CIRCULAR DESIGN OF A HEART RATE MONITORING CABLE SET

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CLIENT: PHILIPS
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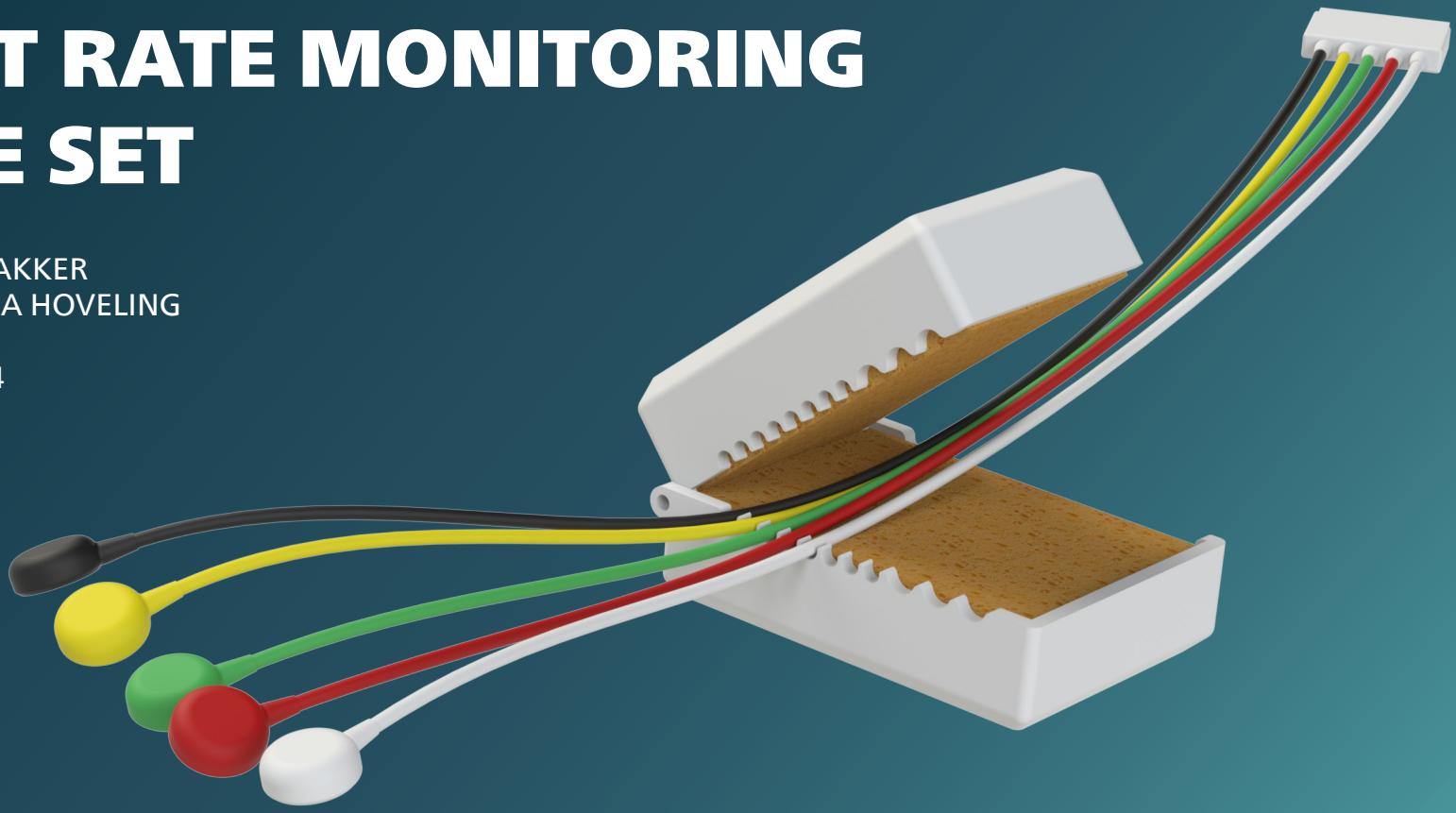

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Preface

This report is the final report in my graduation project. The project is commissioned within the DiCE project with Philips as client. Philips supports the project from a business perspective. In this project I am working 3 days a week at Philips and 2 days a week at the TU Delft. It helps to balance the project between the business and educational priorities. I really enjoyed working on this graduation project and working together with everyone that supported me. For this I want to especially thank Conny Bakker and Tamara Hoveling from the TU Delft and Hans Leijen and Jasper de Vreede from Philips.

Kind regards

Jasper

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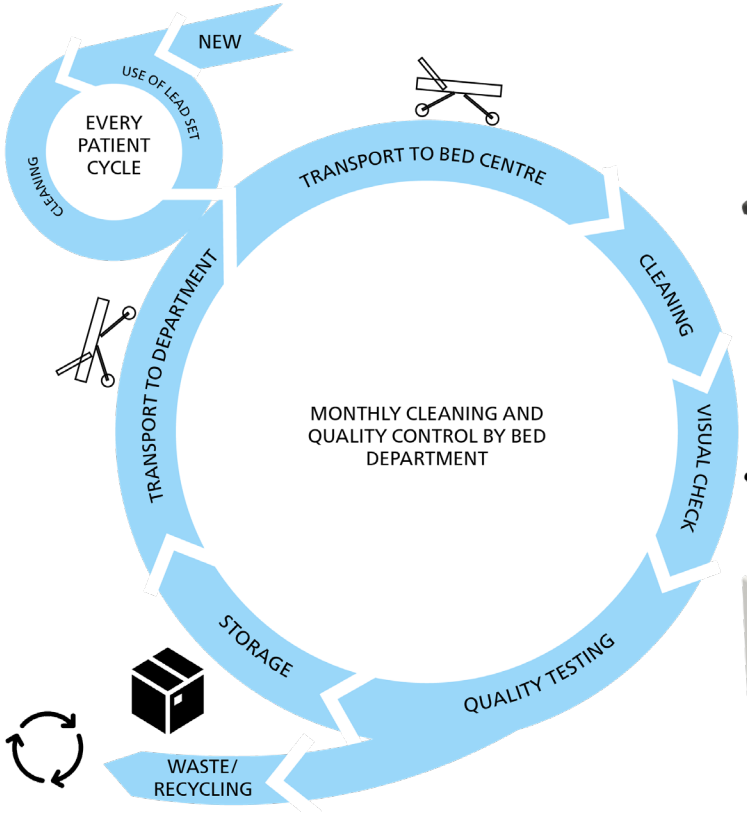
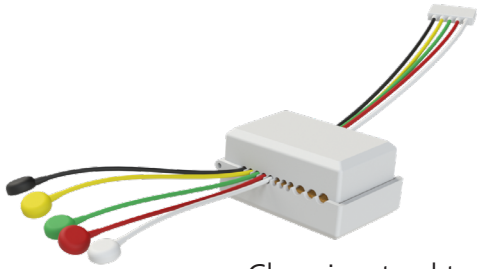
Summary

It is widely known that the healthcare industry is under pressure. On one side the costs keep increasing while on the other side the push to decrease environmental impact grows (Capolongo et al., 2015). Within this graduation project circular methodologies will be used to make a step in decreasing the environmental impact of the healthcare sector. Findings from report 2.1 from a consortium called DiCE are used intensively. One of the aims for this project is to contribute to this consortium as well. As a case study, the focus product is the electrocardiogram (ECG) lead set. A set of cables that are used to measure heart frequencies. Within the impact of the ECG lead set, the increase in the use of single patient use (SPU) lead sets is a problem. This results in the lead set system having more impact. The solution for this is the multi patient use (MPU) lead sets. But with MPU lead sets other problems pop up. To get more hospitals to switch (back) from SPU Lead sets to MPU lead sets multiple aspects are important. First is cleaning. Interviews, observations and research show that MPU lead sets are harder to clean (Albert et al., 2010). The next aspect is the quality of the MPU lead set. Prolonged use increases the risk of a lower quality lead set. Which could result in needless extra alarms and so in dangerous alarm fatigue for the nurses (Albert et al., 2014). To ensure quality a quality control system on lead sets will need to be implemented. Further important aspects for designing for a MPU lead set in a circular proposition would be the durability of the lead set and the ease of use within a hospital system. The proposed concept tackles these problems in the following way. The lead sets are monthly deep cleaned and checked on quality by a centralized cleaning department. The MPU lead set itself is redesigned to be easier to clean and a special cleaning tool is developed to help with cleaning. Combined this will create a system in which the MPU lead set will be a viable solution for hospitals again. Figure 1 creates a visual representation of this whole system.

Easy to clean magnetic connection





Cleaning tool to aid cleaning

Testing device to ensure quality

Figure 1: visual representation of the system

List of abbreviations

CPR	Circular product readiness
DiCE	Digital health in a Circular Economy
ECG	Electrocardiogram
FU	Functional unit
LCA	Life Cycle Assessment
LCI	Life cycle inventory
LUMC	Leids Universitair Medisch Centrum
MPU	Multi Patient Use
RdGG	Reinier de Graaf Gasthuis
SPU	Single Patient Use
TPE	Thermoplastic elastomer

PART I:
INTRODUCTION AND METHODOLOGY

1. INTRODUCTION

The aim of the first part of this report is to set the stage for this project. Much general information will be set out and explained. This introductory part of the report contains the project aim and problem statement, a reader guide, project stakeholders and an introduction to the case study and circular economy.

1.1 Reading guide

The aim of this reading guide is to give a quick overview of this report. The report will be separated in 4 main chapters; introduction and methodology, design case study, method evaluation and conclusions and recommendations. Roughly this project can be seen as two interlacing story lines with the circular design methodology evaluation and design case study. The introduction and methodologies chapter gives a starting point for the case study. In this chapter the introduction sets the scope of the project, and the method will describe what will be done in the case study. Within the case study a storyline to a proposed concept is made. A schematic overview of the case study can be seen in figure 2. Each of the diamonds simulates a diverging and converging loop within this project. The methodology used in the case study will give insights into the method evaluation part and both this method evaluation and the case study directly will give conclusions and recommendations for the last part of this report.

INTRODUCTION AND METHODOLOGY

DESIGN CASE STUDY

METHOD EVALUATION

CONCLUSIONS AND RECOMENDATINOS

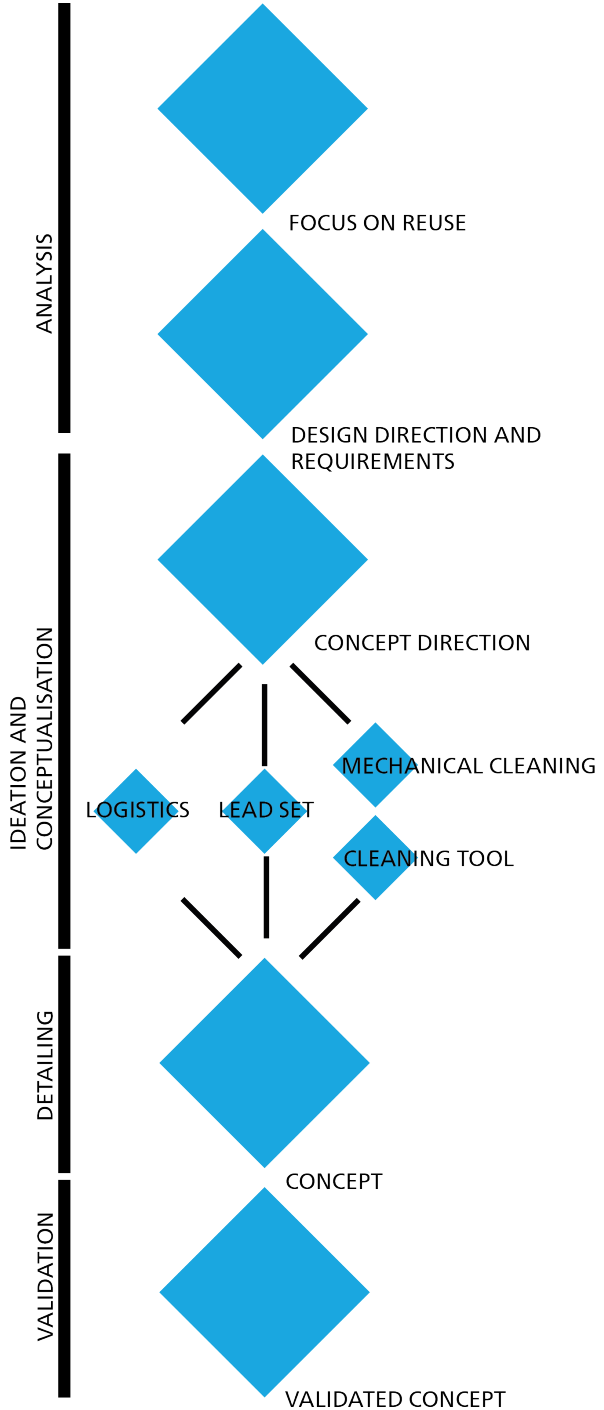


Figure 2: Schematic overview case study

1.2 Project stakeholders

The two main involved stakeholders in this design project are Technical University Delft (TU Delft) and Philips. Both the TU Delft and Philips are partners in the consortium Digital Health in a Circular Economy (DiCE). The goal of this consortium is to reduce electronic waste produced through digital health devices. The DiCE consortium has given a lot of input for this project and therefore is also seen as an important project stakeholder.

DIGITAL HEALTH IN A CIRCULAR ECONOMY

DiCE is a European Union funded project aiming to address the issue of increasing digital health waste. As electronic waste from digital health devices is an increasing problem (Bandyopadhyay et al., 2022), this needs a solution where multiple stakeholders come together to address these challenges (DiCE, 2023). That is where DiCE steps in: it is aimed at creating solutions with most of the stakeholders together in one team. In DiCE. TU Delft and Philips are working with 18 other partners on the development of circular solutions for digital health devices.

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As a business in the healthcare sector, Philips has a responsibility to create the opportunity for hospitals to make a more sustainable choice (Alharbi et al., 2021). Philips is committed to minimizing its impact on the planet within the healthcare sector (Purpose and ESG Commitments | Philips, n.d.). To put these commitments into action, Philips is part of the DiCE project.

1.3 Problem statement and project aim

The initial goal of this design project is to evaluate the methodologies of Life Cycle Assessment (LCA) and Circular product readiness within circular design and develop or combine methodologies for circular design. This is done by using the circular design methodologies in a case study of one specific product. This case study is focused on the Electrocardiogram (ECG) lead set, a heart rate monitoring cable set that connects a patient with a heart monitor. This resulted in the following assignment:

Develop and evaluate LCA and Circular product readiness methodologies with the multi-use lead set for Philips as a case study in hospital settings.

The full project Brief of this graduation project can be found in Appendix A. The project aims for solutions that can be implemented in a time frame of 5 years. It is aimed for the findings from this study to be used within Philips as well as input for the DiCE consortium. A picture of the ECG lead set can be seen in figure 3. The implementation time frame resulted in requirement Bu 1.

