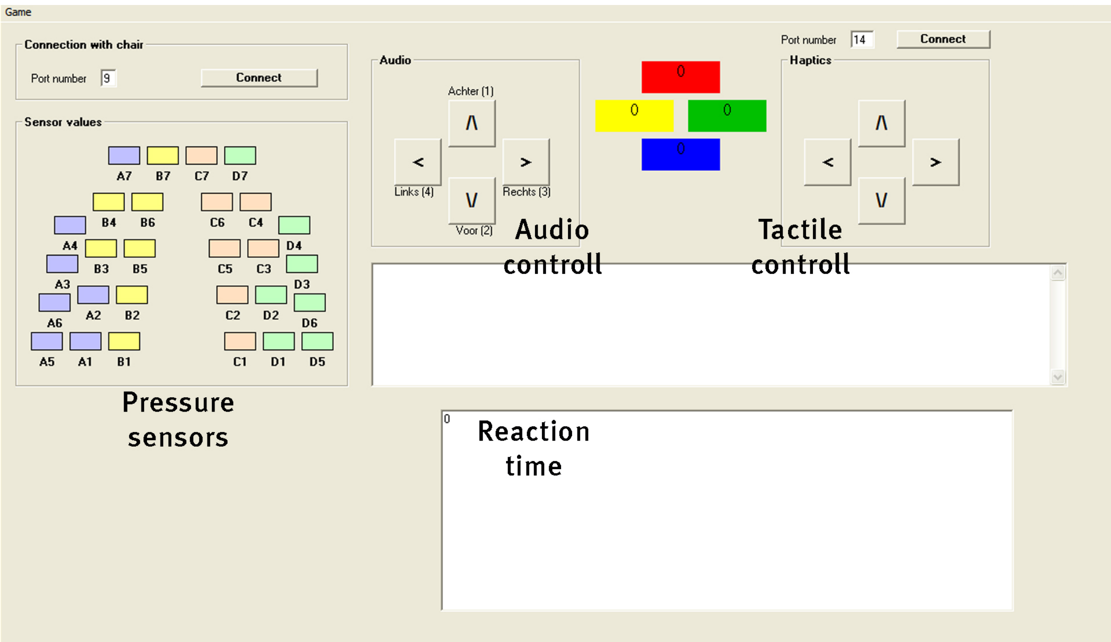


Figure 5.6 *Measurement tool*

by Microsoft Visual Basic. When the program sends a feedback signal (audio or tactile) it counts the time it takes for the participant to reach the right posture. When the participant moves the wrong direction no time will be recorded.

Procedure

Each experiment starts with a short introduction about the experiment. After the introduction each participant needs to sign the consent form. Before the test starts the participant will get 4 feedback examples that are used for the test he participates. During the examples the experimenter tests if the participant is good positioned on the chair (check on items as wallet or buttons that might influence measurement)..
The four movements (right, left, front, back) are tested and checked if the systems measures the changes.
When the examples are finished the test starts and each participant will get 12 different tactile or audio feedback patterns. During the experiment the participant watches a cartoon without the sound.
When a specific feedback is send by the system it measures when a 'new' posture is taken. This to prevent from 'false' measurements that are measured during changing the posture. After each measurement the participant is ordered to move back in a neutral position. Also when the participant moves the wrong direction is asked to move in a neutral position before the test continuous. Between each feedback is a randomized delay between the 5 and 20 seconds. Each participant will do one session, or tactile or an audio feedback session.
After the experiment the participant has to fill in a questionnaire and is debriefed by the experimenter.

