Medical Vision Project

Product design and Onscreen design Within Computer Assisted Orthopedic Surgery (CAOS)

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Preface

This Master Thesis project concludes my Master of Science degree in Media technology and Design at Luleå University of Technology. The project was carried out between February 2006 and June 2006 at TheUEgroup in San Jose, California, USA.

The objective has been to investigate the current situation of Computer Aided Orthopedic Surgery. Produce designs that provide a direction-setting vision for the next generation of orthopedic surgical devices drawing upon research conducted by theUEgroup in the past as well as new research conducted as part of this project.

It has been a great experience and I would like to thank my supervisor, Tony Fernandes, at theUEgroup for giving me this opportunity and for his support and guidance throughout the project. I would also like to thank my supervisor, Stig Karlsson, at Luleå University of Technology. Special thanks to the orthopedic surgeons at Norrlands Universitets Sjukhus that allowed me to observe and interview them.

San Jose, June 2006
Anna-Karin Söderström
Abstract

This project dealt with Computer Aided Orthopedic Surgery (CAOS) and it was carried out for the UE group, San Jose (USA) between February 2006 and June 2006. The aim of this project has been to develop designs that provide a direction-setting vision for the next generation of orthopedic surgical devices focusing on providing visualization and feedback to surgeons.

In the past growth in this market have mainly been the result of copying of the present user interfaces by competitors and research of the current generation of devices has suggested that there is a need for the devices and user interfaces to evolve into a new highly portable, highly usable, form factor. There had also appeared to be social, technological and practical reasons for why the adoption of COAS had lagged behind its value in the operating rooms. The next generation designs to be developed must therefore cater to the surgeons work environment and process in new ways to reduce the amount of inconvenience to the surgeon and surgical staff.

Systematic problem solving is the methodology used in this thesis including; information gathering, problem determination, problem clarification, idea generation, Idea assessment and final design. It is a widely known methodology and it is a good help in product development to find good solutions to the problem.

Through research, interviews with orthopedic surgeons and observations of surgeries a lot of important information was gathered and translated into requirements. From this a range of ideas were then generated. These ideas were evaluated and further developed into a final result. The final result of this thesis consists of two parts; a product design and an onscreen design. They can be used as two individual solutions as well as one solution combining the two.

The product design is a slim, portable and disposable product that communicates wirelessly and that has a small screen to display feedback with the current generated data. It is intended to be worn on the lower arm but could also be placed on another surface if wanted. It allows the surgeon to remain in position and easily be in control of the system.

The onscreen design has a minimalist design and is composed by three different sections. The menu sections are organized for easy navigation and each section can be hidden. This onscreen design can be customized after the surgeons’ individual needs. It allows the surgeons to choose what information they want displayed when performing a task and can use the ones they feel most comfortable with to help them deliver the best result.
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1. Introduction

1.1 Background

1.1.1 The Company
The UEgroup LLC, located in Silicon Valley, has been involved in designing a new generation of surgical devices collectively called Computer Assisted Surgery (CAS) for its clients. Specifically, they have designed user interfaces and interaction concepts that presently lead the market in ease of use.

1.1.2 Project Background
Growth in this market has lead to copying of the present user interfaces by competitors. Additionally, additional research and feedback regarding the current generation of devices suggests that there is need for the devices and user interfaces to evolve into a new highly portable, highly usable, form factor.

At the same time, the adoption of the technology has lagged behind its value in operating rooms. There appear to be social, technological, and practical reasons for this. In order to overcome these problems, the next-generation designs must cater to the surgeon’s workflow and process in new ways to reduce the amount of inconvenience to the surgeon and the general surgical staff.

1.2 Project outline
To work with the UEgroup to conceive on next generation designs both in terms of onscreen experience and device form-factors specifically focused on orthopedic surgical environments, Computer Assisted Orthopedic Surgery (CAOS). Although the project will be focused on human use, it may also encompass use in veterinary applications. The general structure of the project is foreseen as follows:

- Conduct general research on present CAS implementations on the market
- Evaluate the present onscreen design and form factor of a system design by the UEgroup
- Assess attitudes toward this technology with established surgeons and medical students
- Identify areas where new designs could increase the acceptance and use of CAS technology in operating rooms
- Develop design concepts that based on the findings of the research
- Conceive of an overall framework and approach that may allow the direction to be applied in general medical devices
- If time allows, gather feedback about the designs and refine the concepts accordingly

1.3 Objective
The objective is product rendered designs of onscreen experiences and device form factors that directly address the interaction need of the surgeon and surgical team. The focus of the concepts will be to reduce the resistance of surgeons to this technology through usability and emotional satisfaction. The designs will draw upon research
conducted by the UE group in the past as well as new research conducted as part of this project. Collectively, these will create a direction-setting vision for the next-generation of orthopedic surgical devices.

1.4 Scope

The project will deal specifically with orthopedic surgery and will be focused on providing visualization and feedback to surgeons. The work will involve developing a research strategy to ensure that the goal of the design are met, conducting needed research, analyzing the results, and producing original designs, onscreen and physical, based on what was learned. These designs will be electronic in form. 3-D will be used as much as possible for the rendering of the devices. If there are obstacles to the primary research methods, alternate research methods must be developed to allow the design work to be completed. Direct contact with medical facilities, medical equipment makers, surgeons, and the observation of live surgery may be involved.

1.5 Delimitations

The goal of the project is to develop product concepts and onscreen design concepts, the result will not be a finished technical product, no drawings, and exact technical, mechanical or electrical solutions will be presented in the end result for the product design. The onscreen design is limited to one screen with a set of menus; it is not intended to be a complete system or complete solution including sub menus or how to get to other parts of the system.
2. Theoretical background

2.1 Computer Assisted Orthopedic Surgery

Computer Assisted Orthopedic Surgery (CAOS) is the use of a computer to assist the surgeon with decision making during the process of surgery (PLUS Orthopedics). It consists of computer assisted technology that uses specialized surgery tools to enable the orthopedic surgeon to receive better results by ensuring accuracy during the procedure. It provides the surgeon with a degree of accuracy and precision with real-time data that is not possible to achieve with the naked eye or the conventional surgical instruments. CAOS has been compared to Global Positioning System (GPS) in that it works in a similar way for mapping and locating of specific points. It lets the surgeon know the exact position of the instruments, how to align bones and what part of the anatomy to remove (Carilion). CAOS provides reduced surgical exposure and shortened recovery time (Virtual Medical Worlds). It provides positional information about surgical tools or implants relative to the target bone/anatomy and visualizes it on a computer display.

![Computer Aided Surgery products from Smith & Nephew](www.smith-nephew.com)

There are many types of CAOS technologies being used and they are not all the same but usually CAOS consist of a computer workstation, a screen for displaying data, a positioning system, and special surgical instruments. The positioning system can be small reflective spheres tracked by an optical camera that registers the relative location of the instruments and bone structure (see Fig.1). The system is dependent on ‘line of sight’ where the spheres have to be visible to the system for it to work. For example if someone would step into the ‘line of sight’ they would block the signal and the system would not be able to register the location.

CAOS works by having the positioning system gathering and storing information about specific body structure, the motion and alignment of the anatomy. With gathered
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data the system calculates and develops a framework providing the surgeon with accurate information to support and assist the surgeon to achieve an optimally aligned implant (PLUS Orthopedics). By allowing the surgeon to more precisely position the implant CAOS enables implants to be more accurately placed giving the artificial joint the best force distribution which leads to a more even wear on the surface. The more accurate the alignment is the implant will wear out less and the longer the implants can last (PLUS Orthopedics).

2.1.1 Orthopedics

Orthopedics is a “medical specialty concerned with the preservation and restoration of function of the skeletal system and its associated structures, i.e., spinal and other bones, joints, and muscles.” (Encyclopædia Britannica) Orthopedics is also called orthopedic surgery and in some contexts it can also be referred to as orthopaedics.

2.1.2 Orthopedic surgeons in the US

Only 3.3% of certified orthopedic surgeons are female (Watkins-Castillo, S., Frankowski, J., Schmalz, H., 2004). The number is increasing however, since the American Academy of Orthopedics Surgeons (AAOS) started tracking the gender of orthopedic surgeons the percentage has gone up from 2.7% in 2000. The average age of an orthopedic surgeon is 50.9 years old and has been the same two years in a row. The average orthopedic surgeon performs 31 procedures in a month.
2.2 Interaction design

Interaction design is designing interactive products that support people when carrying out their tasks at work and in everyday life. It is about finding ways to support the users and creating user experiences that extend and enhance peoples work, communication and interaction (Preece, P., Rogers, Y., Sharp, H., 2002).