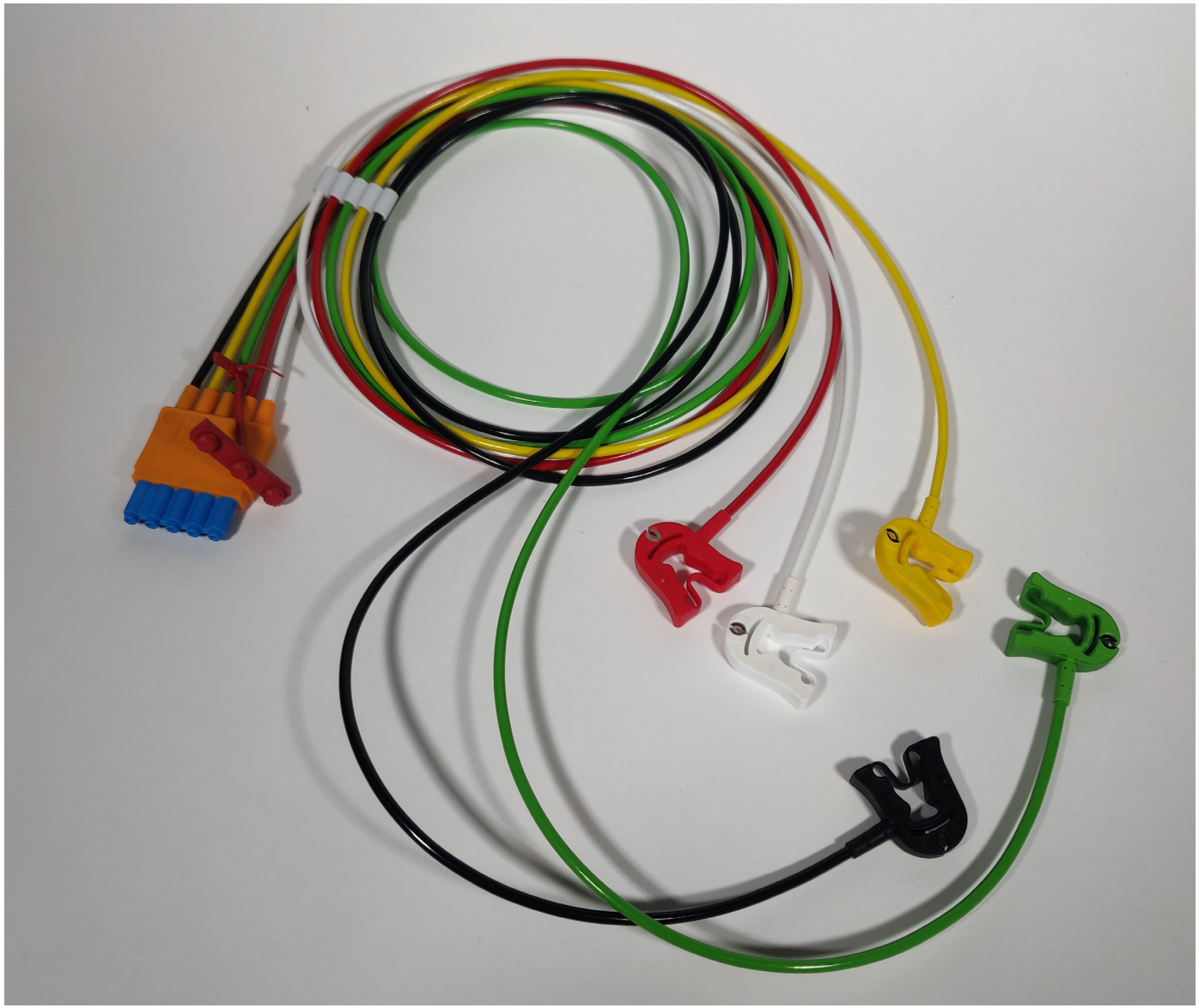


Figure 3: An ECG Lead set

1.4 Introduction ECG Lead set case study

Within medical diagnostics the Electrocardiogram (ECG) is a cornerstone tool for the diagnostics of cardiac health and function. Throughout the hospital it is used in multiple departments for short measurements and/or long-term monitoring. The principle of an electrocardiogram is based on the detection of the electrical signals produced by the heart. These signals go via an electrode on the skin, to an ECG Lead set. The wires (or leads) of the ECG lead set pass the signal to the trunk cable and via these the signals are sent to the monitor. This is shown in figure 4. While in use the patient stays connected to the monitor. Apart from the ECG lead set also other products are used to measure critical parameters. Examples of this are a blood pressure cuff and SPO2 meter. A connected heart patient can be seen in figure 5. To keep the scope of this project under control there has only been focused on the ECG Lead set. The currently available leWad sets are either single patient use (SPU) or multi patient use (MPU), it is up to a hospital to choose which one to use. Possible reasons found within this graduation project to choose one or the other are; infection prevention, ease of use and cost but other reasons could play a role as well. The ECG lead set itself seems from the outside a simple product, but the environment it is used in is rather difficult. Apart from the attachment to complicated machines to measure heart signals, it is also embedded in a system with a lot of legislation and different users and use scenarios (Lappalainen, 2011). All combined this results in an interesting case study for this design project.

Figure 4: A patient connected to a monitor

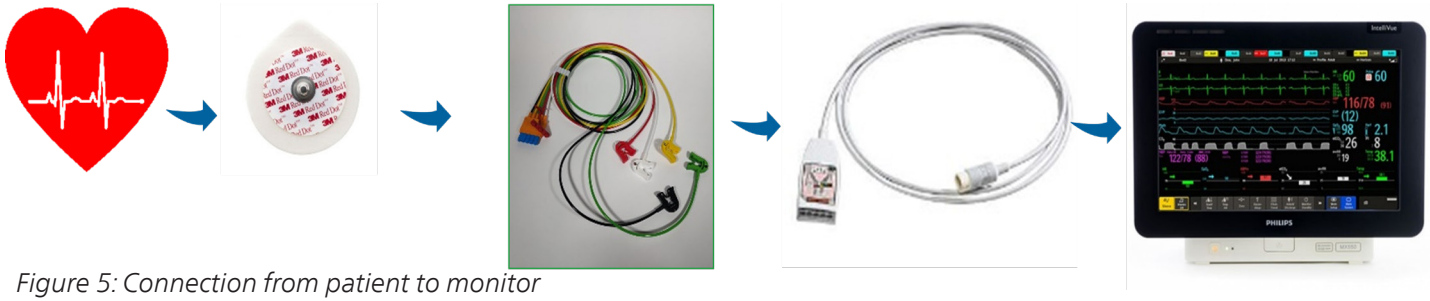


Figure 5: Connection from patient to monitor

1.5 Introduction to the circular economy

In this chapter a short introduction to the circular economy will be made. Here an emphasis lays on the work that has been done within the DiCE consortium.
Kirchherr et al. (2017) gives the following definition for the circular economy:

"An economic system that replaces the 'end-of-life' concept with reducing, alternatively reusing, recycling and recovering materials in production/distribution and consumption processes. It operates at the micro level (products, companies, consumers), meso level (eco-industrial parks) and macro level (city, region, nation and beyond), with the aim to accomplish sustainable development, thus simultaneously creating environmental quality, economic prosperity and social equity, to the benefit of current and future generations. It is enabled by novel business models and responsible consumers. "

This project is mainly focused on the model of the circular economy within the healthcare sector of report 2.1 from the DiCE consortium. Within the DiCE consortium the term Circular Recovery Flows (CRFs) is used to describe the circular flows within a circular economy. In earlier TU Delft related research these would be called recovery pathways. The new term for this medical setting prevents confusion between recovery pathways for patients and the recovery pathways for products.

For the DiCE project the CRFs are determined based on the 9R-strategies framework (Potting et al., 2017) and the Butterfly Diagram (Ellen MacArthur Foundation, n.d.). For report 2.1 (Hoveling et al., 2023) the CRF's are further developed using multiple expert interviews and a multitude of iterations. The CRF's within DiCE are still in development. At this point in time the defined CRFs are the following: Refuse, Rethink, Reduce, Reuse, Repurpose, Remanufacture, Recycle, Regenerate, Compost (regrow), Biodegrade (regrow) and Recover energy. Within the clinical setting these CRFs resulted in figure 6. In this figure all CRF's and steps in these CRF's are described. It gives a detailed insight into the flows within the medical sector. Within this project the CRF's can help in the analysis phase to gain knowledge and sort out stakeholders as well as in the ideation stage to ideate upon.

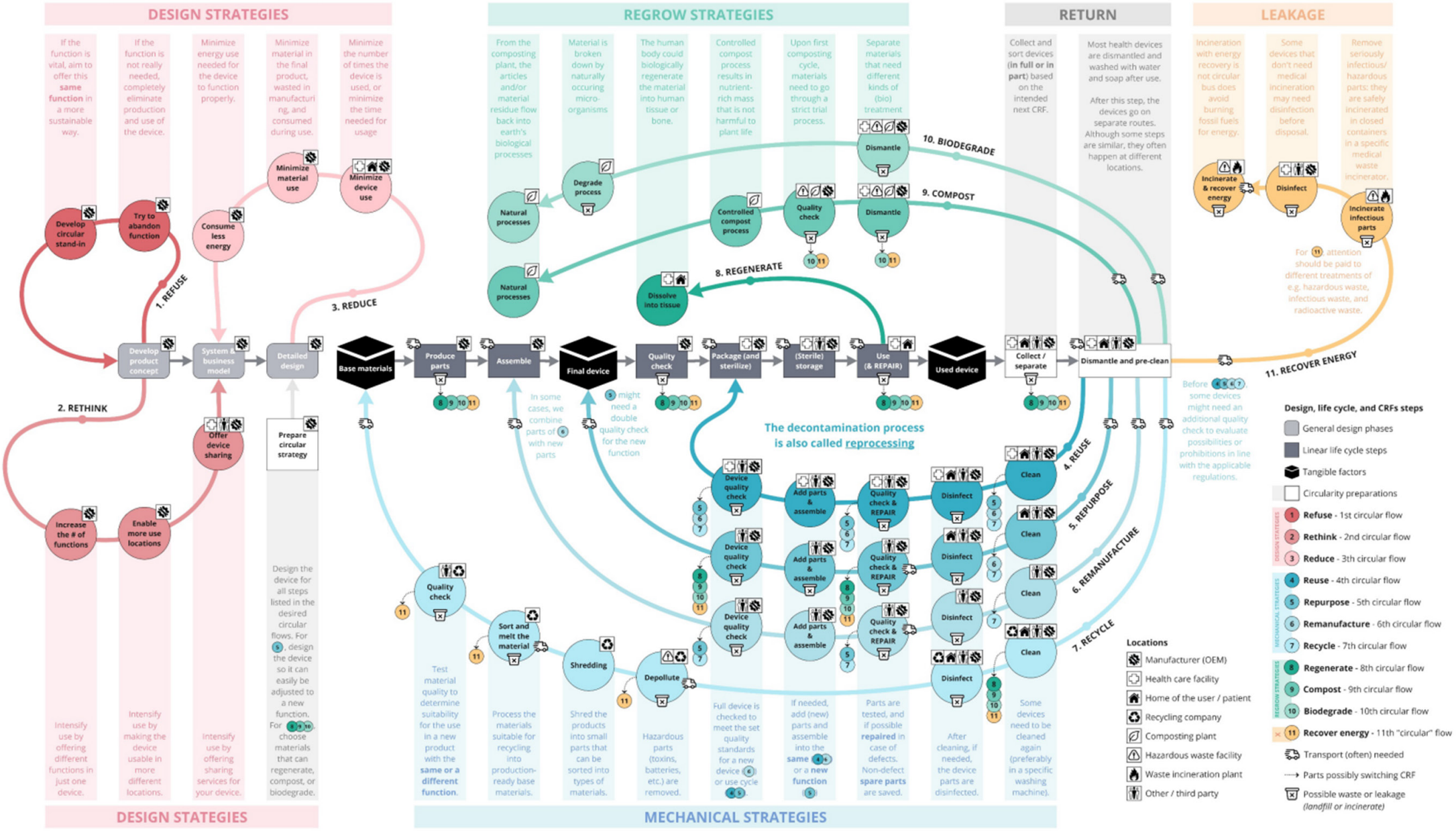


Figure 6: The circular recovery flows as formulated in report 2.1 of DiCE

2. METHOD

This project is shaped around circular design methodologies evaluation and adaptation. However, the main part of the report will be a case study regarding the ECG Lead set. This case study is used to evaluate the circular design methods used. In this chapter the methods within this case study are described including the reasoning behind the chosen methods. After this chapter the report will go into the case study and the corresponding design phases. Following the case study a chapter will be included to evaluate the methods used within the design project.
The methods regarding the case study will be described along the design phases within the project; Analysis, Ideation, Conceptualization and Finalization/validation. An emphasis will be put onto the circular methodologies used within the project as this was the focus point within this graduation project.

2.1 Analysis

To gain important basic information regarding the ECG Lead set this project started off with literature research and qualitative interviews with different stakeholders. To be able to determine which stakeholders to talk to, a stakeholder map is used (see part 2 chapter 1.3) Another source that turned out to give valuable insights was sales data provided by Philips.

To be able to come up with a circular proposition it is important to know the current state of the product and product environment. For this reason, the following methods are implemented in the analysis phase of this project: Life Cycle Assessment and the Circular Product Readiness method.

2.1.1 Life Cycle Assessment

The Life Cycle Assessment (LCA) method looks at the 4 life cycle stages of a product: Manufacturing, Transport, Use and End of Life (Van Boeijen et al., 2020). For each stage the impact of every component and process can be determined by using databases. This includes production processes, raw materials, transport, energy or other materials used during the product's life as well as energy or materials that can be won back at the end-of-life stage. Therefore, the LCA gives an estimate of the impact a product makes on the world. All different kinds of impact are converted into the unit kgCO2 equivalent. This makes multiple options and products comparable. Within this project there was no time to do a full LCA, so chosen is to do a fast track LCA. In which the following uncertainty factor is included in the data: 10% for precise data & perfect database match, 30% for plausible substitution, 100%+ for wild guess. Due to this the results are shown in a gradient instead of a precise number. The LCA will be used to compare current scenarios as well as future possible solution directions.

2.1.2 Circular Product Readiness method

Where the LCA Methodology mainly focuses on the product impact, the circular product readiness assessment methodology mainly focuses on the readiness of the product system (including the company producing the product) to implement circular solutions (Boorsma et al., 2022). The method comprises of a questionary filled in by two employees of the company of a specific product. The assessment and questionary are based on 6 themes with indicators for each theme. These can be seen in figure 7.

The results of the methods consist of a total percentage for the whole system and percentages per indicator. This gives insight in what parts the ECG Lead set is lacking and what could be valuable directions to explore.
All insights of the Analysis phase are combined to a set of requirements, which together with the found design direction are used as input for the ideation and conceptualization of this project.

Figure 7: Themes and indicators circular product readiness

2.2 Ideation

With the design direction and requirements, the ideation phase was initiated. The start of the ideation is with the ideas that came up during the analyses phase of the project. Further an Ideation based on each of the CRF's is done. This way of ideation is a test to see if this is a valuable way of working to create circular ideas. It is done to give inspiration and to make sure to not miss whole CRF's in the ideation phase of this project. With these initial ideas a co-ideation is done at the factory site in Boblingen Germany.

2.3 Conceptualisation

To converge from the multitude of ideas to concepts a morphological chart is used. This will lead to grouped ideas, but to get these to a coherent concept, storyboarding is used. This resulted in 3-5 concept directions with a clear storyline. To further develop these concepts the method SCAMPER is used (Van Boeijen et al., 2020). This to try to Substitute, Combine, Adjust, Modify, Put to other uses, Eliminate and Reverse the concepts with earlier ideas. After this the concept choice is made. This is done by scoring the concepts against the requirements in a weighted objectives method and by input sessions with stakeholders. With this, one of the concepts is chosen. The chosen concept is checked on the Eco Design checklist and strategy wheel to further detail the circular proposition.

2.4 Finalisation and validations

With the concept the first validation steps are undertaken. This consists of low fidelity prototype testing. This is supported by interviews with stakeholders on those low fidelity prototypes. Further an evaluation of the life cycle impact is done with a follow-up fast track LCA.

PART II:

DESIGN CASE STUDY

In this chapter this report will dive into the case study done. The case study consists of 4 phases. In the first phase, the analysis, the main goal is information finding and evaluation on current situation. It results in a list of requirements for this project. In the ideation phase following the goal is to find a lot of solutions for the set problem to give input for the concepts in the conceptualization phase. These two phases go to iterative processes and are therefore captured in one chapter. After this the concepts are converged back to one concept, which is shown in the chapter concept detailing. The last phase consists of some validation and finalization of the concept and project. This will be how this report will show the process but as in any design process it has not been a linear process at all with a lot of iterations and excursion.

1. ANALYSIS

The analysis will start with an investigation on general information around the ECG Lead set. The focus will lay on the important insights for the rest of the report. The information came from literature research, observations, interviews and circular evaluation methods.

1.1 3 current use scenarios

As described earlier there are two versions of the ECG Lead sets, a multi patient use (MPU) and a single patient use (SPU). With these two versions there are 3 use scenarios. To be able to understand the current situation, in this chapter the 3 main use scenarios are described. These are:

- Multi patient use lead set that is used over a multitude of patients
- Single patient use lead set that is used through the hospital for 1 patient only
- Single patient use lead sets that are reprocessed (see 1.1.3 for definition) to be used by up to four patients.

The information for these 3 use scenarios came from block diagrams made by the university of Gent in the DiCE project. The block diagrams can be found in appendix B. The block diagrams are supplemented with interviews and observations. The following paragraphs will go into the 3 use scenarios. An overview of the lead set in use can be seen in figure 8. This is an AI generated illustration but gives a good idea of the setting. In this figure the lead set are the wires coming from the chest.