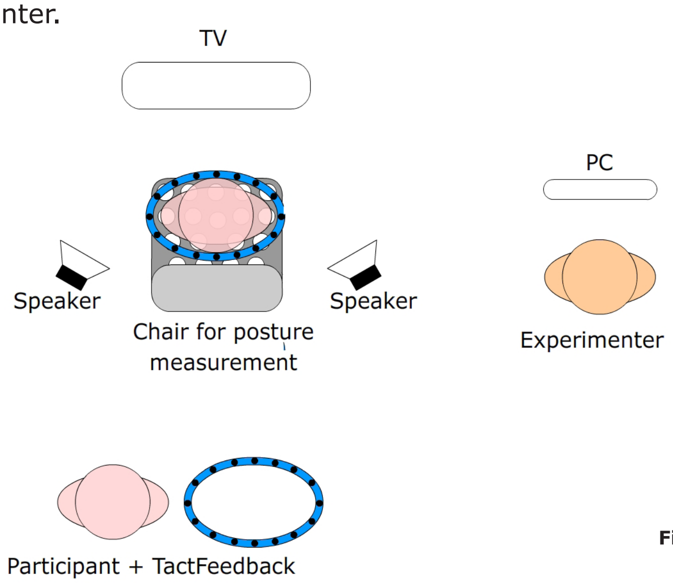


Figure 5.6 *Set up Experiment*

Results

From the experiment can be concluded that there is no significant difference in errors between the understanding of tactile and audio feedback (F(.59)=1.944, p=.177). This means that for communicating a posture change tactile feedback is an interesting medium. Another result is that there is a significant difference between tactile and audio feedback for time of acting (F(.86)=6.964, p=.015). This means that it takes more time to understand or act out the received message in tactile feedback. There might be two reasons for this result. The first reason is that the tactile command itself takes more time than the audio command (0.6 seconds). A second reason is the newness of tactile feedback. Instead of audio feedback the tactile feedback was new for most of the participants.

Descriptive Statistics

	con...	Mean	Std. Deviation	N
time	haptic	2.4908	.30134	12
	audio	2.0707	.39566	14
	Total	2.2646	.40863	26
error	haptic	.5833	.66856	12
	audio	.2143	.42582	14
	Total	.3846	.57110	26

5.4 Market introduction

Before a medical product can be introduced to the market the manufacturer first needs to decide if the product is concerned as a medical device. For the European market this means that the device must fit the description(s) of the EU Medical Device Directives.

Because it is not feasible to subject all medical devices to the most severe assessment different classes are defined (three in total). The type of class defines the type of assessment that is needed before a device may enter the market. The classification is coordinated by the manufacturer and according the classification the type of testing is defined. The device must meet the essential requirements irrespective of the class and be subject of the reporting requirements under the medical device vigilance system. After the product is assessed according the right class it may wear a CE Conformite Europeenne) mark.

Through a classification system that is supported with annexes the manufacturer classifies the medical device and if necessary (classes 2 and 3) contacts a Notified Body for assessing the product and process of testing. The Notified Body works in relation with the Competent Authority which ensures the safety of the inhabitants of the country. The Competent Authority acridities the Notified Body and is the only stakeholder that can withdraw the CE mark in case of a problem with the medical product. When a medical product is classified and receives a CE mark it can be introduced to all European countries, for the American market another assessment is needed.

For the CE mark it is necessary that the medical device satisfies the claim that is made by the manufacturer (performance of product) and guarantees the safety of the user. Dependent on the claim a product can be classified as a class 1, 2 or 3 product.

Classification Sensing Senses

To classify a medical product 18 rules are defined to support the classification process. The manufacturer must take into consideration all the rules in order to establish a proper classification for the medical device. The characteristic that rates the highest class determines the class for the device.

For the decubitus prevention method first needs to be decided if it is a medical device. According the first rule the device for decubitus prevention is defined as medical device:

‘medical device’ means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software necessary

for its proper application intended by the manufacturer to be used for human beings for the purpose of:
- diagnoses, prevention, monitoring, treatment or alleviation of disease,

At the current state of the project the product can be classified as a class 1 product. This means that the manufacturer can supply the device with a CE mark. With a class 1 classification the claim of the product (what's in the manual) is 'a device that senses peak pressures and gives support for posture changes'. Before the manual can claim that the product prevents decubitus this claim must first be proven. With this claim the device will need to be classified into class 2. When a product is classified into class 2 this means that the device must be clinical tested to prove the claims made by the manufacturer. To ensure the quality of the validation this process is assessed by the Notified Body (KEMA).

Clinical study

A clinical study is used to support the claim of a medical device. Before a clinical study is performed a claim must be defined. The second step is to collect publications of related products and technologies. The information that is missing, for example the effectiveness of the prevention, must be collected with a clinical validation. This validation must be done according the Declaration of Helsinki.
A clinical study starts with a investigational plan which must be approved by the Notified Body. The clinical investigation is documented with a clinical report. For this project a clinical study is needed when is claimed that the decubitus prevention method decreases the risk on decubitus.

What to test with a clinical study?

The product exists out of three elements that are interesting for classification. The three elements are the measurement, the feedback, and the user's (inter)action.
For the measurement it is important that it is able to detect peak pressures. With a technical report it is possible to explain the working and asses if the technology is appropriate for its function. Also the feedback can be described with a technical report. Because the use of tactile feedback is not very common the report must be supported with relating studies about tactile feedback. The supporting literature must guarantee the plausibility of the used technology. The feedback designed for this project is slightly different than the existing technologies and therefore a test is created to measure the understanding of the feedback.
As third element for classification 2 the 'result' of the product must be measured: what is the effect of the product on the prevention of decubitus? Because this takes

a lot of time and expertise this part is mostly coordinated by a company specialized on clinical studies. For this project it means that a specialist on decubitus exposes different patient's during a certain period to the decubitus prevention product. The procedure is defined by the external company and the specialist on decubitus is frequently checked.
When all three elements match the claim of the product the Notified Body is able to asses the classification of the product and agree (or not agree) with a CE mark.

