CHALMERS

MedicView: Increasing Life Quality

Extracting customer requirements on a medical device for surgical treatment of cancer

Master of Science Thesis in Product Development

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Göteborg, Sweden, 2011

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Abstract

This master thesis is conducted by two master students in the Product Development program in Chalmers University of Technology. This report addresses the early phases of a traditional product development process that is due to the character of the problem.

MedicView is a prototype that has been in use since 2006 and the Medic View Company wants to transform it into a product. The problem to be solved showed to be the missing of a proper requirements list, thus the product development students were contracted to fill in this gap. The product MedicView is a monitoring and measuring system used in HILP (Hypothermic Isolated Limb Perfusion) surgery. HILP is a complicated surgery with toxic drugs to treat malign melanoma, this type of cancer is the most increasing type of cancer today. HILP requires a measuring and monitoring of leakage, temperature and pressure in order to be performed with minimum risk.

To establish a requirements list the thesis students had to divide the problem into two parts. The first part was the needs of the past to compare it with the prototype in order to see what is not fulfilled. The second part was to explore the problems of today in order to set a base for further development. This was done by collecting data through interviews with key persons in the field and conducting field studies. The data was then supplemented with questionnaires and KJ-Shiba workshops. Afterwards the data was then reduced before it was analyzed. Most of the mentioned methods were conducted twice in order to deal with the two parts of the problem but also because establishment of requirement list is an iterative process rather than a linear. The outcome of this project became a requirements list which is meant to be used as a base for further development. The results show that the most important needs of the past such as the measuring and monitoring of leakage, pressure and temperature are fulfilled. Another interesting finding is the need for documentation and a database of HILP treatments in the coming generations.

Acknowledgements

In the name of God, Most Gracious Most Merciful
All praise and thanks are due to God, and peace and blessings be upon His Messenger.

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List of Abbrevations

SUH	Sahlgrenska University Hospital
CE	Conformité Européenne (European health and safety product label)
Cytotoxic drug	Drug that has a toxic effect on cancer cells
Lymph	A yellowish coagulable fluid containing white blood cells
Sarcoma	One of the four major types of cancer
Melanoma	Any of several types of skin tumours characterized by the malignant growth
TNF-α	Tumor Necrosis Factor-Alpha (a protein, produced in humans and other animals that is destructive to cells showing abnormally rapid growth)
Chemotherapy drug	A treatment of cancer with an antineoplastic drug
Incision	A cut made on the patient to proceed with surgery to reach internal organ
Tourniquet	A device for arresting bleeding by forcibly compressing a blood vessel
Catheter	A tube used to drain fluids from body
Oxygenator	A device to enrich the blood with oxygen
Perfusion	Pumping a liquid into an organ or tissue
Therapeutic agent	Fractional dose
HILP	Hypothermic Isolated Limb Perfusion
ILP	Isolated Limb Perfusion
Scintillator	A phosphor that produces scintillations
Ratemeter	The client that is used to measure the leakage
Multimeter	The client that is used to measure the flow rate and the average blood pressure
Collimator	A tube likely device that brings the rays of light into a parallel beam
Subcutaneous	Performed or introduced under the skin, as an injection by syringe
CAD	Computer Aided Design
CAM	Computer Aided Manufacturing
FEM	Finite Element Method

Table of Contents

1. Introduction

A traditional product development process is often divided into six phases [1]; planning, concept development, system-level design, detail design, testing and refinement and production ramp-up (see Appendix D, Fig 45). The issue with MedicView's prototype is that nothing in neither the planning nor some parts of the concept development phase has been documented. The product has been developed gradually through a list of oral requirements of two surgeons from Sahlgrenska University Hospital (SUH) by the innovator. MedicView wants to achieve a user-friendly product and explore different possible concepts with respect to manufacturing, customers, users and other stakeholders. Before starting to generate concepts it is important to understand what needs have to be satisfied by the product.

1.1 Background

A surgery is a very intense and difficult procedure to perform, especially when toxic drugs are involved. When it comes to a surgical procedure called Hypothermic Isolated Limb Perfusion (HILP) high doses of cytotoxic chemotherapy drugs are used on the patients as well as the working temperature on the affected area has to be at 39 – 40 degrees Celsius. These kinds of drugs are often applied to patients to treat or remove cancerous cells. That is why the limb that is to be operated has to be isolated from the rest of the body. The oxygenation and temperature has to be monitored while the blood flow in the limb has to be controlled to assure there is less than 10% of leakage to the rest of the systemic blood flow plus the temperature of the tissue that is heated should not rise to a lethal level. That is where MedicView's role comes to play. MedicView has developed a measurement system monitoring leakage during the whole surgery procedure as well as the temperature of the heated tissue and the blood pressure inside the isolated area. With the help of this system the quality of a HILP treatment has been improved significantly.

Today MedicView has a prototype up and running in SUH since 2006 mainly under two surgeons supervision. They have commented that weighing in the risks of this procedure they would not have performed a HILP surgery without the MedicView measurement system. MedicView stand today in a position to launch the product internationally and to be able to do that it has to be designed according to CE standards with documented requirements.

1.2 Purpose

The purpose of this thesis is to explore the needs in order to fill in the gaps in the product development process i.e. an appropriate requirement specification. MedicView wants to launch the product and extend their market, which requires a transformation of the prototype into a product. The requirement specification will set the foundation to these adjustments and can be revised later for further development of the product. This report is to answer the following research questions:

1. What are the needs and the desires of the user and the MedicView Company?
    a. What were the needs before the existence of the MedicView product?
    b. Which product related needs of a measuring and monitoring system are present today?

The reason for having a documented requirements list is:

1. To be able to justify the product in the future.
2. To be able to identify the product specifications that must be fulfilled by the product.
3. To be able to make changes in the future if new demands need to be satisfied.

1.3 Scope

Within the scope of this thesis a formal requirements list is to be established that can serve as a base for further development of the product as a separate product development project. The approach to achieve this will be an iterative process and it will contain requirements from the user, customer, functional requirements as well as product specifications. Within the scope of this thesis a functional description is to be set. The desires of the users will also be taken into consideration which will be a base to exceed the requirements of the product to market the MedicView measurement system in an improved way.

1.4 Delimitations

Out of scope of this thesis are any final concepts of the product or any cost analysis due to a time limitation. The deliverables are:

- A formal requirements list
- Functional description of the product
- Needs and desires of the users and customers.

1.5 Reading guide

Initially, the report starts with the description of how the surgery is performed and the different types of procedure. This chapter is called *Surgery Procedures* (chapter 2) and in detail this chapters describes the usage of the cytotoxic drugs that are necessary to undergo the treatment. Next chapter to follow is *The MedicView Product* (chapter 3), with an introduction of the product used today in the surgery procedures. By the end of this chapter the reader will have understood how the procedure is undertaken together with how the product is used during the treatment. The reader will get an overall view of the surgery. *Methodological Frame of Reference* (chapter 4) defines the different types of methods that can be used in regards to data collection and analysis. The chapter also describes the methods that are available to validate the requirements which are the outcome from the data analysis. Following this chapter is *The Adopted Approach* (chapter 5) describing the process of the conducted research which explains how the methods have been used, modified and adjusted to be more effective for the research. This chapter is important to understand because it describes the overall process of how the analysis has been conducted in an iterative process. The chapter *Analysis and Results* (chapter 6) details the data that has been collected and how it has been analyzed. The chapter describes in great details of what has been collected, observed and also the final results are presented in this chapter. The final result, which is a requirement list, is designed in such a way for the reader to see how the requirements can be validated and their traceability to the different sources. The analysis and the results are then concluded in *Conclusion* (chapter 7) following with proposed future actions in the chapter *Recommendations for further actions* (chapter 8). The report ends with a final discussion of the report in chapter *Discussion* (chapter 9). The overall procedure of this report can be seen in fig 1.

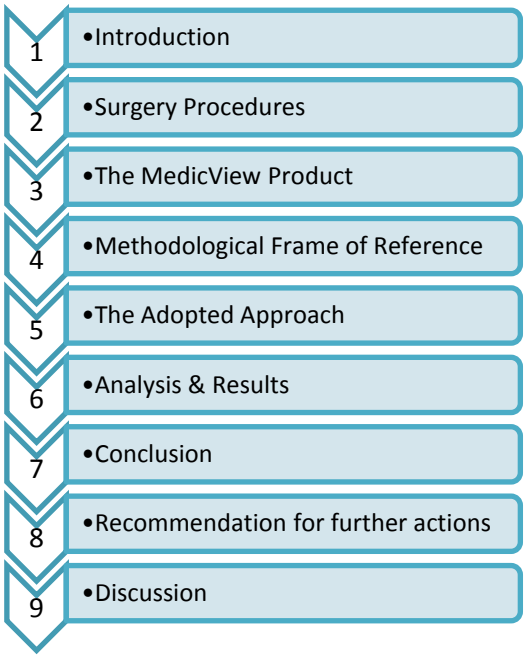


Fig 1: Visualizing the chapters of the report

2. Surgery Procedures

Melanoma is an increasing [2] skin cancer diagnose in the society today. For example, in United States an average annual increase rate of 4 percent of new malignant melanoma cases are diagnosed [3]. The rate of malignant melanoma is generally higher in Caucasian populations with the highest incidences occurring in Australia. Australia compared to Europe has 10 times higher annual rate of malignant melanoma cases for women and 20 times higher annual rate for men. If a patient diagnoses with malignant melanoma it will undergo a treatment to have it removed by using cytotoxic drugs. Melanoma is the type of skin cancer that has the highest possibilities to spread to internal organs and lymph nodes [4]. Then there is also sarcoma, which is a soft tissue cancer. Sarcoma is the type of skin cancer that transforms into a lymph. Both of these cases are treated with the procedures called Isolated Limb Perfusion or Hypothermic Limb Perfusion.

2.1 Isolated Limb Perfusion (ILP) Procedure

Fig 2: Limb isolated with a tourniquet

To perform ILP there are some certain necessary roles that have to be present in the operation theatre. There is a need of one perfusionist monitoring the perfusion circuit, one anaesthetic that monitors the patient's condition with respect to the anaesthetic, often two nurses helping around in the room, usually two ILP surgeons working together (sometimes only one) and sometimes there is a nuclear radiologist present. The patient is often prepared and sterilized before the surgeons enter the operation theatre. The principle of the procedure is that the limb is isolated from the rest of the system to be able to send high doses of cytotoxic chemotherapy drugs to the extremity i.e. the tumour. What the surgeons basically do is a small incision on the upper part of the limb, for e.g. the leg and change the blood circulation by clamping the major artery and vein to the level necessary while the vessels are re-connected to the heart and lung machine (see Fig 4). The surgeon also makes a small incision on the vessels that are affected and inserts a catheter (see Fig 2) from where the blood flow is to change direction. The upper leg is also strapped with a tourniquet (see Fig 3) to increase the isolation of the limb from the rest of the body system. When the surgeons have successfully isolated the limb they then connect rest of the necessary measuring equipments to create a perfusion circuit.

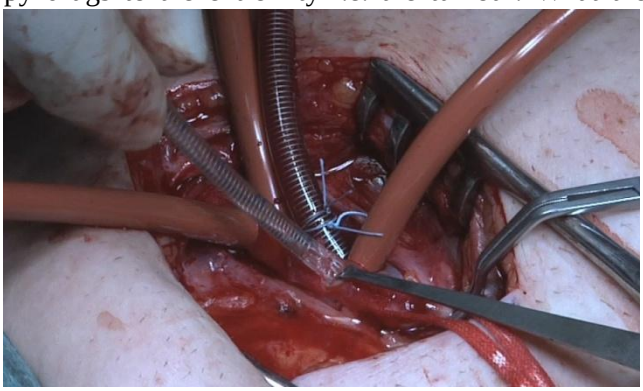


Fig 3: A catheter being inserted into a vessel to change direction of the blood flow

The perfusion circuit consists of an oxygenator, a rotary head pump and a heat exchanger to control oxygenation, temperature and the blood flow of the limb (see Fig 4). One of the major reasons of having a perfusion circuit is to monitor and assure that the drugs inserted do not leak into the rest of the system, especially when using the drug Tumour Necrosis Factor-Alfa (TNFα). The function of TNFα is to alert the patient's immune response. These drugs generate high risks of toxic effects if they leak into the system, such as organ failure, tissue injury, protein release etc.

The actual operation takes approximately four to six hours to perform, where approximately ninety minutes of the operation is observation of the patient when the drugs are administered into the perfusion circuit. The drugs are injected with the help of a Therapeutic agent i.e. to divide the dosage into 3-4 fractions during these ninety minutes of observation. Too high dosage at once could cause complications. At the end of the ninety minutes treatment the surgeons disconnect the perfusion circuit, remove the isolation and sew back the vessel and the incision. The subsequent regression of the tumour takes place over 2 – 10 weeks. In certain cases the patients have to come back and undergo the procedure again if the response of the treatment was not totally successful. For melanoma there are certain cases when TNFα is used while a patient with sarcoma, TNFα is always used.

Fig 2: Heart and Lung machine used during surgery

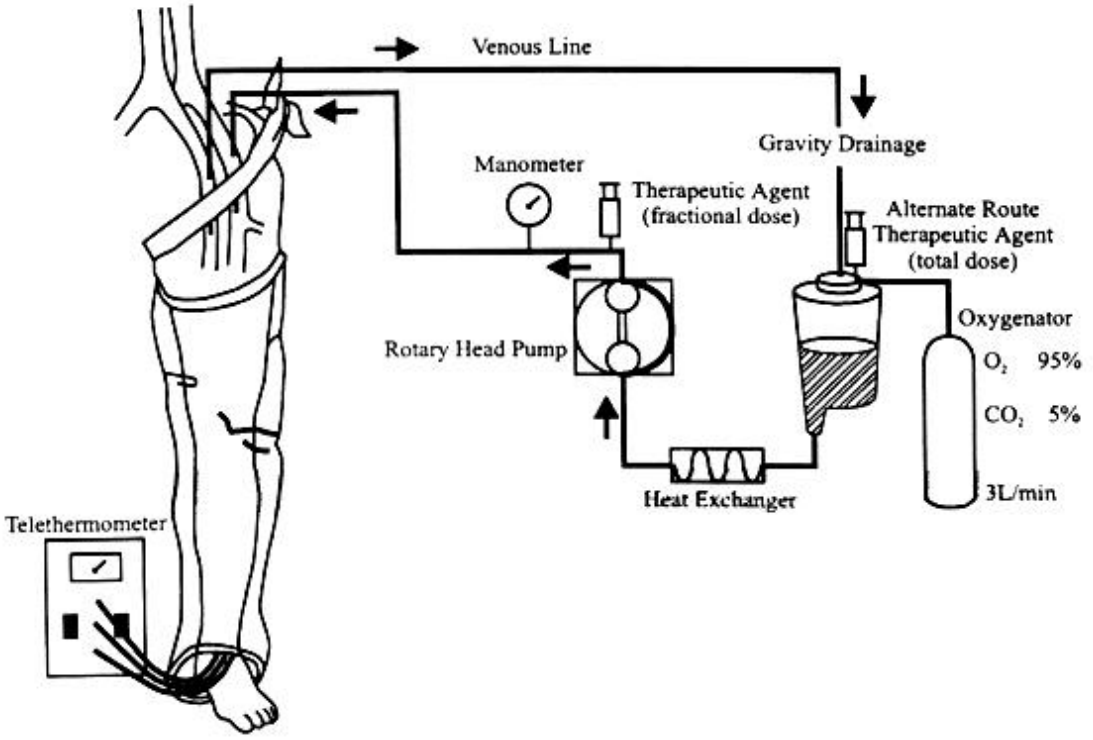


Fig 5: Demonstrating figure of how a limb is isolated during a surgery

2.2 Hypothermic Isolated Limb Perfusion (HILP) Procedure

HILP is a more effective procedure compared to ILP. The main technical difference between the procedures is that the limb is heated through the perfusion circuit up to around 40ºC - 41ºC. This is mostly done due to the tumour becomes more vulnerable to the cytotoxic chemotherapy drugs i.e. it potentiate the effects of the drugs, which in return gives a better response rate of the procedure. To sustain the working temperature of about 40ºC- 41ºC, the limb is often isolated with heat blankets wrapped around the extremity or in some cases isolation blankets are used instead which cover the whole limb.

Fig 6: A surgeon covering the heated isolated limb with heat blankets to sustain the temperature at a constant level of between 40ºC - 41ºC

3. The MedicView Product

The MedicView product is a measurement and monitoring system especially used during the surgical procedure HILP. The MedicView product helps the surgeon to monitor the leakage of the cytotoxic chemotherapy drugs such as Melphalan and/or TNFα. Since these drugs are highly toxic, any leakage more than ten percent to the rest of the system could be lethal for the patient undergoing HILP. This product eases the surgeons control over the patient who can keep the patient stabilized with the help of this system.

The MedicView product was designed by the Senior Engineer Mats Olsson who was contacted by the surgeon Jan Mattsson at Sahlgrenska, Gothenburg, Sweden. Jan Matsson needed a product that measured and monitored some parameters and Mats saw this as a simple task which he then later developed to today's MedicView. This product has undergone several upgrades and new generations have been developed since 1992.

The system consists of three wireless measurement modules (clients), one computer (host) with a wireless server, a scintillator (scintibase) and software. All clients simultaneously operate during the HILP procedure and communicate with the software i.e. the host. The clients continuously collect and transmit the data to the software which in its turn performs calculations and plots the data onto a graph during the procedure. The three clients are battery-powered and wireless, which simplifies their placement in the operation theatre giving the surgeons more mobility. The three clients are a ratemeter, multimeter and a thermometer. The ratemeter measures the leakage of the chemotherapy drugs from the isolated limb to the rest of the circulation system. The multimeter measures the flow rate and the average blood pressure of the isolated limb through the perfusion circuit.

Fig 7: The MedicView System

3.1 Ratemeter

The ratemeter is used to measure the leakage of the chemotherapy drugs and is connected together with the scintibase (more described below). The leakage is measured by injecting two doses (a larger and a smaller) of radioactive tracer into the limb and the systemic circulation. The larger dose is injected into the limb (which is ten times higher than the smaller dose) while the smaller dose is injected to the systemic circulation. With the help of the scintibase which is placed directly above the heart, the leakage to the systemic circulation

Fig 8: Ratemeter client

can be detected if any activity occurs. The ratemeter is a battery-powered wireless module connected to the MedicView server which in its turn is connected to the host. The server and the client operate in a Point-to-Point architecture design in which data is transmitted. The ratemeter can be used for a variety of different purposes, from patient monitoring to biomedical and laboratory measurements [5].

3.2 Multimeter

The multimeter is used to measure the flow rate and the average blood pressure in the perfusion circuit of the limb. The multimeter has the same basic hardware concept as the ratemeter i.e. Point-to-Point architectural design and wireless from client to host. The sensors are connected from the multimeter to the limb under the tourniquet (see Fig 3).

Fig 9: Multimeter client

3.3 Thermometer

The thermometer is used to monitor the temperature of the limb. Temperature monitoring is quite crucial in a HILP procedure because the cytotoxic drugs are most effective at a temperature of 41 degrees (see Ch 2.2). The thermometer has the ability to connect seven sensors to the limb to be able to measure and monitor the actual temperature in real time. One sensor is connected to the Hot Bath, which is placed at the heart and lung machine. One is for the internal blood temperature, two for upper limb subcutaneous (SC) and inner muscle and two for lower limb, subcutaneous (SC) and inner muscle. The seventh is left for any other purposes necessary. The seven input channels have good capabilities to be immune to any outside noise and can be connected into a wide variety of other purposes than just the operation theatre. A unique thing with this thermometer is that every channel can be calibrated separately to the desired sensitivity [6].

Fig 10: Thermometer client

3.4 Scintibase

The scintibase is intended to be used together with a scintillation detector which is placed directly above the heart and then connected to the ratemeter to measure leakage through the operator software. The scintibase is a photomultiplier base consisting of a network, power supply and a spectroscopy preamplifier [7]. It is used for time-activity and spectral analysis purposes.

Fig 11: Scintillator connected to the Scintibase

3.5 Software

The software comes as a CD which is already pre-installed on the host computer. It consists of a single window with all the graph plots visible to the surgeon. The interface is designed in a simple and easy-to-use way. The parameters that are shown on the main screen are the flow rate, flow resistance, leakage calculated, blood pressure and the temperature of the sensors connected. One unique aspect of this software is that everything is visualized and calculated in real-time. The software helps the

surgeon to have an overview of the activities in the isolated limb so the surgeon can take necessary actions quicker.

3.6 Set-up

The set-up of the MedicView product is done in two different phases, before and after the isolation of the limb. The first phase is before the patient gets the limb isolated and connected to the perfusion circuit. In this phase the Scintibase is installed and the stand is mounted to the bed. The unique characteristic of the MedicView scintillation detector is that it is directly mounted to the operation bed, while in other cases it is mounted to the floor. If the patient suddenly has to be moved, the scintillation detector moves along and there is no need for re-calibration. At the same time when the Scintibase is installed it is then directly connected to the Ratemeter. The second phase is when the Multimeter and the Thermometer are connected. After the limb has been successfully isolated the temperature sensors are inserted in the limb (see Ch 3.3). For the Multimeter the sensors for measuring the average blood pressure and the flow rate are connected (see Ch 3.4). When all the clients have been connected to the patient, the next step is to connect them to the host computer where some parameters are inserted for calibration. In the end when the set-up is finished (see Fig 11) everything is set for the injection of the cytostatic drugs.

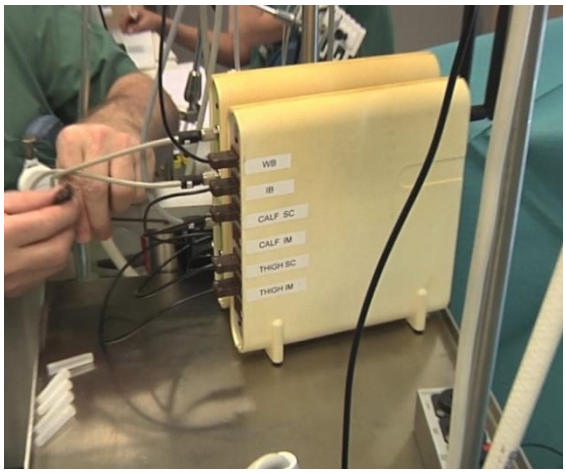


Fig 12: Demonstrating the thermometer client connected to the patient with the four sensors to the patient and one to the catheter for the ingoing blood and one checking the temperature in the water bath. Multimeter client is put beside the thermometer.

Fig 13: Scintillator connected to the patient during surgery above the heart

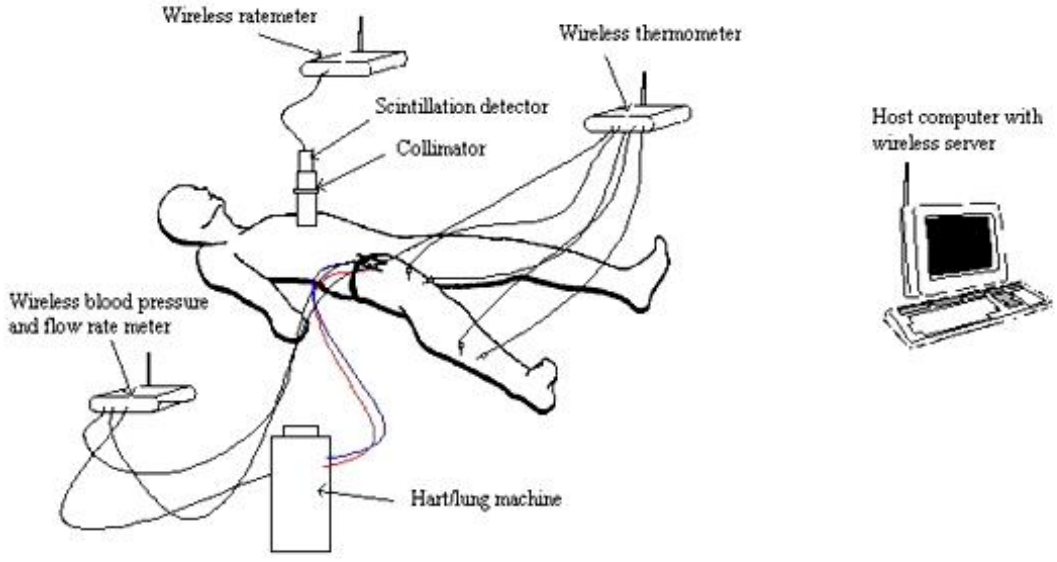


Fig 3: A sketch demonstrating how the MedicView system is connected to the patient.

4. Methodological Frame of Reference

There are a vast number of methods that are available for collecting and analyzing data related to product requirements. In addition, methods for how to validate the product with respect to the requirements (which are an outcome from the data analysis) are also interesting from the perspective of this thesis. The methods identified are narrowed down and selected carefully by theoretical research.

4.1 Data Collection Methods

There are two main categories of data collection methods used generally to gather information for the requirements list [8]. The first category is questions based methods for e.g. interviews and questionnaires, while the second is observation-based methods for e.g. field studies.