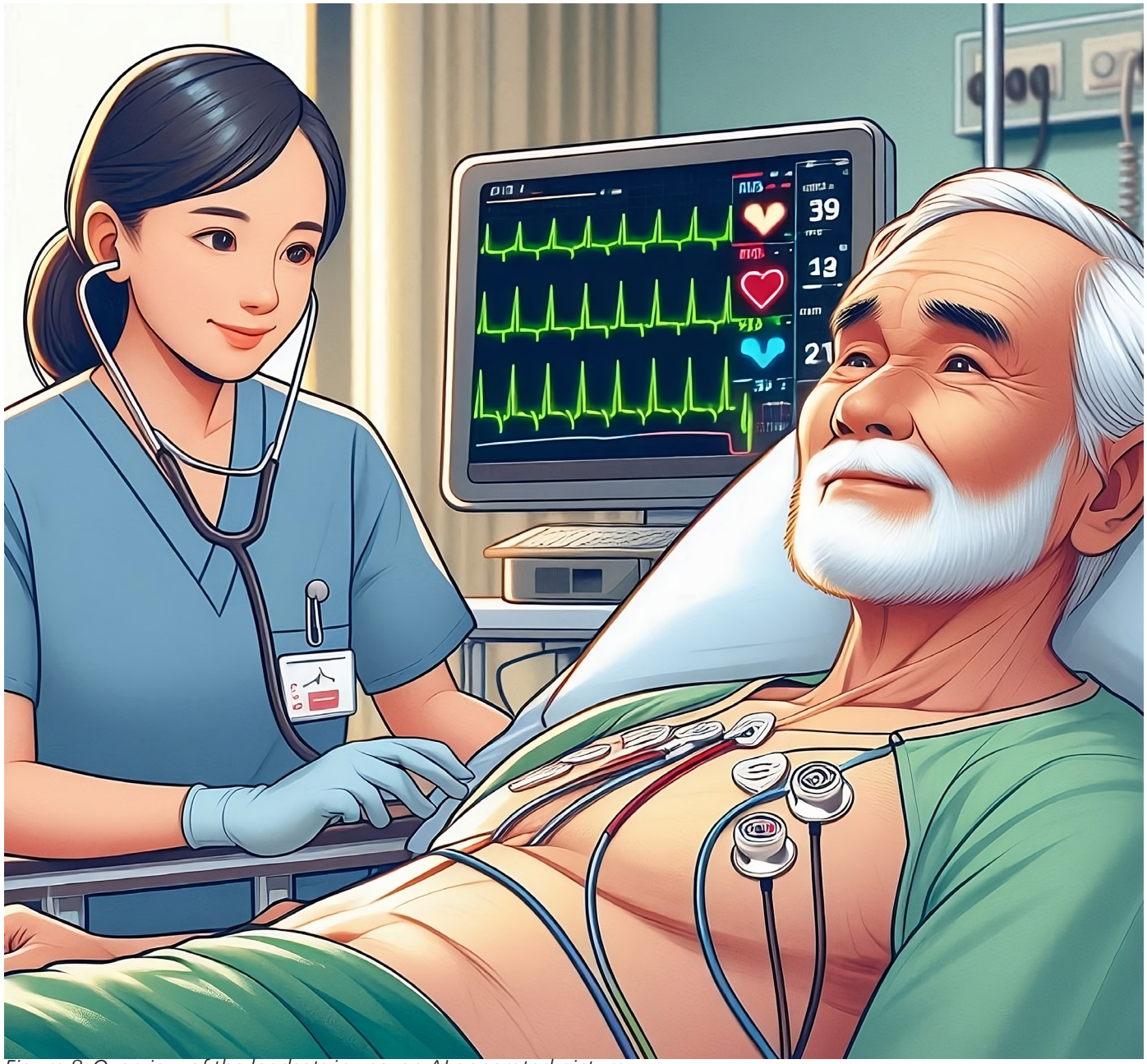
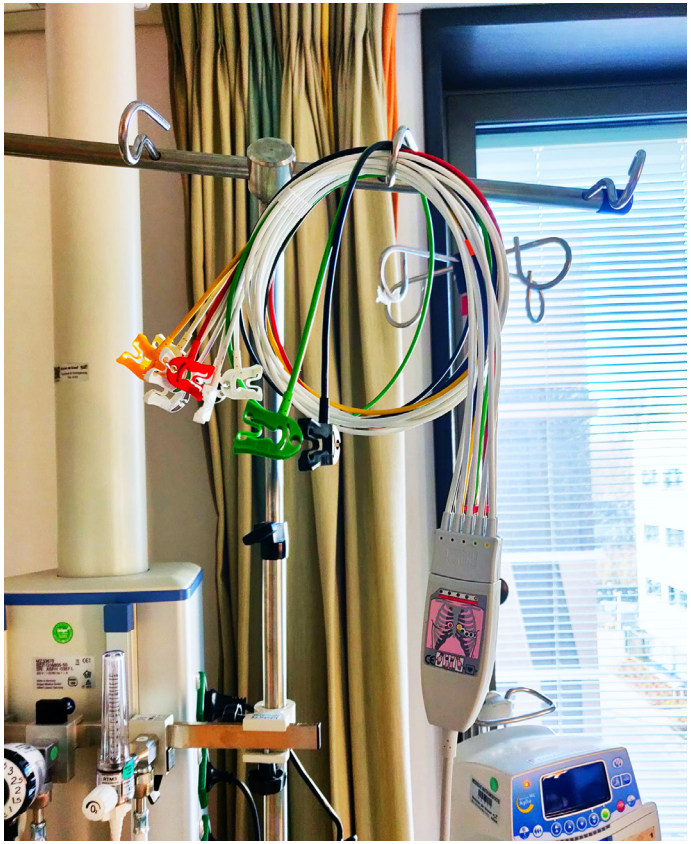


Figure 8: Overview of the leadsets in use, an AI generated picture

1.1.1 Multi patient use (MPU)

In the multi patient process the Lead sets are used and cleaned at the monitor and stay mostly with the monitor. The cleaning is done by the nurse operating the machine. This is done with microfibre towels and water. The lead sets are used till they break down, how long the ECG lead set lasts is dependent on the amount of use cycles and way of use. Lead sets up to 7 years old are observed while the advised use time is 12 months (Philips - 5 Lead Grabber AAMI ICU Lead Set, n.d.).



1.1.2 Single patient use(SPU)

For the single patient process the lead sets stay as much as possible with the patient. Every patient gets their own new lead set. The lead sets are not cleaned and are thrown away after a single use.

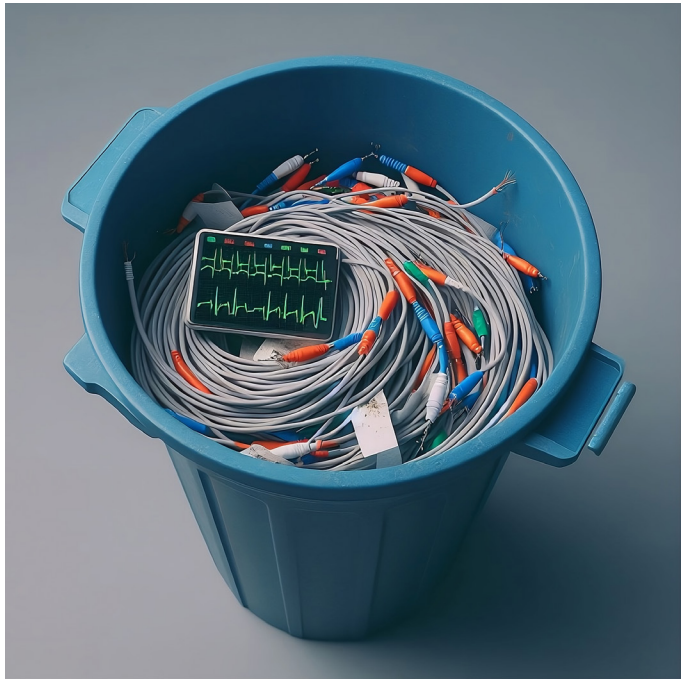


Figure 9,10,11: From left to right the Multi Patient use lead set, single patient use lead set get thrown away (AI generated), reprocessing of the single patient use lead sets.

1.1.3 Single patient use reprocessing

To reprocess the single patient use lead set the sets are recovered by a company using special bins on the wards. They ship them to a centralized location. Reprocessing in this scenario means that the lead sets are thoroughly cleaned by hand with towels and small brushes. The lead sets are tested and after that they are put into a sterilization process. This is sterilization with ethylene oxide, which is costly and has more safety risks than traditional steam sterilization and therefore less applicable for hospital settings (Mubarak et al., 2019) . After sterilization the lead sets are sold again to hospitals. This is for a reduced price in comparison to a new single patient use lead set. The singe patient lead sets can be cleaned 3 times in north America before they must be thrown away. This process is mainly limited to North America as legislation does not allow reprocessing of single use items in Europe if not specifically authorized by single countries (Hoxey, 2019). The last 5 years the number of countries that do allow SUD reprocessing is growing but each has its own conditions (European Commission, 2024).

1.2 Literature and data

This part of the literature research focused on the workings of the ECG Lead set and general information on how the healthcare system works. Later on specific research is done on cleaning and quality control of lead sets, this will be discussed in chapter 1.5.1. As it is more relevant information in that chapter. Another source of information for this project was the sales data from the different kinds of lead sets from Philips.

1.2.1 Background information ECG Lead set

In this part it will be shortly described how an ECG Lead set works. Apart from the SPU and MPU lead set there are many different variations. One thing that can differ is the number of wires on the lead set. Mostly used are 3, 5, and 10 wires on the lead set. The main difference between the number of leads is the quality of the ECG vs the ease of use. Also, how the lead set is connected to the patient can differ. Options for this are a grabber and snap mechanism, for this see figure 12 and 13.

The Grabber,
The grabber works by connecting from the side and using a clamping force to connect to the electrode. The system is favoured by nurses as it connects from the side without needing pressure on the chest of the patient. Both the grabber and the snapper are designed for 2000 mating cycles. A potential redesign should also fit this and this resulted in requirement Pr 4.

The snap
The snapper works the same way as a push button known from clothing. This is also based on a clamping mechanism to create the contact. A disadvantage for the snapper in use is the need to push on the patient to connect. This can create unwanted pressure on sensitive areas of the chest for heart patients which often have operations done in this chest area. The different number of leads used in different situations are placed differently on the body. To comprehend this project it is not needed to understand the exact placement of the lead sets. The leads placed on the body measure the electrical difference produced in the heart while beating. On the shape of this measurement for each of the different leads, conclusions can be made to diagnose illnesses. With a larger number of leads the electrical difference can be measured more precisely and so more information for diagnostics can be optained.

Figure 12: The grabber

INSIGHTS

For this project an important learning is the importance of the quality of the measurement. The quality of the measurement is dependent on the connection between patient and monitor. Every connection point is a potential point of loss of quality. The first is the patient to the electrode, this is out of scope for this project. The second is the connection of the electrode and lead set. Important considerations here are the area of this connection, a bigger area gives better signal throughput. Also, the stability of the connection has an impact on signal quality. Movement of the connectors on the electrodes or muscle contractions can result in artefacts on the measurements. The signal is sensitive for interruptions as the measured difference is only from 0.1 up to 5 mV (Xie et al., 2020). This insight resulted in requirement Pr 2.

Figure 13: The snap

1.2.2 Sales number analysis

Within Philips there are central sales data banks. From this I got the data on all products within the ECG Lead set group. This is then separated into the SPU and MPU lead sets and the data is compared. A rising trend in the use of single patient lead sets can be seen world-wide. The percentage of lead sets being SPU of the total sold lead sets increased by 16 percent and the sales numbers of SPU lead sets almost tripled (see figure 14 and 15). This rising trend occurred in a period of only 7 years.

This trend is worrying as the MPU lead set and the SPU lead set do not differ much in terms of weight and materials used (see figure 16). Which results in the assumption that the environmental impact of the material cost per patient for the SPU lead set is way higher than for MPU lead sets. This assumption has been tested with a LCA, this can be seen in chapter 1.4. From this it can be concluded that the CO2 eq impact of SPU is much higher. It could be a valuable direction to focus on optimizing MPU Lead sets to bring down the use of SPU lead sets.

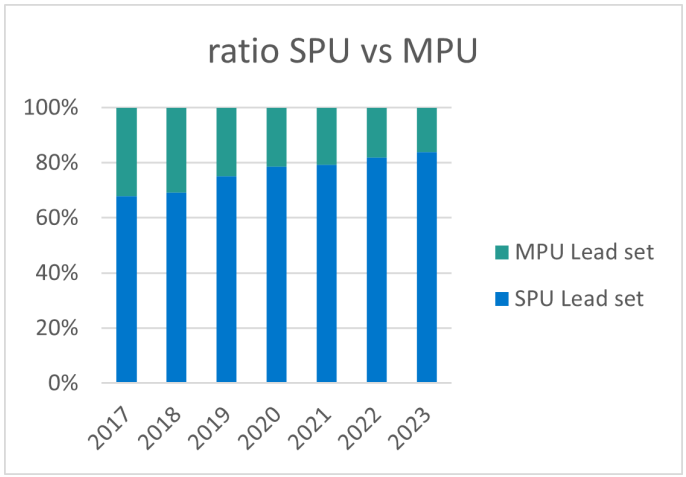


Figure 14: Ratio of sold SPU vs MPU lead sets

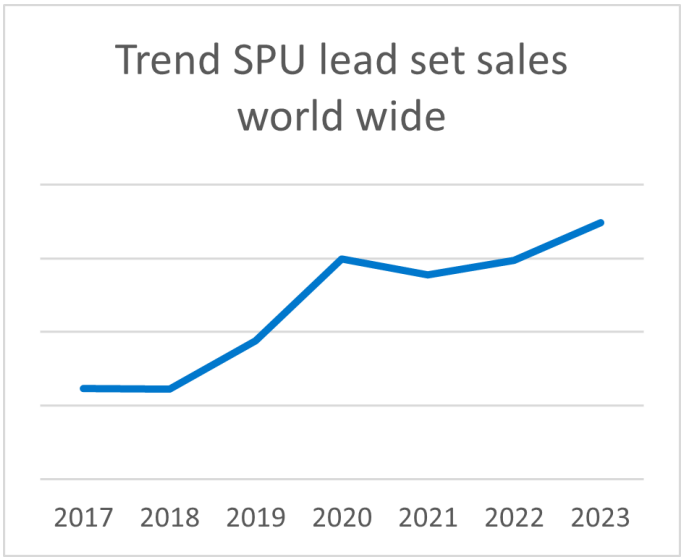


Figure 15: Number of SPU lead sets sold, equally distributed legend is not included as this is sensitive data.

Figure 16: Multi Patient Use lead set (upper) and Single Patient Use lead set (lower)

1.3 Observations and interviews

Within this project a multitude of interviews and observations are done. For a full list of interviews see appendix C. From Philips there has been access to industry experts and via the TU Delft two hospital visits have been undertaken at Leiden Universitair Medisch Centrum (LUMC) and Reinier de Graaf Gasthuis (RdGG).
The interviews consisted of open questionnaires. The hospital interviews where based on an excel document that can be found in appendix D.
Before starting the rounds of interviews, based on literature, a stakeholder map was made. The stakeholder map is visualized using concentric circles to prioritize the stakeholders (figure 17). All stakeholders in the inner two circles have been interviewed. Product and user-related learnings from interviews and observations are gathered in a product journey and user journey map. The product journey map can be seen in figure 19. The user journey map can be seen in figure 20. The maps are mainly used to combine al findings in one place. In the observations and interview two main themes came up; cleaning and quality of the lead set at point of care. These will be the themes of the following sub chapters.