Afterword

During the past years I had the opportunity to work at one of the most creative and innovative spots in the world. From the knowledge and expertise of both staff as students I developed myself into the Designer I am now. The Bachelor enabled me to develop the skills that are needed to manage design projects. During the Master I had the opportunity to define my own design projects and use the developed skills from the Bachelor to Master them. The Master thesis is the project where I could expose my identity and the skills I developed the past years.

As a designer it is a pleasure to have the ability to surprise, guide, and educate other people with my work. One of the biggest challenges is to design products or systems that improve the quality of the user's life. Healthcare therefore is an interesting domain for designers. The difficulty I experienced during my project was the complexity of decubitus and the many rules that are related to the development of medical products for European markets.

With the end of my graduation project there starts a new phase for the designed prevention method. The project resulted into new opportunities for decubitus prevention but before the prevention method can be applied to the market more information needs to be gathered. With the development and validation of the prototype is proven that in theory the method is able to prevent people from peak pressures. If this is enough to decrease the risk on decubitus needs to be validated. With a validation the behavior of the product needs to be analyzed in its future environment. Another important aspect is the implementation of the technology into clothing and seating surface.

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Appendices

Appendix 2.3-A Braden and Norton scale for risk determination

BRADEN SCALE FOR PREDICTING PRESSURE SORE RISK

Patient's Name ________________ Evaluator's Name ________________ Date of Assessment

SENSORY PERCEPTION ability to respond meaning-fully to pressure-related discomfort	**1. Completely Limited** Unresponsive (does not moan, flinch, or grasp) to painful stimuli, due to diminished level of con-sciousness or sedation. OR limited ability to feel pain over most of body	**2. Very Limited** Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness OR has a sensory impairment which limits the ability to feel pain or discomfort over ½ of body.	**3. Slightly Limited** Responds to verbal com-mands, but cannot always communicate discomfort or the need to be turned. OR has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities.	**4. No Impairment** Responds to verbal commands. Has no sensory deficit which would limit ability to feel or voice pain or discomfort..	
MOISTURE degree to which skin is exposed to moisture	**1. Constantly Moist** Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient is moved or turned.	**2. Very Moist** Skin is often, but not always moist. Linen must be changed at least once a shift.	**3. Occasionally Moist:** Skin is occasionally moist, requiring an extra linen change approximately once a day.	**4. Rarely Moist** Skin is usually dry, linen only requires changing at routine intervals.	
ACTIVITY degree of physical activity	**1. Bedfast** Confined to bed.	**2. Chairfast** Ability to walk severely limited or non-existent. Cannot bear own weight and/or must be assisted into chair or wheelchair.	**3. Walks Occasionally** Walks occasionally during day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair	**4. Walks Frequently** Walks outside room at least twice a day and inside room at least once every two hours during waking hours	
MOBILITY ability to change and control body position	**1. Completely Immobile** Does not make even slight changes in body or extremity position without assistance	**2. Very Limited** Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently.	**3. Slightly Limited** Makes frequent though slight changes in body or extremity position independently.	**4. No Limitation** Makes major and frequent changes in position without assistance.	
NUTRITION usual food intake pattern	**1. Very Poor** Never eats a complete meal. Rarely eats more than ⅓ of any food offered. Eats 2 servings or less of protein (meat or dairy products) per day. Takes fluids poorly. Does not take a liquid dietary supplement OR is NPO and/or maintained on clear liquids or IV's for more than 5 days.	**2. Probably Inadequate** Rarely eats a complete meal and generally eats only about ½ of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take a dietary supplement. OR receives less than optimum amount of liquid diet or tube feeding	**3. Adequate** Eats over half of most meals. Eats a total of 4 servings of protein (meat, dairy products per day. Occasionally will refuse a meal, but will usually take a supplement when offered OR is on a tube feeding or TPN regimen which probably meets most of nutritional needs	**4. Excellent** Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation.	
FRICTION & SHEAR	**1. Problem** Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, requiring frequent repositioning with maximum assistance. Spasticity, contractures or agitation leads to almost constant friction	**2. Potential Problem** Moves feebly or requires minimum assistance. During a move skin probably slides to some extent against sheets, chair, restraints or other devices. Maintains relatively good position in chair or bed most of the time but occasionally slides down.	**3. No Apparent Problem** Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair.		