2.2.1 Usability

Usability addresses the extent to which the interactions users have with products can be optimized. It is about ensuring that an interactive product is effective to use, easy to learn and enjoyable for the user and that it enables the user to best carry out the task at hand. Usability is broken down in a set of usability goals (Preece, P., Rogers, Y., Sharp, H., 2002):

- Effective to use
- Efficient to use
- Safe to use
- Have good utility
- Easy to learn
- Easy to remember how to use

There is also a number of design principles that can help explain and improve design working as a set of reminders to the designer. Ensuring certain things has been taken into consideration and what to avoid when designing an interface. Listed below are the most common ones as described by Preece, P., Rogers, Y., Sharp, H., (2002):

- **Visibility** - The more visible functions are to the user the more likely it is that the user will know what to do and in contrast; functions that are difficult to find makes them hard for the user to know how to use. The relationship between how controls are positioned in relation to what they control is important.

- **Feedback** - Feedback is related to visibility. It concerns sending information back to the user about what has been done to allow the user to continue and know what is going on. There are various types of feedback, for example; audio, visual, verbal or tactile.

- **Constraints** - Constraint is about limiting the number of actions that the user can make at a given moment. This can prevent the user from wrong actions and thereby it reduces the chance of making a mistake for the user. For example menu items can be deactivated at a certain stage and then only activated once the user has taken appropriate actions.

- **Mapping** - Mapping addresses the relationship between controls and their effect. It also addresses the relationship of the relative position of controls them selves together with their effect. For example the play, rewind, and forward button are usually aligned with a configuration that maps onto the
Consistency - Consistency addresses having similar actions and similar objects for performing similar tasks. Interfaces that have good consistency are easy to learn and easy to use. The user only has to learn/remember one way to do a task and it will apply to all tasks.

Affordance - Affordance is about how a feature of an object can allow the user to intuitively know how to use it. It should be obvious by looking at the product to know what to do with them. For example a cup handle that invites grasping or a button that invites pushing.

2.2.2 Icons and symbols

Using a picture is a very effective way of showing something. Symbols and icons can be understood more quickly and more correctly compared to text. It is important that the symbols and icons are good descriptions of the functions they represent. When choosing icons or symbols for something it is important to choose them well so that they can best be understood by the intended user. Icons and especially symbols can be interpreted differently depending on who the user is, cultural differences need to be taken into consideration too. Description of a symbol and icon according to Monö (1997):

- **Symbol** – A symbols does not have any relation to what it represents. It can have certain similarities but is often the result of an agreement between individuals on what the symbol represents. The meaning of a symbol must therefore often be learned.

- **Icon** – An icon resembles what it represents. Because an icon has a relation to what it represents it is easy to know what it is o be used for.

2.2.3 Color

Color is used in visual displays for both practical and aesthetic reasons and using color right can bring a lot of advantages. Color is pre-attentively processed and the human visual system is in most cases better able to see different color than to see different shades of grey. Color coding can also help distinguish one area from another, help us see patterns and also be used to group items, make items stand out or to make a display element. Color used improperly can however lead to errors and confusion so it is not always better to add color if it is not thought through properly (FAA Human Factors). Color should be used with caution to make sure that they add value and does not confuse. Color displays have the benefit of being more interesting and appealing to the eye (FAA Human Factors).

2.2.4 Gestalt laws

The principle behind the Gestalt laws is "Gestalt – an arrangement of parts which appears and functions as a whole that is more than the sum of its parts." (Monö, R., 1997) It addresses the perception of a composition as a whole; form, color and material
are not isolated pieces. While each of the individual pieces has a meaning on their own, taken together, the meaning may change. Our perception of the piece is based on our understanding of all the bits and pieces working together in unison creating the perception of a gestalt.

There are a number of factors that help us distinguish gestalts according to Monö (1997), with a few of the most important ones being:

- **Proximity** - The proximity factor occurs when objects are placed close together and are then perceived as a group. When objects are given close proximity, unity occurs and are perceived as a unified whole. The gestalt becomes clearer the closer the objects are. If controls on a control panel are grouped according to their function that helps make the control panel clearer.

  ![Proximity Example](image)

- **Similarity** - The similarity factor states that objects that look similar to one another and share visual properties such as color, shape, size, orientation or texture will be perceived as a unit. In the same way that the similarity factor can be used to emphasize that objects belong together one can use it to emphasize that it is dissimilar from others.

  ![Similarity Example](image)

- **Area** - The area factor addresses the perception of a smaller object in relation to a larger one. A smaller enclosed area is more easily seen. For example the Swedish flag is seen as a yellow cross on a blue background instead of being seen as having a yellow background with four blue squares on it, this is because of the area factor.

  ![Area Example](image)

- **Symmetry** - The principle of symmetry describes the instance where symmetry creates a gestalt. Objects that are grouped symmetrically stand out as a unified whole. The lines in the middle create a gestalt.

  ![Symmetry Example](image)
• **Enclosedness** – The inclusion factor states that lines that enclose an area create a gestalt that is more easily seen as a whole. The same vertical lines create different gestalts with different locations of the horizontal lines.

![Diagram of enclosed lines](image)

### 2.3 Displays

A display is a device that display signals as images on a screen. There are a lot of different technologies for displays and in this thesis the focus is on technology for thin/flat computer displays. The display should be energy efficient and have good contrast and legibility to be able to be readable under the hard light in the operating room as well as being able to be view from a distance. With the prevailing circumstances within an operating room it is also important that the display is easily cleaned and that the surface is resistant to dirt and water. A description of some flat display technologies follow below.

#### 2.3.1 Liquid Crystal Display (LCD)

LCD is a flat display device that uses a very small amount of power, is thin and is made up of any number of color or monochrome pixels (Universal Display Corporation). Enhancement solutions to LCD can improve the readability in more demanding lighting conditions and increase resistance to fluids, dirt and scratches (Wikipedia).

#### 2.3.2 Organic Light-Emitting Diode (OLED)

OLEDs are thin, light weight and it’s a technology that is less costly to manufacture than LCD displays and has an organic compound as the emissive layer (Universal Display Corporation). They can be used for computer displays, portable system screens and since “OLEDs can be printed onto flexible substrates” it’s a good technology for exploring new applications with, especially applications where thinness, contrast and low power consumption is wanted. They have fast response times, argued to be faster than LCDs (Universal Display Corporation). They draw little power, less than LCD displays since they do not need a backlight function and hence can operate longer. They do have a limited lifetime of around 1000hrs for flat panel displays which is less then LCD. It is sensitive to water and needs a protective layer which might limit the flexibility (Wikipedia).
2.4 Short-range wireless technology

Short range wireless technology provides devices with a connection for transferring data. Using short-range wireless technology enables the user to connect a wide range of telecommunication and computing devices in near vicinity without the need of cables. Many different technologies exist and one has to look at their capabilities, strengths and weaknesses to determine which technology is best suited for the specific application in question (Wireless Developer Network). Due to the fact that these devices are wireless they have a limited lifetime because of the limited battery capacity. The data transfer also affects the choice since the battery life is closely related to the amount of information sent (Hunn, N. 2005). Other factors that affect the choice of short-range wireless technology for an application are range, cost and security. The basic foundation for short range wireless technologies is that they all use radio technology of some kind to enable the actual wireless transmission of data in between the devices (Wireless Developer Network). This short-range wireless technology does not need line of sight since radio is not directional (Bray, J., Sturman, C., 2001). Consideration has to be taken to the fact that bodies and furniture can absorb microwaves hence compromising the range of the technology. A realistic figure for the range could because of that be slightly less then the stated range for the specific technology (Bray, J., Sturman, C., 2001).

2.4.1 Bluetooth

Bluetooth is a short range, low cost, low power technology that was originally developed as a cable replacement to enable connection between devices such as headsets, portable computers and mobile phones (Bray, J., Sturman, C., 2001). Bluetooth has a small-form factor and it operates at 2.4GHz, one of the license-free globally available Industrial, Scientific and Medical (ISM) radio bands. It is available in applications for the consumer-, industrial- and medical-device market. Bluetooth supports Quality of Service and allow for multiple connections to coexist (Hunn, N., 2005). There are three different power classes for Bluetooth which allows for three different ranges of operation, approximately 10m, 20m and 100m (Bray, J., Sturman, C., 2001). A Bluetooth device operating within 10 meters have an output power of 1mW.