4.1.1 Interview

There are two types of interviews: person to person and focus group. Person to person interviews can be conducted face to face or through telephone. In order to conduct a successful interview the interviewer must be well prepared and have social skills as well as experienced. This experience should include the ability of communicating and actively listening, the interviewer should also know how to guide the interview without leading it [8]. The ability of extracting the most important statements from an interview relies heavily on the transcription. The transcripts in turn rely on the documentation of the interview and that is best done by recording or videotaping with additional notes to grant the quality of the documentation. Another issue to cater for is the size of the sample and how representative it is with respect to the desired result. That means the size of the sample should not be too small or too large. If too small, the result can be unreliable, and if too large, it might cost more than necessary. An important issue is how well the sample represents the targeted population [9] i.e. users, customer, supplier, manufacturer etc. Interviewing is a good method for extracting customer requirements and it is one of the most used methods to gather information. There are plenty of benefits with interviews. For example the high response rate in comparison to questionnaires. The main benefit is the possibility to reformulate the question if misunderstood in the moment. The major disadvantage mentioned in most literature is the high cost and that it is time consuming. In this context the interview can be structured with predefined order of the specific questions or semi structured that guarantees the topics covered without exactly formulating the questions and with varying order. In unstructured interviews on the other hand the questions are not formulated at all and the interviewer takes a passive role while the interviewee governs the interview [8]. In this report structured interview is dealt with and is termed simply as interview. An interview should be designed in three sections which are introduction/prologue then body and at last finish with epilogue. The context of the interview should move from general questions and facts to specific questions which require reflection and evaluation.

4.1.2 Questionnaire

Another frequently used data gathering method is a questionnaire. This method has also its benefits and disadvantages. Questionnaires are beneficial when time or money is limited but on the other hand response rate is lower in comparison to interviews. There are two types of questionnaires qualitative and quantitative and the design of it depends on which of these is desired. Quantitative questionnaires are more exact than qualitative. Qualitative questionnaires require more effort to design, administer and to interpret the result. The questions are often explained as open format respectively closed. Open format is difficult to handle since it allows the respondent to answer free whatever he/she wants while the closed format restricts the response to a predefined range of answers and makes it easier to handle with respect to statistics. Questionnaires are often used to follow up or confirm data gathered through some other expensive method, i.e. to confirm or to disprove a trend analyzed from a previous result.

There are some issues to think of when designing a questionnaire. The questions should be clear and unambiguous to minimize misunderstandings and to ease for the participant and avoiding the chance of losing his/her interest. Watch out for leading questions which tend to make the participant choose a certain answer, this happens often due to vague answer alternative. There are guidelines of how to design a questionnaire, core of the steps from a guideline [9] by Edward F. McQuarrie is explained below.

At first make clear what topics should be covered and what type of information is desired from the questionnaire. It could be helpful to conduct a group session in order to list the required topics and clarify the type of information. The second step is to construct a preliminary draft which consists of actual questions and answers which are meant to be in the questionnaire. The draft helps to identify potential problems and makes them apparent before the design of the final questionnaire. This step is simply about putting it aside, let the draft be for a few days and then go back and look at it. It will probably be apparent that it needs some changes right away. Once the responsible person is satisfied with the first draft it can be useful to spread it through the organization for feedback. The main advantage of sending it to colleagues is to get feedback from other perspectives which uncovers mistakes and makes the questionnaire more robust. After the needed modification is done with respect to the feedback it could be necessary to iterate a second round. In this phase the designer proposes a draft that caters for all the issues like phrasing and sequencing and instructions of how the survey will be conducted. In many projects it could be wise to perform a pre-test of the questionnaire on a small population and gather feedback about how the questionnaire felt. The final questionnaire should be ready by this time.

4.1.3 Field Study (Observation)

Field study is a method that is used to gather qualitative data about users and their needs by observing a process or a product in context [8]. The strength of the method is that you get an opportunity to observe the product in real world in order to identify unspoken needs. The method is useful especially when dealing with a new area for the developers and facilitates understanding of the process. Observation can be done directly where the observer is on site and interacts with questions without getting in the way or indirectly by video. The investigator should be careful of simplifying the task on the other hand the expert user might over-simplify the task in order to make it graspable for the investigator. These two types of bias are addressed as the *simplification bias* (by the investigator) and the *translation bias* (by the user) [10]. The investigator should also be aware that users can tend to change their behaviour due to the circumstance of having an investigator watching them; this is known as the Hawthorne effect.

There is plenty of literature which addresses the process of conducting a field study, most of them are similar and a collection of the common content is briefly explained below.

- First of all, as in most data gathering methods, it is important to identify and select a sample carefully [11]. It doesn’t matter how skilled the researcher is, if the sample doesn’t reflect the reality of a common user then the result become useless.
- If some investigators conducts field studies independently they will probably come to similar results [10], thus it is beneficial to decide different foci for each investigator. It is impossible to learn and grasp everything in a field study so if there are enough resources a foci for each investigator would give a better result.
- Another important issue is the selection of the team to conduct the field study [12]. This team is recommended to be composed of cross-functional members skilled in the art of extracting needs and thinking outside the box.

- The means of documenting the visit should also be selected with respect to the study, different type of documents require different time to analyze. Questions to be answered are; is it sufficient to take notes or is recording necessary etc.
- After the study is conducted the data must be analyzed and presented to the stakeholders.

4.2 Data Analysis Methods

There are several methods of analyzing the data that has been collected. However, for this report there is only one interactive analysing method chosen.

4.2.1 KJ-Shiba Method

The KJ method sometimes also named affinity diagram is a method used to reach consensus and was developed by a Japanese scholar Jiro Kawakita. The technique is often used to categorize customer statements and prioritize them in order to identify the more important ones. The KJ method is a tool that could be helpful to identify conflicting constraints when designing a new product. This technique is widely used in product development in the phase of analyzing the customer needs. The procedure of the method is quite easy to use after the first time. This method is explained below using an eight-step [13] process as recommended by User Interface Engineering.

1. At first a focus question must be determined and clear to the participants which should not exceed a number of 7 totally including the team leader. It is important that the focus question is well defined since it is the guide throughout the session and influences the result. This question can be general e.g. "who are our customers" or "what are the biggest obstacles preventing our products from selling".

Fig 15: This picture shows an example of how it looks like when the grouping is done in KJ method.

2. The next step is to organize the group in order to have the different perspectives represented in the setup of the team.

3. In this step the real brainstorming starts where the participants should write statements that are facts on sticky notes. They should brainstorm as many statements as they can.

4. In step 4 every participant puts their sticky notes on the wall and reads the other's notes. In this step it is encouraged to come up with more sticky notes inspired by the other's notes.

5. When everyone has added their contribution to the wall the grouping of the notes starts in the fifth step. In this step when somebody groups some of the notes others should feel free to rearrange them if they don't agree until they come to a consensus regarding the grouping of the notes. It is also noticeable that the activity of grouping should be done in silence and no talking is allowed. No discussion is allowed at this stage because it is seen as insignificant at

this stage and just a waste of time. This step is finished when all the notes are in some group and the team members agree on the grouping.

6. In step 6 the team gives a name to each group, this should be done with sticky notes with another colour. In this step it is advisable to reflect upon the name and the notes included, it should be representing the content.

7. Step 7 is the "voting phase" where every participant is supposed to list the names of the three most important groups, each participant then ranks the chosen three groups before continuing to the next step. This must be done with the focus question in mind all the time and reflect whether these group names answers the question in the best way. In this step each person sets their votes on the wall with dots or other mark on every group.

8. In step 8 the team ranks the groups as a result of the voting and at this point the team is allowed to discuss the outcome. Hopefully the team has reached consensus at this point.

4.3 Product Validation Methods

A requirement list is the set that forms the basis for the product. In order to develop a successful product the requirements must be fulfilled [8]. The definition of validation, or more correctly product validation is *"product validation is a process by which a new product (or service) is proven to meet essential customer requirement for a particular purpose or fitness"* [14]. Thus the requirements should be interpreted into measurable entities or into some binary statements that can be tested somehow. The main idea of physical prototyping, CAD/CAM models and mathematical models among other type of models is to validate that requirements are met by the product [15]. A typical requirement that usually is validated through CAD/CAM is the fitting or assembly of components while FEM is used for validating that a product withstands a certain load. Other requirements that are more difficult to validate are subjective requirements such as aesthetics. It is possible to make it measureable through setting a limit such as "a certain percentage of the users should find it aesthetically appealing". This can be handled as a measureable requirement and is possible to validate by asking how the users perceive it with respect to aesthetics. Physical prototype is maybe the most used method for validation since it often can be used to validate many attributes. Cost of validation is always an issue and that is why physical prototypes are used only when necessary. Otherwise it is more convenient with CAD/CAM or other computer aided methods which are less expensive and easier to change. An uncommon way of validating the fulfilment of a requirement is through expert opinion. An example of that can be to validate requirements for a sensor which will be placed inside a muscle. The fulfilment of these types of requirements can be validated

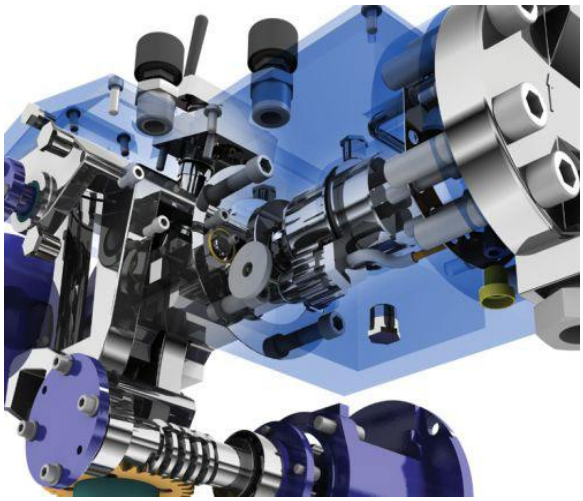


Fig 16: This is an example of a CAD-assembly model that can be used to validate a dimension requirement (fitting of the parts).

by expertise which in this case would be a surgeon. Some of the common methods for validating requirements are listed in table 1.

Table 1: A list of typical types of requirement and the methods for validating them.

Type of requirement	Validation method
Dimension requirement	CAD-assembly
Strength	FE-simulation
Aesthetic/Design	Physical prototype
Ergonomical requirement	Physical test
Functional requirement	Usability test
Production requirement	CAM

5. The adopted approach

The methods used to conduct this research have been adjusted and in some cases modified to suit the purpose of this research. The theory behind the methods was in the previous chapter and in the following paragraphs the methods are presented as applied by the thesis group. Each step of the methods (which are identical to the theories in the previous chapter) are not addressed. Instead the focus is set on the parts of the methods which have been adjusted.

5.1 The process of the conducted research

Before conducting this work a planning report was written to obtain a general overview of the framework applied in this thesis along with important steps and actions that need to be taken. From the planning report the thesis was planned to have the work conducted in a process form. Working in processes is structured and companies that have implemented process thinking have experienced major benefits [16]. This process was to aid the thesis group to achieve better results in an effective way. This also helped to keep a better focus on the work and the reader is able to understand how far the work has come more easily.

The research presented here was conducted in iterative processes. When the first iterative process was completed and satisfactory results were not reached, the work automatically proceeded into iterative process two where the same working procedures were conducted. This process is visualized in fig 17 which will be seen in the next chapter. To predict how many iterative processes were necessary to achieve good results was a bit complicated to set before hand.

The process was divided into four parts which were: data collection, data analysis, validation and results. The process started from data collection where all information was gathered through interviews, questionnaires, field studies and articles. Here the idea was to gather as much information as possible to be able to continue further in the process. The second step was the data analysis where all the information gathered was analyzed through methods mentioned in the previous chapter. The analysis of the information was the base for the quality of the results. After the analysis the results and validation were presented simultaneously. The validation of the results in this research was not within scope but instead suggestions were given on how the requirements could be validated. That is why in this report the requirements and the validation are in one set instead of being presented as separate parts. Basically all the steps, data collection, data analysis and validation were the foundation of a good quality requirements list. Throughout in the analysis and the results chapter, this process scheme is shown to ease the understanding of the reader to realize where in the process each part of the research has been conducted (see fig 17).

5.2 Iterative process 1

The first iterative process was conducted mainly to analyze the user needs of the product before it even existed. This approach was taken to make sure that all the necessary needs had been documented and analyzed to be able to proceed to the next step of further development of the product.

5.2.1 Interview, Iteration 1

The interviews conducted in this thesis were structured to the extent of formulated questions with space for spontaneous follow-up questions. The interviews were conducted face to face with key persons relevant to the MedicView product. The key persons interviewed in the first iterative process were composed of three HILP surgeons one from Finland and two from Gothenburg and the inventor of the product. Three interviews were performed during this stage of the research and all of them were conducted by two interviewers. All interviews were audio recorded and additional notes were taken.

These two methods of documenting the raw data were seen to be most suitable for capturing the details of the interview. The notes were used to complement the recording in regards to the unspoken things that was observed and the audio recording captured the oral words. Conducting the interviews in pair has the tendency to be risky if one of the interviewees has a dominant personality. The disadvantage of a dominant personality is more probable to affect a focus group than a pair with similar backgrounds, thus the thesis group had decided to conduct the possible ones two by two. The identified advantage of this approach was to have an open dialogue between the participants and unearth their thoughts. The purpose of the interviews in the first iterative process was focused on finding user requirements, even though the interviews included other product related issues than pure pre-product user requirements.

5.2.2 Field Study, Iteration 1

The thesis group observed two HILP surgeries, both took place in the first iterative process. The aim of the study was to acquire an understanding of the complexity in HILP procedures in order to extract requirements for MedicView. The procedure was quite similar although it was different type of limbs in both occasions. Still it was important to observe two surgeries, the reason for that was the completely new environment for the thesis group. Thus the first field study was done more for getting used to the theatre and the procedure but also in order to identify what areas were needed to be focused on the next visit. The thesis group was prepared and knew what to expect in the second field study which made it easier to grasp the needs. The second visit was performed with focus on the usage of the MedicView product and its interactions with other equipments and staff. In the first visit a camera man was filming the surgery which was an aggravating factor for the thesis group to observe the procedure.

5.2.3 Questionnaire, Iteration 1

Since the design of a questionnaire was a time consuming and iterative process, the thesis group had designed a closed format questionnaire. The questionnaire in this thesis was executed mainly to confirm or repel the needs that were identified through other methods. Thus the closed format questionnaire was good enough to achieve the purpose while optimizing the time resources. The answers of the questionnaire also became easier to handle when they were analyzed due to the closed format.

5.2.4 KJ-Shiba, Iteration 1

The KJ-Shiba workshop was conducted twice in order to clarify the problems and needs in the different phases of the developed MedicView product. The participants were composed of product developers, surgeons, the inventor and members of the management team representing MedicView. The first workshop was dealt with the needs and problems regards to the HILP procedure before the MedicView product existed. This session served two purposes, first to clarify the problems of the procedure and the surgeon's needs of a product before the existence of a similar MedicView system. The second purpose was to identify if the current product satisfies the stated needs. This step was important because there were no documented requirements specified for the current product. As mentioned earlier in the description of the method a KJ-Shiba workshop should have a focus question which guides the session. The focus question was set to *'What were the biggest problems of performing a HILP surgery before 1992?'*. The method had been a bit modified due to the lack of time since getting surgeons off work was not the easiest thing to do. The thesis group basically did the first steps of the KJ-Shiba method i.e. to define a focus question and have the statements ready on post-it's. Previous to the workshop an e-mail was sent to every participant with the focus question and to think of any statements they would find necessary which would contribute to the results of the KJ-Shiba. The statements written on the post-it's by the thesis group were all based from the data collected (interviews, field study, questionnaire). The KJ-Shiba started off from having the statements clarified

among the participants and to have a consensus if they understood the post-it's. After this step the KJ-Shiba continued exactly as the theory described in the previous chapter.

5.3 Iterative process 2

The second iterative process was necessary to perform in order to understand more present product related (and MedicView's) needs and requirements. In the previous process, the main focus was set on user needs. The results from the first iterative process did not contribute with enough information. The second iterative process was to cover the missing gaps left in the first process. The gathered information from the first process set the foundation of the interviews in the second iterative process.

5.3.1 Interview, Iteration 2

In the second iterative process the thesis group performed one interview with two members of the MedicView management group representing the owner. This interview was conducted in the same manner as the previous ones in iterative process one when it comes to the setup. It was advantageous to conduct the interview in this phase of the thesis since the Interviewers and the interviewees knew each other by now which eases the dialogue. The information gathered from this interview was product related and included important information regarding costs, production etc.

5.3.3 Questionnaire, Iteration 2

A similar questionnaire to the previous one was designed and sent to additional HILP surgeons in Europe. The purpose for this questionnaire was to confirm or repel stated requirements achieved in the first iterative process. The outcome of the other methods of iterative process one and its result were used as input to design the second questionnaire. Unfortunately no response had been received until the writing of this report.

5.3.1 KJ-Shiba, Iteration 2

The second workshop addressed the current needs and areas that could be improved. Participants of the second workshop were composed of members with the same background as in the first session. It was good to have some members from the previous workshop because this accelerated the process since they were prepared for the steps of the method. On the other hand it was also good to have new members in order to gain new aspects. The purpose of this session was to explore and extract more product related requirements. Thus the focus question was set to *'What are the biggest problems with the MedicView product of today?*'. The second KJ-Shiba, compared to the first one had some modifications. The only difference this time was that the approach of the thesis group completely finishing off the first step was not conducted. Instead the thesis group only introduced a focus question to get things started. The statements and the consensus of understanding them were from where the KJ-Shiba starts off. In this KJ-Shiba as well as the previous one, an e-mail was sent to the participants to prepare some statements before coming to the workshop. The only thing provided to the participants was the focus question. This was a strategic way from the thesis group to stimulate the thinking of the participants beforehand.

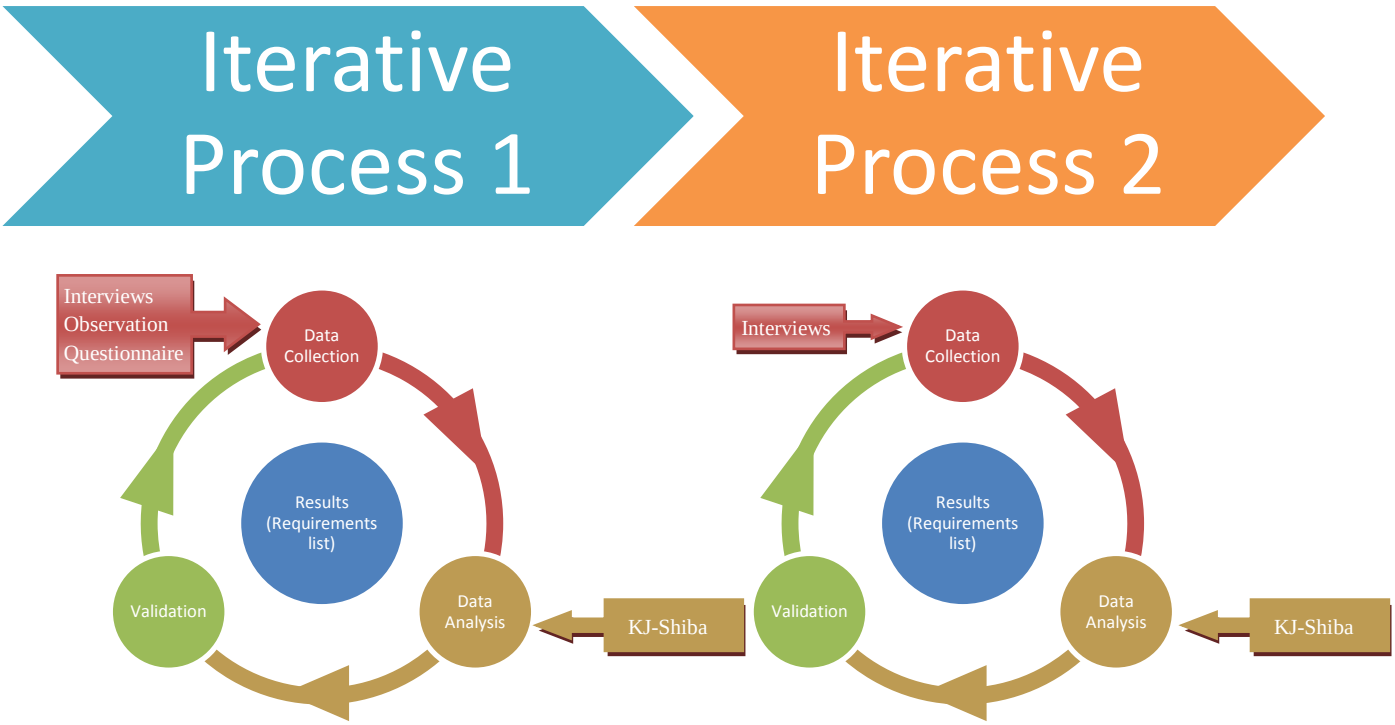


Fig 14: This figure shows the process of the conducted research with two iterations

6. Analysis & Results

The analysis of the gathered information is done in the way that has been prescribed in the previous chapter. The analysis of the information gathered constitutes the main foundation for the requirements which are compiled in a requirements list that is the main result of this work.

6.1 Flowchart analysis of the MedicView system

To understand the product properly and how the clients are correlated to the rest of the system a functional description of the system had to be made. The functional description describes how the sensors and the scintibase interacts its information with the clients (ratemeter, multimeter and thermometer) and how the clients send the information to server back and forth. The server sends the information to the software which calculates and displays the data in graphs which is visualized on the screen from where the parameters are monitored. From the software, the user is also able to calibrate the clients to the desired level. The signals are sent to the server which then further transmits the data to the clients (see fig 18).

6.2 Data Collected, Iterative process 1

The first step in the process is to collect as much information as possible The information that is presented here is a combination of data that has been collected and our analysis of it simultaneously, but still is in the initial phases of the iterative process 1.

6.2.1 Interview, Iteration 1

As mentioned earlier in this report a larger part of the data gathered was through interviews with key persons in the development of the MedicView product. In order to extract useful statements from the interviews the data had to be reduced and analyzed. To grant the quality of the data the interviews were audio recorded with additional notes to ease the transcript. In order to reduce the data, transcripts were made of the recorded interviews. Later on these transcripts were analyzed. The analysis was done by highlighting important statements. Each statement resulted in one or several requirements. Some of the answers that can be found in the transcripts are missing in the analysis below. This is due to either one of the facts that follow. The first fact is that it does not contain any explicit or implicit requirement, the second is that it is similar to another one and thus redundant. There are also two contradicting answers by different surgeons regarding if the fluid resistance of the product is necessary or not. This conflicting constraint is not given any concern since it is assumed to be taken care of by the standard for electrical devices in operation theatre that must be fulfilled by the MedicView product. The results of these interpretations and from the other data collecting methods were organized in hierarchical order as can be seen in the requirement list. For traceability reasons all statements that were interpreted from a certain answer of the interviews are listed as bullet points. All the statements are listed in appendix B and as an example two of them are stated below.

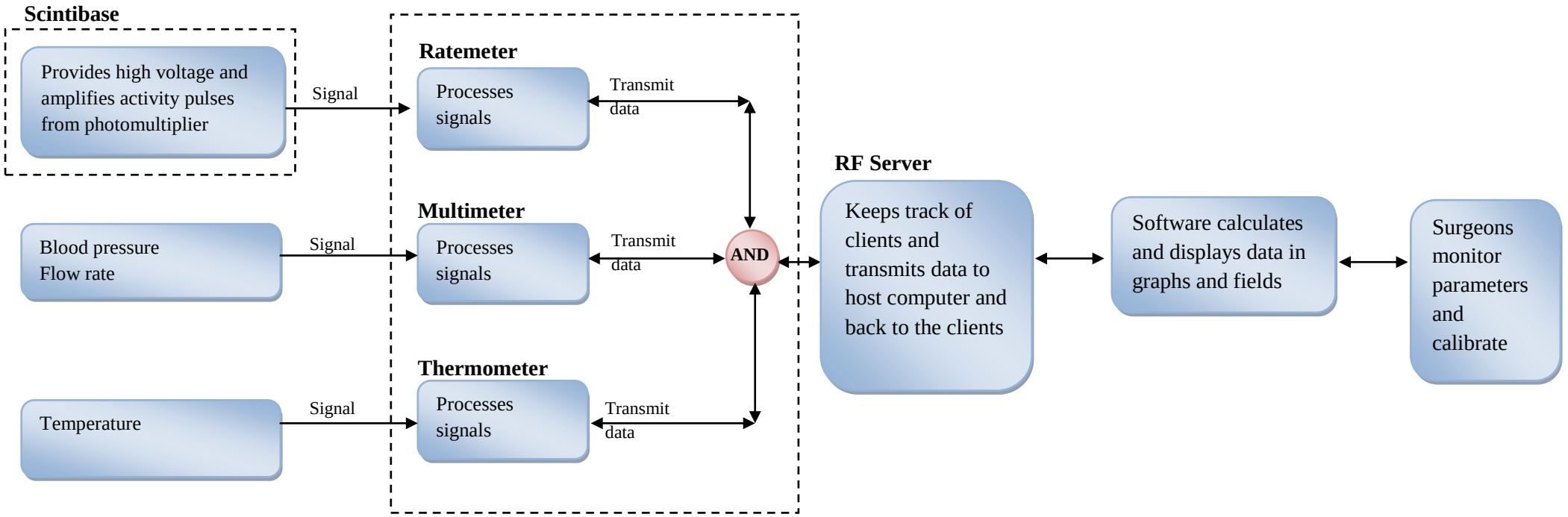


Fig 18: A functional description of the MedicView system showing the process from measuring to monitoring

How is the system packaged today? Pros and cons? How is it transported to and inside the hospital /other similar devices?
It is kept in Dr Jan's office in a bag, backups of the files are made frequent and is decided to be made every week. The scintillator is sensitive and is kept in a closet in the locker room. A box for everything would be good maybe something on a wheel. And maybe everything can be charged with one connection through the "box". The stative is also left in the locker room. It would have been good to be able to see if everything is working fine in the system before you add substance to the patient. As it is now you will not detect the failure until you get wrong signals when you start. A background activity that assures the correctness of the equipment would be helpful.