Total Score

	Physical Condition	Mental Condition	Activity	Mobility	Incontinence	Total Score
	Good 1 Fair 2 Poor 3 Very bad 4	Alert 1 Apathetic 2 Confused 3 Stupor 4	Ambulant 1 Walk/help 2 Chairbound 3 Bedridden 4	Full 1 Slightly 2 Limited 3 Very limited, Immobile 4	Not 1 Occasional 2 Usually-urine 3 Doubly 4	
Name: Date:						
Name: Date:						
Name: Date:						
Name: Date:						
Name: Date:						
Name: Date:						
Name: Date:						
Name: Date:						

Appendix 2.3-B CBO list for risk determination (Dutch)

Tabel CBO scorelijst

Aantal punten	0	1	2	3
Mentale toestand	Goed.	Lusteloos gedeprimeerd. Gedesoriënteerd, angstig	Zwaar depressief, psychotisch Verward, volledig apatisch	Stuporeus, comateus.
Neurologie	Geen afwijkingen.	Geringe Stoornissen. Krachtsvermindering	Sensibiliteitsstoornissen. Lichte hemiparese x2	Hemiparese x2 Dwarslaesie: Onder Th.6 x3 Boven Th.6 x4
Mobiliteit	Goed.	Licht beperkt. Loopt met hulp de hele dag of regelmatig op. Rolstoelpatiënt met een goede armfunctie.	Voornamelijk bedlegerig: Alleen uit bed voor wassen en bed verschonen. Hele dag passief in de stoel.	Geheel bedlegerig.
Voeding en vochttoestand	Goed. Eetlust is goed. Goede huidturgor.	Matig: enkele dagen niet gegeten. Huidturgor matig, verminderde urineproductie	Slecht, langer dan 1 week niet gegeten. Bij braken en diarree Negatieve vochtbalans, dehydratie aanwezig.	Uitgeteerd: eetlust is sinds geruime tijd zeer slecht of afwezig. Er bestaat een ernstig gewichtsverlies, geen vochtopname.
Voeding	Eet zelf.	Parenterale voeding.	Krijgt sondevoeding, maar heeft geen eetlust. Wl niet eten.	Geen voeding.
Incontinentie	Geen	Af en toe urine	Voor urine en/of faeces urinecatheter of uritip.	Geheel incontinent
Leeftijd	Jonger dan 50 jaar.	50-60 jaar.	60-70 jaar.	Ouder dan 70 jaar.
Temperatuur	Lager dan 37,5 graden.	Tussen 37,5 - 38,5 graden	38,5 -39,0 graden Circulatiestoornissen	Hoger dan 39,0 graden Lager dan 35,5 graden.
Medicatie	Geen.	Corticosteroïden, slaapmiddelen, anticoagulantia (niet heparine)	Pijnstillers, Tranquillizers, cytostatica, orale antibiotica	Parenterale antibiotica.
Diabetis	Geen.	Alleen dieet.	Orale middelen.	Insuline.

Hoe hoger het aantal punten, hoe hoger het risico om decubitus te ontwikkelen

Niet verhoogd risico < 8 / verhoogd 8 - 12 / extra verhoogd risico > 12

Appendix 2.4 Decubitus prevention and pressure measurement

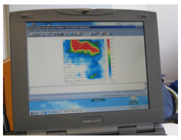
Drukmeting ter preventie van decubitus

Probleem

fase 1

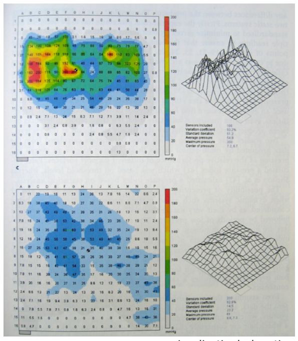
Een drukmeting wordt gedaan om de druk te visualiseren van een bepaald huidoppervlak op een vlak. Een drukmeting kan worden gebruikt om een keuze te maken uit het assortiment preventiekussens. Met een drukmat is het mogelijk een realtime visualisatie te genereren en daarmee een preventiemiddel te kiezen.
Met de drukmat is het ook voor de patiënt duidelijk te zien wat voor invloed de houding heeft op de druk van het lichaam op een vlak.

Meting



opstelling drukmeting

FAS drukmat



visualisatie drukmeting

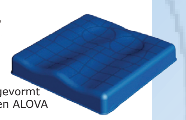
De druk van het lichaam op het vlak wordt met 256 sensoren gemeten. Rechts van de visualisatie wordt weergegeven; aantal actieve sensoren, gemiddelde druk, de maximale druk, en het druk 'centrum'.
Omdat een meting op een bepaald moment met een bepaalde houding wordt gedaan is dit in mijn ogen onvoldoende. Voor iedere activiteit (lezen, tv kijken, computeren, eten, etc) zou een meting gedaan moeten worden en een advies worden gegeven aan de patiënt. Omdat dit praktische problemen met zich mee brengt zou een realtime feedback systeem een mogelijkheid bieden voor de patiënt om zichzelf te monitoren.