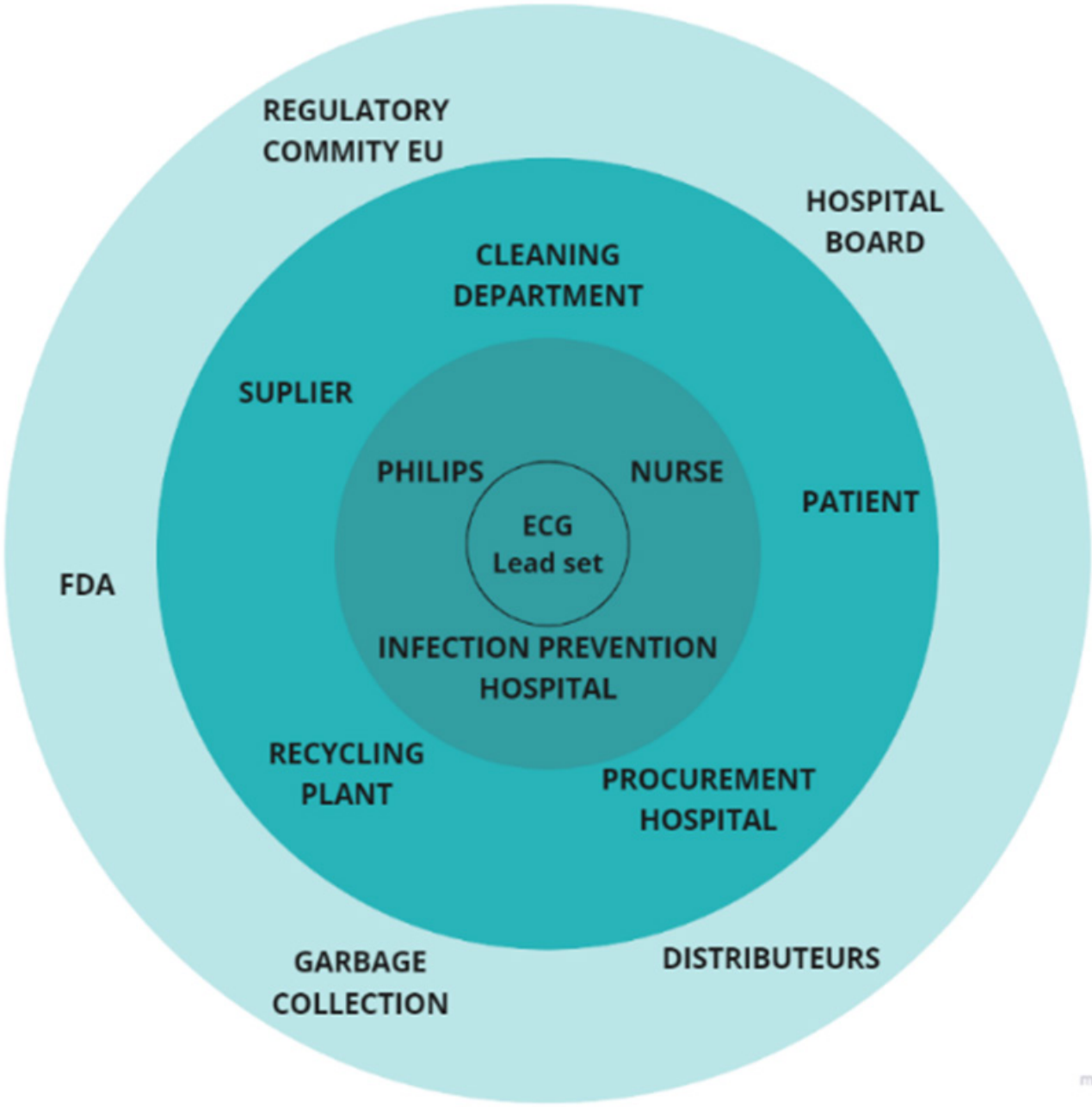


Figure 17: Stakeholder map

1.3.1 Cleaning the lead set

The current lead sets are cleaned by hand. Most of the time just with a disposable microfibre towel and some water. In some cases, disinfection wipes are used with an oxidizer to clean the lead sets better. In the interview it was said that this was not following the manufacturer specifications on cleaning, but they felt it was necessary to ensure cleanliness. When asked about the state of the lead set it was mentioned that they felt they were not really clean. The glue from the electrodes created a sticky layer what resulted in dirty, hard to clean lead sets. It was also mentioned that it took a lot of time to clean the lead sets well. The end of the cables was found hard to clean due to the strange shape; the clamping mechanism creates a lot of cavities in the grabber. The snapper looks a lot simpler and easier to clean, but on the inside in the snap mechanism small cavities exist that are almost impossible to keep clean well. When it got busier this also resulted in the lead sets being cleaned faster and not as thoroughly. With the pressure nurses are under within the healthcare system (Harvey et al., 2020) this is not a desirable situation. This resulted in requirement Lo 4.

1.3.2 Quality lead set

The clamping mechanism is prone to failure and fatigue over time. The observations in Reinier de Graaf hospital and interviews showed that the plastic spring could break down. In practice the lead sets are used till they break. Which is of course a lot more sustainable but can give extra risks. A half-broken lead set can result in extra alarms going off or a loss of quality in the ECG. This can result in alarm fatigue, where reaction to alarms can get compromised (Albert et al., 2014). Observations and qualitative interviews gave insight that the part most susceptible to failure is the grabber end of the lead set. The plastic spring breaks which results in the grabbers coming of the electrodes easier. For this see the picture in figure 18.

Figure 17: Broken grabber

INSIGHTS FROM INTERVIEWS AND OBSERVATIONS

Multiple insights came from interviews and observations, the journey maps did help to combine these. The most important are listed below.

- The first insight is that the MPU lead sets are used till they break down and that the on package 12 month use time is not adhered to. This results in broken lead sets that do not work as they should and need to be taped down to stay connected. The nurses just add some medical tape over the whole electrode to keep the connection stable. This insight led to requirement Lo 3.
- Another insight was that the MPU Lead sets were experienced as hard to clean. This is due to small cavities on the lead ends and the need to clean all the wires separately.
- In practice cleaning is done quickly or not done at all in busy periods.
- Another insight from the interviews and observations was the need to have the Lead set close to the monitor to not waste time searching for a lead set to connect. The normal situation with MPU Lead sets where the lead sets are connected full time to the monitor is favourable. This resulted in requirement Lo 1.
- The wires getting tangled is not perceived as a big problem for nurses, most are put straight, next to the monitor.

These insights are valuable input for the design phase of this case study. Most insights found in observations and interviews are themed around the re-use of the ECG Lead set. This resulted this being a promising design direction in this graduation project.

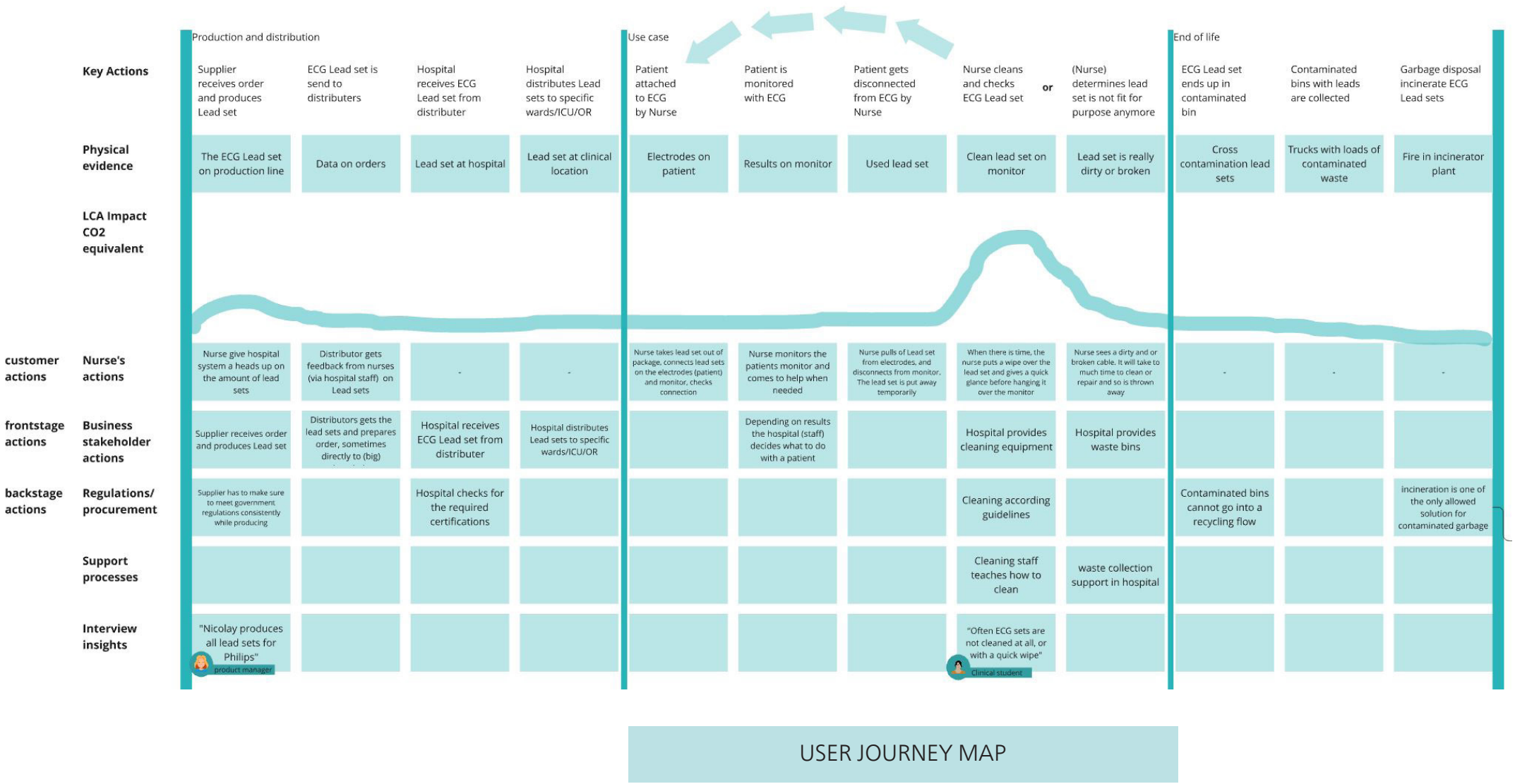


Figure 19: Product journey map

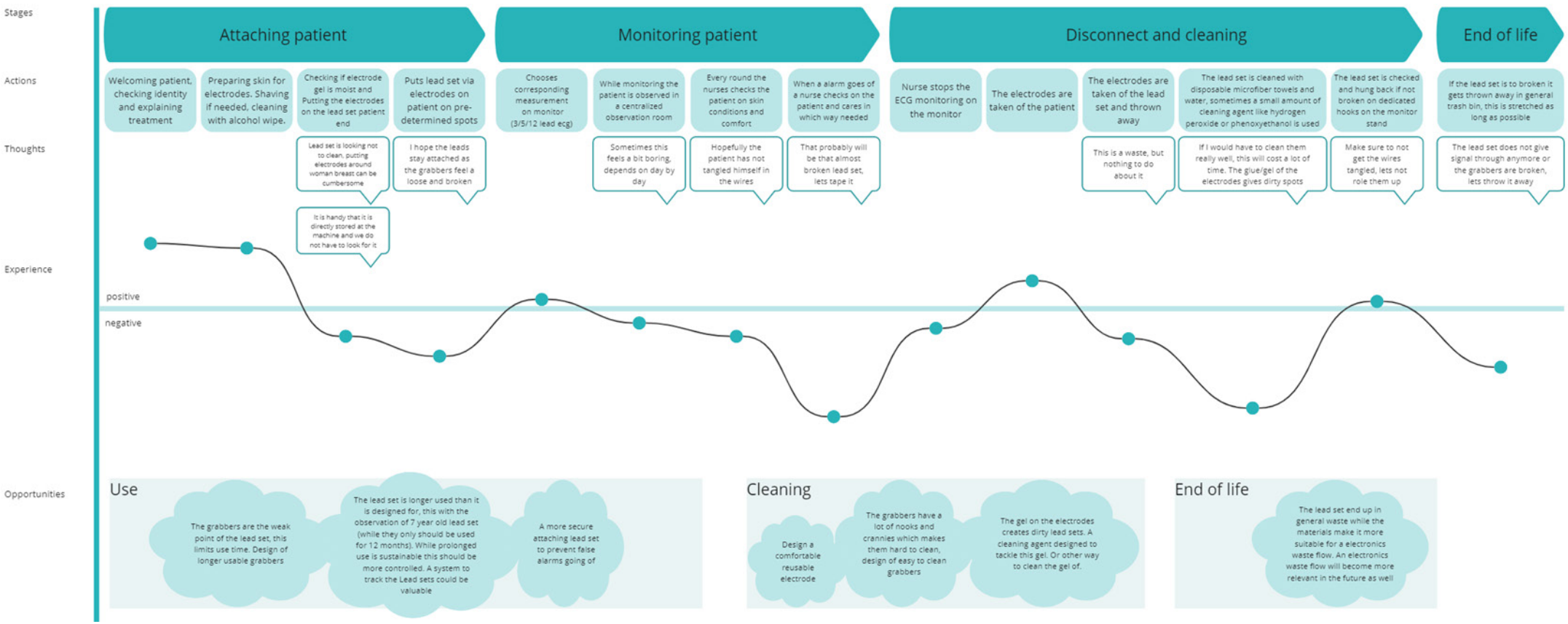


Figure 20: User journey map

1.4 Circularity and LCA evaluation

To be able to get the concept more circular it is important to find the hotspots of the impact and possibilities for this redesign. Therefore, in this chapter two circular evaluation methods will be used to showcase the state of the current designs and solutions. Apart from this it will give an indication which circular design directions could prove most valuable. The two methods used are a fast track LCA and the Circular Product Readiness method.

1.4.1 Fast track Life Cycle Assessment

To analyse the current situation a fast-track life cycle assessment has been done. The assessment has been done on the 3 use scenarios of the current Lead sets. Single patient use, multi patient use and single patient use reprocessing.

1.4.1.1 Scope

To be able to fairly compare the 3 different scenarios the scope should be said. This done with the help of a functional unit (FU). For this life cycle assessment, the following functional unit (FU) is chosen.

Sending signals from the electrode on the patient to the beginning of the trunk cable for 200 patients within the Reinier de Graaf Gasthuis in Delft.

There has been chosen to include 200 patients as the MPU lead set is rated for 2000 mating cycles and based on observation and interviews a maximum of 10 mating cycles per patient is expected. A mating cycle consists of connecting and disconnecting the leads from the electrode. Reinier de Graaf Gasthuis has been chosen due to the observations made there and the availability of information due to the direct contact.
With the FU a simplified life cycle inventory (LCI) is made which can be seen in appendix E. The choices for the LCI can be seen in the assumptions chapter. The data for the LCI is gathered from the Idemat 2024 database with additions from the EcoInvent v3.8 database where needed.

1.4.1.2 Assumptions

To be able to do the fast-track LCA some assumptions are needed, these are described per use scenario.

Single patient use,
The main plastic used is PVC. The total weight is 80 grams, of which an expected 20 percent by weight is copper and the other 80 percent plastic. The copper is 100% primary as secondary copper does not have the properties to be used in production. The production site in Europe is in Motzingen. The transport will be from here to the hospital and is 640 km. End of life will be in general hospital waste and as PVC can be harmful in incineration it will end up in land fill (Mersiowsky, 2002).

Multi patient use,
In contradiction to the SPU lead set the MPU lead set is made of mainly TPE. Total weight is 91 grams. The number of materials needed to clean one MPU Lead set is 1 microfibre (polyester) towel and 2 litres of cold water. This is based on observations in the hospital. For further assumptions see single patient.

SPU lead set reprocessing,
Use of single patient lead set, but the lead set is cleaned centrally in between uses. This use case is based on the solution Stryker offers in America. The Lead set can be cleaned 3 times, so 4 cycles per lead set. This means 50 SPU lead sets to manufacture for the FU. For cleaning a microfibre towel, soap and Ethylene oxide (sterilization process) are used. The distance from the centralized cleaning facility (central Netherlands) to Reinier de Graaf is approximated at 100 km. This distance is travelled every use cycle, but shared over other products packed in the van, this is taken into consideration within the LCA. Added to this is also an estimation of the extra packaging needed for the lead set when repossessed.

1.4.1.3 Results

With these assumptions the impact in kg CO2 equivalent is determined for each of the use scenarios. The total impact per FU per use scenario can be seen in figure 21. The results per life cycle stage per use scenario are shown in figure 22.

INSIGHTS

The main important insight for this project is that MPU lead sets have per FU total a lot less impact. If this is combined with the insights from chapter 1.2.2 where we saw a rise in SPU Lead sets used we have an outcome that is the opposite of the objectives set forth by this case study. The solution of SPU reprocessing does not yield a big improvement in the current context of Stryker due to the extra cleaning, packaging and transport cost. In both MPU lead sets as the SPU Reprocessing scenario the use phase can be seen to have the most impact. This use phase impact comes from cleaning the lead set and the consumables used with this. For the design case study, MPU lead sets seem to be the best option. Additionally, it is crucial to minimize the impact of the cleaning process to further optimize the use of MPU lead sets. This resulted in requirement Bu 2.