2.4.2 Ultra-Wideband (UWB)

UWB is a short-range technology that uses very short low power pulses for transmitting data. It is capable of transmitting large quantities of data at a fast rate using very little power. It is a very secure technology that has in the past been used by military and espionage agencies (Kay, R. 2006). It is a technology that can also be used as a measuring technology and is more accurate than Global Positioning System satellites. It has been mandated to legally operate in the range of 3.1GHz to 10.6GHz and has an operation range of about up to 10 meters (Kay, R. 2006). It is a relatively new technology that is still emerging and has not been deployed widely yet.

2.4.3 ZigBee

ZigBee is a short-range wireless technology that is power efficient and can have years of battery life. It has been specifically developed to allow for low power consumption and it is able to sleep for extended periods conserving power in order to achieve this and at the same time wake-up quickly to respond to the network (Baker, N.
2005). This however can be a draw-back if really fast access is needed it is not as fast as a technology that does not ‘sleep’. It supports most of the unlicensed ISM bands that are widely used around the world. It is a secure technology that also allows for user defined security. ZigBee is a scalable technology that with ease enables a network to grow (Baker, N. 2005). It has a relatively slow data rate transfer compared to other short-range wireless technologies and operates on a range of up to about a 100 meters (ZigBee Alliance). ZigBee is a relatively new technology and products using this technology are only just emerging to the market (ZigBee Alliance).

2.5 Radio Frequency exposure recommendations

Radio Frequency (RF) exposure recommendations are guidelines that specify the restrictions between 10MHz and 10GHz for radio waves found close to an emitting device and these guidelines are referred to as SAR. Emitting devices that have an output power of less than 1.6mW can not exceed these restrictions (Bray, J., Sturman, C., 2001).
3. Methodology

3.1 Systematic problem solving

This project was realized with the help of Systematical problem solving. This approach deals with problems step by step and facilitates with making sure that all the necessary steps are taken for a successful result. The approach uses different methods throughout the stages to find information, help clarify, analyze and solve the problem. The stages of the systematic approach are:

- Gathering information
- Problem determination
- Problem clarification
- Idea generation
- Idea assessment
- Final design

The methods used are from Johannesson, Persson and Pettersson, (2005) and from Paul and Beitz, (1995).

3.2 Gathering information

Gathering information is an important part of the process to create a good foundation for the project. Collection of information should also continue throughout the whole project. One of the greatest sources of information is the user but it is important to gather information on all aspects of the problem. Methods used for gathering information are interviews, literature studies, observations and benchmarking.

3.2.1 Literature

Literature study can include one or more of the following; books, thesis papers, articles, research papers and web pages on the Internet. Literature sources can be both in electronic form and printed. Suitable literature is usually found in libraries and library catalogues. Web pages are also a good way to find information, although one has to be careful about the source.

3.2.2 Observation

This is a method of gathering information that entails one person observing and registering the behaviors of the person being observed in the direct environment that the product is being used/will be used. The principle is to observe the users without interfering in their work.

3.2.3 Video recording

Video is a very valuable and useful technique that can be used to gather large quantities of information. The method can be very time consuming but it can provide detailed information about how a task is done and the environment. It also has the benefit of allowing someone to be able to go back and look at specific parts to analyze further and look at the recorded material closer in slow motion or in paused mode.
3.2.4 Interview

Interview is a conversation between the interviewee and one or more respondents where questions are asked to gather information. There are several different types of interview techniques that can be used. In this project the semi structured interview was used. The interviews were structured after a set of steps to help plan an interview according to Preece, Rogers, Sharp, (2002):

1. **An introduction** – interviewer introducing himself and explains what the purpose with the interview is and informs the interviewees about how they are documented and ask if that is ok
2. **A warm-up** – easy “non-threatening” questions
3. **A main session** – questions presented in a logical order
4. **A cool-off period** - few easy questions again to “defuse” any tension or uneasiness that might have arisen
5. **A closing session** – thanking the interviewee and ending the interview

3.2.5 Benchmarking

Benchmarking is the process of looking at similar products to investigate the current situation on the market to find out what the standard is, what competitors’ products are and what the trends on the market are. Related markets and products can also be explored for new solutions.

3.3 Problem determination

One method of determining the problem is by using the questions method from Johannesson, Persson and Pettersson, (2005). With this method one tries to gather facts that can be used as a foundation for the final problem determination. This is done by asking a relevant set of questions. The answers should be based on facts; they should be objective and precise. The questions considered were:

- What is the problem/problems? Why does it exist?
- Where does the problem occur? Why is it there?
- When does the problem occur? Why at that time?
- Who is involved/affected by the problem? Why are those people involved/affected?
- How common is the problem? Why is it of this extension?
- How can the problem be broken up? Why can it be divided into these?
- What are the risks?

3.4 Problem clarification

The problem needs to be thoroughly examined in order to make a concise and neutral problem statement. The purpose of problem clarification is to interpret and analyze the material gathered during the information gathering process conducted earlier in the project. To clarify the task at hand methods from Paul and Beitz (1995) were used. These methods are; Problem Elucidation, a list of Requirements and finally an Abstraction.
3.4.1 Problem Elucidation
This first step consists of answering a set of questions:

- What is the problem really about?
- What implicit wishes and expectations are involved?
- What tasks should the product be able to handle?
- What qualities must the product posses?
- Are there any pre-defined conditions in the task?
- What qualities can the product not posses?
- Current technical situation?
- Legal demands? Standards?
- Technical trends, design trends, potential development
- Requests, desires concerning possibilities of changing performance and appearance?

3.4.2 List of Requirements
The answers from the problem elucidation are translated into a list of requirements that the product should fulfill.

3.4.3 Abstraction
The final stage of the problem clarification is to sum the problem up in an abstraction. A short, clear and neutral statement of what the problem is.

3.5 Idea generation
This is an important part of the work when ideas to solve the problem at hand are formed. By generating several ideas that can be evaluated and improved a good solution can be found. There are a several methods available that can help with the idea generation.

3.5.1 Matrix of ideas
One method that can help solve a complex problem is to divide a problem into sub-functions (Paul, G., Beitz, W., 1995). Ideas can then be generated to each of the sub-function in search for a solution to the problem. The sub-functions and the ideas for each sub-function are then sorted into a matrix of ideas and the different ideas for the different functions can then be combined to find a good solution to the problem.

<table>
<thead>
<tr>
<th></th>
<th>Sub-function 1</th>
<th>Sub-function 2</th>
<th>Sub-function 3</th>
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<tr>
<td>Idea 1</td>
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<tr>
<td>Idea 3</td>
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</tbody>
</table>

Example of a matrix of ideas
An idea for a preliminary solution can be conceived and then it can be abstracted into sub-functions through the process of iteration. These sub-functions can then be inserted into the matrix of ideas.

### 3.6 Idea assessment

When a satisfying number of ideas have been created the next step is to evaluate them to exclude those ideas that are unsuitable. The ideas that do not seem feasible and that are not going to be able to be realized can be excluded early in the process with common sense.

The concepts that still remain after this initial assessment are then to be further evaluated in order to see how well they fulfill the requirements that were established earlier in the process.

#### 3.6.1 Value analysis

Conducting a value analysis the importance of each of the requirements is determined. This is done so that in the next stage the ideas can be compared correctly to see which one(s) best meet the requirements. When dealing with a large list of requirements a shorter list with the most important requirements can be used.

The requirements are sorted in relation to each other and are given a letter notation. The requirements are then compared in pairs so that all requirements are put in relation to each other. The following steps are then taken (Johannesson, Persson and Pettersson (2005)):

1. If A is more important than B, two points are awarded in square A-B. If B is more important than A, zero points are awarded in square A-B. If A and B are of equal importance, one point is awarded in square A-B.
2. All the requirements are then evaluated in this manner.
3. The points are added vertically and a minus is added in front of the sum.
4. Points are added horizontally together with the correction term. This correction term is made up of a series of uneven numbers.
5. Confirm that $\Sigma p_i = n^2$, where $n$ is the number of requirements.
6. Calculated the importance factor for each requirement $k_i = p_i / \Sigma p_i$ and confirm that $\Sigma k_i = 1,00$
### 3.6.2 Evaluation chart