Advies en preventie

Met verschillende materialen en technieken worden kussens ter voorkoming van decubitus aangeboden. Het doel van de kussens; het gelijkmatig verdelen van druk. Bij de drukmeting zullen een aantal kussens een goede drukverdeling aangeven maar wat bij veranderingen van temperatuur en een langere tijdspanne. Een voorbeeld is traag-foam dat een goede waarde aangeeft maar naarmate de tijd verstrijkt steeds hogere drukwaarde registreert. Ook de voorgevormde kussens leveren 'goede' waarde maar alleen als je correct zit. Deze voorvorming voorziet niet in een actieve zithouding het beperkt deze juist. Een meting met een ringkussen geeft aan dat deze de druk centreert en dus vergroot.
Met een drukmeting kan een preventiemiddel getoetst worden maar het effect over tijd en tijdens verschillende activiteiten is moeilijk te voorspellen.

Air flotation kussen

traagfoam



voorgevormt kussen ALOVA

ring kussen

Mogelijkheden

In mijn ogen is het geven van (realtime) feedback aan de patiënt over de drukverdeling van zijn lichaam een mogelijkheid een stukje controle terug te geven. Ook wordt er een bewustzijn gecreëerd van de invloed van zithouding op de drukverdeling.
De huidige meting is erg primitief en onvoldoende om een patiënt te informeren over zijn zithouding. Met de huidige kussens wordt een actieve zithouding soms belemmert terwijl met een visualisatie deze gestimuleerd zou kunnen worden.

high-tech rolstoel

2007 Marcel Verbunt

Appendix 2.6.3 Interview target group

Technische Universiteit Eindhoven

Contact: Stichting revalidatie Limburg
April 2008

De invloed van decubitus tijdens en na de revalidatie

Doel:
Het in kaart brengen van de rol die decubitus speelt tijdens en na de revalidatie.

Inleiding:
Wie ik ben: Student Master Industrial Design Technische Universiteit Eindhoven.

Wat ik doe: Ontwerper van intelligente producten en systemen waarbij de be hoefte van de gebruiker centraal staat. Het doel van mijn afstudeer project is het verminderen van het risico op decubitus voor mensen in een rolstoel.

Mijn focus is: Het geven van (real-time) feedback aan een persoon met een lage dwarslaesie ter preventie van decubitus.

Ik wil weten: De invloed van decubitus tijdens en na de revalidatie.

Vragen

Tijdens verblijf revalidatie centrum

1.) Wat is de invloed van decubitus tijdens het verblijf in Hoensbroek bij de revalidatie van een dwarslaesie? Hoe belangrijk is decubitus in vergelijking met de rest van de zorg aspecten?

1.b) Welke preventiemaatregelen worden er getroffen om decubitus te voorkomen tijdens de revalidatie in Hoensbroek? Passief (materialen), Actief (beweging, eten, verzorging, etc?)

Tijdens revalidatie thuis

2.) Wat is de invloed van decubitus gedurende de revalidatie na het verblijf in Hoensbroek?

2.b) Wat is volgens u het grootste verschil betreffende de preventie tijdens en na het verblijf in het revalidatie centra, en had u specifieke moeilijkheden wat betreft de preventie van decubitus? Wat waren de problemen die u tegenkwam?

Appendix 2.6.3 Interview target group

De rol van decubitus tijdens het dagelijkse leven?

4.) Welke maatregelen worden er door u getroffen om decubitus te voorkomen tijdens het dagelijks leven? Passief (materialen), Actief (beweging, eten, verzorging, etc?)

4.b) Welke producten heeft u aangeschaft om Decubitus te voorkomen?

5.) Moet u daarbij uzelf op decubitus controleren? En hoe doet u dat dan?

6.) Zijn er naast de adviezen die u kreeg ook maatregelen die u zelf ontwikkelt heeft of neemt?

7.) Let u ter voorkoming van Decubitus op uw zithouding en of uw activiteit tijdens het zitten ter voorkoming van drukpunten ?

8.) Zijn er activiteiten waarbij u extra rekening moet houden met het risico op Decubitus?

9.) Zijn er activiteiten waar u niet meer aan kan deelnemen door het risico op decubitus

10.) Heeft u wel eens een meting gedaan met een FSA (drukmat) om een geschikt kussen te selecteren?

11.) Zo ja, wat heeft die meting u toen voor informatie opgeleverd en wat heeft u met die informatie gedaan?

12.) Wat zou in uw ogen helpen om het risico op decubitus te beperken? Voorlichting, bepaalde materialen, of producten?