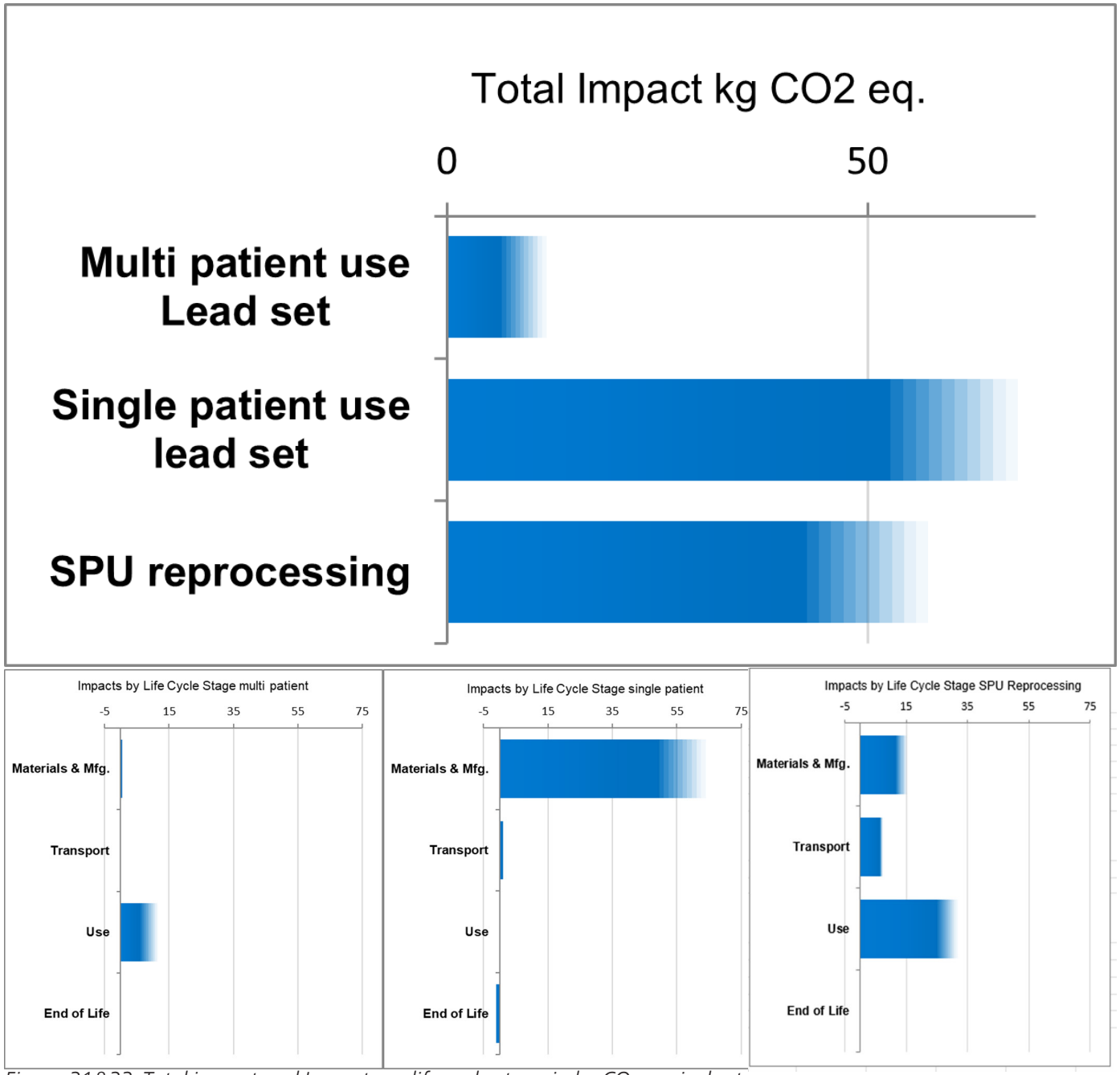


Figure 21&22: Total impact and Impact per life cycle stage in kg CO_2 equivalent

1.4.2 Circular product readiness method

As described earlier, the circular product readiness assessment (CPR) methodology mainly focuses on the readiness of the product system (including the company producing the product) to implement circular solutions. (Boorsma et al.,2022) The assessment method comprises a questionnaire of 63 multiple-choice questions. In the initial phase of this project, I undertook the task of answering the questionnaire myself. This decision stems from my confidence in possessing both some expertise in circular economic principles and an understanding of the intricacies of the product in question. The overall result of the circular product readiness method can be seen in figure 24. The detailed results can be found in appendix F. The themes and indicators from the questionnaire can be seen in figure 23.

INSIGHTS

The CPR method shows that in terms of strategy and planning the ECG lead set scores strong, this area is more on a business level. It means that Philips as a business could be ready for circular solutions. The areas this product scores lower are more on product support services, recirculation services and recoverability. After sales Philips has little knowledge of what happens with their ECG Lead sets. This makes it harder to implement circular solutions. An opportunity would then be to find a way to get information on the lead sets after the moment of sale. Not only would this help to implement more circular solutions but it could even help to further develop the products in Philips their line-up. This insight resulted in requirement Lo 5.

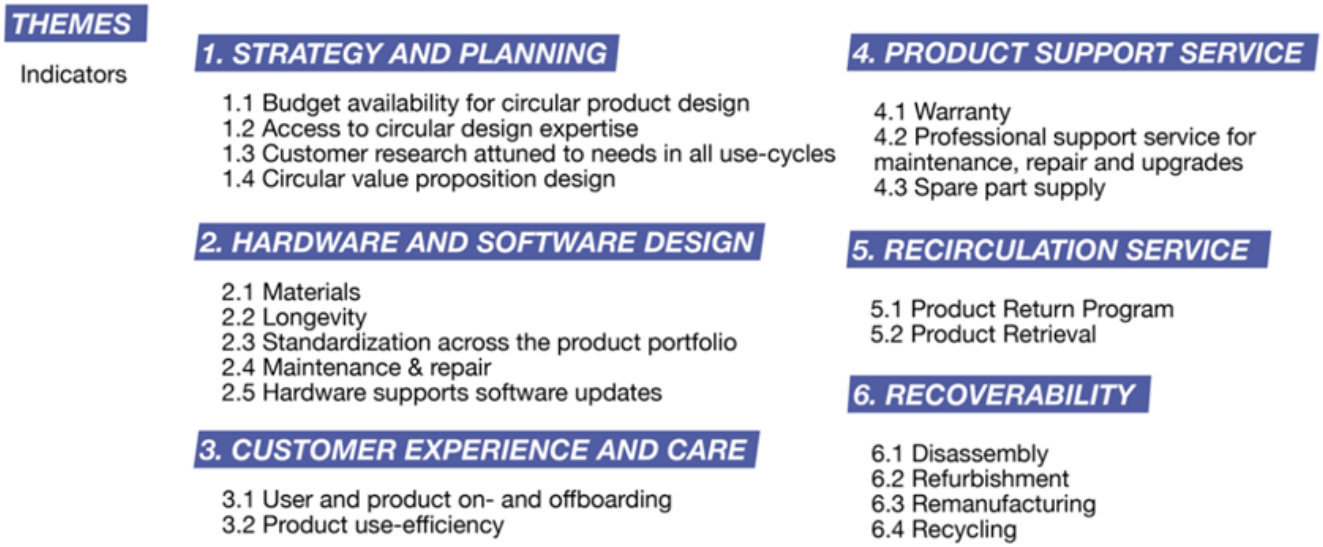


Figure 23: Themes and indicators

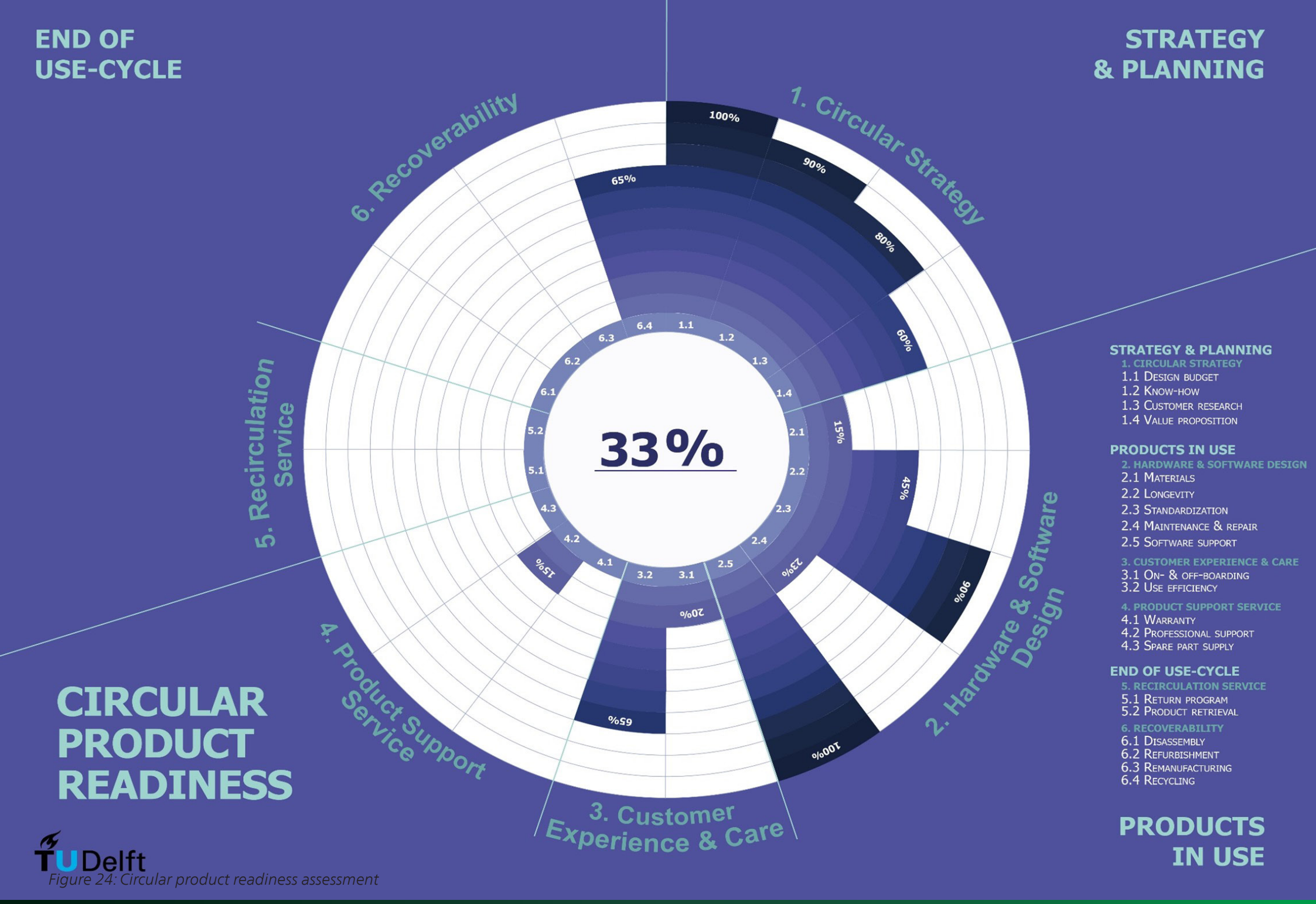


Figure 24: Circular product readiness assessment

1.5 The circular recovery flow reuse

While conducting the analysis phase of this report one of the CRF's came up as a key player within the ECG Lead set system. This was the Re-use CRF. A lot of practical problems around re-use of an MPU lead set could be seen in the interviews and observations in chapter 1.3. This while there could be seen a switch from MPU lead set to SPU lead set. This switch could be explained by the problems found in the interviews and observations, but no evidence is found of this. As re-use plays a big role within the lead set system this analysis chapter focusses on the 2 main themes that were mentioned in the interviews and observations: Cleaning and quality control. These two themes can also be found in literature as essential within the healthcare sector (Branaghan et al., 2021).

1.5.1 Cleaning

Cleaning in a hospital setting is a complicated process. There are a lot of different systems in place to clean, for example medical equipment, operating theatres and beds. To know how the ECG Lead set could fit in we take the insights from chapter 1.3. And add some literature to this within this chapter.

1.5.1.1 Literature on situation ECG lead set

The interview and observational insights from chapter 1.3 in cleanness correspondent with research done within the clinical setting. A study in America showed 77% of lead sets contaminated with antibiotic resistant pathogens (Albert et al., 2010) and a study in the IC unit in Germany showed 51% contaminated with bacteria or risk pathogens (Lestari et al., 2013). The combination of the observations, interviews and the research found shows that the current methods of cleaning could benefit from improvements.

1.5.1.2 How clean is clean enough?

With the insights from the previous paragraph the big question is when a product is clean enough. In the hospital setting this is mainly dependent on how the product is used. To set standards for cleaning and use medical devices are classified in roughly said 3 classes.
Class 1 are mostly non-invasive devices, which come in contact with healthy skin. Class 2 (a and b) are mostly devices coming in contact with for example blood (think of blood filtration systems). Class 3 are mostly invasive devices. In practice the classification is more complicated and flow diagrams are made to help the classification of devices (Medical Device Coordination Group, 2021).
We used this flow diagram to determine the Lead set falls into Class 1 in most of the use scenarios, including at the CCU that is the focus within this project.
For cleaning this means it is classed as a non-critical patient care item (Rutala & Weber, 2004). This means that low to intermediate level disinfection is sufficient (Rutala & Weber, 2013).
In practice this means that the lead set does not need to be sterilized or disinfected at a high level and that hand disinfection or machine washing disinfection with mild cleaning agents could be fitting cleaning methods for this project. This could be valuable as higher level disinfection methods and sterilization could be harmful for plastic products (Rogers, 2012). This conclusion led to requirement Lo 2.

1.5.1.3 Cleaning flows in hospital

Within a hospital there are different cleaning methods used in different scenarios. Information on this is gathered from hospital observations at LUMC and Reinier de Graaf Gasthuis Delft as well as earlier literature research.

- Bedside cleaning: Cleaning non-critical devices, surfaces and the bed with disinfection cloths. Mostly done by nurses or cleaning staff. What disinfection agents are compatible with the ECG Lead set can be seen in appendix I.
- Local washing: Most wards have a small washing station where non-critical reusables are washed and dried. This can be done by hand or by a washing machine. Depending on the agents and temperature used this would be low to intermediate level disinfection.

- Centralized bed cleaning department: Beds go to this department monthly for more extensive cleaning (still low to intermediate level disinfection) of all surfaces and testing. Cleaning staff do this by hand most of the times, in some big hospitals there is mechanical bed cleaning.
- Sterilization department: all critical devices go to the sterilization department, here they are sterilized elevated temperatures or chemicals. Mostly used for operation room related products. Cleaned by specialized cleaning staff. For a deeper explanation about the sterilization department see appendix G. As the ECG Lead set cannot be cheaply and effectively sterilized this is out of scope.

1.5.1.4 AAMI TIR30:2011 section 4, Device Design

This part of this AAMI standard gives guidelines what to watch for when designing healthcare devices. In 4.2 it gives features offering difficulty for cleaning. Important ones mentioned are:
- Lumens, Crevices and dead ended chambers.
- Fittings with very close tolerances
- Rough, irregular, discontinuous surfaces.

Among others mentioned these will be considered when designing for the cleanability of the lead set (AAMI TIR30, 2017).
Implementing AAMI TIR 30 has been considered within requirement Pr 3.

1.5.2 Ensuring quality

Next to cleaning it is important to make sure that the ECG Lead sets are up to specification while in use (Branaghan et al., 2021). For the ECG Lead set this means it gives through the signal from the electrodes without disturbances. Another important aspect of quality is safety in the hospital environment. Within the lead set environment this means being safe to use together with defibrillators. As a shock with a defibrillator should not travel through the lead set. A broken lead set or one containing water or residues could result in the shock traveling through the lead set. Normally when the suggested lifetime of 12 months is adhered to the lead sets should not have a lot of problems with breaking down. As described in the observations in chapter 1.3 the lead sets are used till they break down, and sometimes even after that. To capture broken lead sets, a check on the status of the lead sets should be in place. This will be added to the requirements.

INSIGHTS

The insights are twofold. On cleaning the current situation is not sufficient, the redesign should be able to be fitting low to intermediate disinfection methods. Cleaning the ECG Lead set thoroughly is a problem on a system level as well as on a product level. To add some guidance on a product level the standard AAMI TIR30:2011 (2017) section 4, Device Design could help to improve the design of the lead set. Secondly, for quality control, a system to catch broken lead sets should be in place. To be able to detect hidden failures, a testing procedure as used with the SPU reprocessed lead set could be helpful with this. Apart from controlling the quality of the product in use, a design that does not break down will also help to elongate the life cycle. This creates less impact as less ECG Lead sets will be needed.