Using an evaluation chart the ideas are ranked on how well they meet each specific requirement. The ideas are rated on a scale from zero to ten (Paul and Beitz (1995)):
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This is then put in relation to the importance previously established for each requirement in the value analysis. The value (Val.) is multiplied with the importance factor (Imp. factor) which results in the weighted value (Wt.Val.) for the concept. By adding all the weighted values for each concept the total score (Sum Points) is established. The idea that has the highest total score is the best one.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Criteria 1</th>
<th>Criteria 2</th>
<th>Criteria 3</th>
<th>Sum Points</th>
<th>Ranknig</th>
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<tbody>
<tr>
<td></td>
<td>A</td>
<td>B</td>
<td>C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imp. factor</td>
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<td>0,250</td>
<td>0,250</td>
<td>1,00</td>
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</tr>
<tr>
<td>Concept A</td>
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<td>9</td>
<td>2,25</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1,5</td>
<td>6,25</td>
</tr>
<tr>
<td>Concept B</td>
<td>7</td>
<td>3,5</td>
<td>4</td>
<td>1,0</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2,0</td>
<td>6,5</td>
</tr>
<tr>
<td>Concept C</td>
<td>9</td>
<td>4,5</td>
<td>10</td>
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<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2,0</td>
<td>9,0</td>
</tr>
</tbody>
</table>

*Example of an evaluation chart (after Paul and Beitz)*

3.7 Final design

After a final design has been decided upon the next step is to transform the design idea into a finished product with all details thought out. Simulation models like CAD models can be used or prototypes can be made for showing the final design. For onscreen design, drawings or computer generated pictures can be used to show the result.
4. Implementation

4.1 Information gathering

4.1.1 Literature
Existing data has been gathered from the library at Luleå University of Technology and also from databases LIBRIS and LUCIA. Information was also gathered from web pages. The literature study was focused on gathering information about Orthopedics, Minimal Invasive Surgery and Computer Aided Surgery. Once the basic issues were understood, information was gathered on existing technologies that appeared to be the most promising to provide solutions with wireless data transmission and display technologies.

4.1.2 Observation
Observation of surgeries was done at Norrlands Universitets Sjukhus (NUS); three operations in total were observed, two total knee replacements and one half knee replacement. A set of questions and things to look for while observing was drafted. This was done with the help of supervisor at TheUEgroup in addition with things to look for from the information gathered in the literature search.

4.1.2.1 Observation result
The operating room is a busy environment with a lot of people, equipment and noises present. The operating table is in the center and tools and instruments are placed around it. The sterile area around the operating table is marked out on the floor as well as the extracting fan box in the ceiling covering the whole sterile area (See Appendix C). No one outside of this area is allowed to step into it and those inside it are not allowed to step out unless they are leaving. The people inside the sterile field are the surgeon, the surgeon in training and the nurses assisting the surgeons (scrub) handing them instruments. Most tools that the surgeon uses are within 0,5m of reach.

The other people present in the room is a nurse handing implants and other equipment to the people within the sterile field, an anesthetic nurse and one to two nurses in training on each position. The work done is a team effort with the surgeon on top, double checking decisions and coordinating. There is a lot of communication where anyone can speak up asking questions or give information.

See Appendix C for list of observation results.

4.1.3 Video recording
All the observations were recorded in order to be able to go back at later stages in the project and look at specific tasks/notes. It was also used to be able to compare the observation results done in Sweden with those made by theUEgroup previously in the USA. An edited video recording from one of their observations was also viewed.

4.1.4 Interview
To learn about the surgeons opinions and experience with the technology interviews were held. A set of questions were designed to aid in the semi-structured interview with the goal to explore the prevailing conditions of their work environment,
their experience with CAOS and their attitude towards this technology and its future. The interviews were held after the observations so that possible questions that arose during them could be brought up and discussed during the interviews. The questions were put together with the help of supervisor at TheUEgroup. The interviews were held in Swedish which was the native tongue of the surgeons, this was done to make them feel more at ease. (see Appendix B for interview questions.)

To find orthopedic surgeons to interview, NUS and Sunderby Sjukhus was contacted. Three interviews were held; one at Sunderby Sjukhus and two interviews were conducted over the phone with surgeons at NUS. Two of the interviewed surgeons had no live experience of using CAOS, but had observed or watched it being used. One surgeon had two years experience working with CAOS.

4.1.4.1 Interview result

The surgeons do not choose members to the surgical team and the staff present changes during surgery especially round shift changes. There are often new people in training present. It is important to have a good scrub that knows what instrument to give the surgeons at the right time, the more they know about what is going on the better they are at helping. All surgeons are different and like to do things slightly different, it is important that the surgeon can customize the tools and systems they use to suit his/her needs.

The best thing about CAOS is the increased performance in precision and support it can give in decisions. The worst things about CAOS is that it can restrict the knowledge the surgeon has, can cause conflict with the surgeon and not being very good at interpretation of new situations. As it is perceived today it is very rigid and can be a source of error. It also forces the surgeon to look up often to concentrate on information on the screen and take focus off the patient. Another big drawback is the cost; it is hard to convince management to invest when it is so expensive and not working properly today in their eyes. It has also changed the dynamics a little with the scrub often having to do a lot of the interaction with the system becoming a middle hand between the system and the surgeon at times. Any products should be wireless since cables are in the way and products should avoid being dependent on ‘line of sight’.

See Appendix D for list of interview results.

4.1.5 Benchmarking

The benchmarking process consisted of two parts; finding information about leading competitors on the market through their websites and attending a conference, the annual meeting of American orthopaedic surgeons (American Academy of Orthopaedic Surgeons/AAOS) from March 22 to 24 in Chicago, USA, 2006.

The benchmark led to the conclusion that all the major companies providing CAOS products have rather similar products and also the way the screen based information is shown is similar. There are slight differences but none of the companies benchmarked stand out from the others in terms of having a system that work very different or being ahead of the others, they all seem to be at the same stage in the development. The competitors that were investigated during the benchmark were: Smith & Nephew PLC, GE Healthcare, PLUS Orthopedics, ORTHOsoft, Medtronic, Medacta International, BrainLAB, Stryker Corporation, Zimmer Inc., Nuvasive Inc.,
4.1.5.1 Using CAOS product

At the conference in Chicago a simulation of a product for complete knee replacement was tested. The product was from PRAXIM medivision. It gave good insight in both the competitors’ product but also in general a good overview of how CAOS works.

4.2 Problem determination

Future products within CAOS should be a tool(s) that bridges the knowledge and capabilities of the surgeon and that of the computer. Products should be portable so the surgeon can place it where necessary for his/her individual needs. The smaller the devices the better since there is already a lack of space close to the operating table as well as on the instrument table. Ultimately the surgeon should be able to decide how he wants his feedback, if others should be able to take part or if information should just be directed at the surgeon. If using audio signals, they should be distinct in order to be able to be heard over all the other noises present in the operating room to avoid confusion. Visual feedback should have a lot of contrast and color, both for the visual needs but also for aesthetics reasons. It should be easily understood how to operate to accommodate for easier changes of personal during surgery and also to reduce the learning curve to save that extra time. Consistency throughout future products is important.

4.3 Problem clarification

The information gathered together with the requirements the UEgroup had, was interpreted into a list of requirements with the help of a set of questions. Based on these requirements an abstraction was then formed.

Product concepts are to be developed, the result will not be a finished technical product, no drawings, and exact technical/electrical solutions will be presented in the result. Cost should be taken into some consideration but does not have to be considered in detail. The result of this project is new creative ideas to aid the surgeons; the ideas should be realistic solutions to the problem and a direction-setting vision for the next-generation of orthopedic surgical devices.

4.3.1 Problem Elucidation

In this part of the process a set of pre-defined questions were answered in order to get a better understanding of the problem at hand.

What is the problem really about?

To develop a product and an onscreen design that will aid the orthopedic surgeon in his/her work.

What implicit wishes and expectations are involved?

Product Design

- Easy to handle
- Less noticeable
- Portable
- Slim design
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- Easy to upgrade
- Colorful
- Eliminate issue of ‘line of sight’
- Low cost
- Markers less visible
- Allow surgeon to keep eyes on patient as much as possible

**Onscreen Design**
- A change of the information/how the information is shown on screen at present
- Address issue of not completely trusting system
- Easy to ‘upgrade’
- Colorful
- Allow surgeon to keep eyes on patient as much as possible
- Consistency
- High legibility
- Adaptable to surgeons needs of information shown
- Critical points emphasized
- Instant feedback
- Be as tactile and physical as possible

**What tasks should the product be able to handle?**
- Enable the surgeon to easily interact with the information on main screen
- Provide the surgeon with higher precision in the task (compared to that without CAOS)
- Be portable or easily moved
- Gives support in decisions in showing the correct data about the anatomy at relative instruments
- Minimizing the time the surgeon has to take his eyes of patient and task at hand

**What qualities must the product posses?**
- Easy to use
- Adjustable
- Wireless
- Must be able to be sterilized
- Provide surgeon with accurate information
- Consistency
Are there any pre-defined conditions in the task?

- Product can not enter sterile field if not sterilized
- The work procedure of the surgeon and other staff present
- Touch screen based

What qualities can the product not posses?