Fig 19: This is a capture from the analysis of the first interview. The highlighted parts shows the identified needs from the answer which are transformed into requirements as can be seen in the bullet points below.

The highlighted sentences leads to the requirements listed below.

- Everything should be packaged in a way that caters for the portability in the hospital.
- Every chargeable item should be charged through one connection if possible.
- The system should give a go-ahead indication if everything is correct.

Do you use the product for any other purposes? Do you think it will be possible to use the product for anything else?
No we don't use it for other purpose. Yes it is possible to use it in other type of operations where you need to register or measure temperature/ pressure and other parameters, this is very wide

Fig 20: This is another capture ripped from the analysis which can be found in appendix A

This customer statement leads to the requirement below.

- The development team should consider introducing the system in other type of surgeries.

6.2.2 Field Study, Iteration 1

One of the most effective ways of understanding problems and complications is through observation [17]. In this case the thesis group observed two live HILP procedures at SUH and recorded at one session by MedicView's initiative. From the observation some complications were identified which were not brought up in neither the interview nor the questionnaire.

The first obvious obstacle identified was all the cables, catheters lying on the patient and hanging on the side of the operation bed towards the thermometer and ratemeter clients. Due to the high number of cables to the thermometer, ratemeter and the heart and lung machine, standing on the patients right side to operate is almost impossible (see fig 21).

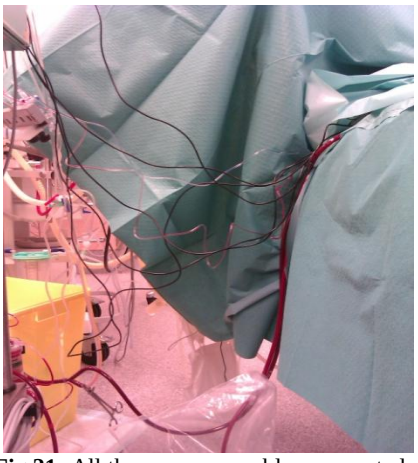


Fig 21: All the necessary cables connected to the patient making it impossible for the surgeon to operate from the patients' right side.

Another complication identified through observation were the restrictions by the clients imposed on the user. The user has the ability to position the client in two different ways because of the design. When the clients are upright they become too tall which makes them quite unstable. Even though the surgeons deny this as a problem the thesis group observed the complications that occurred when installing the thermometer sensors. In one case when the procedure ended and the perfusionist was to dismount the thermometer sensors, he had to hold the client with one hand and pull out the sensor cables with the other. When he let go of the client it then tipped over on the other client standing beside it resulting both to fall down on the table, indicating that the design is not appropriate. Another issue here was the connection sockets of the thermometer sensors which could be modified. It was a bit hard for the surgeon to release cable from the socket on the thermometer client (see fig 12 Ch 3.6).

Fig 22: The scintillator stand which is heavy and bulky.

The scintillator stand that is installed before the isolation of the limb is heavy and bulky. The stand has to be mounted and then screwed onto the bed while the surgeon is holding it. From an ergonomical point of view the stand is not convenient which advocates for a more appropriate solution or design. A possible solution is to have a clamp function instead of having the user to screw it onto the bed which reduces the time of bending down and holding the stand at the same time.

Fig 23: The perfusionist and the surgeon monitor from the distance demonstrated in the picture.

Observing the procedure at SUH an important thing discovered was the limited ability for the perfusionist and the surgeons to monitor the measurements of the parameters on the screen. The problem was that they were not able to see from some distance but were always forced to go closer to the screen to read. As a conclusion from this the thesis group estimated a distance of 3 meters from where the parameters should be easily read to be satisfactory. The 3 meters comes from the distance where the perfusionist usually sits and operates on the heart and lung machine.

6.2.3 Questionnaire, Iteration 1

A questionnaire (see appendix B) was sent out to four surgeons who took their time to fill it out. The surgeons were Dr. Jan Mattsson and Dr. Roger Olofsson from Sweden, Dr. Anna Stas surgeon from Belgium and Dr. Anders Ahlbäck surgeon from Finland. The questionnaire was designed in such a way that it the covers as-is and to-be solution. The designed questionnaire had two purposes, to get some needs validated and to explore the demand for some other needs identified by the thesis group. The questionnaire was performed in combination with a conference in Gothenburg at the Biomedical Technical Centre.

The first question was regarding which roles that are necessary in the operation theatre to perform the procedure. By experience, all the surgeons agreed upon having the same number of perfusionists and

anaesthetic present in the operation theatre. The opinion on the number of nurses that should be available in the room differed among the surgeons. Some suggested that at least two nurses should be available while some suggested that one is sufficient enough. The interest of having a nuclear radiologist was only shown by one surgeon who saw it as a necessity to have that role present during the procedure. In general, among the roles suggested in the questionnaire, the distribution of the roles necessary in the operation theatre was surgeons and nurses with one perfusionist performing the procedure. (see appendix c, fig 27).

The number of HILP procedures completed every year differed significantly especially when it came to procedures for in-transit malignant melanoma on the leg. In total there were approximately sixty HILP procedures (see appendix c, fig 28) completed in the leg for in-transit malignant melanoma and only in Sweden these kinds of HILP procedures were approximately thirty procedures per year. We asked why there was such a huge difference between the countries and one of the surgeon's main responses was mainly because of the changing trend of sun bathing habits. Another reason is that the technical assistance to the HILP procedure has improved lately.

After the treatment it is not necessary that every patient has a full response rate. There are cases where people have to undergo the treatment again who only get a partial response from the procedure. The positive aspect of this is that 63% of the patients that undergo this treatment get a total response rate and never have to come back for the treatment again.

When trying to see if there is a demand for having a continuous measuring and monitoring system, all the surgeons responded that they would like to have a similar system as MedicView provides (see appendix c, fig 30).

Some of the important parameters were already identified by the interviews and the questionnaire asked the surgeons to rate the importance of measuring and monitoring these parameters. The parameters that were asked for were leakage, flow rate, mean perfusion circuit blood pressure, mean arteriour blood pressure, temperature (both subcutaneous and intra muscular) and the flow resistance. The outcome became more or less according to the expectations that the thesis group had. All the parameters mentioned above were somehow necessary to measure and monitor, except flow resistance (see appendix c, fig 31 and fig 32).

From the questionnaire we also got that the surgeons would like to have a measurement and monitoring system weighing less than 10kg but is not that important (see appendix c, fig 34) as compared to the flexibility of the product where the surgeons found it highly important (see appendix c, fig 35). This means that having a flexible product which is not in the way for the surgeons is highly important, such as the solution provided today.

Further on, the questionnaire also touched upon a solution for the surgeons to have the possibility to store the data collected from the HILP procedure in a database. The response for this was positive (see appendix c, fig 36) which results in a new invention that could provide an added value for the MedicView product. When it comes to measuring and monitoring, all the surgeons were in consensus that it is something highly important for them to be able to perform an effective HILP procedure (see appendix c, fig 37).

The number of measuring points on the limb for monitoring the temperature did differ when it came to the arm but regarding the calf and the thigh all the surgeons agreed upon having four measuring points. Two were for the upper limb and two for the lower (see appendix c, fig 37).

From the observation study done by the thesis group, it was found that most of the machines have different interfaces. A question in the questionnaire regarding this was put to know how important the surgeons found having a measurement and monitoring system integrated with the rest of the machines/screens in the operation theatre. The outcome became quite distinguished, some thought it was highly important and some thought that it was not that necessary (see appendix c, fig 39).

Having the system kept wireless for the sake of flexibility of moving around the clients and keeping them away from the surgeons working area was also highly important for all the surgeons (see appendix c, fig 40).

Having a measuring and monitoring product all in one place is a necessity when it comes to storing it in a big hospital where it can be moved around to several places. An outcome from the questionnaire was that 75% thought that it was highly important to have the product in one case for easier transportation (see appendix c, fig 41) which justifies the outcome of the next question also stating that the easy accessibility and storage of the product in one place is highly important (see appendix c, fig 42).

6.3 Data Analysis, Iterative process 1

After the data collection through interviews, observation and questionnaire of the first iterative process, the KJ-Shiba method was conducted. All the information gathered was analysed in one workshop with different experts present and actively participating in the activities of the workshop.

6.3.1 KJ-Shiba Method, Iteration 1

The participants of this workshop were Mats Olsson who is a senior electrical engineer, a surgeon Roger Olofsson, Anna-Klara Carlsten from MedicView, Osman Nuru (was presented as a product developer) and Umair Chaudry who was the team leader of the workshop. According to theory, the group has to come up with a question together and then write down statements on post-its in regard to the question. Since there was lack of time, the first step was already prepared by the team leader and the product developer where the statements were already derived from the data collection. The KJ-Shiba workshop started off with the participants adding some more statements to ensure that the necessary information was up on the board. The question that the thesis group formulated before hand was *'What were the biggest problems of performing a HILP surgery before 1992?'*. The idea of this KJ-Shiba was to overlook the existing product today and try to think as if the product was never invented. It was done this way to stimulate more creative thinking than just to be focused around the existing product. This could bring up new needs of the customer that may have not been fulfilled or identified previously, hence iterative process 1. The outcome of the KJ-Shiba became better than expected. After all the steps were conducted, the following groups of issues emerged as the result of this method:

- **No clear overview of parameters**
    - The measurement not visible to everybody from 3m of distance
    - Register temperature parameter
- **Access to equipment and consumables**
- **Lack of ability to measure and minimize leakage**
    - Lack of ability to minimize leakage through pressure control
    - Lack of ability to measure leakage absolute accurately (without outer disturbances)
- **Complex procedure risks patients safety**
    - Operation Procedure too complex
    - Operation procedure has no guarantee to patients safety

- Problems measuring the leakage of TNFα

- **Documentation and storage of data**
  - Ability to store and collect data for comparing
  - Documentation of flow parameters for scientific reasons
  - Documentation of parameters for scientific reasons
- **Further research is needed**
  - Not knowing what side effect leakage gives
  - Not knowing the optimal level of cytotoxins and/or Melphalan/ TNFα
- **Communicate and stimulate research to get more patients**
  - Low collaboration/exchange between HILP surgeons

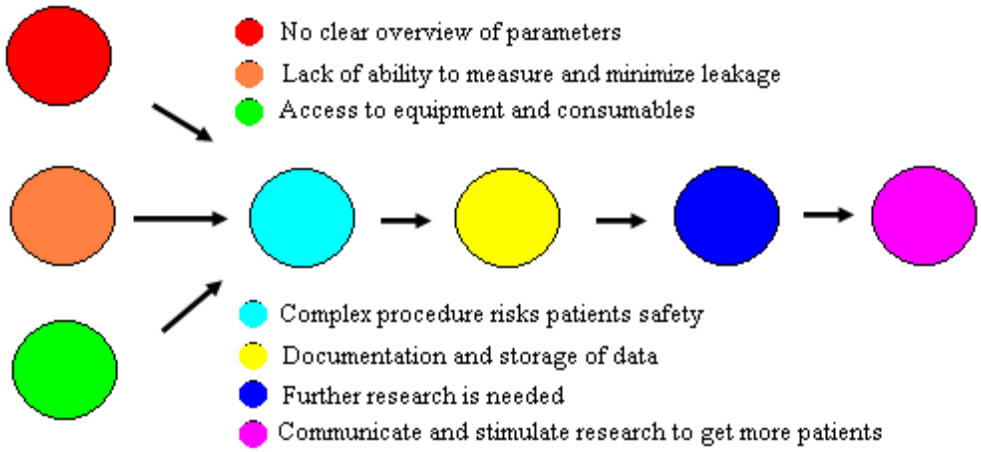


Fig 24: This shows a scheme of a logical connection between the groups (see also Appendix D, Fig 44)

Out of the KJ-Shiba the team was able to find a logical connection between all the groups (see fig 24) which made everyone see the actual problem of not having a measuring and monitoring system.

In the end the KJ-Shiba team was to rank the most important groups which they found was crucial, in this case connecting it back to the question set from the beginning, to see if it answered the question or not. The rankings were set in the following order:

1. **Lack of ability to measure leakage absolute accurately (without outer disturbances)**
2. **Communicate and stimulate research to get more patients**
3. **Operation procedure too complex**
4. **No clear overview of the parameters**
5. **Lack of ability to store and collect data for comparing**
6. **Lack of documentation of flow parameters for scientific reasons**
7. **Access to equipment and consumables**
8. **Lack of ability to minimize leakage through pressure control**

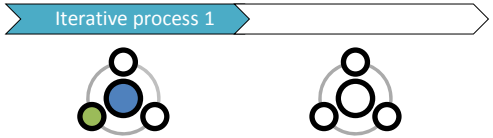
This result shows that the biggest problem before the existence of the MedicView product was to be able to measure leakage absolutely accurately (without outer disturbances). This means that without a measuring and monitoring system there are complications to proceed with an ILP or HILP surgery if there is no ability to measure leakage, especially when it comes to the use of TNFα which is lethal to a

leakage exceeding more than 10%. Since the procedure is already too complex and having no overview of the parameters necessary to monitor justifies the need for a product which can fulfil the necessary requirements. Usually an ILP procedure before 1992 was conducted by using only cytotoxic Melphalan and everything was calculated and documented every ten minutes on paper. Due to the tremendous risks with using TNFα, the surgeons avoided the use of TNFα without a proper measuring and monitoring system. Those patients did not respond to the treatment when treated using Melphalan were forced to amputate the infected limb.

There is a great need to bring the ILP and HILP procedures to perfection and set a standardized way of performing it. A structured way of collecting and storing data from ILP and HILP has never been present. To be able to reach the level of a standardized procedure, the data that is gathered during the procedure has to be stored somewhere where it is easily accessible for surgeons. This stimulates research around ILP and HILP which could, as an effect of it, treat more patients quicker and more efficiently.

Furthermore there has always been a minor problem with having access to necessary equipments to perform the procedure. Understanding the analysis from the KJ, indicates there has to be some sort of easy accessibility to the equipment that needs to be present for the procedure. Running around and gathering equipment and disposables is not optimal.

As a conclusion from the KJ-Shiba team, the question set from the beginning *'What were the biggest problems of performing a HILP surgery before 1992?'* was answered with *'The limited ability to measure leakage complicates the procedure which is the fundamental basis for stimulating further research'.* This clarified and created a better understanding of the fundamental needs surgeons have during an ILP or HILP procedure. The team was able to structure and rank the needs identified from the interviews and the KJ-Shiba to see which are the important reasons for having a measurement and monitoring system.



6.4 Results, Iteration 1

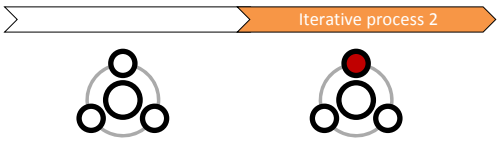
The information analysed in the previous chapters was transformed into requirements and categorized in the list below. In the requirements list there is traceability to each requirement's background and method for how they can be validated.

Table 2: This table shows the result of the first iteration in three columns representing the requirement, validation method and traceability.

	Demand (D)/ Wish (W)	Validation	Traceability
1 Functionality & Usability			
1.1. The surgeon should be able to register the leakage measurement	D	Prototype	IP1
1.2. The surgeon should be able to measure the leakage of the toxic drug into the systemic circulation	D	Prototype	IP1
1.2.1 The measurement system should measure the leakage accurately	D	Testing by technician	
1.2.1.1 The unit for leakage should be counts per second (c/s)	D	Prototype	
1.2.1.2 The accuracy should be ±2%	D		
1.3 The surgeon should be able to register the flow rate	D	Prototype	IP1
1.4 The surgeon should be able to measure the flow rate of the perfusate in the isolated limb	D	Prototype	IP1
1.4.1 The measurement system should measure the flow rate accurately	D	Testing by technician	
1.4.1.1 The accuracy should be ±1%	D		
1.4.1.2 The unit for flow rate should be millilitres per minute (ml/min)	D		
1.5 The surgeon should be able to measure the average blood pressure in the isolated limb	D	Prototype	Questionnaire 1
1.5.1 The accuracy should be ±5%	D		
1.5.1.1 The unit for average blood pressure should be millimetre of mercury (mmHg)	D		
1.6 The surgeon should be able to register the temperature	D	Prototype	IP1
1.7 The surgeon should be able to measure the temperature	D	Prototype	IP1
1.7.1 The measurement system should measure the temperature accurately	D	Testing by technician	IP1
1.7.1.1 The unit for temperature should be degrees Celsius (^{o}C)	D	Prototype	
1.7.1.2 The accuracy should be at 0.1 ^{o}C	D	Testing by technician	IP4
1.7.2 The surgeon should be able to measure the temperature on different points of the limb	D	Surgeon	IP4
1.7.2.1 The surgeon should be able to measure the temperature on two different points on the upper limb	D	Surgeon	Questionnaire 1
1.7.2.1.1 The surgeons should be able to measure the temperature under the skin (Sub cutaneous)	D	Surgeon	Questionnaire 1

1.7.2.1.2 The surgeons should be able to measure the temperature in the muscle (intra muscular)	D	Surgeon	Questionnaire 1
1.7.2.2 The surgeons should be able to measure the temperature on two different point on the lower limb	D	Surgeon	Questionnaire 1
1.7.2.2.1 The surgeons should be able to measure the temperature under the skin (Sub cutaneous)	D	Surgeon	Questionnaire 1
1.7.2.2.2 The surgeons should be able to measure the temperature in the muscle (intra muscular)	D	Surgeon	Questionnaire 1
1.7.2.3 The surgeon should be able to measure the temperature of the ingoing blood	D	Surgeon	IP4
1.7.2.4 The surgeon should be able to measure the temperature of the water bath which heats the blood.	D	Prototype	IP4
1.8 The surgeons and the perfusionist should be able to monitor the parameters necessary	D	Testing by technician	IP1
1.8.1 The surgeons and the perfusionist should be able to monitor the parameters from a 3m of distance.	D	Testing by technician	Observation
2 Research and documentation			
2.1 The solution should provide means to exchange information and data between experts	D	Prototype	KJ-Shiba
2.1.1 The system should store the registered measurements in a database	D		KJ-Shiba
2.1.1.1 The registered measurements should be stored automatically	D		Thesis Group
2.1.1.2 The surgeon should be able to store the registered measurements manually	W		Thesis Group
2.1.2 The system should store the registered flow rate in a database	D		KJ-Shiba
2.1.2.1 The registered flow rate should be stored automatically	D		Thesis Group
2.1.2.2 The surgeon should be able to store the registered measurements manually	W		Thesis Group
2.1.3 The system should store the average blood pressure in a database	D		KJ-Shiba
2.1.3.1 The registered average blood pressure should be stored automatically	D		Thesis Group
2.1.3.2 The surgeon should be able to store the registered average blood pressure measurement manually (ö)	W		Thesis Group
2.1.4 The system should store the registered temperature in a database	D		KJ-Shiba
2.1.4.1 The registered temperature should be stored automatically	D		Thesis Group
2.1.4.2 The surgeon should be able to store the registered measurements manually	W		Thesis Group
3 Transportation and packaging			
3.1 All the equipments necessary should easily be accessible	D		KJ
3.1.2 The system should contain the necessary equipment for HILP surgery in one package	D		IP1
3.2 The system must be possible to be moved by one man	D		IP1
3.2.2 The system should not exceed a total weight of 10 kg or should include other solutions of portability than carrying	W		Questionnaire 1
4 Design and aesthetics			
4.1 The system should not take much space	D		Observation
4.1.2 The size of all parts together except the disposables should not exceed a volume of 15000 cm^3	W		Thesis Group

4.2 Every part of the system should be easy to hold	D		Thesis Group
4.2.2 Each part should be designed to cater for griping with one hand	W		Thesis Group
4.2.2.1 The design should avoid pockets	W		Thesis Group
4.2.3 The material should be easy to clean	W		IP1
4.2.3.1 The surface should be easy to wipe and resistant to regular detergents in hospital environment	D		IP1
4.3 The system should be fluid resistant to a certain degree (fulfil standard IEC 60601)	D		IP4
4.3.2 The design and the material must withstand drops of fluid	D		IP3
4.4 The product should be perceived as aesthetically appealing by at least 70% of the users.	D		IP1
4.4.1 The colour of the product should sustain within the guarantee period with respect to light exposure and cleaning	D		IP1
4.4.1.1 The colour is preferred to be stainless steel or similar	W		IP1
5 Design and aesthetics			
5.1 The parts of the system should withstand an impact load of total mass*10	D	FEM analyses	Thesis Group
6 Safety			
6.1 The system should not be plugged in to power supply while connected to the patient.	D		IP4



6.5 Data Collected, Iterative process 2

The first step in iterative process 2 is to collect as much information as possible again regarding the product itself and MedicView's plans for the system. The information that is presented here is a combination of data that has been collected and our analysis of it simultaneously. The methods used to collect information in iterative process 2 are through interviews.

6.5.1 Interview, Iteration 2

There is only one interview conducted in the second iteration and that is also with one of the key stakeholders of the product. The interviewees are composed of two of the management group representing the owner of MedicView. This interview is also analyzed and documented in the same way as explained in chapter 6.2.1. The core of this interview lies in questions that can only be answered by the MedicView company such as cost issues, legislations and the company's responsibility regarding environment. During the analyses of this interview the thesis group is comparing the extracted statements with other statements identified earlier in the research process. An important finding is occurring at this moment and that is a conflicting constraint towards a statement that has been repeated by other interviewee. That statement can be seen below from the analysis but is still in context with the question and the answer. This shows the interest of the different stakeholders where the owner wants to ease the procedure for the surgeon without taking more legal responsibility. The surgeon is more interested in making the procedure less risky and more simple.

13. **Have you thought of any standard processes for the procedure and the set-up as an added value to the product?**

    Yes we have since HILP is a complex procedure so a guide or a manual will be considered. This is important especially for the less experienced surgeons and the ones who conduct fewer surgeries per year. There is a suggestion to include a guide in the software but that is problematic since it means we will be part of the medical procedure and that makes us more responsible. But we intend to provide other types of guide or manuals like video or other educational materials. Other add-ons that have been discussed are a set of disposables but we don't know how possible that is since hospitals differ from each other with respect to compatibility of cords among others. Instead of kit we might provide special tool that is always needed for the treatment.

Fig 25: This is another capture ripped from the analysis in the second iteration

- A guide or a manual of the important steps in the procedure should be provided separately with the system. (Note conflicting constraint, see IP1's answer to question 3 in the first interview)

6.6 Data Analysis, Iterative process 2

After the data collection in iterative process two the information is analysed again using the KJ-Shiba as in the previous iterative process. The second KJ-Shiba workshop conducted had experts from the same field but some were new to get new perspectives.