1.6 Design direction and requirements

From this analysis phase and all the insights it gave this project, the following design direction is formulated:

OPTIMIZE THE MULTI PATIENT USE LEAD SET FOR REUSE

In this design direction there is a focus on the CRF re-use. For reuse quality control and a clean lead set at the patient's point of care turned out to be two important factors. Other important factors are the durability of the lead set and the need to be able to follow the lead sets after sales. In the ideation phase of the project, it will be made sure to not exclude other CRF's to strengthen the ideas. The insights from the analysis phase also resulted in a list of requirements. The requirements are divided into 3 categories, Logistic requirements, product level requirements and Business level requirements. The requirements are described in figure 25. This list of requirements forms the basis of the redesign and will be tested on in the evaluation phases of this project. It should be noted that only lead set specific requirements are considered and that standard safety requirements should not be forgotten. Examples of these are no sharp edges or toxic materials.

nr	***Logistic requirements***	*Chapter*
Lo 1	The lead set is available at the patient point of care when a new patient comes in	Part II, 1.3
Lo 2	The lead set is clean to a low to intermediate level of disinfection at the patient point of care when a new patient comes in	Part II, 1.5.1.2
Lo 3	The lead set is in working order and safe to use at the patient point of care when a new patient comes in	Part II, 1.3
Lo 4	The extra work (and work costs) for hospitals (staff) must be minimalized	Part II, 1.3
Lo 5	It has to be possible to count the number of use cycles the lead set has gone through	Part II, 1.4.2
	Product requirements	
Pr 1	Fit the current connections on both sides, the electrodes and trunk cable	Part II, 1.1
Pr 2	The connection between electrode and ECG Lead set should be firmly. In a way that normal movement from the patient does not disconnect the wires from the electrode and does not cause artefacts.	Part II, 1.2
Pr 3	The lead set should be designed to be easy to clean holding to the considerations of AAMI TIR30:2011 section 4, Device Design	Part II, 1.5.1.4
Pr 4	The ECG Lead set should fit the current design requirements of 2000 mating cycles. A mating cycle consists of connection and disconnecting from a patient and cleaning	Part II, 1.2
	Business requirements	
Bu 1	The solution should be implementable in 3-5 year	Part I, 1.2
Bu 2	The lifecycle impact with the functional unit described in chapter Part II chapter 1.4 should stay equal or be decreased in the redesign in comparison to the multi patient lead set.	Part II, 1.4.1

Figure 25: Requirements

2. IDEATION AND CONCEPTUALISATION

Ideating is inherently a non-linear process. In this chapter it is tried to capture the essentials of the ideation and conceptualization phase of this project to understand the storyline and choices made. To diverge and create a lot of ideas some idea generation methodologies are used. Apart from the ideas already found during the analysis an ideation on the circular recovery flows is done and a collaborative session at the factory side of the ECG Lead set has been undertaken

2.1 Ideation on circular recovery flows

Firstly, a round of ideation on the Circular Recovery Flows is initiated. This combines a more traditional ideation with the CRF to set the subjects to ideate around. This is to make sure to not miss valuable concept directions and further develop or change these to fit the desired recovery flows. Within ideation on the flows, I made mind maps to help me put ideas on fast. If an important aspect of the design came up in one of the mind maps and felt as essential for the solution, I used how to's to find solutions in other areas to solve this aspect of the design. An impression on this ideation can be seen on page 34 . The different groups are ideation rounds on each of the circular recovery flows. On the background the circular recovery flow chart can be seen.

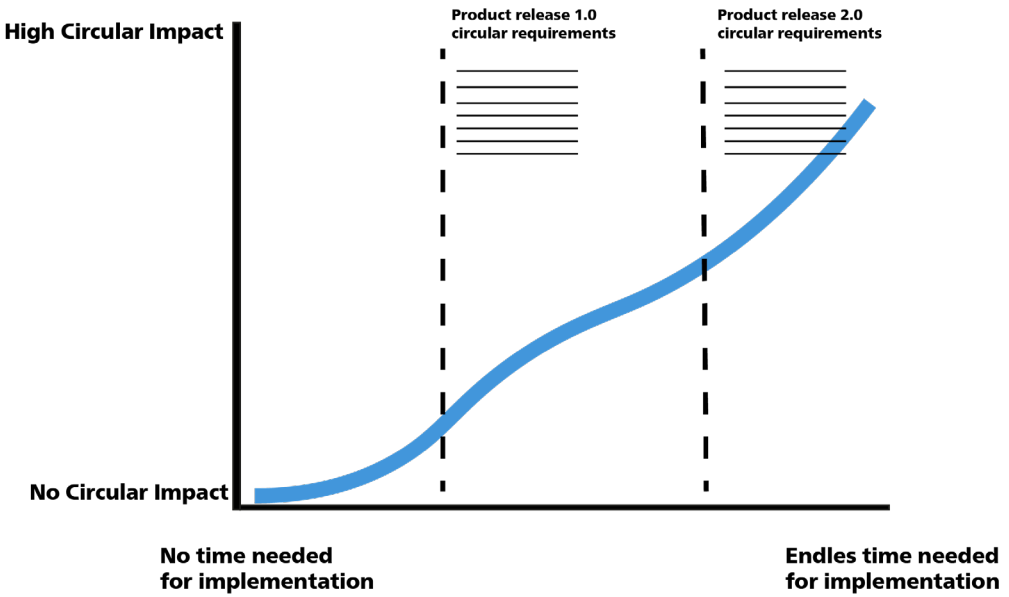
INSIGHTS/VALUABLE IDEAS

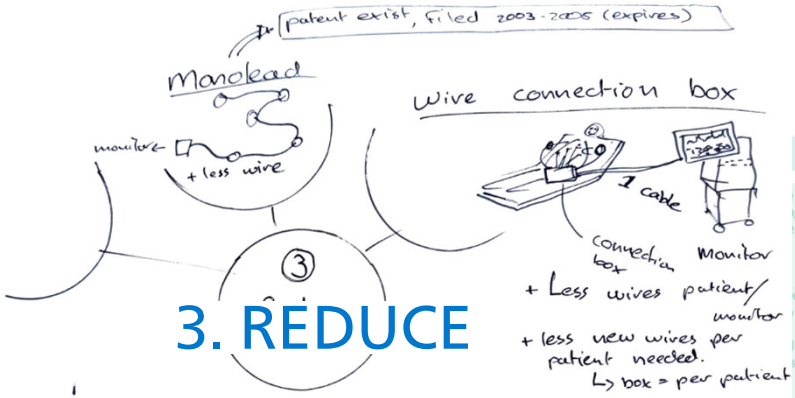
Important ideas from this ideation, which will come back in the conceptualization phase of this report, are the need for an easier cleanable lead set end without moving parts. The ideas that came with this are a magnetic lead set end and a lead set end in the form of a hook. The use of mechanical washing to make reuse easier did also came up as a promising direction. A impression on idea sketches can be seenon page 35. Here the two ideas are highlighted and explained in a bit more detail.

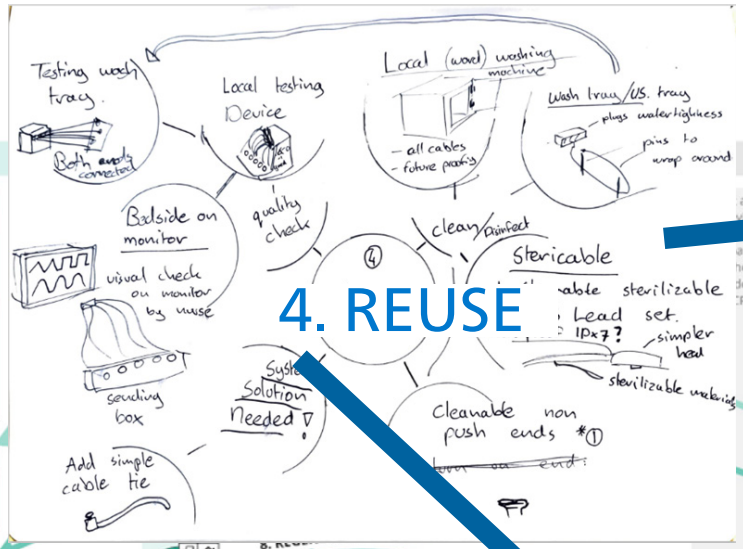
2.2 Collaborative design session

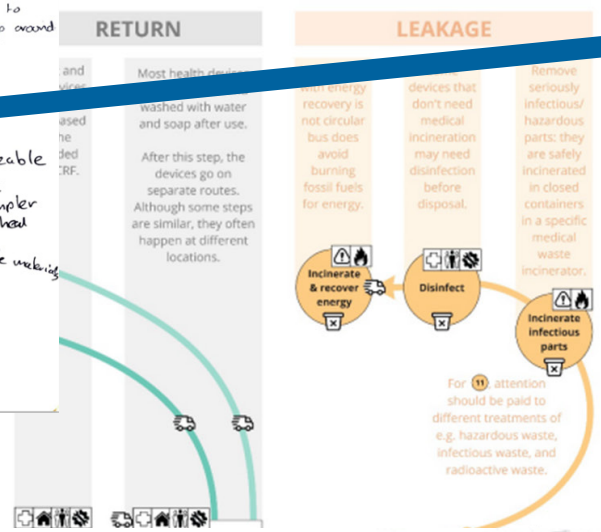
In week 11 of this project a visit to the manufacturer site and R&D site is conducted. The plan was to use the MATCEMIB (Belski et al., 2016) method to ideate on sub-categories. As it turned out, the session went differently than expected. While generating the first purge of ideas, the session took a side path into a more conceptual direction. The ideas where placed on a time line vs impact chart and so the idea for a circular roadmap came up. A representation of the session on this roadmap can be seen in figure 26. The idea of this roadmap was that small improvements with small impact would be implemented first and that at every product release deadline new circular improvement would be implemented. This roadmap is a sidetrack on the main design direction and will be further discussed in the discussion chapter of this graduation report.

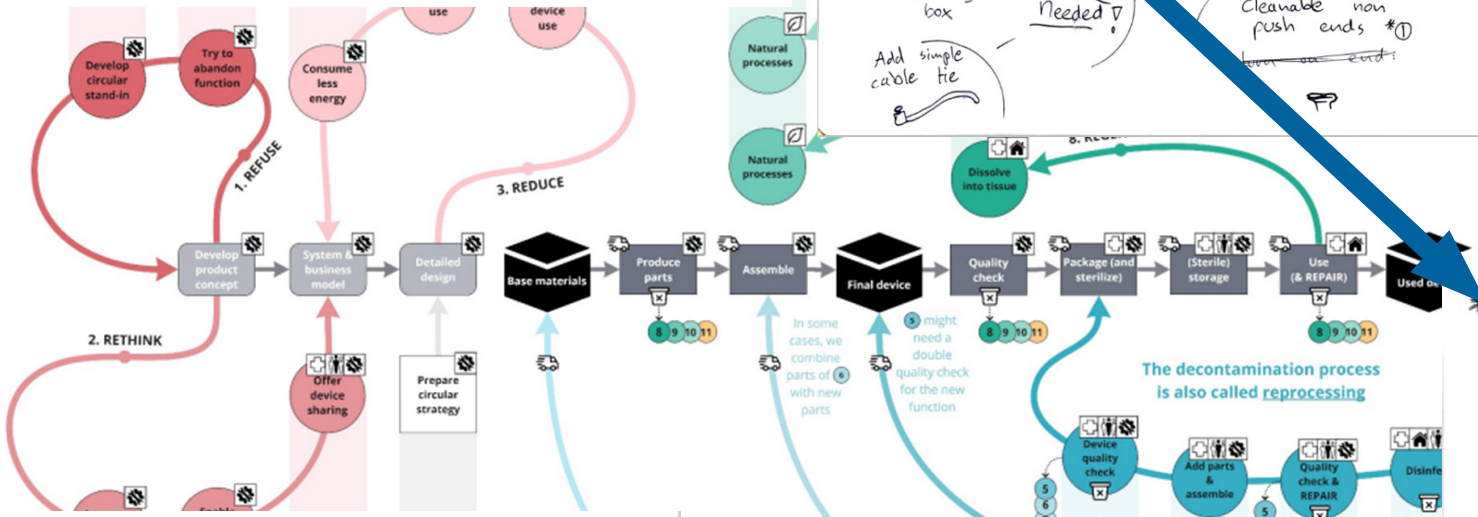
Figure 26: Roadmap visual

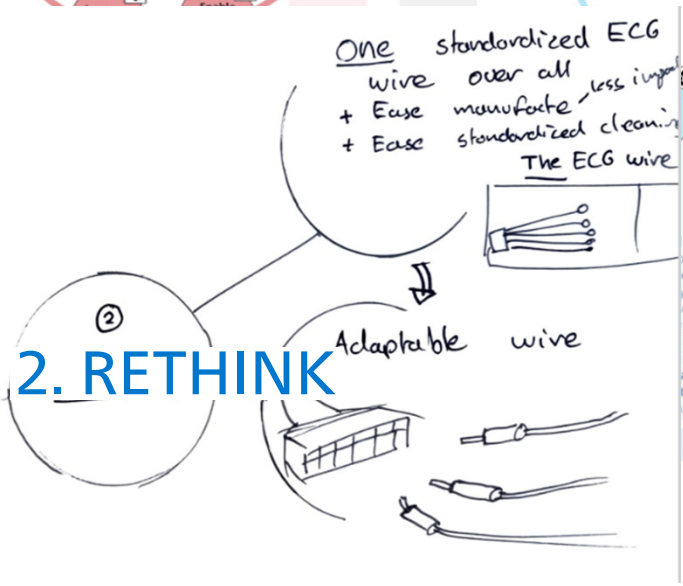


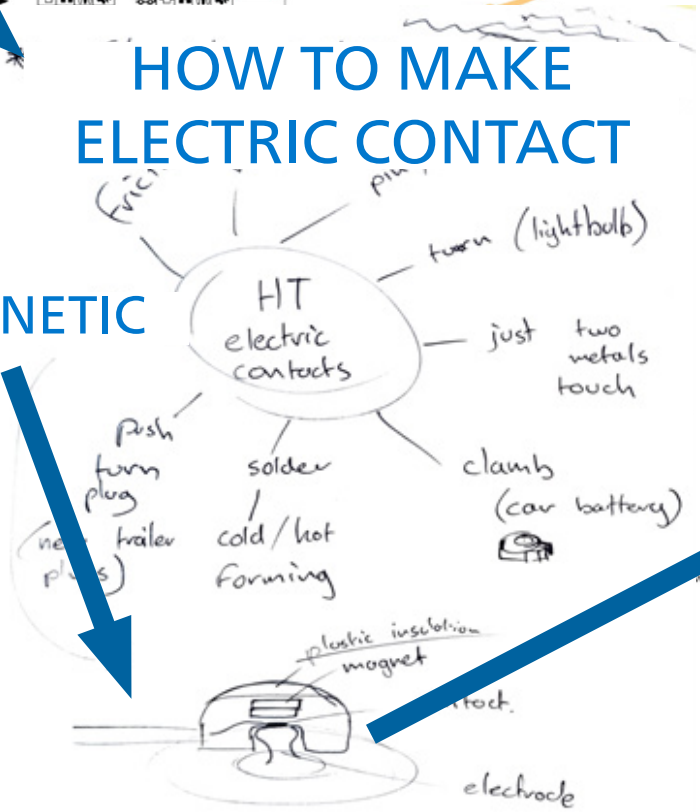

patent exist, filed 2003-2005 (expires)
Manolead
monitor
+ less wire
Wire connection box
1 cable
connection box
Monitor
+ Less wires patient/monitor
+ less new wires per patient needed.
↳ box = per patient
3. REDUCE


Testing wash trays
Both ends connected
Local testing device
Local (wand) washing machine
all cables
future proofing
Wash trays/US. trays
plugs watertightness
pins to wrap around
Bedside or monitor
visual check on monitor by nurse
quality check
sending box
clean/disinfect
Sterilizable
sterilizable
Lead set.
IDx7?
simpler head
sterilizable marking
Solution Needed?
Cleanable non push ends *①
Add simple cable tie
4. REUSE


RETURN
Most health devices can be washed with water and soap after use.
After this step, the devices go on separate routes. Although some steps are similar, they often happen at different locations.
LEAKAGE
with energy recovery is not circular bus does avoid burning fossil fuels for energy.
devices that don't need medical incineration may need disinfection before disposal.
Remove seriously infectious/hazardous parts; they are safely incinerated in closed containers in a specific medical waste incinerator.
Incinerate & recover energy
Disinfect
Incinerate infectious parts
For ⑪ attention should be paid to different treatments of e.g. hazardous waste, infectious waste, and radioactive waste.