- Cause injury to patient
- Cause injury to surgeon
- Loss of data with wireless connection
- Only be able to be placed in one place, have docking station
- Not restrict the knowledge of the surgeon/cause conflict with surgeon
- Rigidity and source of error

Current technical situation

- Many companies are offering products within CAOS
- Operating rooms are crowded and have a limited amount of space
- Sterile field around the operating table, approximately 1.5 m from operating table
- Light sources outside of sterile field are very bright
- Surgeries can last up to about approximately ten hours, so lifetime of products needs to be relatively long
- Noisy environment, background noises and high pitch warning signals

Legal demands? Standards?

- Electrical standard
- Health standards of the operation room – sterilization
- Radio Frequency exposure recommendations (SAR limits)

Technical trends, design trends, potential development

- Be more versatile, adaptable to surgeon’s needs
- Ergonomics, better grips of tools
- Brighter coloring on products among manufacturers
- Better technology
- Better computing power
- Help with patient selection

Requests, desires concerning possibilities of changing performance and appearance

- Should not add any more elements to the procedure/surgery
- Should be easy to update
- Address the role of the scrub, help them in their preparation work during surgery
- Contribute to making the work a team effort
4.3.2 List of Requirements

For the onscreen design the UEgroup had a predefined list of requirements of things that the menu system should contain. These were: projected lines, instruments, implant, patient landmarks, numeric values, recommended numeric values, and anatomy perspective/angle changes. Another requirement they had was that the design should also be focused on being more like a ‘palette of tools’ for the surgeon to use as he wishes so that each surgeon can use the tools he wants when he wants. Customize after their own needs. The way similar onscreen design done by the UEgroup had worked previously is more focused on a set of steps through the system to complete the task.

See appendix E for requirements.

4.3.3 Abstraction

The findings from the previous stages of the problem clarification were summed up in an abstraction. The abstraction covers both product design and onscreen design since the task is to use them together to solve the problem at hand. It is a complete system that addresses the problem in a neutral statement. The abstraction is presented below:

“To develop a product and onscreen design that will support the orthopedic surgeon and his staff in their work. They should make their work easier, provide them with accurate information and allow them to easily interact with the system. They should be adaptable to the surgeons’ individual needs and not restrict them in their work. They should create a direction-setting vision for the next-generation of orthopedic surgical devices”

4.4 Idea generation

The idea generation was performed alone by the author of this thesis and also together with Tony Fernandes, CEO of the UEgroup. The idea generation was categorized into two separate groups and idea generation was done separate for each one; first one for the product design and secondly one specifically for solving onscreen design problems. A number of solutions to the problem in part and whole were generated for both product design and onscreen design. During the first part of the idea generation process general solutions were thought of and then complemented with simple ideas on how to solve different sub problems, for example; controls, shapes and attachments mechanisms.

4.4.1 Matrix of ideas

The ideas were inserted into a matrix of ideas, one for product design and one with the ideas for onscreen design. The different solutions were then looked at and combined and put together into different concepts that were then further developed. Some completely new ideas also came together during this stage.

See Appendix F for matrix of ideas.
4.5 Product design concepts

4.5.1 Concept A

Concept A is a small screen that is attached to a mechanical arm that in turn can be attached to the operating table or other appropriate tables. It attaches with two screws and the bendable arm allows the screen to be moved to the desired location using the handle on the side and can be controlled using the buttons on the right side. The screen allows for information being able to be shown on the screen close to the surgeon and allowing him to stay in his place and control the system bringing the feedback closer to him. The surgeon does not have to take his attention away from the patient as much. It communicates wirelessly with the system and runs on batteries.

![Concept A](image1)

4.5.2 Concept B

Concept B is a small triangular portable product with a small screen, it is intended to be fastened with a self-adhesive and be attached to the surgeons arm or any flat surface. It has five buttons to allow for navigation, one main button that is slightly elevated bump so the surgeon easily can find the button when wearing gloves. The buttons on the side are indented for the same reason. It communicates wirelessly with the system with the small screen giving the surgeon feedback on the present activity and enables the surgeon to remain in position without taking too much attention from the patient. It is a disposable product that is run on batteries.

![Concept B](image2)
4.6 Onscreen design concepts

4.6.1 Concept C

Concept C has a layout with the menu being at the bottom of the screen so it will not get in the way of the main part of the screen where the information is shown. It has objects related changing the view of the object on either side of the middle main part. This main part consists of objects for tools that can be displayed. When a button is activated it lights up with color. The buttons are blended into the surface and shape of the background for the menu. They do no not have a bounding circle or area but the icon itself is the actual button.

![Concept C](image)

4.6.2 Concept D

Concept D has a layout with a scroll at the bottom of the screen with which the surgeon can scroll through the different tools he want displayed. When scrolling through the different options it will give the impression of being a transparent ‘box’ with the different sides containing different tools. The hold button is for stopping at an option and placing that tool in the main part of the screen. No part for changing angle has been incorporated into this concept.

![Concept D](image)
4.6.3 Concept E

Concept E is divided into three different menus. The one on the left consisting of computer calculated objects relating to angles and targets that were thought probably would not be able to be shown at the same time as the others on the right hand side menu. In this right hand side menu are tools that were thought could be visible at the same time. The menu at the bottom is for changing the angle and they are smaller than the other buttons. The information is shown in the middle of the screen. The menus have handles so the menus the surgeon are not using can be hidden and that way not distract. The background of the menus are dark grey to mark them off from the surrounding black background and for the light grey buttons to stand out and be more visible. The buttons are designed to resemble a physical button to invite pushing (for the touch screen).

Fig. 5                                 Concept E

4.6.4 Concept F

Concept F has only one menu that contains all the buttons. The buttons for changing the angle and zooming are placed at the bottom and like in concept C with these buttons the icons themselves are the actual buttons. The other icons are slightly indented to give the impression of a button. The menu has a handle so it can be hidden.

Fig. 6                                  Concept F
4.6.5 Concept G

Concept G has one menu at the bottom of the screen with a middle part with a slider that separates the zoom and changing of angle at either side. Like in concept C and F these buttons have the icons themselves as the actual buttons. The middle part has a slider with which to control which buttons to activate/deactivate. This concept has the strength of being easily combined with the two product designs with rotating clockwise/anticlockwise with the forward/backward button on the product design.

![Concept G](image1)

4.6.6 Concept H

Concept H consists of one menu with all the buttons with the zoom and changing of angles at the bottom and with smaller buttons. It is a clean design that leaves a lot of space for showing the information and does not distract much from it. The menu is meant to be present at all times and not be hidden. The background of the menus is dark grey like in concept E to mark them off from the surrounding black background and for the light grey buttons to stand out and be more visible. Also like in concept E the buttons are designed to resemble a physical button to invite pushing (for the touch screen).

![Concept H](image2)
4.7 Idea assessment

The evaluation of the concepts was done with criteria weighting and value analysis (Ulrich, Karl T., Eppinger, Steven D., 2004) and also together with Tony Fernandes, CEO of the UE group. In this initial idea assessment the concepts that were unfeasible were excluded. (See Appendix F for ideas on product design and ideas on onscreen designs solutions)

The concepts that were chosen for further development were chosen because they were thought to have the highest probability to success and fulfillment of requirements.

A shorter list of the most important requirements was put together to be able to evaluate the concepts, some were requirements directly from the requirement lists while others were a combination of requirements.

See Appendix G for criteria weighting and Appendix H for value analysis.

4.8 Final design

The final concepts from the evaluation Concept B and Concept E were further developed and finer adjustments were made until a satisfying result was achieved.

4.8.1 Product Design

Ideas on how to improve the concept were taken into account. This was done together with the supervisor at the UE group, Tony Fernandes. Icons for the buttons were added and the shape was also slightly alternated to create a more interesting shape that also helps the product to stay steadily on the surgeon’s arm. It is mainly intended to be attached to surgeons arm but it can also be attached to any other surface if needed. What specific display and wireless technology best suited was also explored at this stage.

See Appendix G for criteria weighting and Appendix H for value analysis.

4.8.2 Onscreen Design

The onscreen design was finalized. The concept was further developed with the requirements in mind and also a few new features to incorporate were added to the requirements. The buttons were placed slightly different to group the tools that belong together and to make better use of the space on the screen.
5. Result

The result of this thesis project is a product design and an onscreen design that aids the surgeon in his work. They can be used together but the solutions also work as individual solutions.