13.) Op het moment dat decubitus optreedt wat voor gevolgen heeft dit op de revalidatie?

14.) Op het moment dat decubitus optreedt wat voor gevolgen heeft dit op uw dagelijks leven?

15.) Beperkt het risico op decubitus u in bepaalde activiteiten en zo ja waarom?

16.) In hoeverre bent u afhankelijk van andere op het gebied van de preventie van Decubitus?

17.) Als u een futuristische bril opzet wat zal u kunnen helpen in de toekomst om het risico op decubitus te verkleinen? Wat mis je in de huidige zorg?

Appendix 2.6.3 Interview target group

Een kijkje in de Toekomst:
Voorstel van mogelijke methoden van het helpen bij preventie.

Mijn visie op zorg en het belangrijke van onafhankelijkheid? Mening persoon?

In hoeverre is persoon afhankelijk van kennis van expert bij het voorkomen van decubitus? (niet - klein beetje – beetje – redelijk veel – veel)

Mijn idee over concept met realtime-feeback? Mening peroon?

Appendix X4.4 Arduino code feedback device

```
#include <Wire.h>                          //include wire library to read I2C commands

//Definities variabelen

int drukmatOutput = 99;              //output drukmat
int intensiteitMotor[16];           //intensiteit
int staatMotor [16];                // staat van motor 0 uit, 1 aan, -1 over top
int delayMotor = 20;                // delay van feedbackgolf
boolean waardeIsBinnen=false;       // komt er wel of geen waarde binnen  zo niet in rust zo wel dan start met feedback
int incomingByte = 0;
int startPositie = 99;              // is drukmatOutput maal 2 en het startpunt van vibratie de motoren P0 -P15


// configurarie leddriver

void setup(){
  Wire.begin();                          // join i2c bus (address optional for master)
  Serial.begin(9600);

  //set up led driver
  sendCommand(0x20,0x0F,0x88);           // config leddriver 08
  sendCommand(0x20,0x0E,0xFF);           // master O 16 intensity
  sendCommand(0x20,0x07,0x00);           // ports config p15-p8 (schakelt poorten aan
  sendCommand(0x20,0x06,0x00);           // ports config p7-p0  schakelt poorten aan mogelijk om intensiteit te geven
  resetMotor();
  Serial.println("started!");
}


// zenden commando naar Leddriver

void sendCommand (byte address,byte reg, byte command) {
  Wire.beginTransmission(address);                      //start zenden
  Wire.send(reg);                                  //adress
  Wire.send(command);                                   //command
  Wire.endTransmission();
}


// reset motoren

void resetMotor(){
  for(int i=0; i<16; i++){
    staatMotor[i]=0;
    intensiteitMotor[i]=0;
  }
}


// start loop

void loop(){
  if (Serial.available() > 0) {
    // read the incoming byte:
    incomingByte = Serial.read();

    // say what you got:
    //Serial.println(incomingByte, DEC);
    drukmatOutput = incomingByte-48;   //asci to decimal
    Serial.print("I received: ");
    Serial.println(drukmatOutput);
  }



  //data Lezen van de drukmat

    if(!waardeIsBinnen){            //wacht todat een waarde van de mat binnenkomt en koppelt deze aan programma
    startPositie = drukmatOutput * 2;

    if (startPositie<99){
      waardeIsBinnen=true;
       staatMotor[startPositie]=1;                     //staatmotoren 0 uit, 1 aan, -1 over top
    }
    delay(10);
  }
  else{
```

Appendix 4.4 Arduino code feedback device

```
for(int i=0; i<16; i++){
      if (staatMotor[i]>0){
        intensiteitMotor[i]++;
        if (intensiteitMotor[i]>15){

  staatMotor[i]=-1;
          //ervoor zorgen dat er maar drie keer naar het naastliggende motor wordt geschakeld
          if((abs(i-startPositie)<4) || (abs(i-startPositie)>12)){
            if ((i>0)&&(staatMotor[i-1]==0)){
              staatMotor[i-1]=2;
            }
            else if ((i==0)&&(staatMotor[15]==0)){
              staatMotor[15]=2;
            }
            if((i<15)&&(staatMotor[i+1]==0)){
              staatMotor[i+1]=2;
            }
            else if((i==15)&&(staatMotor[0]==0)){
              staatMotor[0]=2;
            }
          }
        }
      }
      if((staatMotor[i]<0)&&(intensiteitMotor[i]>0)){
          intensiteitMotor[i]--;
       }
    }


    // om te controleren of er gereset moet worden

    boolean resetValue = true;
    for (int i=0; i<16; i++){/*
      Serial.print("staatMotor[");
      Serial.print(i);
      Serial.print("] = ");
      Serial.print(staatMotor[i]);
      Serial.print("        intensiteitMotor[");
      Serial.print(i);
      Serial.print("] = ");
      Serial.println(intensiteitMotor[i]);*/
      if ((staatMotor[i]>0)||(intensiteitMotor[i]>0)){
        resetValue = false;
        //i=15;
      }
    }
    if(resetValue){
      resetMotor();
      waardeIsBinnen=false;
      startPositie=99;
      drukmatOutput=99;
      Serial.println("reset!!!");
    }


    // de intensiteit van de motoren wordt bepaald en verzonden naar de juiste actuator
    for(int i=0x10; i<0x18; i++){
      int val1 = 15-(i-16)*2;
      int val2 = 15-(i-16)*2-1;
      int command = 0xFF-0x10*intensiteitMotor[val2]-0x01*intensiteitMotor[val1];
      sendCommand(0x20, i, command);
      //delay(20);
    }

    //Wire.endTransmission();
     delay(delayMotor);
  }

}
```