6.6.2 KJ-Shiba Method, Iteration 2

The approach to the KJ-Shiba method conducted for the iterative process 2 was a bit different to the first KJ-Shiba performed in iterative process 1. The participants for this KJ-Shiba method were Mats Olsson (electrical engineer), Jan Mattsson (surgeon), Fanny Boije and Grete Kuura (MedicView), Osman Nuru (was presented as a product developer) and Umair Chaudry who was the team leader of the workshop. In the previous KJ-Shiba workshop, the thesis group had prepared the majority of the activities represented in the first stage such as creativity thinking of the group and the statements of the problem due to lack of time. For this KJ-Shiba workshop the group proceeded with an approach of only formulating the problem-based question of the product but the brainstorming of the statements based on facts are done together. The question that the thesis group formulated before hand was *'What are the biggest problems with the MedicView product of today?*' The idea of this KJ-Shiba workshop was to keep the focus only on the product itself which is the basis for further development and improvement of the existing products. The outcome of this KJ-Shiba workshop was correlated to the expectations the thesis group had. After all the steps were conducted, the following groups of issues were the result:

- **The software calculations and settings needs to be modified**
    - **The current pressure measurements needs to be improved**
        - The correct pressure in patient is not calculated
        - The mean arterial pressure graph is missing an input
    - **The software functions are not appropriately adapted to all intended perfusions**
        - The software does not have an arm/liver volume measurement algorithm
        - All possible vessels are not specified in the software
- **The software needs to be more user-friendly**
    - **The user lacks the ability to easily select information**
        - No touch Screen
        - The figures/graphs on the screen cannot be easily adjusted
    - **The software lacks useful functions**
        - No step by step guide of the start-up of the software
        - The software does not export to Microsoft Excel
    - **The graph user interface contains too much information in a small format**
        - Too small/many graphs while sitting behind the computer
        - The value fields are too small while sitting behind the computer
        - The graph for peripheral resistance is not necessary
- **The limited knowledge hinders development of new intellectual property rights**
    - **Lack of intellectual property rights**
        - No proprietary technology
        - No MedicView logo neither on the computer nor the software
    - **Product was developed with a narrow scope**
        - Applicable only for a narrow treatment due to lack of research
        - Only one user's needs considered when developing the product
- **The usability of the product is limited by the design**
    - **The modules are instable while standing**

  - **The current design function of the client material is not optimal**
    - The surface is not smooth enough to clean
    - Plastic of the client does not have a clinical look (does not look sterile)
  - **The mechanical design of the tripod-collimator stand is not offering the optimal usability**
    - The weight is a problem for easy instalment of the collimator
    - The tripod and the collimator are bulky
    - Lead in the collimator is difficult to construct
- **Lack of coherent hospital regulations considering signal communication is a problem**
  - **Using cables in an operating theatre is not optimal**
    - Too many cables from the temperature client to the patient
    - The cables are not adjustable in length
  - **The sustainability of wireless signals in an operating theatre is a concern**
    - The system is not completely wireless
    - The wireless signals can be a problem/disturb the sensitive hospital environment
- **Facing outdated radion modules hardware**
- **Parts of the system blocks the easiness of CE-marking the system**
  - It is not CE marked
  - Temperature probes (parts) of the system are invasive (meaning inside the body which means harder to get ce marked product)
- **The production is currently too expensive in regards to mechanical parts**
  - The tripod/collimator is an expensive construction
  - The current plastic cover is made for moulding

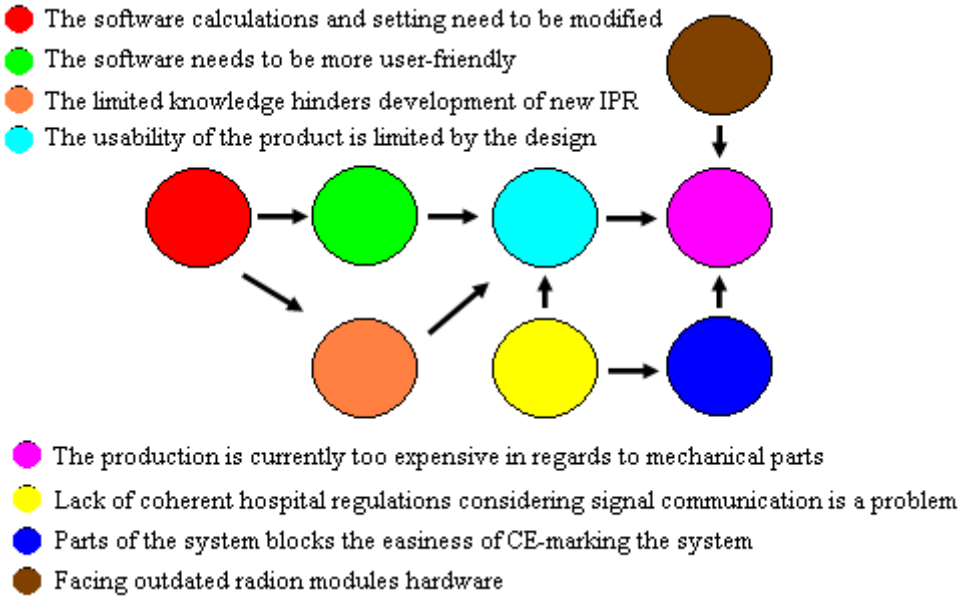


Fig 26: This is the logical scheme from the KJ workshop conducted in the second iteration (see also Appendix D, Fig 45)

One of the outcomes from this method is the logical connection of the groups that are discussed and then visualized between the members. When the connections of the groups are visualized (see fig xx), it makes it easier for the participants to understand and see the underlying cause of a certain problem.

In the end the KJ-Shiba ranked the most important issues which the group members found crucial. In this case relating it back to the question set from the beginning, to see if it answered the problem-based question or not. The rankings were set in the following order:

1. **Product was developed with a narrow scope**
2. **The production is currently too expensive in regards to mechanical parts**
3. **The current pressure measurements needs to be improved**
4. **Parts of the system blocks the easiness of CE-marking the system**
5. **The software functions are not appropriately adapted to all intended perfusions**
6. **The graph user interface contains too much information in a small format**

The result from the KJ-Shiba method is that the main problem with the current product available today has been developed with a narrow scope only considering one user's needs. The product is only applicable for a narrow treatment due to lack of research done in the initial stages. From this, the core problem of the product was identified and even the logical connection verified this. The narrow scope of the whole system results in an expensive product to manufacture. Careful research done by MedicView has shown that the mechanical parts are too expensive to manufacture.

Another problem with the product today is that the approach taken to measure the pressure in the limb is not the most optimal. The pressure is measured in the catheter approx five to eight centimetres outside the actual limb which shows a different measurement compared to if the pressure is measured directly inside the limb.

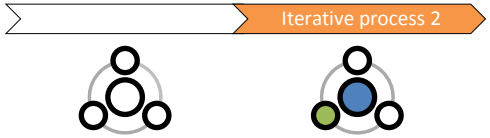
The aim of MedicView is to get the system CE-certified and some of the parts used in the system today hinder the simplicity of proceeding with the CE certification. The main underlying problems to this are the temperature probes which are invasive and become more of an obstacle.

The software functions and the software interface have been discussed since the beginning of the thesis as the biggest issue to confront. The results show that the interface issue was not seen as the most prominent problem among the ones listed, but taking into consideration it became one of the issues that was ranked indicating some importance to the problem.

Among other problems identified that were not ranked was the solution of having the system wireless. The problem here was that there were too many cables hanging from the clients which are a problem from the flexibility point of view for the surgeon. A wireless solution also has its downsides in a hospital environment in a way that it could interfere with other signals in the operation theatre. These kinds of issues play a big role in the trade-off between wireless and cable.

Furthermore the stand and the collimator that is installed on the operation table has a bulky design making it a bit difficult and heavy to install. The stand is divided into two parts and it was discussed before in previous field study analysis (see Ch 6.2.2). One thing that lacks in the system today (which the KJ-Shiba group identified) was the level of marketing of the MedicView brand. This will essentially play a big role in respect to commercialization.

As a conclusion by the KJ-Shiba team the question set from the beginning *''What are the biggest problems with the MedicView product of today?'* was answered with *'Due to that the product was developed with a narrow scope it doesn't have all necessary functions, has high production costs and complicates CE-marking'.* This clarified and created a better understanding of the underlying problem with the MedicView system.



6.7 Final Results, Iterative process 2

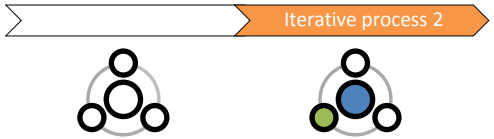
The second iterative process has changed some categories which are shown in the list below. The result shown in this chapter is the final requirements list which is a combination of the outcome from iterative process one and iterative process two. Some of the categories of the requirements are inspired by Pughs Balloons [18] while others are just grouped under a suitable name by the thesis group.

Table 3: This table shows the final result which is an outcome of the first and second iteration.

	Demand (D)/ Wish (W)	Validation	Traceability
1. Functionality			
1.1 The surgeon should be able to register the leakage measurement	D	Prototype	IP1
1.2 The surgeon should be able to measure the leakage of the toxic drug into the systemic circulation	D	Prototype	IP1
1.2.1 The measurement system should measure the leakage accurately	D	Testing by technician	
1.2.1.1 The unit for leakage should be counts per second (c/s)	D	Prototype	
1.2.1.2 The accuracy should be ±2%	D		
1.3 The surgeon should be able to register the flow rate	D	Prototype	IP1
1.4 The surgeon should be able to measure the flow rate of the perfusate in the isolated limb	D	Prototype	IP1
1.4.1 The measurement system should measure the flow rate accurately	D	Testing by technician	
1.4.1.1 The accuracy should be ±1%	D	Testing by technician	
1.4.1.2 The unit for flow rate should be millilitres per minute (ml/min)	D	Testing by technician	
1.5 The surgeon should be able to measure the average blood pressure in the isolated limb	D	Prototype	Questionnaire 1
1.5.1.1 The accuracy should be ±5%			
1.5.1.2 The unit for average blood pressure should be millimetre of mercury (mmHg)	D	Testing by technician	
1.6 The surgeon should be able to register the temperature	D	Prototype	IP1
1.7 The surgeon should be able to measure the temperature	D	Prototype	IP1
1.7.1 The measurement system should measure the temperature accurately	D	Testing by technician	IP1
1.7.1.1 The unit for temperature should be degrees Celsius (^{o}C)	D	Testing by	

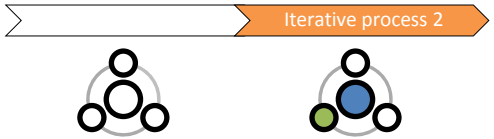
		technician	
1.7.1.2 The accuracy should be at 0.1 °C	D	Testing by technician	IP4
1.7.2 The surgeon should be able to measure the temperature on different points of the limb	D	Surgeon	IP4
1.7.2.1 The surgeon should be able to measure the temperature on two different points on the upper limb	D	Surgeon	Questionnaire 1
1.7.2.1.1 The surgeons should be able to measure the temperature under the skin (Sub cutaneous)	D	Surgeon	Questionnaire 1
1.7.2.1.2 The surgeons should be able to measure the temperature in the muscle (intra muscular)	D	Surgeon	Questionnaire 1
1.7.2.2 The surgeons should be able to measure the temperature on two different point on the lower limb	D	Surgeon	Questionnaire 1
1.7.2.2.1 The surgeons should be able to measure the temperature under the skin (Sub cutaneous)	D	Surgeon	Questionnaire 1
1.7.2.2.2 The surgeons should be able to measure the temperature in the muscle (intra muscular)	D	Surgeon	Questionnaire 1
1.7.2.3 The surgeon should be able to measure the temperature of the ingoing blood	D	Surgeon	IP4
1.7.2.4 The surgeon should be able to measure the temperature of the water bath which heats the blood.	D	Prototype	IP4
1.8 The system should include more than one output for monitors or other means for the perfusionist to observe the parameters	D	Prototype	IP3
1.9 The product should have the possibility to take input from relevant devices.	D	Prototype	IP3
1.10 The system should strive for wireless solution	D	Testing by technician	KJ2
1.10.1 The system should include as low number of cables as possible	W	CAD	
1.10.2 The wireless signals of the system should not interfere with other equipment in the hospital environment.	D	Testing by technician	
1.11 The MedicView product should be developed for usage in additional procedures than HILP.	D	Surgeon	IP5
2 Research and documentation			
2.1 The solution should provide means to exchange information and data between experts	D	Testing by technician	KJ-Shiba
2.1.1 The system should store the registered measurements in a database	D	Testing by technician	KJ-Shiba
2.1.1.1 The registered measurements should be stored automatically	D	Testing by technician	Thesis Group

2.1.1.2 The surgeon should be able to store the registered measurements manually (desire)	W	Testing by technician	Thesis Group
2.1.2 The system should store the registered flow rate in a database	D	Testing by technician	KJ-Shiba
2.1.2.1 The registered flow rate should be stored automatically	D	Testing by technician	Thesis Group
2.1.2.2 The surgeon should be able to store the registered measurements manually	W	Testing by technician	Thesis Group
2.1.3 The system should store the average blood pressure in a database	D	Testing by technician	KJ-Shiba
2.1.3.1 The registered average blood pressure should be stored automatically	D	Testing by technician	Thesis Group
2.1.3.2 The surgeon should be able to store the registered average blood pressure measurement manually	W	Testing by technician	Thesis Group
2.1.4 The system should store the registered temperature in a database	D	Testing by technician	KJ-Shiba
2.1.4.1 The registered temperature should be stored automatically	D	Testing by technician	Thesis Group
2.1.4.2 The surgeon should be able to store the registered measurements manually	W	Testing by technician	Thesis Group
2.2 The information gathered during the procedure should be able to be exported to frequently used formats	D	Testing by technician	KJ2
3 Transportation and packaging			
3.1 The system should contain the necessary equipment for HILP surgery in one package	D		IP1
3.2 The system must be possible to be moved by one man	D		IP2
3.3 Everything should be packaged in a way that caters for the portability in the hospital.	D		IP1
4 Design and aesthetics			
4.1 The system should not take much space	D	Prototype	Observation
4.1.1 The size of all parts together should not exceed a volume of 15000 cm^3	W	CAD	Thesis Group
4.2 Every part of the system should be easy to hold	D	Prototype	Thesis Group
4.2.1 Each part should be designed to cater for griping with one hand	W		Thesis Group
4.2.2.1 The design should avoid pockets	W		Thesis Group
4.3 The system should be fluid resistant to a certain degree (fulfil standard IEC 60601)	D	Prototype	IP4



4.4 The design should cater for to withstand drops of fluid	D	Prototype	IP3
4.5 The product should be perceived as aesthetically appealing by at least 70% of the users.	D		IP1
4.5.1 The colour of the product should sustain within the guarantee period with respect to light exposure and cleaning	D		IP1
4.5.1.1 The colour is preferred to be stainless steel or similar	W		IP1
5 Robustness			
5.1 The product should be robust	D	Prototype	Thesis Group
5.1.1 The parts of the system should withstand an impact load of total mass*10	D	FEM analyses	
6 Safety			
6.1 There should be no current going through the cables during procedure.	D	Testing by technician	IP3
6.1.1 The system should not be plugged in to power supply while connected to the patient.	D		
6.2 Some type of warning is necessary with respect to the change of parameters.	D	Testing by technician	IP1
6.2.1 A warning signal is especially important for the leakage with respect to time.	D		IP1
6.2.2 The system must indicate if the leakage measuring system is malfunctioning.	D		IP1
6.3 The system should give a go-ahead indication if everything is working properly.	D	Testing by technician	IP1
7 Ergonomic			
7.1 The surgeons and the perfusionist should be able to monitor the measurements	D	Testing by technician	KJ
7.1.1 The surgeons and the perfusionist should be able to monitor the measurements from a 3m of distance.	D	Testing by technician	Observation
7.2 All the equipments necessary should easily be accessible	D	Surgeon	KJ
7.3 The mechanical design of the rack and the collimator should be ergonomically optimized.	D	Prototype	KJ2
7.3.1 The design of the rack and the collimator should not be bulky	D		
7.3.2 The weight of the stand and the collimator should not exceed 5 Kg	W		
8 Weight			
8.1 The system should not exceed a total weight of 10 kg	W	CAD	Questionnaire 1
9 Material			
9.1 The material must withstand drops of fluid	D	Prototype	IP3
9.2 The material should be easy to clean	D	Prototype	IP1
9.2.1 The surface should be easy to wipe and resistant to regular detergents in hospital environment	D		IP1

9.3 The cables and needles of the thermometers must be able to be sterilized.	D		IP1
9.3.1 If there are weak parts then they should be replaceable. (talking in respect to sensors that may be too weak).	D		IP1
9.3.2 Needles of the thermometers should be disposable if possible.	W		IP1
10 **Processes**			
10.1 A guide or a manual of the important steps in the procedure should be provided separately with the system.	D	Owner	IP5
10.2 Manuals/tutorials should be easy to understand; even non physicist should understand it after training.	D	Owner	IP3
10.3 The system should include a start-up guide.	D		KJ2
11 **Usability**			
11.1 Every chargeable item should be charged through one connection if possible. (Docking station)	D	Testing by technician	IP1
11.2 If the solution requires cables then they should be of the same length as the cables from the lung heart machine.	D	Supplier	IP1
11.3 The user should have the possibility to choose what parameters should be observed on the monitor.	D	Technician	IP1
11.4 The user should have the possibility to adjust the setting of parts or the entire alarming system.	D	Technician	IP3
11.5 The system should be easy to calibrate since it is different for each surgery.	D	Testing by technician	IP4
11.6 The software should be adjustable to all intended perfusions.	D	Testing by technician	KJ2
11.7 The system should cater for the flexibility needed with respect to ILP surgery.	D	Surgeon	IP4
11.7.1 The design should facilitate the ratemeter to be placed close to the upper body.	D		
11.8 The surgeons and the perfusionist should be able to monitor the parameters necessary	D	Testing by technician	IP1
12 **Regulations and legislations**			
12.1 The system should fulfil the IEC 60601 standard.	D	Notified body	IP4
12.2 The product should be CE-branded.	D	Notified body	IP4
12.2.1 The product should be CE-marked by January 2012.	W		IP5
13 **Maintenance/Support**			
13.1 The customer should have the possibility of choosing a service or support agreement	D	Owner	IP4
13.2 The system should provide means to be maintained with guidance through telephone or the internet.	W	Owner	IP5
14 **Product cost**			
14.1 The product cost of one unit should not exceed 50000 SEK.	W	Owner	IP5
15 **Performance**			
15.1 The pressure should be measured inside the limb. (Today they measure in the catheters - see bullet point 2).	D	Testing by technician	KJ2



16 **Marketing**			
16.1 The product should promote the MedicView brand.	D	Owner	KJ2
17 **Product Lifecycle**			
17.1 There should be a plan for taking care of the product when its working life ends.	D	Owner	IP5
18 **Production**			
18.1 The design of the system should cater for low volume series.	D	Manufacturer	IP5
19 **Environment**			
19.1 The system should follow the hospital's rules and regulations regarding the radioactive substance.	D	Owner	IP5

6.8 Methods for Validation of Requirements

When specifying a requirements list one should make sure that these requirements can be validated somehow. There are several ways to validate the requirements e.g. prototype testing or different type of measuring which can assure that a certain requirement is fulfilled by the product. In the case of MedicView the analysis part included methods for how each requirement can be validated; this list can be found integrated in the result spreadsheet (see chapter 6.7). Many of the identified requirements can be validated through testing of a prototype. Nevertheless it must be distinguished what is meant by a "surgeon" as a validation method. It means that the part is technically tested by technician (software, physicist, mechanical) or granted by manufacturer but a surgeon must approve that it works. A typical example of this is the accuracy of sensors which are tested by a technician while the usability, with respect to surgery, should be validated by a surgeon. Another frequently repeated label in the validation list is "prototype" that is stated for requirements which can be validated by anyone who knows the equipment or the software. There are some requirements validated by testing, this label is set to the ones which are tested by a technician or a manufacturer. There are regulatory requirements that can only be validated by a notified body and these are listed as notified body in the validation column. The issues that should be taken care of by the MedicView Company are just listed as owner.

6.9 IEC 60601-Standard overrules the requirements list if possible conflicts arise

The IEC 60601 standard is an internationally recognized standard which contains guidelines for developing a range of different electrical medical products. The standard is divided into 59 sub-categories and helps to regulate the design of the product. Following this standard optimizes the product for direct use in several different medical environments.

The requirements list is based on the analysis of the data collected in this research and the IEC 60601 standard has not been taken into consideration due to a tight budget. The standard was never bought to analyze and implement in the requirements list since the cost of the standard is approximately 110 Euros for each sub-category. This will result to that if any requirement from this report contradicts with anything in the IEC 60601 Standard, the requirement should be overruled by the standard.

7. Conclusion

The problem with the MedicView product today is that they are lacking a properly documented requirements list of the needs the user and MedicVew has. For further development of the product, the absence of a requirements list decreases the possibilities to CE standardize the system. Reflecting back to the research questions, the results from this thesis have been able to answer the questions. From this research the thesis group is able to conclude that the basic needs of the user and MedicView have been identified to be able to perform a successful HILP procedure. Also the thesis group concludes that the present product related needs have been identified to be the ability to measure and monitor leakage.

The thesis group is able to conclude that the basic needs of the user are the functional needs listed in the chapter *Results, iteration 1* under category *Functionality & Usability* (see Ch 6.4). The most important things to be measured and monitored for the user are leakage, temperature and the average blood pressure in order to be able to have an overall view of how the treatment is progressing. Without the control over these parameters the user would have difficulties to take necessary actions to avoid any unfortunate miscalculations. The temperature has to be calculated in several places to have as accurate measurement as possible of the limb, which justifies the user needs to have more than five measuring points. The thesis group is also able to conclude that the necessary parameters for the HILP procedure have been identified as the appropriate parameters to measure during the treatment. These parameters (mentioned in the requirements list) are the basic parameters that need to be measured and monitored by the surgeon to optimize the treatment. The results from this report show that the necessary needs of MedicView have been identified such as to have the product CE standardized by the year 2012.

Another necessary need that has been identified is the lack of mobility of the MedicView product used today. Since it consists of several different parts, the packaging provided today is not sufficient enough from neither an ergonomically nor safety point of view. That is why the thesis group has been able to identify a specific need of the users to have all parts packaged in one unified mobile unit which can be moved from one destination to another.

From this research, the thesis group has been able to set up an overall requirements list based on the gathered information. The requirements list achieved from this research has been divided into several important categories covering different needs and desires. Furthermore the needs that do not regard the function but rather the usability, the design, ergonomics, aesthetics etc, have been identified as, well i.e. product related needs. These needs are the needs that will form the product from an aesthetic and environmental point of view. The thesis group is able to conclude that even the present product-related needs have been covered to help the product developer to develop the next generation of the product. These needs are related to marketing, product cost, product life cycle, production etc, which covers the areas that are necessary requirements for a measuring and monitoring system. The thesis group is able to conclude that the needs and the desires that are essential for the prototype to transform into a product that has been identified in the requirements list. This solves the previous problem of not having a proper formal requirements list that serves as a base for further development of the product and brings MedicView one step closer to CE standardizing the system.

The thesis group is also able to conclude from this research that the HILP procedure is still young and needs more research. Looking back at this research process, a large portion of the requirements list has been emphasized on the ability to store the data in a database and share it with others. This is a way to stimulate research among the surgeons to get the HILP procedure standardized. The need to have a central data storage system is becoming crucial.

As a closing remark of this report is that the MedicView product is only adapted for the specific type of HILP procedure conducted at SUH. This leads to that the system is only able to be used in similar types of HILP procedures that are being conducted as the one at SUH. The needs and the desires identified here are generally based on SUH and MedicView.

8. Recommendation for further approach

From this research, the thesis group has made it possible for MedicView to fill in the missing parts of a traditional product development process. Still there are additional actions recommended by the thesis group to be taken in order to maximize the use of this research.

A wish that was repetitively touched upon is the possibility of developing a total wireless solution. That would actually exclude the clients from the system and would possibly give one more advantage with respect to the competitors. Therefore it could be valuable to investigate this possibility and its potential.

The thesis group also recommends MedicView to purchase parts of the IEC 60601 standard which are related to the MedicView. The requirements of the IEC 60601 together with the identified requirements in this research can be used as a base for the development of a new generation MedicView product. As mentioned earlier, one of the problems with the MedicView product is that it is designed with a narrow scope. In addition to that, HILP is performed only in a few hospitals around the world that limits the market for the product. One possible solution identified to deal with the problem is to widen the market by adjusting the product or offering additions in order to make the product useful for other procedures. The thesis group strongly recommends the developers of the next generation to give attention to this issue.

Another simpler action that can be taken immediately is the redesign of the stand. As can be seen in the final requirement list the stand is not ergonomic and should be lighter and cheaper.

Another activity that should be undertaken is a design of a step by step guide for the procedure. Even though there are differences in how the guide or manual should be included in the system or just follow with the system as additional learning material. It could be important to distinguish between those two alternatives due to legislation issues. Thus a thorough investigation should be undertaken before deciding to introduce it into the system.

In addition to the mentioned recommendations there is an important area which is addressed in the results as research and documentation. This is of great importance for the practitioners of the surgery as well as for MedicView and the patients. The idea is to create a database that collects surgery data of conducted HILP surgeries with the help of MedicView product. Having an easy accessible database would create a centre for all the HILP surgeons to store the data and having access to other surgeon's treatments for e.g. the response rate. This is to ease the knowledge exchange between surgeons in order to accelerate the research in the field. According to two HILP surgeons one of the obstacles in researching in this field is the small number of documented HILP surgeries available. Automatically this database will also gather all the experts at one place giving the surgeons the possibility to network with each other. The database could also be a step forward in the work of standardizing the complicated procedure with many steps. If the idea of a database is realized then MedicView will have an advantage in locking the practitioners to their technology and in the same time acquire a greater overview of the development. This could give a new dimension in the competence and hopefully place MedicView in pole position.

9. Discussion

Having a company based on a customer-orientated product without properly understanding their needs and desires could be devastating for the company's success. This means that a lot of emphasis should be front-loaded in a product development process because this will determine the quality of the end results. As for MedicView's case they have to take this into careful consideration for their next generation product. Now that we have been able to provide them with a formal requirements list with the basic needs and desires of the users and themselves, the ability to transform these requirements into a product relies on MedicView. A successful company is able to do it in a good manner. Usually this is something that is overseen quite often. As also mentioned in the course *Product Planning and Market Analysis* (Slide 091104) confirms that the determination of a successful product [8] relies on the ability, in this case MedicView, to transform the knowledge of the customer needs into a product solution that satisfies the customer. That is why it is important to have a structured way of developing a product from the beginning implemented in the company, and having a structured way would minimize the possibility to oversee the necessary needs. Furthermore if this information is documented, as it is now, it will prevent MedicView from re-inventing the wheel. Having proper documentation eases the work for the next person that is to further develop the product.

Since this part was overall missing from MedicView, we decided to go back in time as if the MedicView product didn't exist. The importance of going back in time is to understand why the product has taken the form it has today in order to recognize what is fulfilled and what is not. That is also why we divided the processes into two parts; one for identifying the basic needs and desires of the user and the second more product related needs which covered issues such as; what could be improved with the product today, what is missing etc, as well as MedicView's needs. One issue with this was that we didn't know how many iterations were necessary to get good results for this work in the initial stages. We decided to stop after the second iteration because we found that we could not get any more information with a third iteration that would be of value to this work.