5.1 Product Design

The final product has a LCD screen to show the most crucial information to allow the surgeon to remain in position and be able to have the information right in front of him/her. It helps shift the focus back on the surgeon being in control by giving the surgeon a way to control the system easily instead of relying on the scrub or another member of staff for this. The surgeon can change the information needed on the screen from where he/she is standing instead of having to move to access the touch screen or instruct someone else on the staff to make the wanted changes for him/her.

It communicates wirelessly with the main system using Bluetooth technology, enabling safe transmission using little power.

The product is meant to be disposable, be resistant to dirt and fluids, and it has a self-adhesive surface to be able to be attached to the surgeons arm or possibly other chosen surface. It has a lightly bent front to better fit the arm and stay in place. This feature also adds a more interesting touch to the design language. Being disposable makes sure it is always sterile and can be used within the sterile field.
There are five buttons in total; two for increasing/decreasing and two for scrolling between options on the screen and a big button for choosing/accepting the changes made. The buttons on the sides have small icons next to them to show which button does what. They are activated by being pressed in toward the ‘body’ and they are slightly indented so that the surgeons’ fingers can easily locate the buttons. The main button on top is also slightly indented for the same reason.

The increase/decrease buttons are mainly intended to be used for changing the numeric target information. The display shows the current information generated by the surgeon with the tool he is currently using, for example the current angle that the surgeon has with his cutting tool.

It is not intended to give full control of the system, but a simple device that allows the surgeon to work smoothly and control the most vital things without having to take his attention away from the patient for too long and to help avoid an awkward work position with having to turn head and change position to be able to see the readout/numbers on the screen.
5.2 Onscreen Design

The onscreen design has a minimalist design composed by three different sections. The menu sections are organized after what they contain and how to best optimize the space on the screen. This enables the user to navigate easily when related functions are placed closely together.

The sections each have a handle to signal that they are boxes of menus that can be hidden or ‘dragged out’ to use the tools within so the menus the surgeon is not using can be hidden and that way not distract. The center of the screen is devoted to showing the chosen information.

The different menu sections have been placed at the bottom and sides so that they can be used without blocking information on the screen while doing so. One section contains computer calculated targets and objects which are separated with a thin line. The top part is for computer calculated targets and the bottom part is dedicated for representations of physical objects. One section contains navigation tools such as a zoom and change of view. Finally there is a section for the numeric readouts which also have an extra thin line to divide the screen for where the numeric values will be shown in comparison to the main part of the screen.

This onscreen design can be customized after the surgeons’ individual needs. It allows the surgeons to choose what information they want displayed when performing a task and can use the ones they feel most comfortable with to help them deliver the best result.
Since the onscreen design is primarily intended to work on a touch screen, the buttons have been designed to resemble physical buttons to invite pushing and make it easier for the user to know how to use them. The backgrounds of the menus are dark grey to mark them off from the surrounding black background, and for the light grey buttons to stand out and be more visible. The buttons are embossed when not activated and when activated they change to being indented and highlighted in color, again relating to a physical object that has been pushed in. Each button has an icon which is a graphical representation of what they control. The control for changing angles has fixed steps that the user can scroll between using the slider. When being controlled with the remote control the buttons slightly inverted embossed to show which button that would be activated if a button would be pressed.
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The layout of the onscreen design also makes it easy to be used together with the remote control with stepping in between menu options are done clockwise/counterclockwise with the scroll buttons on the side.
6. Discussion

6.1 Project

The project started in Luleå, Sweden where almost all the information gathering was done prior to leaving to continue the project in San Jose, CA, U.S. The project was then finalized there. Despite a nine hour time difference working remotely worked really well although it in part removes the possibility to spontaneously ask questions and discuss things. For communication during this first stage in Sweden we used email, phone and most importantly used a program called Groove Workspace (version 2.5) that provided us with chat functions, messaging, discussions, shared websites and uploading files. This made it a lot easier to work remotely when being able to have good communication. It was a great experience and very valuable to be able to learn from the knowledge at the company; in terms of technology issues, previous research done by them as well as general design expertise.

I am pleased with the result but of course there are a lot of things during this project that I would have liked to do differently. With more time that could have been possible but it has been a great experience to work on a project from start to finish throughout all the stages with a time limit and seeing that everything is a trade-off between what is optimal, desirable and what is feasible.

6.2 Information gathering

The most time consuming part of this project was the information gathering. Since I had no previous knowledge or experience it took a lot of time in the beginning of the project to get familiarized with CAOS and all its aspects. When first starting to search for information and getting familiar with the field of orthopedics and CAOS it was a bit difficult to know what to focus on since the field is so wide and there are a lot of products involved. The project description gave me the freedom to explore the opportunities I found most interesting but it also made it difficult since there are so many areas to CAOS to work with and different stages where different solutions can be found, it has sometimes been hard to concentrate on one.

All the information found was very old, mostly from the 90s and there is not a lot to find from more recent dates on computer aided surgery in general. This is most likely because after it was first introduced and refined not much has happened apart from minor advancements. One of the questions posed in the beginning of the project concerned why this technology has not been more widely deployed. This probably relates to the same thing that it was revolutionary when first introduced but since nothing major has changed and too many problems are seen with the way it works - hence few have deployed it.

I found it hard to find information about how CAOS works; there is no literature that I could find explaining it in general. I found most of that kind of information on competitors’ websites, encyclopedia websites and through watching videos of the technology being used. Most of the information found in books and on the Internet corresponded with each other and were therefore considered to be reliable sources.

In the beginning there were hopes that I would be able to observe surgeries first in Sweden and then in the U.S. This was however not possible to do in part because of time issues. It would also have been interesting to see if there proved to be a big difference in how things were done in the U.S compared to Sweden. There is an interesting culture.
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aspect, products are made in one country and then exported, how do different people/cultures work? I think it could have given more insight into the problem if I had had the opportunity to observe an operation where CAOS was used and also interviewed more surgeons that have used it. There is currently no such system in operation in Sweden so it was a hard task to find people who had used it hands on. Related to this is using statistics for orthopedic surgeons in the US as guidelines for the target group. The general perception however is that it is widely a male dominated profession and that the average age is rather high everywhere.

In the project outline it was stated that part of this thesis would include “evaluate the present onscreen design and form factor of a system design by the UEgroup”. No evaluation according to a method was done. I was however able to see parts on older designs and pictures of new ideas on similar products. Having performed a proper evaluation on both their current onscreen design and product designs with an appropriate method might have resulted in more information.

With there not being that many surgeons at each hospital and a limited amount of time to perform the interviews before leaving Sweden, only three interviews were held. Because of the distance and that there was hard to find suitable times to conduct interviews, one interview was held at Sunderby Sjukhus and two interviews conducted over the phone with surgeons at NUS. It was especially hard to find surgeons with experience with CAS since there (at the time) were no hospitals in Sweden using that technology within orthopedics. However, one surgeon that was interviewed had previous experience from working with CAS for two years in Australia. It would have been desirable to have more interviews especially with surgeons in the U.S with COAS experience.

It was very useful to be able to observe the surgeons at work; it gave a lot of valuable information about the environment they work in and also gave me a chance to see things I had read about being carried out. There proved to be a lot of concerns about the system taking over from the surgeons, that the new way of doing the procedure they think is too different from the way they are used to. I think that being able to observe the way it has been done ‘by hand’ before CAOS was very useful to understand how they work.

In general the operating room is very crammed with different equipment and there is a need for a complete operating room makeover that easier facilitates for the technology used today.

6.3 Idea generation

The idea generation was done alone and also together with the supervisor at the UEgroup. A lot more ideas could probably have been generated by using more methods in this stage but with a small company with only three people working on-site at the company only the supervisor and me were involved. The idea generation was performed in San Jose and I had no contact with surgeons but I think it would have been desirable to include surgeons in the idea generation process to get their input also in this stage. All the surgeons gave good feedback during the interviews and also some feedback was given during the observations on what direction they would want to see the technology develop and therefore I believe this could have produced a lot of different ideas.
The ideas were evaluated together with the supervisor at the UE group as well as with other methods to make sure a good result was reached that best fitted the requirements. We continuously had discussions about the ideas; how to improve them, new ones and which ones to exclude. With the onscreen design they were first evaluated with my supervisor and then I went back and used two other methods to secure that the best concept was chosen.

6.4 Future development

Next step I believe should be to test this product with users to get feedback on the designs, possibly with the help of a simple prototype for the product design and using paper prototype for the onscreen design.

6.4.1 Product design

The product design needs to be further developed and technical issues that were not part of this thesis, like type of battery, placement of battery, type of self-adhesive and transmitter needs to be solved.