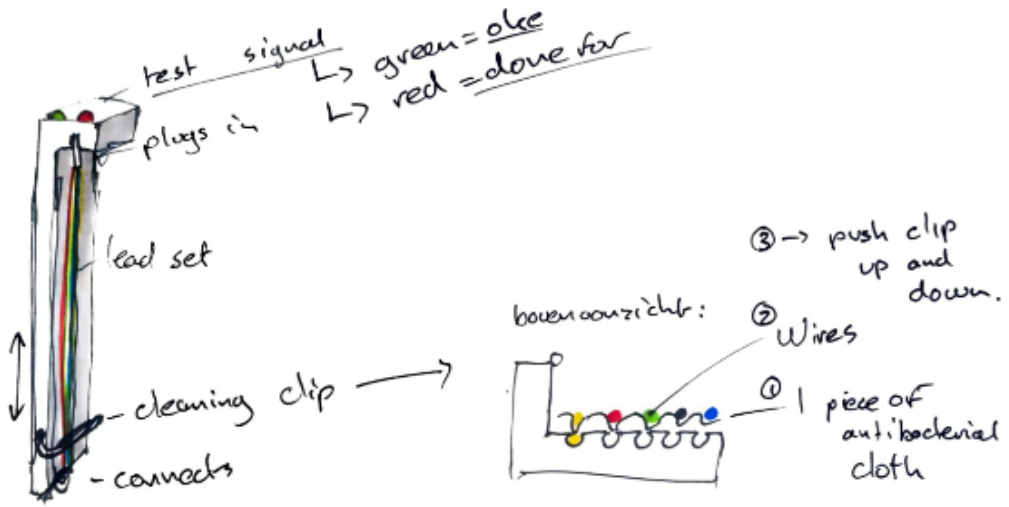

Develop circular stand-in
Try to abandon function
Consume less energy
1. REFUSE
3. REDUCE
Develop product concept
System & business model
Detailed design
2. RETHINK
Offer device sharing
Prepare circular strategy
Base materials
Produce parts
Assemble
Final device
Quality check
Package (and sterilize)
(Sterile) storage
Use (& REPAIR)
Used
Natural processes
Natural processes
Dissolve into tissue
In some cases, we combine parts of ⑥ with new parts
⑤ might need a double quality check for the new function
The decontamination process is also called reprocessing
Device quality check
Add parts & assemble
Quality check & REPAIR
Disinfe
Sort and melt the material
Shredding
Depollute
Process the materials suitable for recycling into production-ready base materials.
Shred the products into small parts that can be sorted into types of materials.
Hazardous parts (toxins, batteries, etc.) are removed.
Full device is checked to meet the set quality standards for a new device ⑥ or use cycle ④⑤
If needed, add (new) parts and assemble into the same ④⑥ or a new function ⑤
Parts are tested, and if possible repaired in case of defects. Non-defect spare parts are saved.
MECHANICAL STRATEGIES


One standardized ECG wire over all
+ Ease manufacte
+ Ease standardized cleani
The ECG wire
②
Adaptable wire
2. RETHINK

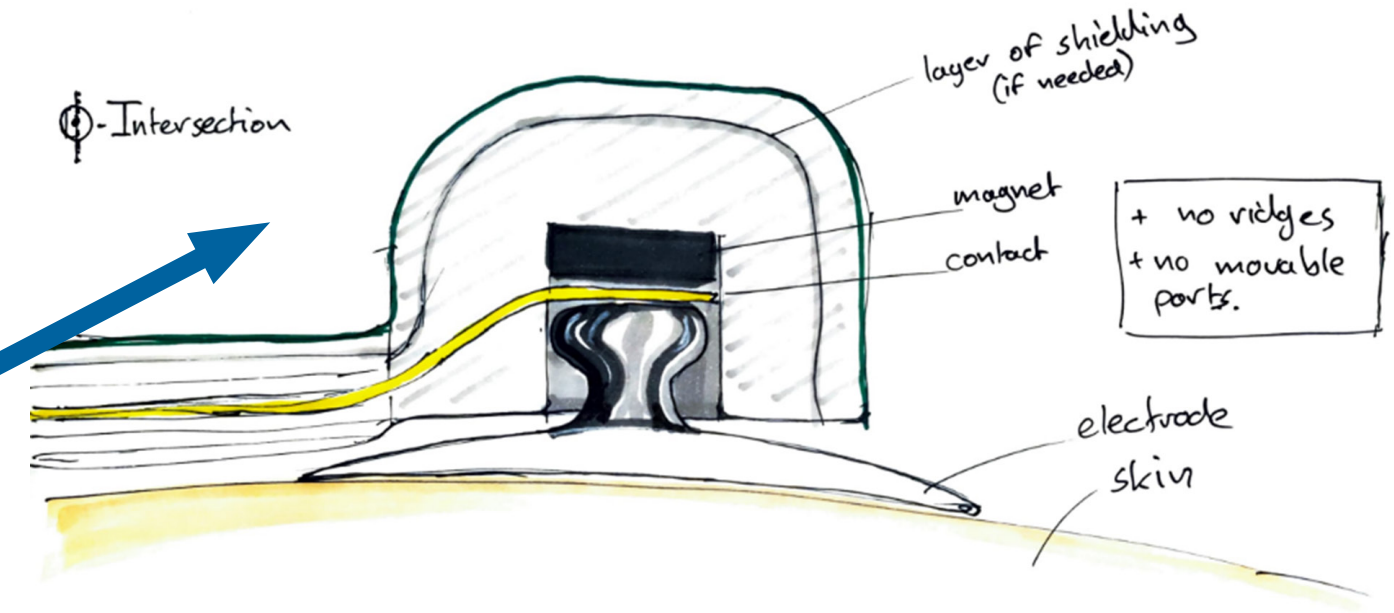

HOW TO MAKE ELECTRIC CONTACT
MAGNETIC
HT electric contacts
turn (lightbulb)
just two metals touch
push
turn
plug
trailer
solder
cold / hot forming
clamb
(car battery)
plastic insulation
magnet
electrode

ECG CLEANING RIG

Following from the reuse ideation on the circular recovery flow reuse; The ECG Cleaning rig makes cleaning the ecg leads easier by putting the ends on each side and then pull a kind of comp over all the leads. This cleans the leads in one movement instead of each lead on its own.



MAGNETIC ECG LEAD



Following from the how to make electric contact; The magnetic ECG lead connects to the electrode with the help of magnets. This creates a connection where there is no need for moving parts that can create cavities that are hard to clean. Further does it create easy of use while connecting and disconnecting the ECG lead set by not having the need to push together something to connect the lead.

2.3 Morphological chart

To bring structure and clarity to the found solutions a morphological chart is made. Within the chart there are 5 function/solution spaces. These are based on the main considerations to design the lead set for reuse. Cleaning is split up in two as it is important on a system level and product level. Quality control, track and trace and durable design are the other 3 solution spaces. The morphological chart can be seen in figure 27. By placing a coloured dots and in this way choosing a solution for each category, 5 idea directions where created. These where based on the amount of investment and technical difficulties it would take to implement the solution. After an evaluation on the requirements and presentation at the midterm point of this report the conclusion was that the idea directions all combined into one concept direction. This concept direction will be described in the next chapter.

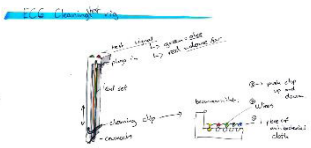
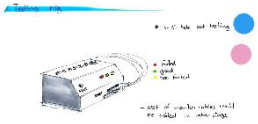
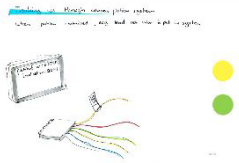
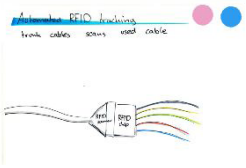
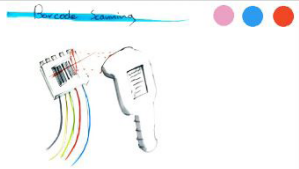
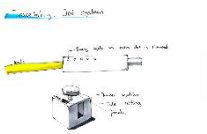
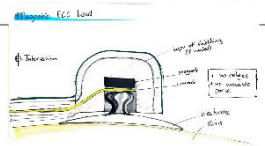
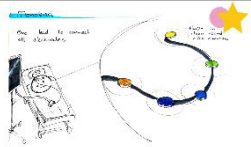
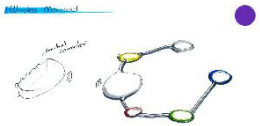
category	option 1	option 2	option 3	option 4	option 5
Way of cleaning	By hand microfiber towl 	Machinal washing disinfection 	Specialized cleaning/testing rig 	ECG Lead set washing/transport tray 	Machinal washing disinfection sterilization dep 
Quality control	Visual control by nurses monthly 			 add RFID scanner for traceability	 conventional testing
Track and trace	 Numbered lead sets	 RFID Scanning	 Barcode scanner		wifi/bluetooth update to system to monitor
Durability	Current leadset design	Waterproof leadset			
Cleanability of the lead set itself	Current lead set design (exeption on waterproofness)				

Figure 27: morphological chart

2.4 Concept direction

This concept direction will serve as a basis to further detail the concept on. The concept works the following: After the use of the lead set, the lead set will go to a washing and testing station, where this is located is still to be determined. In this concept the MPU lead set will be designed to be able to be cleaned using a mechanical washing machine. This reduces the amount of time needed from the nurse to wash the lead set. To make it easier for the machine to clean the lead set and prevent needlessly long cleaning cycles the design of the lead sets is optimized to have no small cavities or moving parts. Quality control will be carried out at the same location as the washing machine. For this quality control a testing rig used at the manufactures site as well would be fully sufficient. This testing rig tests both safety and signal quality. Within this testing rig an RFID reader will be implemented. Using a passive RFID tag in the lead set it is easy to track the lead set. After cleaning and testing the lead set will go back to the ward and be stored locally. A schematic overview of this concept can be seen in figure 28.

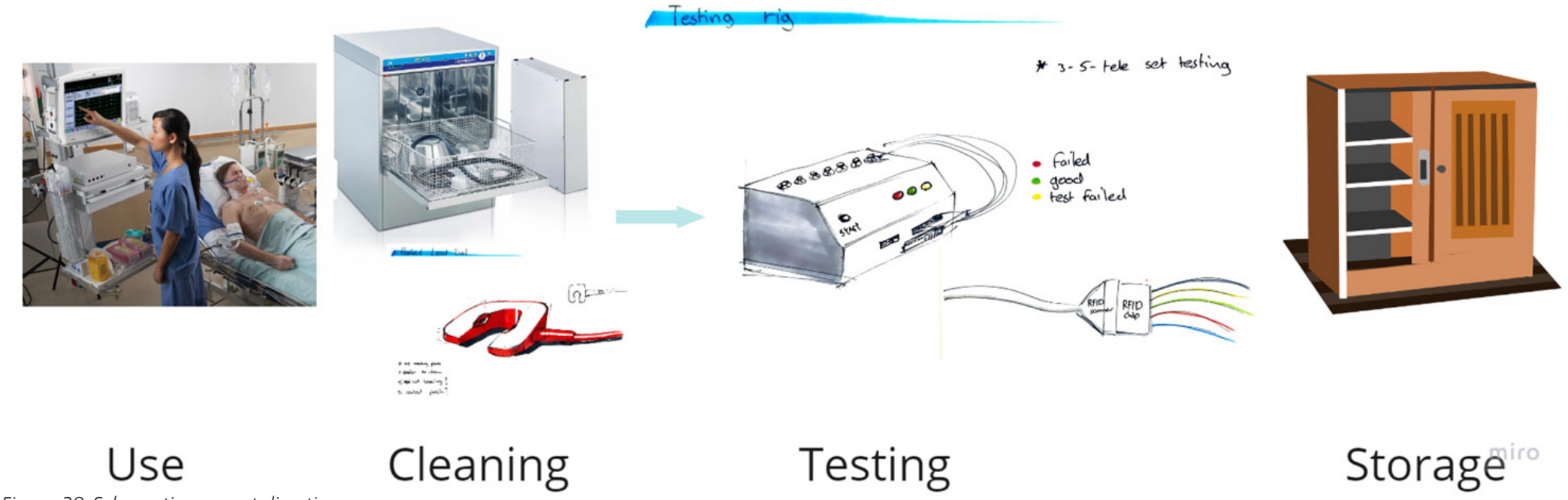


Figure 28: Schematic concept direction

2.5 Conceptualization

To further develop the concept direction three key areas are determined based on feedback from product managers and the visit to the factory in Boblingen. These are on a logistic level, where is the lead set going to be cleaned and tested and how does it get from A to B. On a Product level, how can the lead set be optimized to be easily cleanable. And on the specific way of cleaning, what is the ideal way to mechanically clean the lead set. Using SCAMPER and iterative design for each of the key areas are further developed. The SCAMPER results can be seen in appendix H. SCAMPER stands for substitute, combine, adapt, modify, put to another use, eliminate and reverse. These are the ways the concepts will be strengthened using existing ideas from the ideation phase and new ideas generated in this phase of the project. The conclusions on each of the 3 key areas together form the concept for this graduation project. This will be presented in chapter 3.

2.5.1 Logistics ECG lead set

To clean the lead set 4 departments or cleaning flows can be described, locally at the ward, via the central bed cleaning department, via the sterilization department and via an external service provider. These options come from the analysis of chapter 1.4 and an interview with the logistical manager of Reinier de Graaf Gasthuis. All options are developed using storyboarding. Based on the interview and feedback on the storyboards from the logistical manager of Reinier de Graaf Gasthuis there has been chosen to use the logistical capabilities of the central bed cleaning department for the lead set as well. How this works can be seen in chapter 3.1.

2.5.2 Product optimization for cleaning

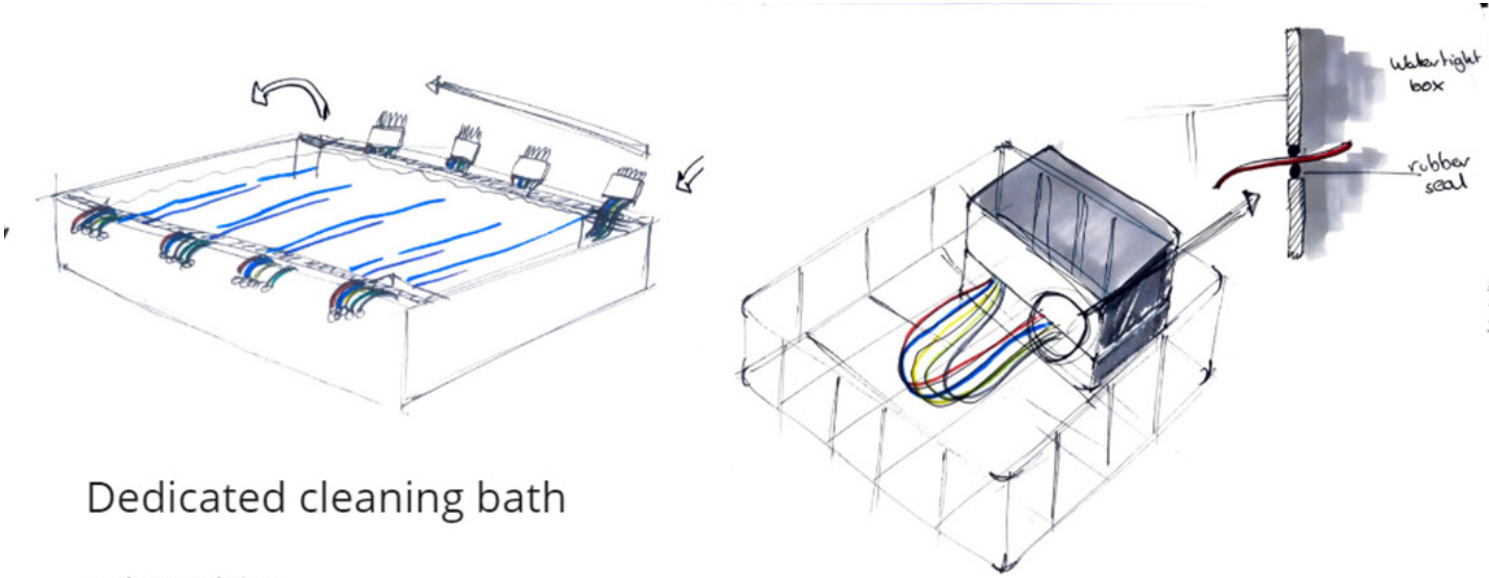
Already early into this project the idea came up to use magnets to connect the electrodes to the ECG Lead set. This idea has been presented at the factory in Boblingen together with other ideas and received the best feedback. Therefore a magnet will be used to connect the lead end to the electrode, further detail on this can be seen in chapter 3.1. The first sketch of this idea can be seen in chapter 2.

2.5.3 Way of mechanical cleaning

At the factory in Boblingen the idea of creating a waterproof washable MPU Lead set has been discussed. Using the 3d models it was explained why it was close to impossible to make the lead set waterproof without changing the whole manufacturing process. Both ends of the lead set included bare metal parts that could easily corrode and on the edge of the metal to plastic water ingress due to the flexibility of the plastic could occur. Therefore, a mechanical cleaning solution had to be ideated with protection for the two vulnerable ends. The results of this ideation can be seen in figure 29. Based on the positives and negative points added to figure 29 there has been chosen to go with a protection box within a specific washing tray. The vulnerable ends will be in the box and sealed from the liquids by rubbers seals around the cables.

2.5.4 Back to hand cleaning

From the validation phase of this project, it turned out that mechanical cleaning is not a valid solution. Mechanical cleaning took more time than cleaning by hand due to the positioning of the wires within the washing machine. Furthermore,it turned out that the washing machine at the bed department felt unnecessary (by the logistical staff) if they also could take a wipe and clean it with this. The low fidelity prototypes to test with at home with the dishwasher did also not create desired results with the lead ends not being protected. This was a step back in the design process; therefore the loop back is made to the initial ideas where an idea for an aid for hand cleaning could be found, this is further developed and taken into the concept at this stage of the project. This can be seen in the concept detailing chapter 3.