Appendix 4.5 communication FSA measurement system and FSA software

The code below is the procedure for reading the value of the pressure sensors with the FSA software. With a serial port monitor* the communication is recorded and analyzed. After a procedure that determines the calibration the software asks with 1B 46 for the values of the sensors. This request is repeated as long as the software sends the request.

Port opened by process "FSA4.exe" (PID: 4028)

```
Request: 6/5/2008 2:59:23 PM.48664 (+0.0000 seconds)
07                                                          (request code for FSA to start)
Answer: 6/5/2008 2:59:23 PM.48664 (+0.0000 seconds)
06                                                          (answer code from FSA)
Request: 6/5/2008 2:59:23 PM.48664 (+0.0000 seconds)
07                                                          (request code for FSA to start)
Answer: 6/5/2008 2:59:12 PM.20964 (+0.0156 seconds)
41 FF 57 41 52 4D 52 45 53 45 54                            (answer code from FSA
Request: 6/5/2008 2:59:13 PM.83464 (+0.0000 seconds)         with information about calibration)
07                                                          (request code for FSA to start)
Answer: 6/5/2008 2:59:23 PM.48664 (+0.0000 seconds)
06                                                          (answer code from FSA)
Request: 6/5/2008 2:59:24 PM.09664 (+0.6092 seconds)
0A 4F 30 46 30 46 32 30 30 30 34 44 0D                      (request code for FSA to start
Answer: 6/5/2008 2:59:23 PM.48664 (+0.0000 seconds)          with information about calibration)
06                                                          (answer code from FSA to start)
Request: 6/5/2008 2:59:24 PM.09664 (+0.6092 seconds)
1B 46                                                       (request code to read sensors)
Answer: 6/5/2008 2:59:24 PM.14264 (+0.0469 seconds)
 0C 00 0B 00 0B 00 0C 00 0B 00 0C 00 0C 00 0C 00  ................   (answer code from FSA with value
 0C 00 0C 00 0C 00 0B 00 0B 00 0C 00 0C 00 0C 00  ................    of each sensor represented with
 0B 00 0C 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00  ................    four characters, sensor A1=0C 00)
 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00  ................
 0A 00 0B 00 0B 00 0B 00 0A 00 0A 00 0B 00 0B 00  ................
 0A 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00  ................
 0A 00 0B 00 0A 00 0B 00 0B 00 0B 00 0B 00 0C 00  ................
 0B 00 0B 00 0B 00 0B 00 0B 00 0C 00 0C 00 0C 00  ................
 0B 00 0C 00 0B 00 0C 00 0B 00 0C 00 0C 00 0B 00  ................
 0C 00 0C 00 0B 00 0C 00 0B 00 0B 00 0B 00 0C 00  ................
 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00  ................
 0B 00 0B 00 0B 00 0C 00 0B 00 0B 00 0B 00 0B 00  ................
 0A 00 0E 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00  ................
 0A 00 0A 00 0B 00 0C 00 0B 00 0B 00 0B 00 0B 00  ................
 0A 00 0C 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00  ................
 0A 00 0B 00 0B 00 0B 00 0B 00 0B 00 0C 00 0C 00  ................
 0B 00 0C 00 0B 00 0C 00 0B 00 0B 00 0C 00 0C 00  ................
 0C 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00  ................
 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00  ................
 0A 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00  ................
 0A 00 0A 00 0A 00 0A 00 0B 00 0A 00 0B 00 0B 00  ................
 0A 00 0B 00 0B 00 0C 00 0B 00 0B 00 0B 00 0B 00  ................
 0B 00 0A 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00  ................
 0B 00 0B 00 0B 00 0B 00 0C 00 0B 00 0C 00 0C 00  ................
 0C 00 0C 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00  ................
 0C 00 0B 00 0B 00 0C 00 0B 00 0C 00 0C 00 0B 00  ................
 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00 0C 00  ................
 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00  ................
 0B 00 0A 00 0A 00 0B 00 0B 00 0B 00 0B 00 0B 00  ................
 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00  ................
 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00 0B 00 0C 00  ................
 1F 00 0B 00 0B 00 0C 00 0B 00 0C 00 0C 00 0D 00  ................
 35
Request: 6/5/2008 2:59:24 PM.09664 (+0.6092 seconds)
1B 46                                                       (repeating request code for
                                                             every reading)
```