Some surgeons may not want to control it themselves but want to leave that to some other member of staff and this design does allow for that. It is however adapted for a male hand since only a small percentage of surgeons are female, it could be a possibility to have another smaller version for a female hand or a version that is completely flat and could be fastened to any surface, and lay flat on a table if wanted to expand the possibilities of use.

Some of the interesting display technologies found are still in the development process and products are not yet available on the market. Those are Field Emission Display (FED) & Surface-conduction Electron-emitter Display (SED), and because of that they will not be explored further for the product but they are interesting to keep in mind for future use. For the short-range wireless technologies there are a few interesting alternatives for the future but in this thesis they were eliminated but like with the display technology they should be kept an eye on for future use.

6.4.2 Onscreen design

For the onscreen design a lot of work has to be done to include everything and to address items like sub menus, exit to other part of system and for the design to be tested with users. Consideration should be taken to what menu options that can be available at the same time and make those that are not available at certain times disappear or in another way ‘hide’ those options to reduce a source of error for the user. A further development on the onscreen design is already being worked on at the UE group.

Interesting further developments:

- There has to be a way of getting out of the ‘View mode’ and getting back to the regular step as well as quitting etc. In other words, it will need to provide access to some sort of menu that allows navigation to other parts of the product.
- The onscreen design must allow for the selection of sub-menu items.
Medical Vision Project

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**Observation**

**Environment**
- How big is the room? What is it mainly consisting of?
- Open spaces?
- \( h: \)
- \( w: \)
- \( l: \)

- How is the sterile field identified?

- What is done in terms of keeping it sterile?

- Lighting? changes?

- Noise level? changes?

- Distance to “devices”?

- Material?

**Interaction**
- Who are present?

- What devices are used?

How do surgeon's physically interact of control current devices? Do they do it themselves or to other members of the surgical staff, interact with them and provide the surgeon information?
Do current devices allow the surgeon to maintain a focus on the patient or must they look away?

How often, why and when, does the surgeon take their eyes off the patient?

How often does the surgeon talk and to whom?

What are the social norms? Do people only speak when spoken to by the surgeon or is it much more of a team effort where everyone can speak up?

How much does the surgeon let people in on what's going on?

When the surgeon is working, what are other people doing? Are they just waiting, are they preparing?

After the surgeon, is there a visible second in command?

What technology, such as x-ray fluoroscopy, is used?

explore surgeon’s attitudes toward using technology in the OR. If they make a mistake, nobody can tell. With a system setting there saying "this is looking bad" everyone in the room knows it. Is there a reaction to this? Do they want a machine to come in a question what they are doing?

Other?
Interview Appendix B (1/3)

Intervju

Allmänt

Namn………………………………………………………     Man □   Kvinna □
Ålder…………

Yrkesroll/arbetsplats……………………………………………………………………
…………………………………………………………………………………………..

Antal år inom ortopedi/kirurgi……………………………………………………………………

Miljö

Vilken teknologi används? Som t.e.x x-ray fluoroscopy………………………………
…………………………………………………………………………………………
…………………………………………………………………………………………

Vilka behov finns det på ljussättning? ………………………………………………….
…………………………………………………………………………………………
…………………………………………………………………………………………

Vilka behov finns det på avstånd? ………………………………………………………
…………………………………………………………………………………………
…………………………………………………………………………………………

Steril miljö

Vad är ett sterilt fält och hur identifieras det i operationssalen……………………
…………………………………………………………………………………………
…………………………………………………………………………………………

Vilka steg ingår för att sterilisera instrument (allmänt)…………………………
…………………………………………………………………………………………
…………………………………………………………………………………………

Är det någon skillnad på sterilisering vid CAS kopplade instrument…………..
…………………………………………………………………………………………
…………………………………………………………………………………………
Interview

Finns det några ”gyllene basregler” för att hålla en steril miljö?.................................
...........................................................................................................................................
............................................................................................................................................
............................................................................................................................................
............................................................................................................................................

Organisation

Hur formas ”lagen” inför en operation?.............................................................................
............................................................................................................................................
............................................................................................................................................
............................................................................................................................................
............................................................................................................................................

Är det ofta samma personer?..........................................................................................

Har du lärt ut användning av systemet?..........................................................................
............................................................................................................................................

Vilka består ”lagen” av? .................................................................................................
............................................................................................................................................
............................................................................................................................................

Vid CAS.........................................................................................................................
............................................................................................................................................
............................................................................................................................................

Vid ”vanlig”....................................................................................................................
............................................................................................................................................
............................................................................................................................................

Finns det en skillnad på hur mycket dom andra i laget involveras i vad som händer nu
jämfört med utan CAS då endast kirurgen visste vad som hände?.................................
............................................................................................................................................
............................................................................................................................................
............................................................................................................................................

Är det positivt eller negativt?........................................................................................

Hur är det positivt.........................................................................................................
............................................................................................................................................
............................................................................................................................................

Hur är det negativt .......................................................................................................  
............................................................................................................................................
............................................................................................................................................

..........................................................
CAS
Antal arbetade år med CAS system.................................................................................................

Utbildning/Träning med CAS...........................................................................................................

Vilka får träning?............................................................................................................................
......................................................................................................................................................

Vad är det bästa med CAS system, dess styrkor?.............................................................................
......................................................................................................................................................
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......................................................................................................................................................
......................................................................................................................................................
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Vad är det sämsta med CAS system?..............................................................................................
......................................................................................................................................................
......................................................................................................................................................
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......................................................................................................................................................
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Hur skulle du vilja att CAS system fungerade?..............................................................................
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......................................................................................................................................................
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Uppfattning/förslag
Varför tror du att denna teknologi inte blivit mer använd, spridd?..................................................
......................................................................................................................................................
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Är det något jag inte tagit upp som du vill berätta som du tror kan vara värdefull information vid utvecklande av CAS system?....................................................................................
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Observation results

Environment

- High pitch noises. For example: blood vessel burner and alarms for other systems. Lot of background noise, in this case extra from the fan noise from the ‘box’. Phone ringing. People talking.
- A lot of equipment surrounding the operating table
- Lightening is bright round operating table and ‘darker’ around.
- Most things not more than 0.5m away from surgeon or scrub, although screens too far away.

Layout of the operation room:

Interaction

- Team effort
- Surgeon on top - Surgeon double checks most things, like drugs after operation to be administered, implants and so on.
- Surgeon talks a lot with the assisting person as well as the others in the operating room, sometimes even with the patient. Anyone speaks up at anytime asking questions or giving information
Observation results

• How much the surgeon lets other people in on what is going on varies; sometimes a lot, sometimes not at all. Often when things are going well, Silence when not or until it has gone well. Others do ask questions about what is being done.
• The surgeon is in command and then the ‘student’ and then the scrub and then the others.
• Communication. Often when things are going well/ are finished
• Rotation of people that are present

Other

• Language issues – English used on products and manuals can be difficult
• A lot of equipment is different, lot of different interfaces for example that they need to be familiar with
• Knee operations extra sensitive, 20 seconds prayer
• Nurses checks vital signs and supplies, except showing implants before opening boxes.
• Surgeons check x-ray themselves but rely on someone else to adjust contrast on the screen.
• Surgeries took about 2 hrs each. (prep done before by nurses)
• All the tools are metal. Few had hard plastic.
• Surgeons often take their eyes away from patient.
• The idea with the technology is good (conversation in-between) it gives better result and especially help with monitoring the patient.
• No head-strap/lights used
Interview results

• The surgeon needs to be able to place equipment where he wants it, (they all pointed this out strongly) differs from surgeon to surgeon how he/she wants it set up. Relates to the distance requirement, depends on surgeon. 1.5 m one mention as max distance.

• In terms of organization, at most surgeries the staff present is not chosen. The people present are there because they have their shift then. Surgeons do not get to choose members to the team they want. It can happen occasionally.

• They quite often have new people present, so there is often double of each ‘position’.

• Scrub not very interested in what surgeon is doing, they just want to know what stage the surgeon is at to give right instrument. Positive that others can see what it going on, helps them to be quick in helping.

• The best things about CAS is perceived to be higher precision, lets scrub know what is going on in a more visible way. (‘Carpenter without water/leveler – is a bad carpenter’) gives support in decisions in showing the correct data about the anatomy. Saves time in later stages of the surgery.

• The worst things about CAS is that it restricts the knowledge the surgeon has, it is not very good at interpretation of new situations, causing conflict with surgeon, rigidness and source of error. The cost of CAS. Takes a bit longer initially (added elements), a long learning curve and also changes takes a while to show on the screen. The scrub has to do a lot, have to look up often.