During the latter part of the thesis in iterative process 2, there were some additional questionnaires sent out to some new surgeons MedicView had established contact with. This was seen as a great opportunity by us to get some validation on some findings we had done from the previous iteration, but we still have not received any responses yet. The result from these questionnaires could have some minor impacts on the results presented in this report, but not necessarily.

If the surgeons do not have time to fill in a questionnaire, then one can understand that getting a surgeon off for 4-5 hours from work is almost impossible. Our KJ-Shiba workshops were very intensive and long, and being able to have at least one surgeon available to participate is a great achievement for us. It is usually hard to book in a surgeon because they have already pre-planned surgeries a month or two prior to the surgery day. For both the workshops we tried to have two surgeons participating, but luckily we at least got one off to actively take part of the KJ-Shiba.

One great set-back of this report was us not being able to get hold of the IEC 60601 standard. By having these standards at hand we could have achieved a better certified requirements list that would be following international standards. Having such an expensive standard to buy in is not appropriate for MedicView to purchase because other priorities are of greater importance to MedicView today than the standard. Nevertheless the requirements list provided in this report is a big step for MedicView's goal to get the product CE-certified by January 2012.

Looking back at the planning report some changes were made such as the planned chapter of identifying the purchase process was disregarded. We decided that the purchase process chapter did

not bring direct value to MedicView from this research and was off track from the main focus of this research. Together with MedicView we agreed upon removing that chapter since MedicView themselves were working with it in parallel to our thesis for other hospitals than SUH. From the planning report there were some few analysis methods suggested to use during the analysis of the data. Together with the supervisor we decided to only analyze the data with KJ and disregard the use-case scenario because it did not contribute anything to the results of the report i.e. it was to be waste of time by working with that analysis method.

In the planning report there was also an intended seminar that was to be attended by us and to have a workshop with several surgeons at one go. During the thesis work, lesser and lesser surgeons booked to attend the seminar. The surgeons were mainly from different countries in Europe such as Norway, Denmark, Germany, Sweden etc. Our hopes to have an extensive workshop with the surgeons were cut off, from having 2-3 hours with them to only 5-10 minutes. This resulted to that the planned workshop had to be cancelled and instead a questionnaire was designed as a replacement which gave satisfactory results.

As mentioned earlier there were some changes with respect to the planning report, the cancelled methods were changed because they were found to be insufficient with respect to this specific research. If this was identified earlier the time resource could have been used more efficiently and some minor changes to the design of the product could have been proposed. Deciding the methods to be used in the research from the beginning had benefits of the thesis work being structured and easy to follow a time plan. On the other hand it had some problems as in our case where the method sometimes tended to become the goal instead of just a tool. It is important to take one step back and reflect upon the milestones during the process and ask oneself "*what do we want to get out of this session or is this the best way to achieve the goal we want".* Another thing that could have been done differently is the documentation of the field studies. The problem was that we were told that a film team would video record the surgery and we thought that we could use the video to fill in with our notes from the observation. It turned out to be difficult to extract what we were looking for from the video such as distances, the localisation of staff, the equipment in the room etc. Sketches could have helped in addition to the notes and the video in order to maximize the outcome of the field studies.

Last but not least the competitors in the market were explored quite late in this thesis by MedicView. Since we got to know about the competitors quite late in the process we were not able to benchmark with Veenstra [19] and Rand [20] which could have lead to additional requirements not listed here in this report. Benchmarking MedicViews product with the competitors stimulates the product developer to see from other perspectives that may have been missed out. This should be taken into consideration when MedicView reaches the concept development phase in the product development process.

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Appendix

Appendix A – Interviews

Appendix B – Analysis of Interviews

Appendix C – Questionnaire

Appendix D – Pictures

Appendix A Interviews

Surgeons 1 and 2 (Interview Person 1 & 2 – IP1)

1. **Why do you need the MedicView product?**
   We want to register different parameter and documenting the treatment mostly for scientific reasons but also to be able to regulate in order to optimize the treatment. Earlier we did this by pen and paper every tenth minute but that was not a good way so we needed a system which could do this in real-time. Thus we asked Mats Ohlsson to develop a system which satisfies this need.
   First of all to measure the leakage of TNF-Alfa, and for scientific purposes as the temp measurements and to make sure that the catheters are placed right and that you have a good increase in the temp and sufficient flow rate. It is a good monitoring system but we don't need the MedicView to perform the perfusion. But the MedicView is a more sophisticated way and easier to where it is documented and all the data is merged instead of looking at different monitors.
   You said you can perform the perfusion without MedicView; does that include a perfusion with TNF-Alfa treatment as well?
   No we can't perform that without MedicView.
2. **What will happen if you perform a HILP surgery without the MedicView product? Other substitutes used?**
   We don't have a substitute but we could ask radiation physicists or the medical technician of the hospital to help us to measure the leakage in some way. The MedicView is a simplification of everything for us.
   Why is it important to document?
   For research purposes, it is around 60 % of the patients with a known tumour (melanoma) that completes the mission (the tumour disappear) but why not for the 40 %? that could be due to technicalities during the operation , to low temp, is the flow to low and etc those questions can be answered if we collect the data
3. **Is the monitoring system easy to use (user interface) even for new surgeons? Standard user interface? What additional training do you think is suitable for the surgeon to use MedicView product. Should there be a certificate? What is easy enough but still safe?**
   No it is not easy for new surgeons you have to get an introduction to it. Once you have understood it then it becomes easy, could probably be simpler (more user friendly). A guide similar to the one for calibration (in the software) could be useful. A checklist approach for the important steps should be considered. The more experienced surgeon finds it easy to just read the manual and use the equipment (could be bias). It is not pedagogical but still doable. No certificate should be required to handle the equipment because if understand what you are doing the interface is not complicated.
   Is there a standard interface in medtech or in Sahlgrenska?
   No
   What is easy enough to use but still safe (safe enough to change the things without knowing that much)?
   Yes it is quite comfortable to change the graph, scale and etc. Once you understand the small buttons (icons) it is easy to use. But it is still easy to forget some steps in the procedure of setting up and etc, a guide for the whole sequence as mentioned earlier would help. A guide like a flow chart maybe in the software or a process map.
   The critical part is the leakage measurement and there is a good guide for that included in the software. I (the surgeon) set up the modules and plug them in to the host and set it in standby and then the perfusionist changes it to the running mode and calibrates the pressure system. This is

a routine that we all know, but if someone is missing and replaced by a new person then it might be critical. A guide about how to arrange the system might be useful to add value to the system.
Can we get your checklist?
We don't have any checklist it is in our minds.

4. **What happens if parts of the monitoring system or the whole system collapse? Are there any backups if the situation occurs?**
   We have got a backup module for the leakage measurement and we will also get a spare detector, these are the most critical ones. We can manage to proceed with the operation If other parts of the system fail, they are not as critical as the leakage measurement. If it is a perfusion with TNF-Alfa then we have to abort the operation.
5. **At what occasions would you end the surgery due to MedicView's system failure? What type of warning signals would you like to have?**
   As it is now we are satisfied with it but we would like to have a warning signal for the leakage but we don't know when that should be because we sometimes allow a little leakage. A warning signal with respect to the time left regarding the critical limit of leakage is needed.
   If there is a rapid change in some parameter it might be of interest to have an alarm.
6. **Do you use the product for any other purposes? Do you think it will be possible to use the product for anything else?**
   No we don't use it for other purpose. Yes it is possible to use it in other type of operations where you need to register or measure temperature/ pressure and other parameters, this is very wide
7. **How is the system packaged today? Pros and cons? How is it transported to and inside the hospital /other similar devices?**
   It is kept in Dr Jan's office in a bag, backups of the files are made frequent and is decided to be made every week. The scintillator is sensitive and is kept in a closet in the locker room. A box for everything would be good maybe something on a wheel. And maybe everything can be charged with one connection through the "box". The stative is also left in the locker room. It would have been good to be able to see if everything is working fine in the system before you add substance to the patient. As it is now you will not detect the failure until you get wrong signals when you start. A background activity that assures the correctness of the equipment would be helpful.
   How would you prefer MedicView's system to be packaged?

   - The three modules?
   - The computer?
   - The scintillator?
   - The stative?

Are there any particular sensitive parts?

Are there parts that needs to be in sterile package?

8. **How are the devices sterilized today? What parts are sterilized? How often?**
   Only the cables and needles of the thermometers need to be sterilized. These can't be heat sterilized and must be plasma sterilized (sterrad)
9. **Is it important if the product is fluid resistant? If yes, why?**
   No not really.
10. **What constraints the placement of the clients/host/monitor? (Such as distance, height etc)**
    One of the cables (the blue tube for pressure measurement) is too short and constraints the placement. On the other hand the cables from the lung heart machine can't be too long, otherwise it

will increase the heat loss. And the modules are placed above the machine. Also the perfusionist needs to see the graph which shows the leakage. See photo for typical arrangement.

11. **How would you like to have the surface of the MedicView hardware product with respect to appearance/handling ? (Materials? Feeling? Senses?)**

It feels too "plastic" and the colour of it is changed probably due to sun exposure. The ideal would have been stainless steel or aluminium. Should be easy to wipe off. It is good that it could be placed vertical and horizontal. We would like to have the modules a little bit smaller if possible (like a Iphone).

12. **How would you like the design of the sensors to be in order to ease the handling of it in general terms and during surgery?**

    The sensor are maybe a little bit too weak and can be bend or broken easily as happened in Finland. But they should not be too thick either with respect to the tubing. The needles maybe can be done replaceable if they are weak (especially if it is possible to make it wireless).

13. **Is there any additional functionality you would like to add with respect to HILP surgery or other potential application areas?**

It would be valuable to measure pressures at more positions (in the tumour and in the muscle) for scientific purposes (like an add on feature), or pressure measurement in the body system as well as in the perfusion system.

14. **Are there any unnecessary parameters on the monitor?**

    Yes the venus pressure, peripheral resistance and the flow rate, they should be recorded but not necessary to be shown in the monitor. You should be able to choose what to see on the monitor. I have to see on the legend each time to see which belongs to which. Some of the graphs could be easier to have as bars instead as the real time temperature.

15. **Are there any additional parameters you would like to monitor?**

    Maybe body system pressure not sure yet. And a calculation of both pressures and an advice of regulating the blood flow as a result of it.

16. **Can you explain the interaction between the pressure of body system and the pressure of perfusion system with respect to HILP?**

17. **In what different steps are the patient prepared before starting the system? Especially exactly before the time MedicViews product comes in contact with the patient or is started. For example, disinfection of the patient, preparation the blood vessels for the catheterization, insertion of the disposable pressure probes, placement of the scintillator etc.**

    The scintillation system is put in place before the sterile washing of the patient and then the temperatures and pressure measuring systems are connected after the sterilization and after the operation and the vessels are prepared those are put in place after disinfection the patient. The catheterization and insertion of the disposable pressure probes are also done after the sterilization.

18. **What are the contraindications for using our system? Allergies to the sensors etc? When would you not use MedicView system?**

    The nurses ask the patient if they have nickel allergy, the temp sensors probably contain nickel. No other contraindication are identified since 1992.

19. **What parts of MedicView's equipment do you handle as waste? Have you received any instruction of how to handle the waste?**

    Nothing is waste

20. **If MedicView would like the surgeon/hospital to send back the equipment when in need for change or how do you normally handle old equipment?**

    All old equipment is taken care of by the medical technician staff, they take it apart and throw the useless parts.

21. **What parts are sterilized? How are they sterilized, how often?**

22. **Have you ever experienced any adverse effects from MedicViews components? Think deeply.**
    No adverse affects have been detected.
    This is something that we must handle formally in the future, by having adverse event reports, error report etc.
23. **Which parts are disposables today? What would you want to be disposable tomorrow?**
    Nothing is disposable today. We would like to have the needles of the thermometers to be disposable in the future, once again especially if it could be wireless but in that case even the transmitter must be sterilized as well as the disposable needles (there are equipments which are placed in sterile bags).
24. **Realistic patient expectations?**
    Nothing because the patient is not informed about the system.

Surgeon 3(Interview Person 3 – IP3)

1. **Why do you need the MedicView product?**
   We started to perform the procedure about five years ago and we wanted to have the best or the latest equipment in the market since we were so late with ILP we did not have any equipment. We wanted to make the procedure as safe as possible that's why we decided to use the MedicView.
2. **What will happen if you perform a HILP surgery without the MedicView product? Other substitutes used?**
   We have not used any other but we know that it would be possible to measure the different parameters with the ordinary equipment in the hospital though it would not give a collected result. But the leakage would be able to be measured from the gamma camera (which is a part of the MedicView system)

   Is it possible to perform a HILP/ILP using TNF-Alfa without MedicView?
   That is one of the reasons why we acquired the MedicView system. But so far we have not done so many surgeries with TNF-Alfa yet.
3. **Is the monitoring system easy to use (user interface) even for new surgeons?**
   It is not so easy, you need some education the interface is not easy it is only our physicist who handles it. Still it is not due to the interface only rather more due to complication about isotopes and etc not everybody understands those issues. I think to commercialize the system you will need to have clear manuals/ tutorials and guidelines. I don't think anybody can use this system without training there are some knowledge one should acquire before using the equipment.
   Do you think a certificate to use the equipment could be good?
   Yes maybe, it is popular nowadays to have certificates for different equipments.
4. **What happens if parts of the monitoring system or the whole system collapse? Are there any backups if the situation occurs?**
   We don't have any backup system and might be forced to terminate the procedure. The most important one is of course the leakage measuring system.
5. **At what occasion would you stop a surgery due to MedicView system?**
   If I am using TNF-Alfa and I don't have leakage monitoring than I would abort the surgery.
   I f I am using melphalan and everything seems to be stable and the patient is well than I might go on.
6. **Do you think a warning signal or alarming when reaching a certain level would be valuable?**
   I think that is one of the most important steps of the development that you could do. I mean to work out the inbuilt warnings not only leakage but also other parameters as temperature. You must alert much quicker than the cumulative 7 % leakage that is when the leakage is coming.

7. **Do you use the product for any other purposes? Do you think it will be possible to use the product for anything else?**
   I don't think so.
8. **How do you transport (portability) and store the MedicView device/other similar devices?**
   We have a trolley where we keep everything and is transported that way. The system is kept together with all the equipment needed for the perfusion in a room.
   It could be good if it could be mounted on a shelf or on the roof (we have a lot of equipments that are placed up there). As it is now we don't perform that many HILP/ILP surgeries and that is why we put it away.
9. **How would you like the system to be packaged?**
   It could be good if it could be one moveable unit especially for low volume centres while for high volume centres I think they would prefer to have mounted somehow.
   The stative and scintibase should be taken away and stored somewhere.
10. **What parts need to be in sterile packages?**
    The temp sensors I think that's it. (autoclay = heat....)
11. **Is it important if the product is fluid resistant? If yes, why?**
    Yes that is important everything that is close to the operation table should be fluid resistant.
12. **What constraints the placement of the clients/host/monitor? (Such as distance, height etc)**
    The monitor should be placed close to the perfusion system because they are the ones who needs to follow the parameters, so it would be good if they can see the parameters so it should maybe not be too big to move. Or it could have more than one output for different monitors.
    The computer works fine even compared to the waterproof keyboards that we have some of they are a bit clumsy.
13. **What is the required performance with respect to response time on the different parameters? Are they met?**
14. **How would you like to have the surfaces of the MedicView hardware product with respect to appearance/handling ? (Materials? Feeling? Senses?)**
15. **How would you like the design of the sensors to be in order to ease the handling of it in general terms and during surgery?**
    It could maybe be good to have a totally wireless system but I don't think it is cost-effective and it is actually not a big deal. The most important is to have it wireless between the host and the clients but if you can do it totally wireless without increasing the cost so much and solving the sterilization issue than why not.
16. **Is there any additional functionality you would like to add with respect to HILP surgery or other potential application areas?**
    The alert as mentioned before. The system should have the interface which makes it possible to take input from other devices as the flow rate from other system. Other thing could be the layout, for instance the lines of the curves are thin and hard to see from a distance. And five temperature curves makes it hard to see if you don't come close to the screen.
17. **In what different steps are the patient prepared before starting the system? Especially exactly before the time MedicViews product comes in contact with the patient or is started. For example, disinfection of the patient, preparation the blood vessels for the catheterization, insertion of the disposable pressure probes, placement of the scintillator etc.**
    We prepare the system before we take in the patient to avoid having the patient lying longer than necessary
18. **Contraindications?**
    We have not had any contraindication and I don't
19. **What training have you had before using the MedicView for the first time?**

Mats (the inventor) came and explained and trained us how to use the system. Our Physicist have read the manuals and trained himself and he is the one who understands the system fully in our team, I just understand the parameters I see and rely on them.

Inventor/Technician (Interview Person 4 – IP4)

1. **How did you come up with this product?**
   It was a request from the surgeon Jan Matsson in the beginning of the 90's regarding a system that could measure some specific parameters. We where 2 people involved in this from the beginning and then my colleague dropped out because lack of interest from his side.

2. **What do you know about the market for this kind of product?**
   Since I found this to be a very interesting application I carried on working with it and saw it more of a hobby and did not know anything about the market at that time. Still today I have limited knowledge in regards to the market potential since I have neither market nor business interest but only technical interest.
3. **What do you know about the circumstances of using electronic products in the operation room?**
   I started following the IEC 60601 standard which is a governmental regulation.
   Requirements such as the surface of the products had to be easy to clean and that it should be powered by a battery to simplify the CE-branding. From the beginning I had the intentions of getting the product CE-branded and that is the reason why I have designed it the way it is today.
   I have had two generations previous to this third generation of measuring and monitoring system which was built in a rack but ergonomically and its flexibility were limited.
4. **How long time did it take you to develop this?**
   I have developed this during my spare time but the third generation of this measuring system has been in Sahlgrenska since 2006.
5. **Have there been any problems/complaints since it has been delivered to Jan Matsson? If yes, why? If No, what do you think the reason is of this?**
   I have had no complaints so far.
6. **How did you validate the software/product? Robust? Errors? System Failure? Etc**
   I have been testing and validating the products at home. All the modules e.g. wireless communications have been tested very carefully and have tested them for a long period. Most of the thorough testing has been done during the third generation of the product system.
7. **Where did you manufacture the product?**
   The circuit board has been manufactured by a Norwegian company and the prototype of the shell was done through CAM (3D-printing). The temperature sensors are from Denmark. The pressure sensors are off-the-shelf components that are already CE-branded.
8. **Who designed the mechanical parts of the product?**
   The shell of the third generation parts of the product is designed by an Industrial Designer who helped me with it. The thermometer has seven inputs in the client such as one measures the water bath, one measures the ingoing blood, one outgoing blood, one just under the skin and one in the muscle. So Jan usually uses 6 of the 7 inputs to measure the temperature of the limb such as in a water bath and the ingoing blood. The accuracy of the temperature sensor were calibrated by me before delivering to Jan and has the tolerance 0.1 ^{o}C.
9. **Where did you get the components from and how did you know that these are the ones required in an operation room?**
   The components are off-shelf components already used today for different applications.
10. **Did you do a research regarding what kind of components/materials are allowed to be used in an operation room?** ***(Or where the ones you bought the most appropriate without regards to the requirements in the operation room?)***

Since I had already developed the first two generations of measuring and monitoring system, I already knew what was necessary. Some of the information as previously mentioned also comes from the IEC 60601 standard.

11. **Why are the clients made in three separate parts?**

    Due to the flexibility required in the operation theatre. One of the clients has to be placed closer to the chest and the other two clients have to position closer to the limb. The previous generation was all in one rack which complicated the access to the patient due to the cables. From my observation and the request from Jan, we decided to make the measurement and monitoring system more flexible, and the third generation is the result. It also became wireless due to this.

    Another suggestion is to make the sensors wireless so that you can get rid of the clients and that the sensors are transmitting directly to the server (computer).

12. **What are the constraints of the client to server in regards to the placement of the clients?**

    Ratemeter - closer to the upper part of the body

    The temperature has short cables and are put on the lower part of the body.

    Regarding the wireless sensors are often the price issue, are often won out. Today they cost ca 1800 - 1900 Kr each - the wires one. Possibility is there.

13. **Is the product designed to be water/fluid resistant? If Yes or No, then why?**

    It should be resistant if someone spills some fluid on it, but is not totally fluid resistant if for e.g. dropped in a water bath. Basically it is to a certain extent and already taken into consideration.

14. **What are the challenges/difficulties/constraints of integrating the three clients into one?**

    1 circuit board installed in 1 box

    3 circuit boards installed in 1 box

15. **How come the clients cannot be charged at during the surgery procedure?**

    The client cannot be charged at the same time when operating on the patient, due to current going through the cable. This is just to keep the patient safe.

16. **Have you provided any type of support to the sold products since it has been delivered? If yes, what kind of support?**

    I have given support to Jan regards to the system because I have a support agreement with Sahlgrenska which includes everything if the measurement and monitoring system breaks down for e.g. software failure. Often it is smaller problems.

17. **Are the clients able to be used for different purposes in a clinical environment? Ratemeter? Multimeter? Thermometer?**

    It could be used in a lab for e.g. measuring the temperature or measuring radioactivity. It has several functions which widens the market of use of this product. It is very easy to customize and if Jan has any other requests, tell me …

18. **Why are there cables connected from the client to the patient? Is it possible to make it wireless i.e. sensors to client or client to sensors? If yes, how would you validate the product?**

    It is possible by having a transmitter from the sensor to the computer and then you get rid of the clients. The only thing I would have to think about is the weight of the transmitter.

19. **Regarding the TX period: How do you know if the internal buffer is full?**

    It should not happen, and if it does it will send an error message.

20. **What is the use of the ScintiBase? In what way does it measure the radioactivity?**

21. **How have you designed the calibration of the software so that it can be calibrated without any help from you?**

    For each treatment they do this calibration of the system. Different for every patient.

22. **Why does the ScintiBase have to be warmed up for 5 minutes at 25 degrees Celsius?**

    Most of the electronic components have to be warmed up because of the accuracy. To guarantee the accuracy.

Owner (Interview person 5 – IP5)

1. **In the beginning you had not found any competitors in Europe, have you scanned the market again and found any new competitors?**
   We look at competitors from two perspectives which are: In house developed solutions which is used to fulfil the same need as the MedicView but does not include the same utilities as our equipment, the second is commercially equipment. We have identified two commercial equipments which can compete with our system. The first one is Randi and their competitive equipment Performer which doesn't have a leakage measuring unit but has a pressure and temperature measuring system. The Performer is quite successful since it can be used in another surgery called HYPEC but it is much more expensive than our system, only the machine costs 80000 to 90000 Euros. According to a user of the Performer the equipment is designed for the HYPEC and the blood reservoir should be modified with respect to the needed lower blood volume in HILP. And the other competitor is VEENSTRA which has a leakage measuring system but doesn't have any temperature or pressure measuring system. We also have procedure substitutes which can be seen as competitors that means other type of treatments to the same disease e.g. amputation and ILI. ILI stands for Isolated Limb Infusion and means that they don't use TNF-alpha and high temperature is not needed but the response rate of the surgery is lower. ILI can be as good as HILP in easy cases. Amputation is overall more costly since the patient will need prostheses, hospital nights among other costs and etc.
2. **Have you identified any strengths and weakness of the competitors? If so what are they?**
   See the answer to question 1. The Performer has wider market and is also CE-marked and they have their own disposable kit. And the Veenstra is almost the opposite. And they are probably more expensive.
3. **Have you decided to patent the product? If not, why?**
   NO because the product has been in the market since 2006 and has been disclosed which means it has no novelty. For a patent the product must fulfil three things these are novelty industrial applicability and inventive step. And the greatest step is to be first in the market since it is a small market.
4. **By when have you planned to CE-mark the product?**
   The target is to CE-mark it by January 2012. And we think we are able to achieve this target.
5. **What rules and regulations touch upon the MedicView system that you have encountered? (Safety? Environment?)**
   We have to CE-mark the MedicView, acquire a quality system and create a technical file. We need to test the safety of our product.

Have you any plans of how to test the safety?

We have already tested the electrical leakage current safety but we have also to make electrical magnetic discharge of the med test. We have also to test it according to the radio directive since it transmits wireless signal and other equipment in the hospital could disturb the signals. The only issue with respect to the environment could be the radioactive substance but that is a widely used isotope that disappears a few hours after the surgery. But some users can find it cumbersome to deal with radioactive substance. We intend to call in the product when its working life ends, that is MedicViews responsibility.

6. **What is the expected product cost of this system? And how did you calculate to this cost?**
   The cost is expected to be about 30000 SEK (not public nr)
7. **What is the target price set of the MedicView product?**
   330000 SEK. Education 35000 SEK and for service about 35000 SEK/year.