Configuration port reader: baudrate 115200, flow none, data bits 8, stop byte 1, data pack 2075 bytes.

* *http://realterm.sourceforge.net/*

Appendix 4.5 communication FSA measurement system and FSA software

The sensor are represented with a matrix of 1016 hexadecimal values. Each sensor is represented by two hexamdecimals. Both hexadecimals represent after calculation the value of a single sensor. The two hexadecimals (A4 03) are converted into decimals (X, Y). With the calculation SensorValue = Y*256+X the value is defined.

Start

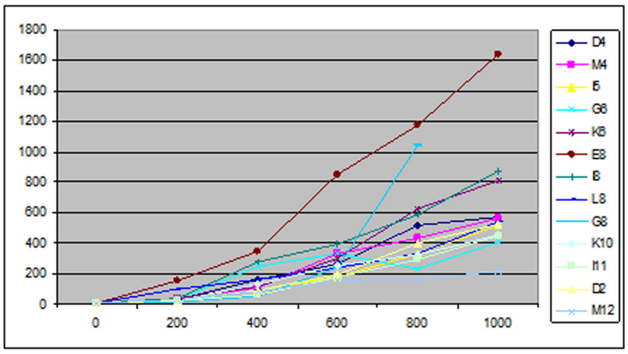
The two hexadecimals are the value send by the FSA to the software. Both hexadecimals represent with a calculation the value of a single sensor. The two hexadecimals (A4 03) are converted into decimals (X, Y). With the calculation sensor value = Y*256+X the value is defined.
Without the calibration from the software it is difficult to estimate which values the sensors measure and if there is a difference in sensitivity between the sensors. With a manual measurement a calibration is done and analyzed if there is a difference in sensitivity.

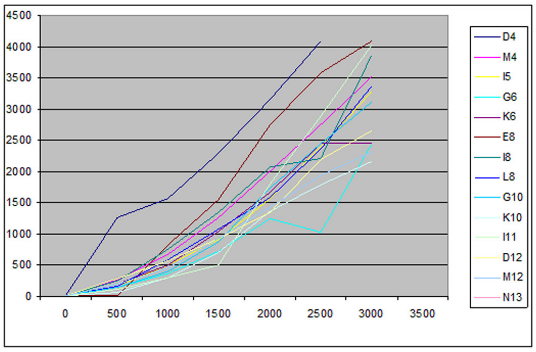
Method

With different weights a pattern of sensors is calibrated. From 0 to 3500kg in steps of 500kg the sensors are pressed and the values from the device are stored in a table. After 32 readings it seemed that there is a linear resistance.

Conclusion

With the information from the software and the results of the manual calibration a good estimation can be made. It seems that 30mmHg corresponds with a sensor value between 1000 and 1500. These values are the starting point for the threshold. When the value of a sensor is above the treshold it will communicate this with the feedback system.





Appendix 5.3Questionairre User Test

NR: ______

Participant name/ ID: ______

Age: ______

Education: ______

Gender: Male ☐ Female ☐

Did you understand the feedback ?

Difficult to understand						**Easy to understand**
O	O	O	O	O	O	O
Comments:						

How did you experience the feedback ?

Unpleasant						**Pleasant**
O	O	O	O	O	O	O
Comments:						

How did you experience the feedback ?

Unnatural						**Natural**
O	O	O	O	O	O	O
Comments:						

How did you experience the feedback ?

Not Private						**Private**
O	O	O	O	O	O	O
Comments:						

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Appendix 5.3 Questionairre User Test

How did you experience the feedback ?

Not disturbing						**Disturbing**
o	o	o	o	o	o	o
Comments:						

How did you experience the feedback?

Non-Obtrusive						**Obtrusive**
o	o	o	o	o	o	o
Comments:						

How did you experience the feedback?

Unreliable						**Reliable**
o	o	o	o	o	o	o
Comments:						

Did the feedback disturb your activity?

Not at all						**A lot**
o	o	o	o	o	o	o
Comments:						

How did you experience the test?

Complex						**Simple**
o	o	o	o	o	o	o
Comments:						

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BOS MEDICAL PRODUCTS

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