• How they would like to see it evolve: the idea is good but not working today. better technology to ‘build it on’, not enough computing power today to support it well. Eliminate the issue of ‘blocking sight.’ The markers should also be less in the way, more supple. Should discuss the information on the screen and also how it is presented, (difference like Mac-PC)

• It is not as widely used today as it should be because of the cost issue and also that it does not work properly.

• Products are released to early, good idea behind but not used fully.

• Economy driven today, should be technology driven.

• New issues of being careful not to trust the system to much.

• Critical parts of surgery should be pointed out by the system so that the surgeon will think it through properly.

• Happier, more colorful.

• Wireless instruments would help, maybe radio waves or electromagnetic ‘pulses’.

• The system should be integrated into instruments used today as much as possible.

• Should be able to be upgradeable, spending so much money on something that might be outdated quickly is an issue

• Should be adaptable to different cultures in the way that some might want ‘privacy’ others might want the scrub to interact with screen others not.
## List of requirements

<table>
<thead>
<tr>
<th>Product Design</th>
<th></th>
<th>D=Demand, W=Wish</th>
</tr>
</thead>
<tbody>
<tr>
<td>Geometry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>Legibility</td>
<td>Screen/display readable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&lt;1.5m</td>
</tr>
<tr>
<td>D</td>
<td>Supple, manageable size, compact</td>
<td>Smaller the better</td>
</tr>
<tr>
<td>D</td>
<td>Easy to clean</td>
<td></td>
</tr>
<tr>
<td>W</td>
<td>Adaptable to updates</td>
<td></td>
</tr>
</tbody>
</table>

| Forces         |                 |                 |
| D              | Easy to adjust  |                 |
| D              | Remain steady in position | Always, not roll of table, not touch unsterilized area |

| Materials      |                 |                 |
| D              | Reject water    |                 |
| D              | Reject dirt     |                 |
| D              | Endure sterilization | Autoclaving, protective seal or disposable |
| W              | Comfortable to touch |           |
| W              | Give a good grip for surgeon | while wearing wet gloves |

| Safety         |                 |                 |
| D              | Radio Frequency exposure recommendations (SAR limits) | 1.6mW |
| D              | Not cause injury to patient | Always |
| D              | Not cause injury to surgeon | Always |
| W              | Be adjustable/controllable without the surgeon being forced to take eyes of patient for too long | |

| Ergonomics     |                 |                 |
| W              | Comfortable grip |                 |
| D              | Enable good work posture | |
| W              | Good mapping     |                 |

| Design and Form|                 |                 |
| W              | Colorful         |                 |
| W              | Strong design language | |
| W              | Slim             |                 |

| Environment    |                 |                 |
| W              | Use environmentally approved materials | |
## List of requirements

### Appendix E (1/2)

#### Onscreen design

<table>
<thead>
<tr>
<th>Geometry</th>
<th>Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>D Indicate status changes</td>
<td></td>
</tr>
<tr>
<td>D Adaptable to surgeons needs of information shown</td>
<td></td>
</tr>
<tr>
<td>W Quicker feedback of what surgeon is doing</td>
<td></td>
</tr>
<tr>
<td>W Adaptable to updates</td>
<td></td>
</tr>
<tr>
<td>W Critical points emphasized</td>
<td></td>
</tr>
<tr>
<td>D Legibility</td>
<td>up to 2 meters from screen</td>
</tr>
<tr>
<td>D Be legible in hard lighting conditions</td>
<td></td>
</tr>
</tbody>
</table>

**Forces**

| D Easy to adjust                              |                                             |
| D Touch screen controlled                     |                                             |

**Safety**

| D Fulfill legal demands                       |                                             |
| D Not cause injury to patient                 | Always                                     |
| D Not cause injury to surgeon                 | Always                                     |
| W Be adjustable/controllable without the surgeon being forced to take eyes of patient for too long | Always                                     |

**Ergonomics**

| W Good mapping                                |                                             |

**Design and Form**

| D Colorful                                    |                                             |
| D Consistency                                 |                                             |
| W Clean design                                |                                             |
| W Intuitive & natural                         |                                             |
| W Tactile and physical design                 |                                             |

**Tools**

| D Projected lines                             |                                             |
| D Instruments                                 |                                             |
| D Implant                                     |                                             |
| D Patient landmarks                           |                                             |
| D Numeric values                              |                                             |
| D Recommended numeric values                  |                                             |
| D Anatomy perspective/angle changes           |                                             |
### Matrix of ideas – Product design

<table>
<thead>
<tr>
<th>ATTACHMENT/ARMS</th>
<th>CONTROLS</th>
<th>GRIP</th>
<th>FORM</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>SCREW</td>
<td>SLIDER</td>
<td>DOUBLE GRIP</td>
</tr>
<tr>
<td></td>
<td>SELFADHESIVE</td>
<td>HANDLE</td>
<td>PRECISION/PEN</td>
</tr>
<tr>
<td>B</td>
<td>GLUE STAMP (WATERMARK)</td>
<td>KNOB</td>
<td>ROUND/CLIPS</td>
</tr>
<tr>
<td>C</td>
<td>MECHANICAL ARM BENDABLE</td>
<td>BALL</td>
<td>GUN/POWER</td>
</tr>
<tr>
<td>D</td>
<td>TELESCOPIC</td>
<td>KEYBOARD</td>
<td>HANDLE</td>
</tr>
<tr>
<td>E</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Appendix F (1/2)*
### Matrix of ideas - Onscreen design

#### Appendix F(2/2)

<table>
<thead>
<tr>
<th>GUIDANCE</th>
<th>PLACEMENT</th>
<th>CONTROLS</th>
<th>PHYSICAL QUALITY</th>
<th>SIGNS</th>
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<td>A</td>
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</tr>
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<td>PREPROMITY</td>
<td></td>
<td></td>
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<tr>
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</tr>
<tr>
<td></td>
<td>SIMILARITY</td>
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<td>C</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>SYMMETRY</td>
<td></td>
<td></td>
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<tr>
<td>D</td>
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<td></td>
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<tr>
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<tr>
<td>E</td>
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<tr>
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<td>AREA</td>
<td></td>
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<tr>
<td>F</td>
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</tr>
<tr>
<td>G</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Criteria weighting

**Product design**

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Easy to use</th>
<th>Pleasing appearance</th>
<th>Low cost</th>
<th>Extent of control</th>
<th>Sterilized</th>
<th>Easily moved/adjustable</th>
<th>Safety</th>
<th>Less noticeable</th>
<th>Minimizing time the surgeon has to take his eyes of patient and task at hand</th>
<th>Correction term</th>
<th>Sum points</th>
<th>Importance factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>A</td>
<td>B</td>
<td>C</td>
<td>D</td>
<td>E</td>
<td>F</td>
<td>G</td>
<td>H</td>
<td>I</td>
<td></td>
<td></td>
<td>0,123</td>
</tr>
<tr>
<td>B</td>
<td>-2</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<td>3</td>
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<tr>
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<td>1</td>
<td>0</td>
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<td>7</td>
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<td>0,123</td>
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<td>1</td>
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<td>9</td>
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<td></td>
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<tr>
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<td>-1</td>
<td>2</td>
<td>2</td>
<td>13</td>
<td>16</td>
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<tr>
<td><strong>Sum</strong></td>
<td><strong>81</strong></td>
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<td></td>
<td><strong>1,000</strong></td>
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</table>
## Criteria weighting

### Onscreen design

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Easy to use</th>
<th>Consistency</th>
<th>Tactile and physical design</th>
<th>Strong design language</th>
<th>Intuitive &amp; natural</th>
<th>Indicate status changes</th>
<th>Good mapping</th>
<th>Adaptable to surgeons needs of information shown</th>
<th>Correction term</th>
<th>Sum points</th>
<th>Importance factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
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<td>1</td>
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Criteria weighting

Product design – display technology

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<th>Response time</th>
<th>Contrast/Legibility</th>
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<th>Dirt &amp; water resistance</th>
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Consideration has been taken to enhancements of the technology available that can better the product within the criteria.
### Criteria weighting

**Product design – Short range wireless technology**

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## Value analysis

### Product design

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## Value analysis

### Onscreen design

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<td>Indicate status changes</td>
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## Value analysis

### Appendix H (5/8)

#### Product design - display technology

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- **OLED**
- **LCD**
### Value analysis

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**Comment:** They both have pretty similar results. However, LCD is the best alternative because of its resistance to water, dirt and scratches. If The OLED had a good protective layer that would be resistant to scratches and dirt too then that would be the better option according to this value analysis.
## Value analysis

### Appendix H (7/8)

#### Product design - short range wireless technology

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