8. **How many have you planned to produce annually?**
   We will make series of five to begin with and then depends on the need.
9. **Do you have any potential manufactures lined up today?**
   We have some for the electronics parts and for some of the mechanical parts but we are also looking into some for the plastic components.
10. **Where have you planned to have the assembly/test of the product?**
    At the electronic manufacturer since they have the ability and the critical part is the electronic part. Software testing will be done internally to have full insight.
11. **How do you intent to deliver service/support/maintenance to the customer of the product?**
    It is not completely defined yet but the service will be available by phone and internet all the time and if major service is needed then a technician could go to the site and fix the problem. And once a year we will calibrate the system.
12. **How have you planned to deliver the products? Any distribution plans?**
    We will deliver it in person since it is not intended to be used without an education of the system. So when delivering the system an education will take place, that is how we plan but it is still not clearly defined.
13. **Have you thought of any standard processes for the procedure and the set-up as an added value to the product?**
    Yes we have since HILP is a complex procedure so a guide or a manual will be considered. This is important especially for the less experienced surgeons and the ones who conduct fewer surgeries per year. There is a suggestion to include a guide in the software but that is problematic since it means we will be part of the medical procedure and that makes us more responsible. But we intend to provide other types of guide or manuals like video or other educational materials. Other add-ons that have been discussed is a set of disposables but we don't know how possible that is since hospitals differ from each other with respect to compatibility of cords among others. Instead of kit we might provide special tool that is always needed for the treatment.
14. **Have you thought of any assigned add-ons to the product?**
15. **By when do you think the 4th generation MedicView product will be launched?**
    The next generation will be launched sometime around 2012. If we will make more radical changes than we guess it will take more time.
16. **What are the rules and regulations of radioactive substances in the operation room?**
    Depends on the hospitals and the substance but we have to come back to you.
17. **Are there other potential areas where MedicView's system can be used with none or minor modifications?**
    I think there could be a market for the temperature sensors with a slight modification in the software this could be used in any hypothermic treatment.
18. **How many customers do you tend to have by the end of your second year of launch?**
    We guess we have about 12 by the end of 2013.

Appendix B Analysis of Interviews

IP 1

1. **Why do you need the MedicView product?**
   We want to register different parameter and documenting the treatment mostly for scientific reasons but also to be able to regulate in order to optimize the treatment. Earlier we did this by pen and paper every tenth minute but that was not a good way so we needed a system which could do this in real-time. Thus we asked Mats Ohlsson to develop a system which satisfies this need.
   First of all to measure the leakage of TNF-Alfa, and for scientific purposes as the temp measurements and to make sure that the catheters are placed right and that you have a good increase in the temp and sufficient flow rate. It is a good monitoring system but we don't need the MedicView to perform the perfusion. But the MedicView is a more sophisticated way and easier to where it is documented and all the data is merged instead of looking at different monitors.
   You said you can perform the perfusion without MedicView, does that include a perfusion with TNF-Alfa treatment as well?
   No we can't perform that without MedicView.

- The surgeon want to register temperature, flow rate and leakage.
- The surgeons want to measure the parameters in real time.
- There is a need to document the measurements for scientific reasons.

2. **What will happen if you perform a HILP surgery without the MedicView product? Other substitutes used?**
   We don't have a substitute but we could ask radiation physicists or the medical technician of the hospital to help us to measure the leakage in some way. The MedicView is a simplification of everything for us.
   Why is it important to document?
   For research purposes, it is around 60 % of the patients with a known tumour (melanoma) that completes the mission (the tumour disappears) but why not for the 40 %? that could be due to technicalities during the operation, too low temp, is the flow too low and etc those questions can be answered if we collect the data

- We need to collect the documented data for research purpose.

3. **Is the monitoring system easy to use (user interface) even for new surgeons? Standard user interface? What additional training do you think is suitable for the surgeon to use MedicView product. Should there be a certificate? What is easy enough but still safe?**
   No it is not easy for new surgeons you have to get an introduction to it. Once you have understood it then it becomes easy, could probably be simpler (more user friendly). A guide similar to the one for calibration (in the software) could be useful. A checklist approach for the important steps should be considered. The more experienced surgeon finds it easy to just read the manual and use the equipment (could be bias). It is not pedagogical but still doable. No certificate should be required to handle the equipment because if understand what you are doing the interface is not complicated.
   Is there a standard interface in medtech or in Sahlgrenska?
   No

   What is easy enough to use but still safe (safe enough to change the things without knowing that much)?
   Yes it is quite comfortable to change the graph, scale and etc. Once you understand the small buttons (icons) it is easy to use. But it is still easy to forget some steps in the procedure of setting up and etc, a guide for the whole sequence as mentioned earlier would help. A guide like a flow chart maybe in the software or a process map.
   The critical part is the leakage measurement and there is a good guide for that included in the software. I (the surgeon) set up the modules and plug them in to the host and set it in standby and then the perfusionist changes it to the running mode and calibrates the pressure system. This is a routine that we all know, but if someone is missing and replaced by a new person then it might be critical. A guide about how to arrange the system might be useful to add value to the system.
   Can we get your checklist?
   We don't have any checklist it is in our minds.

- A manual or a checklist for the important steps should be included in the system.

5. **At what occasions would you end the surgery due to MedicView's system failure? What type of warning signals would you like to have?**
   As it is now we are satisfied with it but we would like to have a warning signal for the leakage but we don't know when that should be because we sometimes allow a little leakage. A warning signal with respect to the time left regarding the critical limit of leakage is needed.
   If there is a rapid change in some parameter it might be of interest to have an alarm.

- Some type of warning is necessary with respect to the change of parameters.
- A warning signal is especially important for the leakage with respect to time.

6. **Do you use the product for any other purposes? Do you think it will be possible to use the product for anything else?**
   No we don't use it for other purpose. Yes it is possible to use it in other type of operations where you need to register or measure temperature/ pressure and other parameters, this is very wide

- The development team should consider introducing the system in other type of surgeries.

7. **How is the system packaged today? Pros and cons? How is it transported to and inside the hospital /other similar devices?**
   It is kept in Dr Jan's office in a bag, backups of the files are made frequent and is decided to be made every week. The scintillator is sensitive and is kept in a closet in the locker room. A box for everything would be good maybe something on a wheel. And maybe everything can be charged with one connection through the "box". The stative is also left in the locker room. It would have been good to be able to see if everything is working fine in the system before you add substance to the patient. As it is now you will not detect the failure until you get wrong signals when you start. A background activity that assures the correctness of the equipment would be helpful.

- Everything should be packaged in a way that caters for the portability in the hospital.
- Every chargeable item should be charged through one connection if possible.
- The system should give a go-ahead indication if everything is correct.

8. **How are the devices sterilized today? What parts are sterilized? How often?**
   Only the cables and needles of the thermometers need to be sterilized. These can't be heat sterilized and must be plasma sterilized (sterrad)

- The cables and needles of the thermometers must be able to be sterilized.

10. **What constraints the placement of the clients/host/monitor? (Such as distance, height etc)**
    One of the cables (the blue tube for pressure measurement) is too short and constraints the placement. On the other hand the cables from the lung heart machine can't be too long, otherwise it will increase the heat loss. And the modules are placed above the machine. Also the perfusionist needs to see the graph which shows the leakage. See photo for typical arrangement.

- If the solution requires cables then they should be of the same length as the cables from the lung heart machine.
- The monitor regarding leakage should be readable also for the perfusionist.

11. **How would you like to have the surface of the MedicView hardware product with respect to appearance/handling ? (Materials? Feeling? Senses?)**
    It feels too "plastic" and the colour of it is changed probably due to sun exposure. The ideal would have been stainless steel or aluminium. Should be easy to wipe off. It is good that it could be placed vertical and horizontal. We would like to have the modules a little bit smaller if possible (like an Iphone).

- The colour should be more sustainable preferable stainless steel or aluminium.
- The material should be easy to clean.
- The design of the modules should be flexible with regards to placement.

12. **How would you like the design of the sensors to be in order to ease the handling of it in general terms and during surgery?**
    The sensor are maybe a little bit too weak and can be bend or broken easily as happened in Finland. But they should not be too thick either with respect to the tubing. The needles maybe can be done replaceable if they are weak (especially if it is possible to make it wireless).

- If there are weak parts then they should be replaceable.

13. **Is there any additional functionality you would like to add with respect to HILP surgery or other potential application areas?**
    It would be valuable to measure pressures at more positions (in the tumour and in the muscle) for scientific purposes (like an add on feature), or pressure measurement in the body system as well as in the perfusion system.

- The system should provide space for customer specific parameters if possible.

14. **Are there any unnecessary parameters on the monitor?**
    Yes the venus pressure, peripheral resistance and the flow rate, they should be recorded but not necessary to be shown in the monitor. You should be able to choose what to see on the monitor. I have to see on the legend each time to see which belongs to which. Some of the graphs could be easier to have as bars instead as the real time temperature.

- The user should have the possibility to choose what parameters should be observed on the monitor.

23. **Which parts are disposables today? What would you want to be disposable tomorrow?**

    Nothing is disposable today. We would like to have the needles of the thermometers to be disposable in the future, once again especially if it could be wireless but in that case even the transmitter must be sterilized as well as the disposable needles (there are equipments which are placed in sterile bags).

- Some of the users wish a totally wireless system.
- Needles of the thermometers should be disposable if possible.

IP 3

3. **Is the monitoring system easy to use (user interface) even for new surgeons?**
   It is not so easy, you need some education the interface is not easy it is only our physicist who handles it. Still it is not due to the interface only rather more due to complication about isotopes and etc not everybody understands those issues. I think to commercialize the system you will need to have clear manuals/ tutorials and guidelines. I don't think anybody can use this system without training there are some knowledge one should acquire before using the equipment.
   Do you think a certificate to use the equipment could be good?
   Yes maybe, it is popular nowadays to have certificates for different equipments.

- Manuals/tutorials should be easy to understand, even non physicist should understand it after training

5. **At what occasion would you stop a surgery due to MedicView system?**
   If I am using TNF-Alfa and I don't have leakage monitoring than I would abort the surgery. I f I am using melphalan and everything seems to be stable and the patient is well than I might go on.

- The system must indicate if the leakage measuring system is malfunctioning.

6. **Do you think a warning signal or alarming when reaching a certain level would be valuable?**
   I think that is one of the most important steps of the development that you could do. I mean to work out the inbuilt warnings not only leakage but also other parameters as temperature. You must alert much quicker than the cumulative 7 % leakage That is when the leakage is coming.

- The user should have the possibility to adjust the setting of parts or the entire alarming system.

9. **How would you like the system to be packaged?**
   It could be good if it could be one moveable unit especially for low volume centres while for high volume centres I think they would prefer to have mounted somehow.
   The rack and scintibase should be taken away and stored somewhere.

- The system should be one movable unit.
- If the system is not easy to move then it should have the ability to be mounted for high volume centres.

11. **Is it important if the product is fluid resistant? If yes, why?**
    Yes that is important everything that is close to the operation table should be fluid resistant.

- The product should be fluid resistant (conflicting statement, compare to question nr 9 in Jan Mattson's & Roger Olsson's interview)

12. **What constraints the placement of the clients/host/monitor?** **(Such as distance, height etc)**
    The monitor should be placed close to the perfusion system because they are the ones who need to follow the parameters, so it would be good if they can see the parameters so it should maybe not be too big to move. Or it could have more than one output for different monitors.
    The computer works fine even compared to the waterproof keyboards that we have some of they are a bit clumsy.

- The system should include more than one output for monitors or other means for the perfusionist to observe the parameters.

16. **Is there any additional functionality you would like to add with respect to HILP surgery or other potential application areas?**
    The alert as mentioned before. The system should have the interface which makes it possible to take input from other devices as the flow rate from other system. Other thing could be the layout, for instance the lines of the curves are thin and hard to see from a distance. And five temperature curves make it hard to see if you don't come close to the screen.

- The product should have the possibility to take input from relevant devices.
- The visualization of the parameters should be clear and easy to observe from the position of the surgeons and the perfusionist.
-

IP 4

3. **What do you know about the circumstances of using electronic products in the operation room?**

    I started following the ES60601 standard which is a governmental regulation.

    Requirements such as the surface of the products had to be easy to clean and that it should be powered by a battery to simplify the CE-branding. From the beginning I had the intentions of getting the product CE-branded and that is the reason why I have designed it the way it is today.

    I have had two generations previous to this third generation of measuring and monitoring system which was built in a rack but ergonomically and its flexibility were limited.

- The system should fulfil the ES60601 standard.
- The product should be CE-branded
- The system should be ergonomically.

8. **Who designed the mechanical parts of the product?**

   The shell of the third generation parts of the product is designed by an Industrial Designer who helped me with it. The thermometer has seven inputs in the client such as one measures the water bath, one measures the ingoing blood, one outgoing blood, one just under the skin and one in the muscle. So Jan usually uses 6 of the 7 inputs to measure the temperature of the limb such as in a water bath and the ingoing blood. The accuracy of the temperature sensor were calibrated by me before delivering to Jan and has the tolerance 0.1 °C.

- The system should contain at least 7 thermometer sensors which can be active simultaneously.
- The system should be able to measure the water bath and the ingoing blood.
- The accuracy should be at 0.1 ^{o}C.

11. **Why are the clients made in three separate parts?**
    Due to the flexibility required in the operation theatre. One of the clients has to be placed closer to the chest and the other two clients have to position closer to the limb. The previous generation was all in one rack which complicated the access to the patient due to the cables. From my observation and the request from Jan, we decided to make the measurement and monitoring system more flexible, and the third generation is the result. It also became wireless due to this.
    Another suggestion is to make the sensors wireless so that you can get rid of the clients and that the sensors are transmitting directly to the server (computer).

- The system should cater for the flexibility needed with respect to ILP surgery.

12. **What are the constraints of the client to server in regards to the placement of the clients?**

    Ratemeter - closer to the upper part of the body
    The temperature has short cables and are put on the lower part of the body (if perfusion of a leg).
    Regarding the wireless sensors are often the price issue, are often won out. Today they cost ca 1800 - 1900 Kr each - the wires one. Possibility is there.

- The design should facilitate the ratemeter to be placed close to the upper body.

15. **How come the clients cannot be charged at during the surgery procedure?**

    The client cannot be charged at the same time when operating on the patient, due to current going through the cable. This is just to keep the patient safe.

- There should be no current going through the cables during procedure.
    - The system should not be plugged in to power supply while connected to the patient.

16. **Have you provided any type of support to the sold products since it has been delivered? If yes, what kind of support?**
I have given support to Jan (the surgeon) regards to the system because I have a support agreement with Sahlgrenska which includes everything if the measurement and monitoring system breaks down for e.g. software failure. Often it is smaller problems.

- The customer should have the possibility of choosing a service or support agreement.

21. **How have you designed the calibration of the software so that it can be calibrated without any help from you?**

For each treatment they do this calibration of the system. Different for every patient.

- The system should be easy to calibrate since it is different for each surgery.

Owner (Interview person 5 – IP5)

1. **In the beginning you had not found any competitors in Europe, have you scanned the market again and found any new competitors?**

We look at competitors from two perspectives which are: In house developed solutions which is used to fulfill the same need as the MedicView but does not include the same utilities as our equipment, the second is commercially equipment. We have identified two commercial equipments which can compete with our system. The first one is Randi and their competitive equipment Performer which doesn't have a leakage measuring unit but has a pressure and temperature measuring system. The Performer is quite successful since it can be used in another surgery called HYPEC but it is much more expensive than our system, only the machine costs 80000 to 90000 Euros. According to a user of the Performer the equipment is designed for the HYPEC and the blood reservoir should be modified with respect to the needed lower blood volume in HILP. And the other competitor is VEENSTRA which has a leakage measuring system but doesn't have any temperature or pressure measuring system. We also have procedure substitutes which can be seen as competitors that means other type of treatments to the same disease e.g. amputation and ILI. ILI stands for Isolated Limb Infusion and means that they don't use TNF-alpha and high temperature is not needed but the response rate of the surgery is lower. ILI can be as good as HILP in easy cases. Amputation is overall more costly since the patient will need prostheses, hospital nights among other costs and etc.

- The MedicView product should be developed for usage in additional procedures than HILP.

4. **By when have you planned to CE-mark the product?**

The target is to CE-mark it by January 2012. And we think we are able to achieve this target.

5. **What rules and regulations touch upon the MedicView system that you have encountered? (Safety? Environment?)**

   We have to CE-mark the MedicView, acquire a quality system and create a technical file. We need to test the safety of our product.

   Have you any plans of how to test the safety?

   We have already tested the electrical leakage current safety but we have also to make electrical magnetic discharge of the med test. We have also to test it according to the radio directive since it transmits wireless signal and other equipment in the hospital could disturb the signals. The only issue with respect to the environment could be the radioactive substance but that is a widely used isotope that disappears a few hours after the surgery. But some users can find it cumbersome to deal with radioactive substance. We intend to call in the product when its working life ends, that is MedicViews responsibility.

- The product should be CE-marked by January 2012.
- The radioactive substance for leakage measurement should be least harmful isotope as possible.
- There should be a plan for taking care of the product when its working life ends.

6. **What is the expected product cost of this system? And how did you calculate to this cost?**

   The cost is expected to be about 30000 SEK (not public nr).

- The product cost should not exceed 50000 SEK.

8. **How many have you planned to produce annually?**

   We will make series of five to begin with and then depends on the need.

- The design of the system should cater for low volume series.

12. **How do you intent to deliver service/support/maintenance to the customer of the product?**
    It is not completely defined yet but the service will be available by phone and internet all the time and if major service is needed then a technician could go to the site and fix the problem.

- The system should provide means to be maintained with guidance through telephone or the internet.

14. Have you thought of any standard processes for the procedure and the set-up as an added value to the product?

Yes we have since HILP is a complex procedure so a guide or a manual will be considered. This is important especially for the less experienced surgeons and the ones who conduct fewer surgeries per year. There is a suggestion to include a guide in the software but that is problematic since it means we will be part of the medical procedure and that makes us more responsible. But we intend to provide other types of guide or manuals like video or other educational materials. Other add-ons that have been discussed are a set of disposables but we don't know how possible that is since hospitals differ from each other with respect to compatibility of cords among others. Instead of kit we might provide special tool that is always needed for the treatment.

- A guide or a manual of the important steps in the procedure should be provided separately with the system. (Note conflicting constraint, see IP1's answer to question 3 in the first interview)

16. What are the rules and regulations of radioactive substances in the operation room?

Depends on the hospitals and the substance but we have to come back to you.

- The system should follow the hospital's rule and regulation regarding the radioactive substance.

17. Are there other potential areas where MedicView's system can be used with none or minor modifications?

I think there could be a market for the temperature sensors with a slight modification in the software this could be used in any hypothermic treatment.

- The development of next generation should cater for adjustment of the system in order to use it for additional procedures.

Appendix C Questionnaire

The purpose of this questionnaire is to get an understanding of what the needs are of a measurement & monitoring system for Hypothermic Isolated Limb Perfusion (HILP). Another important part of this questionnaire is to be able to validate some requirements that MedicView's Product Development group have identified during their research. The questionnaire should not take more than 10 – 15 minutes. Your contribution is exceptionally most important for the progress of HILP.

In the questionnaire there are some questions that have to be rated on an importance scale. The importance scale is rated from 1 – 6, where 6 being highly important.

1. How many of the following ***personnel are involved*** during HILP in your case;
    i. HILP Surgeon ----------
    ii. Anesthatic ----------
    iii. Nurses ----------
    iv. Nuclear Radiologist ----------
    v. Perfusionist ----------
    vi. Other ----------
2. How many HILP procedures are ***completed*** each year?
    a. For sarcoma
        i. Arm ----------
        ii. Leg ----------
    b. For in-transit malignant melanoma
        i. Arm ----------
        ii. Leg ----------

3. What is your ***response rate*** from HILP out of 100%?
    i. Total Response ----------
    ii. Partial Response ----------
    iii. No Response ----------

4. Would you like to have a ***continuous*** measurement & monitoring system for HILP in the operation theatre?

Yes ☐ **No** ☐

5. Rate the importance of being able to ***monitor***;
    i. Leakage
    ii. Flow rate
    iii. Flow resistance
    iv. Temperature, subcutaneous
    v. Temperature, intra muscular
    vi. Mean perfusion circuit blood pressure
    vii. Mean arteriour blood pressure
    viii. Additional measurements

	1	**2**	**3**	**4**	**5**	
	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐

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6. Rate the importance of being able to ***measure***;
    i. Leakage
    ii. Flow rate
    iii. Flow resistance
    iv. Temperature, subcutaneous
    v. Temperature, intra muscular
    vi. Mean perfusion circuit blood pressure
    vii. Mean arteriour blood pressure
    viii. Additional measurements

	1	**2**	**3**	**4**	**5**	
	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐

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7. What do you think is the appropriate ***time of setting up*** (in minutes) a measurement & monitoring system?

< 4.9	**5 - 9.9**	**10 - 14.9**	**15 - 19.9**	**20 >**
☐	☐	☐	☐	☐

8. How important is it for you that the measurement & monitoring product ***weighs less than 10 kg***?

1 ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐

9. How important is the ***flexibility*** of moving and placing the measurement & monitoring product?

1 ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐

10. How important is it for you to be able to ***store*** the measurement data from a procedure in database after HILP?

1 ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐

11. How important is it for you to be able to measure & monitor in ***real-time***.

1 ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐

12. How many ***measuring points*** on the limb do you find is appropriate for monitoring the temperature on;

1 ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐

    i. Thigh — ☐ ☐ ☐ ☐ ☐ ☐
    ii. Calf — ☐ ☐ ☐ ☐ ☐ ☐
    iii. Arm — ☐ ☐ ☐ ☐ ☐ ☐

13. How important is it for you that the measurement & monitoring system is integrated with the rest of the machines/screens in the operation theatre?

1 ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐

14. How important is it for you to have a total wireless measurement & monitoring system in relation to the flexibility of a surgeon?

1 ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐

15. How important is it for you to be able to package the measurement & monitoring system into one case for easier transportation?

1 ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐

16. How important is it for you to be able to store the whole system in one place for easy accessibility?

1 ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐

17. What type of ***support*** would you want for this measurement & monitoring product?

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18. Would you ***benefit*** from this kind of conference twice a year for HILP surgeons to share their knowledge and provide means ***for further research***? If No, why?

Ye ☐ **No** ☐

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19. Additional Comments of the conference and/or the measurement & monitoring system

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Results of Questionnaire

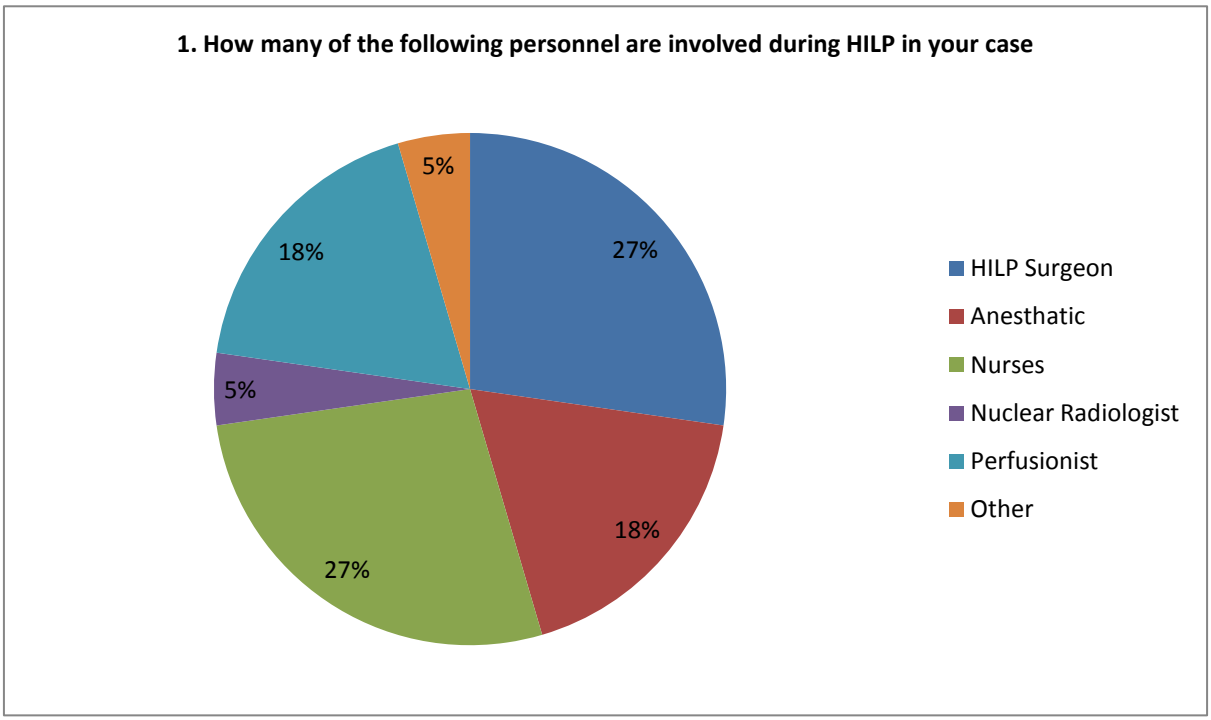


Fig 27: The percentage of personnel necessary in HILP surgery

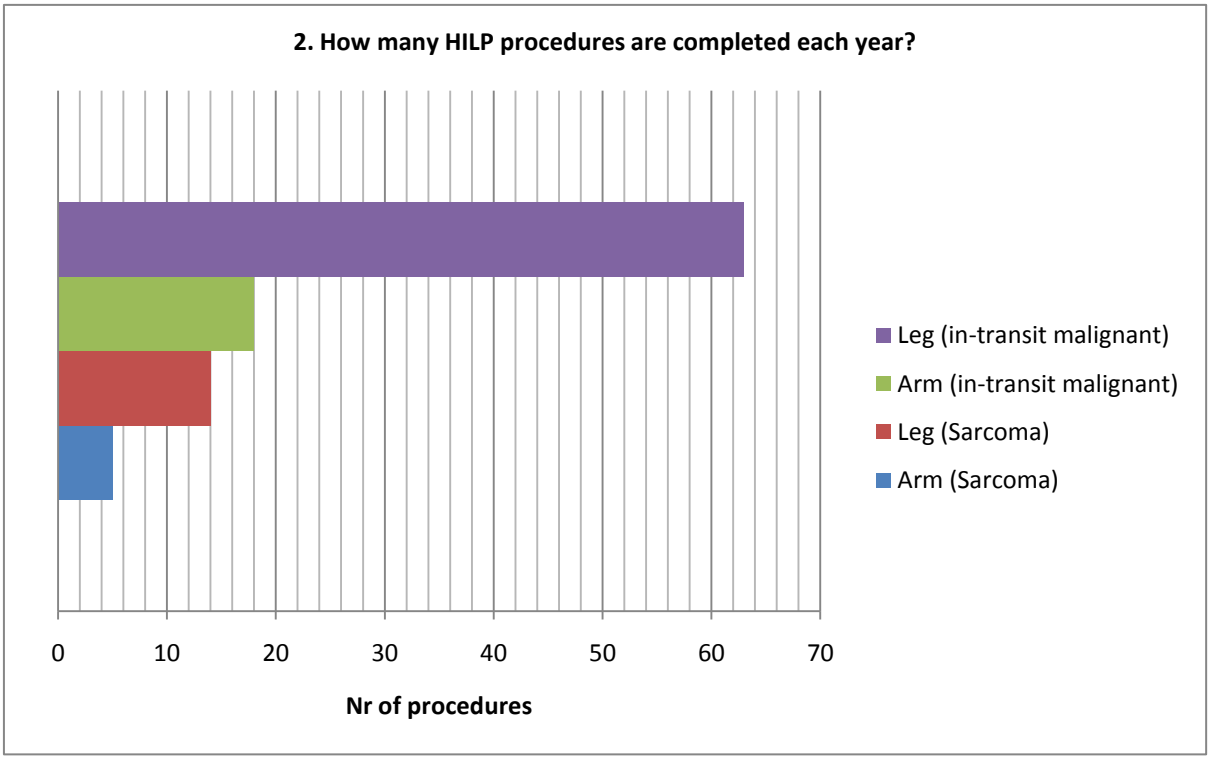


Fig 28: The number of HILP procedures completed each year.

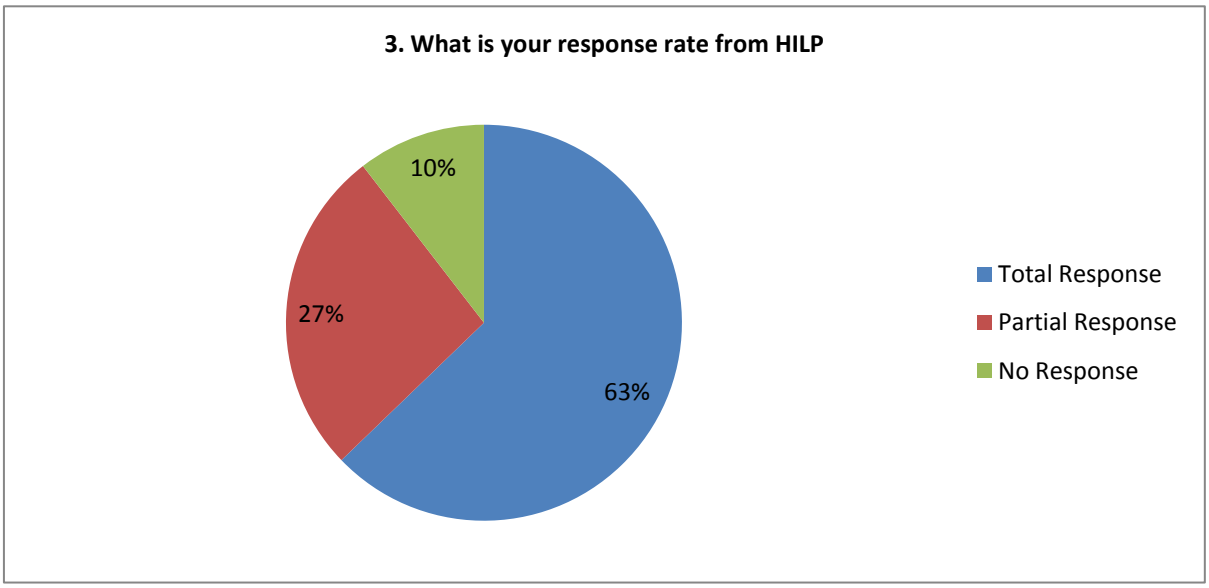


Fig 29: The percentage response rate from HILP

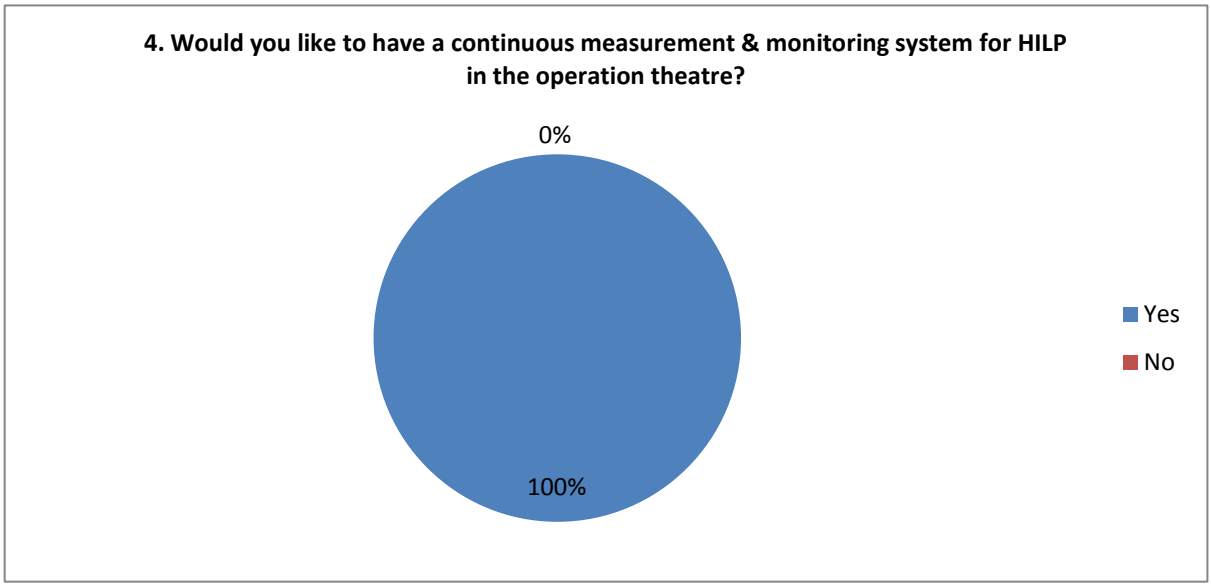


Fig 30: The percentage desirability of having a continuous measuring and monitoring system.

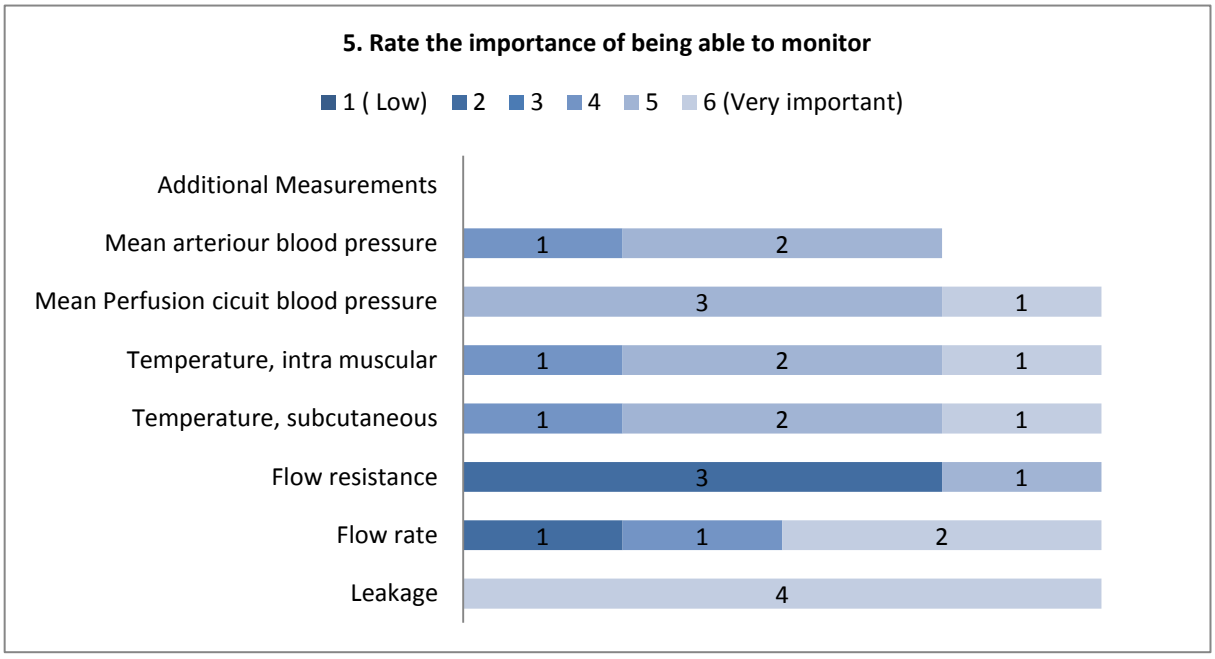


Fig 31: The rated importance of being able to monitor different parameters

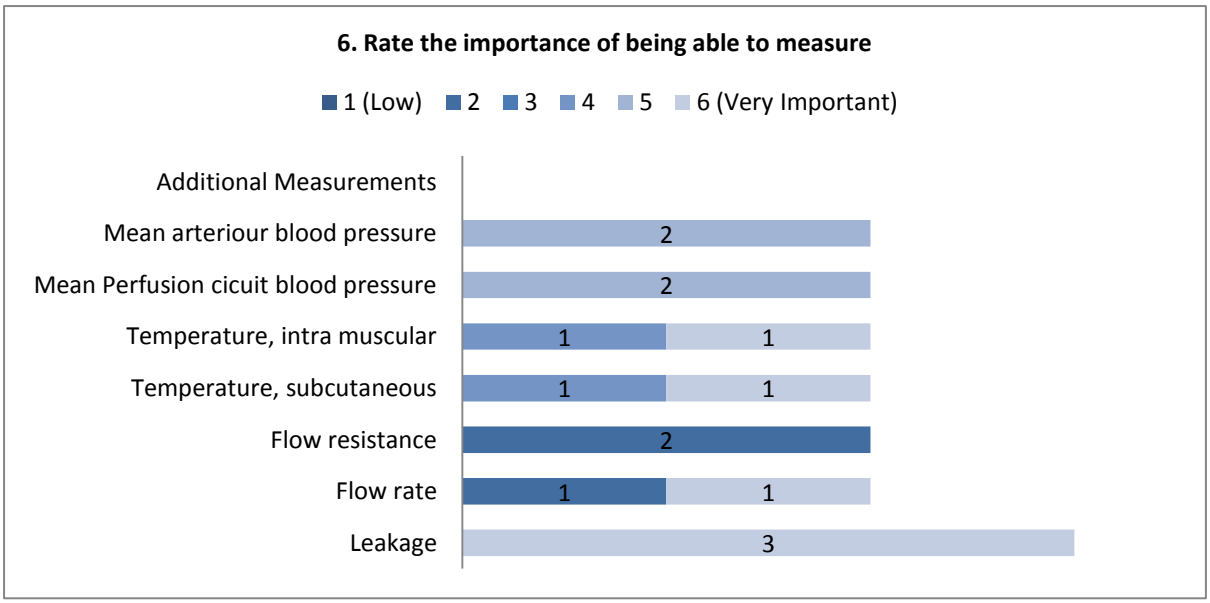


Fig 32: The rated importance of being able to measure different parameters

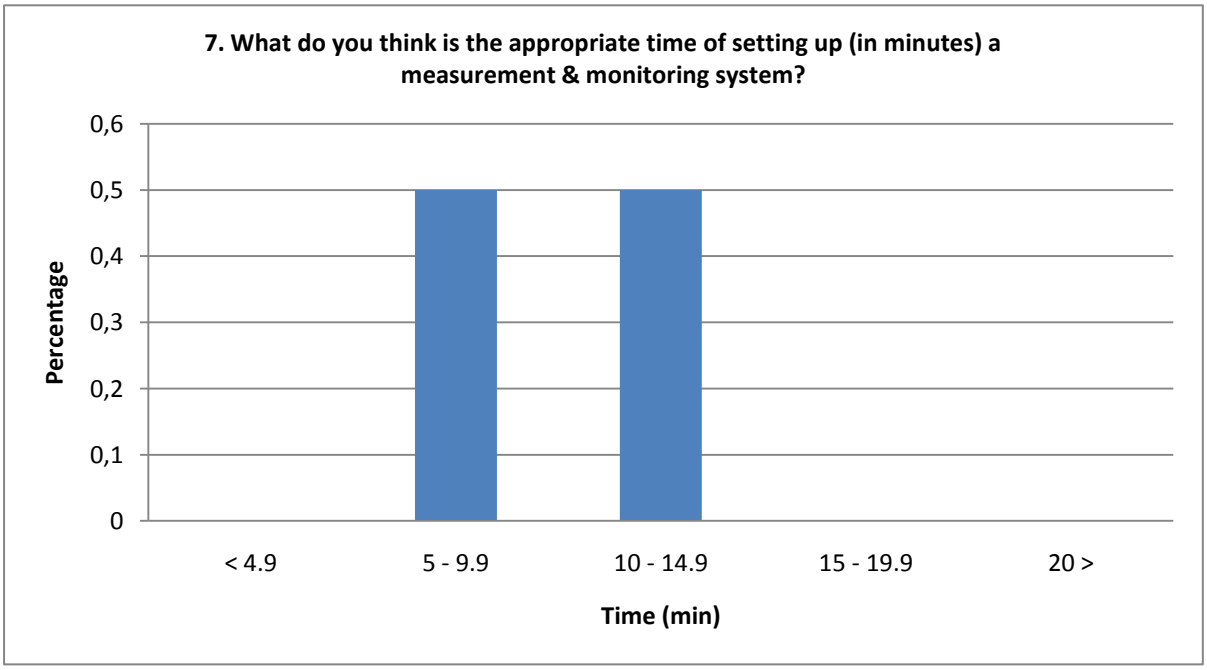


Fig 33: The appropriate set-up time for a measurement and monitoring system

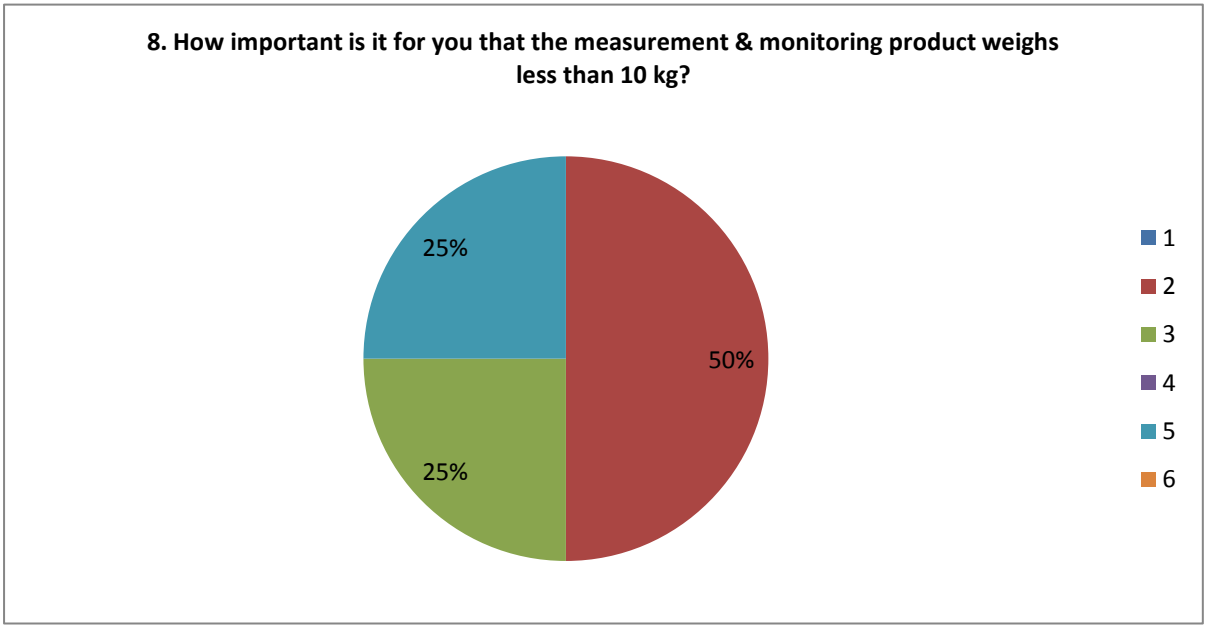


Fig 34: The rated importance of having a light measuring and monitoring system

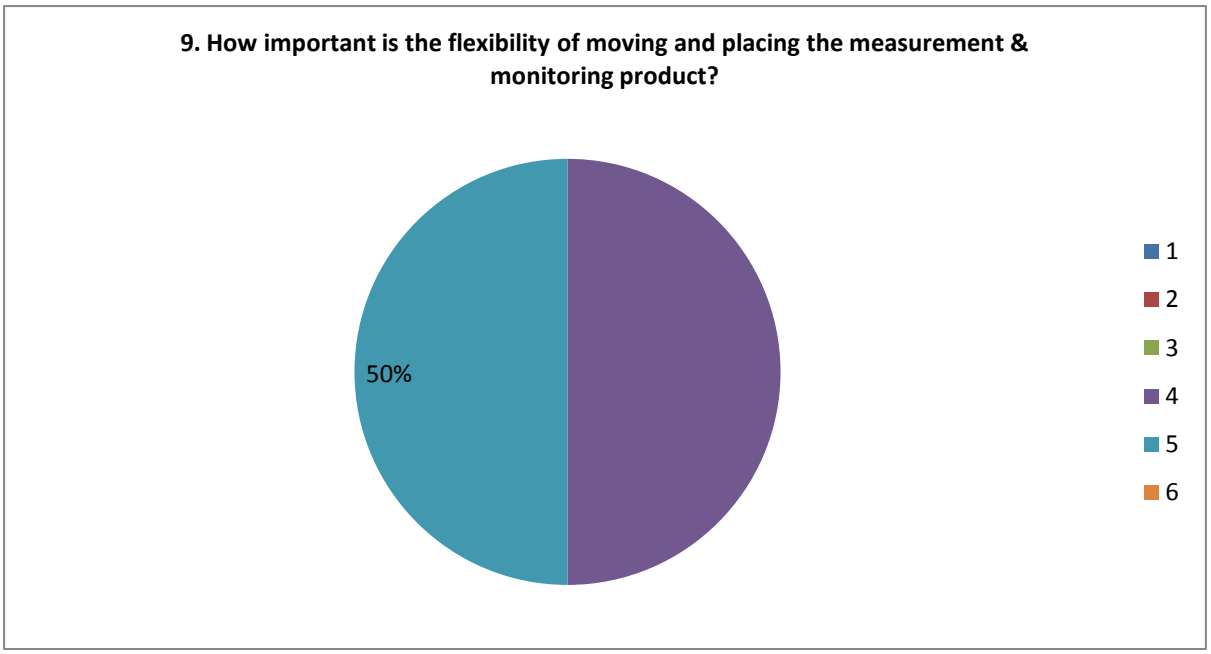


Fig 35: The rated importance of having a flexible measuring and monitoring system.

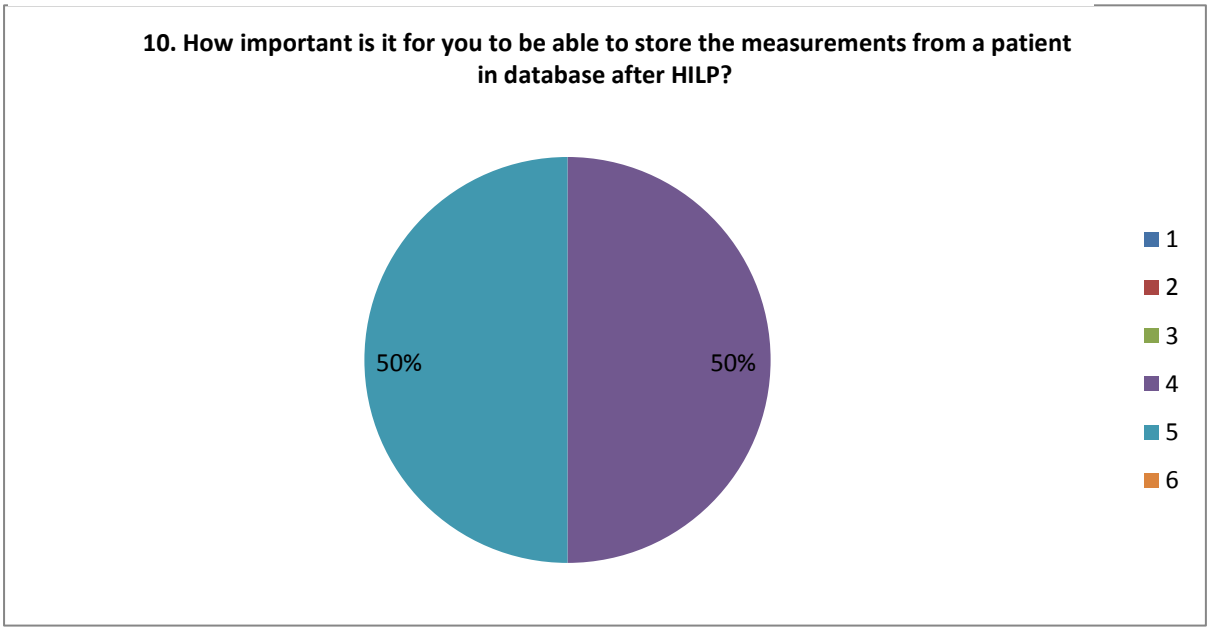


Fig 36: The rated importance of being able to store patient's data after HILP

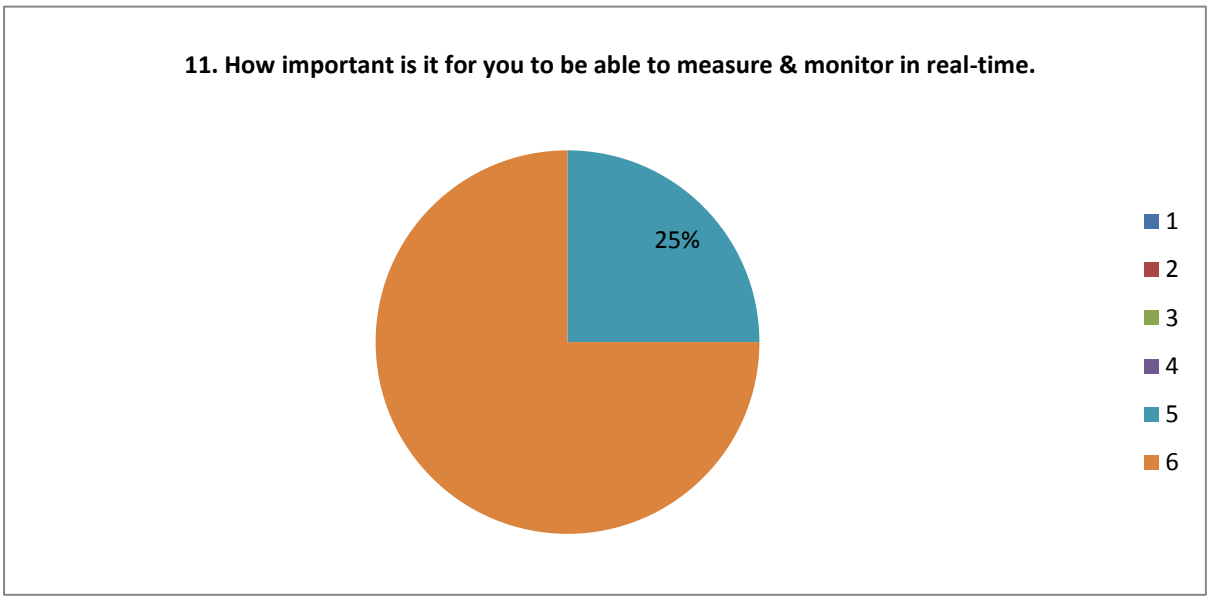


Fig 37: The rated importance of being able to measure and monitor in real-time

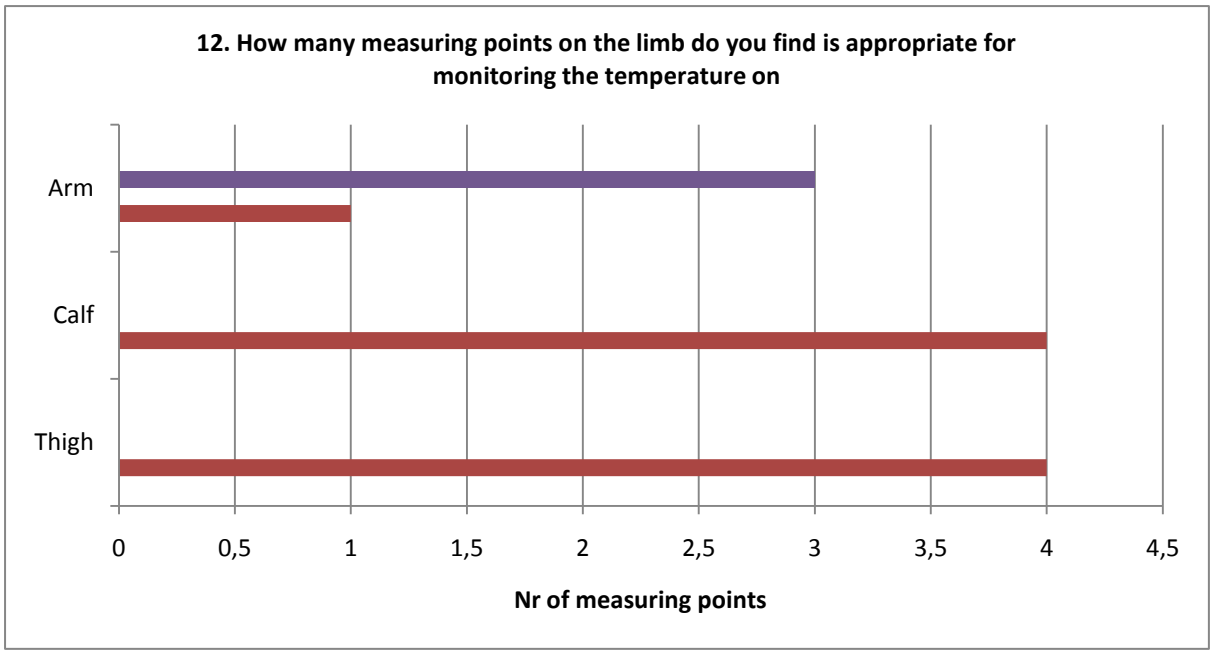


Fig 38: The number of measuring points necessary on the limb to measure and monitor the temperature

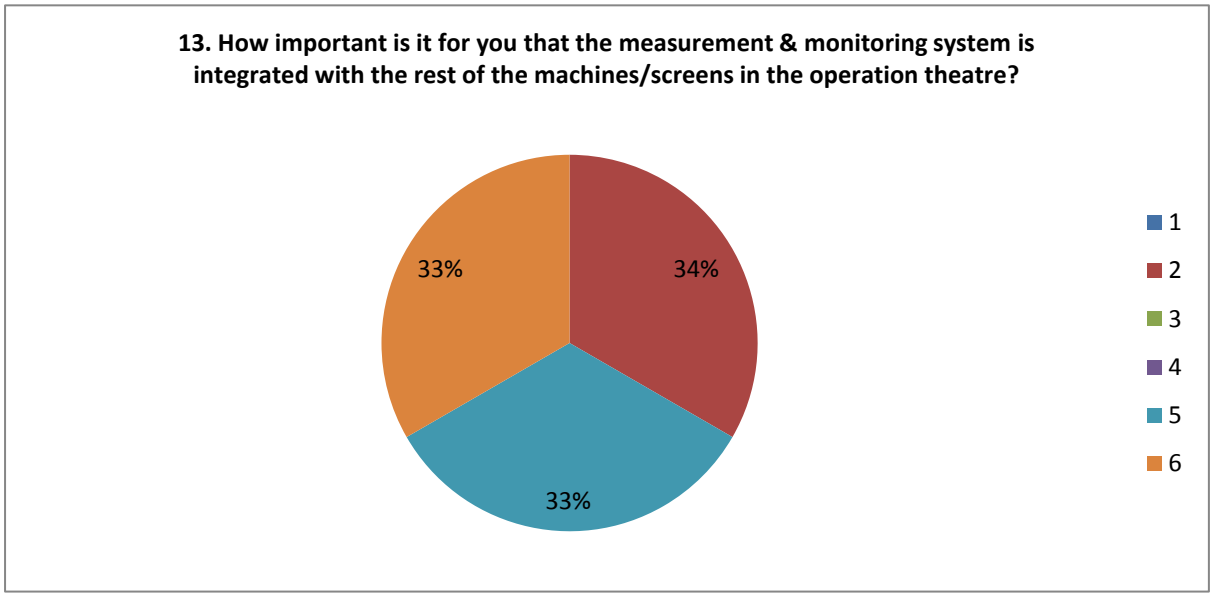


Fig 39: The rated importance of having an integrated measuring and monitoring system with the rest of the machines

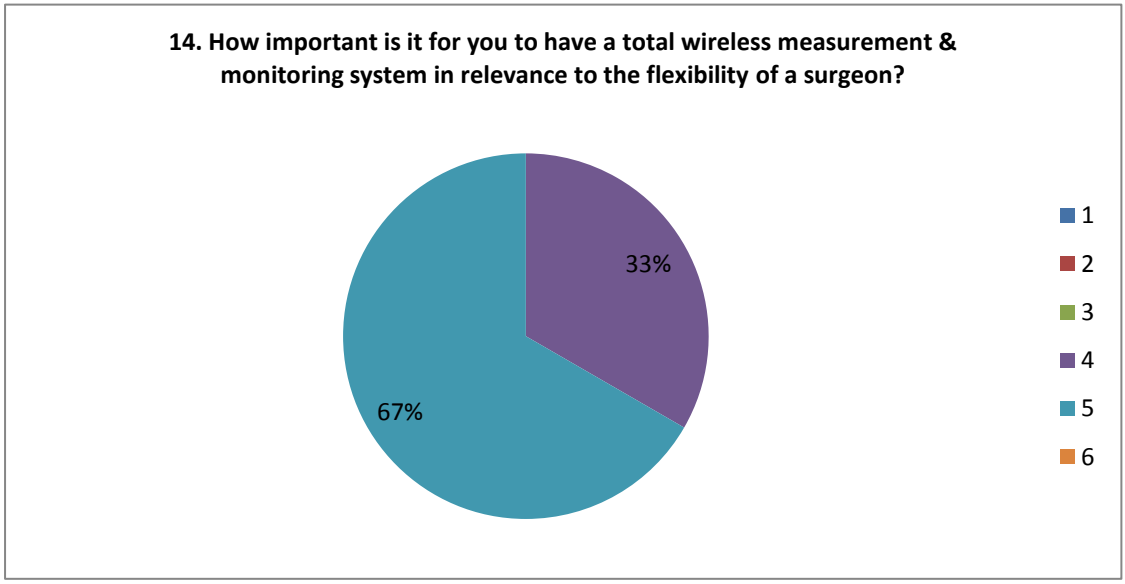


Fig 40: The rated importance of having a total wireless measurement and monitoring system

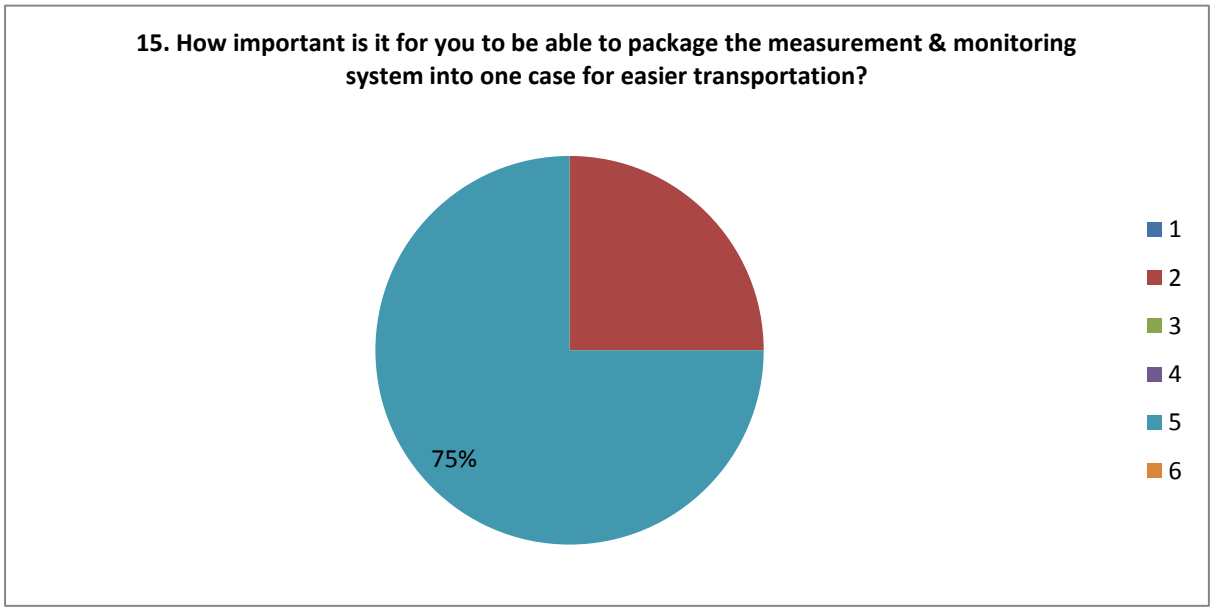


Fig 41: The rated importance of being able to package the measuring and monitoring system into one case

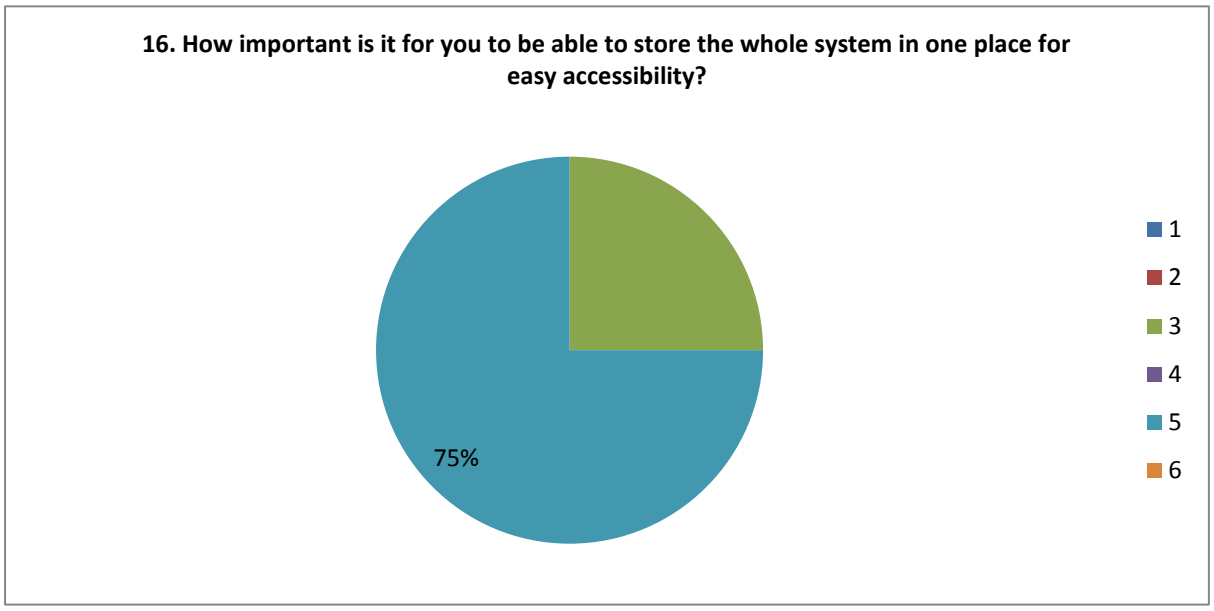
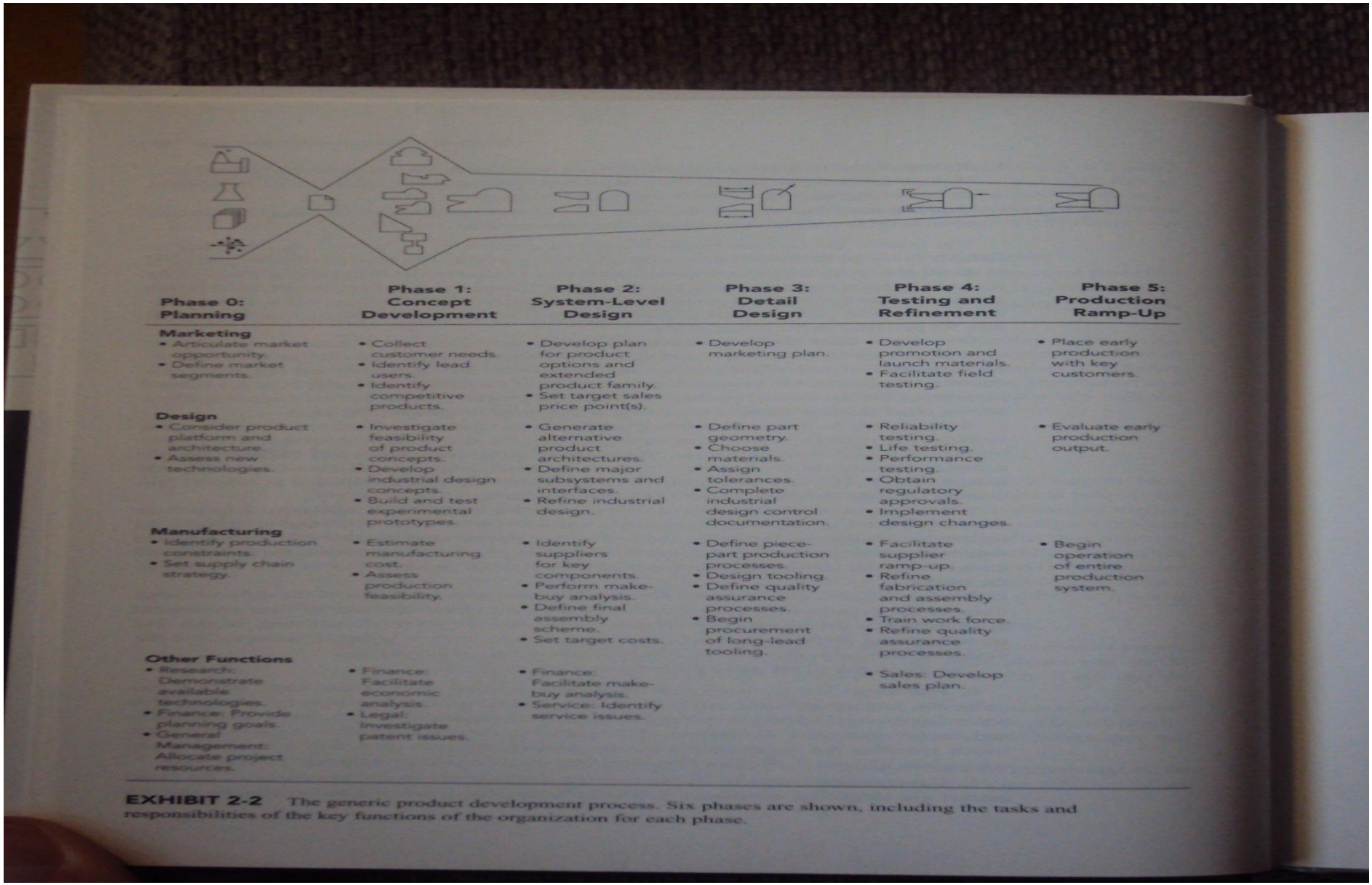


Fig 42: The rated importance of being able to store the whole system in one place for easy accessibility

Appendix D Pictures



Phase 0: Planning	Phase 1: Concept Development	Phase 2: System-Level Design	Phase 3: Detail Design	Phase 4: Testing and Refinement	Phase 5: Production Ramp-Up
Marketing • Articulate market opportunity. • Define market segments.	• Collect customer needs. • Identify lead users. • Identify competitive products.	• Develop plan for product options and extended product family. • Set target sales price point(s).	• Develop marketing plan.	• Develop promotion and launch materials. • Facilitate field testing.	• Place early production with key customers.
Design • Consider product platform and architecture. • Assess new technologies.	• Investigate feasibility of product concepts. • Develop industrial design concepts. • Build and test experimental prototypes.	• Generate alternative product architectures. • Define major subsystems and interfaces. • Refine industrial design.	• Define part geometry. • Choose materials. • Assign tolerances. • Complete industrial design control documentation.	• Reliability testing. • Life testing. • Performance testing. • Obtain regulatory approvals. • Implement design changes.	• Evaluate early production output.
Manufacturing • Identify production constraints. • Set supply chain strategy.	• Estimate manufacturing cost. • Assess production feasibility.	• Identify suppliers for key components. • Perform make-buy analysis. • Define final assembly scheme. • Set target costs.	• Define piece-part production processes. • Design tooling. • Define quality assurance processes. • Begin procurement of long-lead tooling.	• Facilitate supplier ramp-up. • Refine fabrication and assembly processes. • Train work force. • Refine quality assurance processes.	• Begin operation of entire production system.
Other Functions • Research: Demonstrate available technologies. • Finance: Provide planning goals. • General Management: Allocate project resources.	• Finance: Facilitate economic analysis. • Legal: Investigate patent issues.	• Finance: Facilitate make-buy analysis. • Service: Identify service issues.		• Sales: Develop sales plan.	

EXHIBIT 2-2 The generic product development process. Six phases are shown, including the tasks and responsibilities of the key functions of the organization for each phase.

Fig 43: This picture is illustrating the phases that are present in a generic product development process

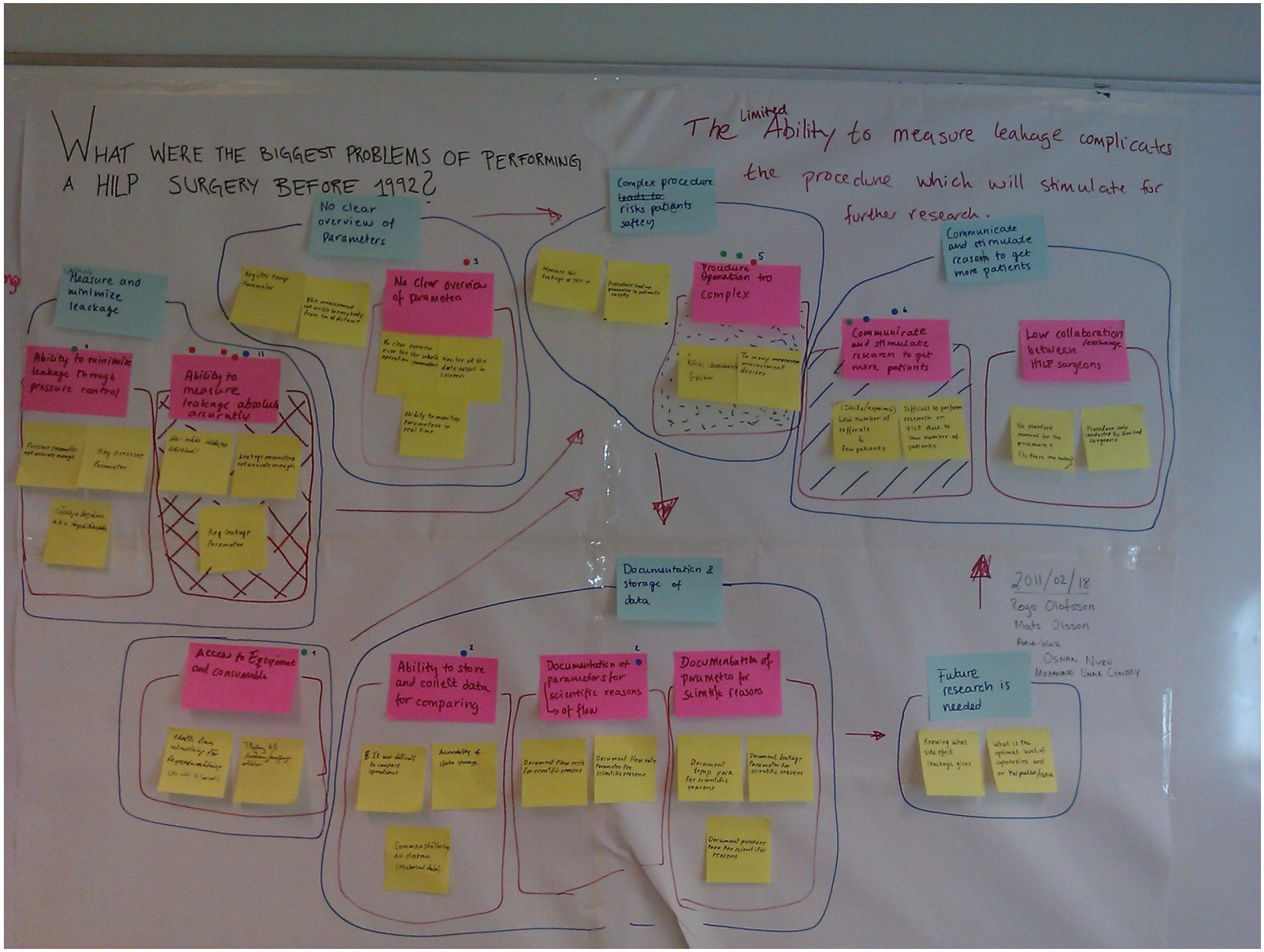


Fig 44: This picture is showing the result from the KJ-Shiba workshop performed in iteration 1

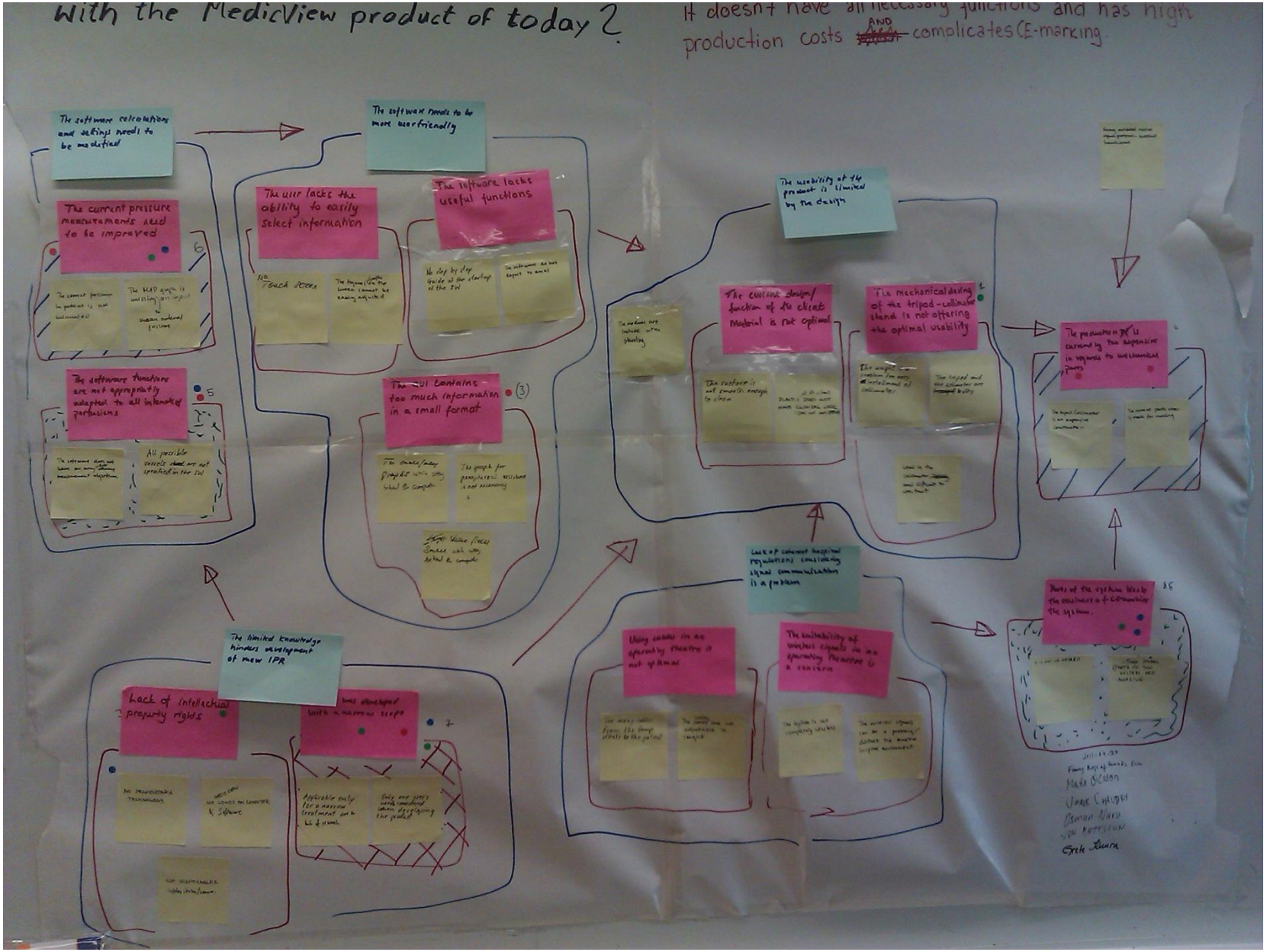


Fig 45: This picture is showing the result from the KJ-Shiba workshop performed in iteration 2