Dedicated cleaning bath

+ long week time,
+ low risk of water in connectors
+ easy to use

- Dedicated machine for lead set
- Costly investment
- Every product own machine costs a lot of valuable space

Protection box in washing tray

+ Simple solution, no special machine needed
+ low risk of water in connectors
+ easy to use
+ cross compatible with other wire sets from monitor

- Chance of getting cables stuck and brake them in this way
- Settings on washing machine and ditergent used should fit cable sets and other products
- Chance of tangling of cables

Connected washing tray

+ Simple solution, no special machine needed
+ easy to use

- Higher risk of water ingress in cables
- Connecting cables reduces the amount of lifecycles that can be used on patients, cables wear faster
- Settings on washing machine and ditergent used should fit cable sets and other products
- Special rack needed for multiple product solutions

miro

Figure 29: Ideation mechanical cleaning

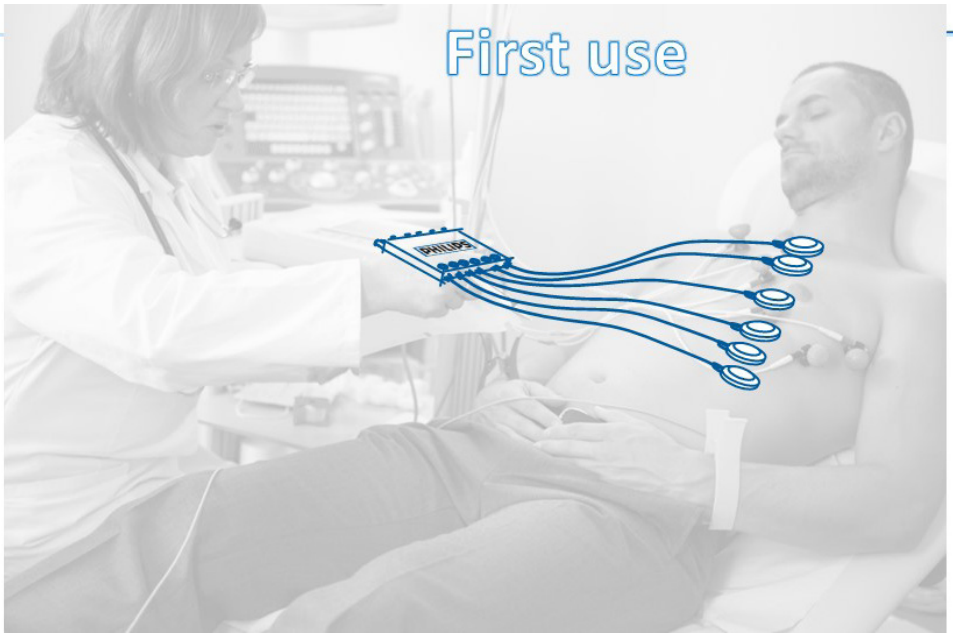
3. CONCEPT DETAILING

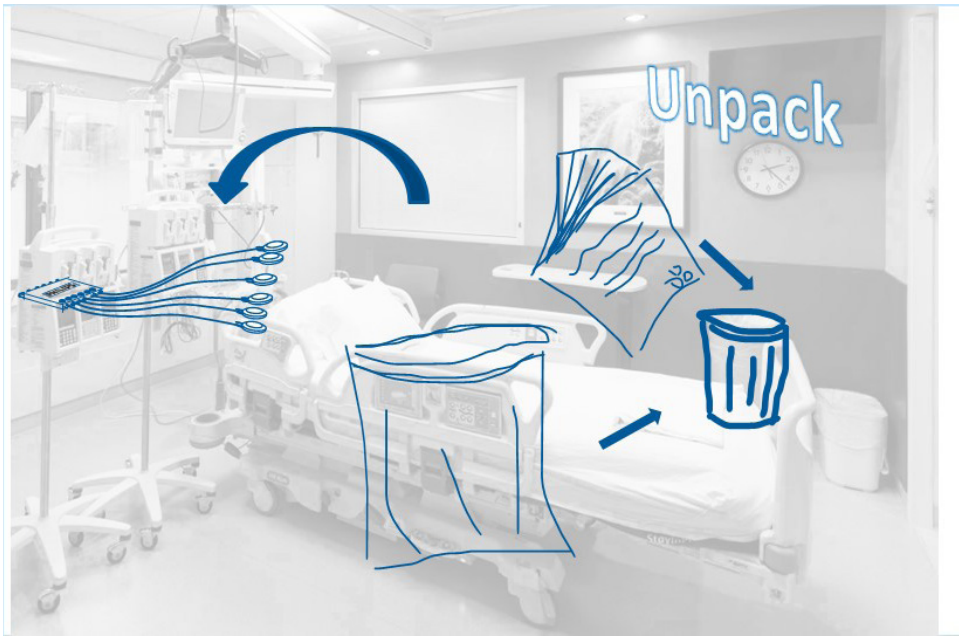
This chapter will mainly serve the purpose of showing the design concept and has more detailed information on the proposed solution. To make sure the key area solutions from chapter 2.2.5 work together well a final storyboard is made. This will be presented in the first paragraph and will also highlight the logistic system. In the next paragraph the report will go into the redesign of the lead set. Concluding with a paragraph on the hand cleaning tool and its specific use scenario.

3.1 Storyboard of the proposed solution

This storyboard shows the logistical system. Beds are collected when dirty or monthly when they expire. This is done when a nurse puts an order for a clean bed in a centralized system. With this order, the order for a Cardiac Care Unit (CCU) package would be included in the new scenario. This makes sure that a bed comes in with the right equipment for the next patient. This system is expandable for other parts of the hospital where the ECG Lead set is used. In between the monthly deep clean and testing cycles the bed and lead set will still be manually cleaned. For the manual cleaning at bedside of the lead set the cleaning tool can be used as well.
From this point the storyboard will be shown.


Storage

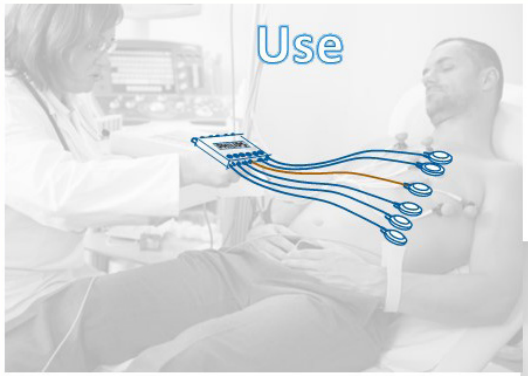

First use


Unpack


1hr to 7 days of use
Dirty spots

Hand cleaned with bed

Use

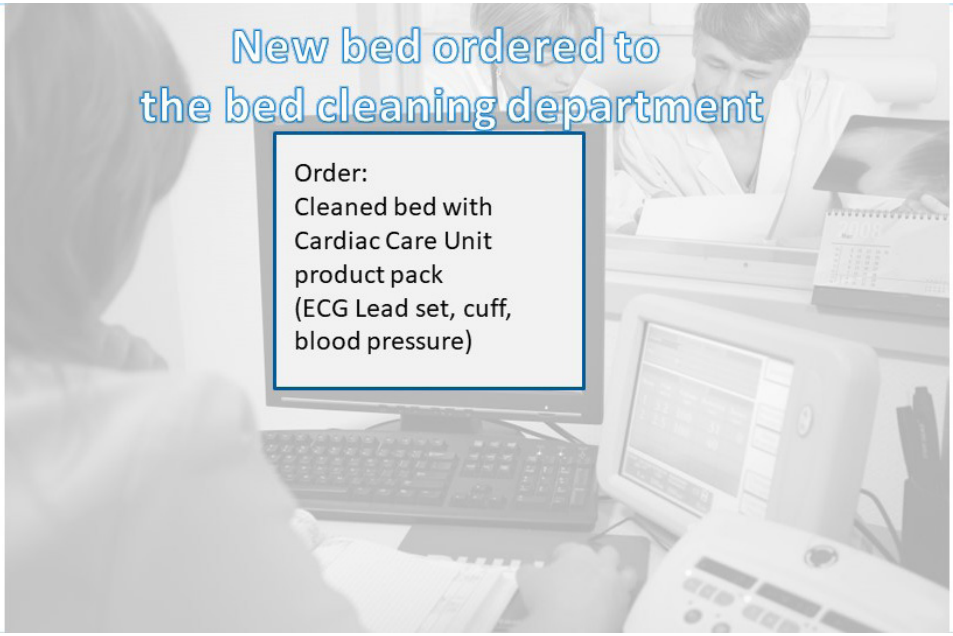


10 – 30 cycles

Hand cleaned

Monthly scheduled deep clean and quality of the bed

New bed ordered to the bed cleaning department



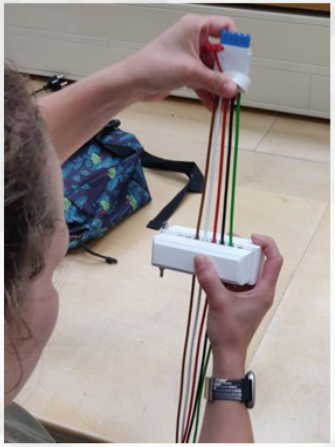
Bed goes to cleaning department

Clean bed with CCU package comes in

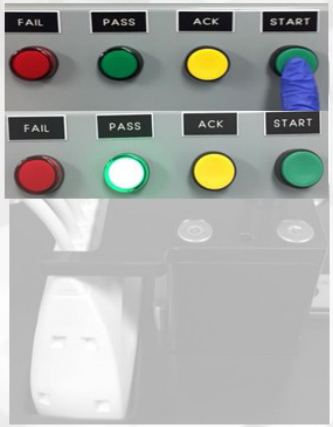
At the bed cleaning department

Deep clean bed and lead set

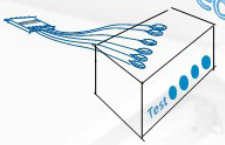
Hand cleaning with tool



Quality check of bed systems and lead set



Broken? Thrown away clean for recycling



RFID and data system, to ensure safety and quality

Storage of bed and lead set

Waiting for next order
in logistic system

Electronic waste recycling

3.2 Redesign of the ECG lead set

For the redesign of the ECG Lead the core idea was to put the contact between the electrode and a magnet. To get forces to hold the lead set in place the magnet should be partly above the electrode nipple. But to ensure that the magnet sits tight the magnets should also exert a sideways force. For this reason the magnets are put in the lead set end with an angle. This with the idea to create a force upwards as well as sideways. In the renders in figure 30 the contact and magnets can be seen. In production the contact metal (bronze coloured) could also help to keep the magnets in place, as they will attract each other. With this design there are no moving parts needed. The shape of the lead end can be rounded and without edges which makes it easy to clean. Another strong point for signal integrity that came up at the factory visit is the possibility to increase the contact patch in comparison to the original design. This could result in enhanced signal quality.
For this project multiple options on the placement of the magnets have been developed. This with the goal to increase the stability and strength of the connection made. These can be seen in figure 31 In chapter 2.4.2 it is further explored which of the options works best with force tests. It will show that the ideal solution has not yet been found.

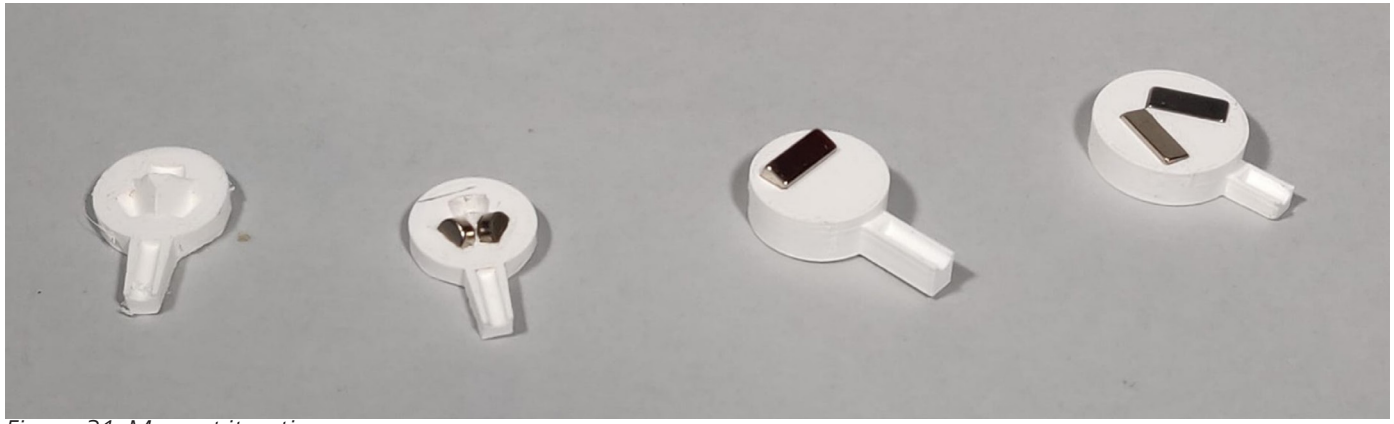


Figure 31: Magnet iterations

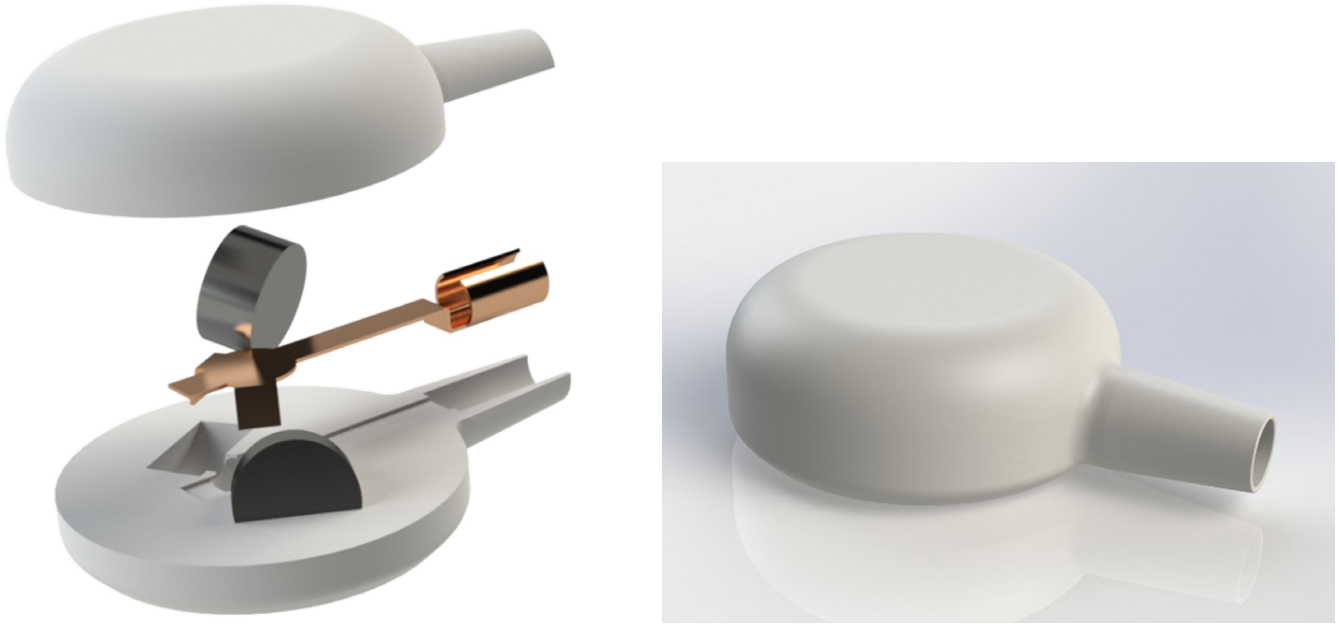


Figure 30: Renders lead set end

3.3 Design of the hand cleaning tool

The hand cleaning tool is a late adaptation in this project. Based on the original idea which can be seen in chapter 2 a simplification step has been done by discarding the big rig to put the lead sets in and only keeping the cleaning comp. Of this small tool multiple options are developed. It consists of two halves that are clipped over a lead set to grab all the wires. Due to the small arches the leads do not tangle and cross each other while pulling the tool over the wires. The cleaning should be done from the monitor side to the lead ends. A sponge with cleaning agent (see appendix I for list of compatible cleaning agents derived from a cleaning guide by Philips) in the centre of the tool does the cleaning. In this way the wires can get easily and fast cleaned in one movement. Note that different lead sets are compatible with different cleaning agents. The lead ends still need to be cleaned by hand with a cleaning cloth. A standard size sponge does fit in the tool. But to ensure a good fit this will have to be ordered from Philips. See figure 32 for the iterations of the lead set cleaning tool.

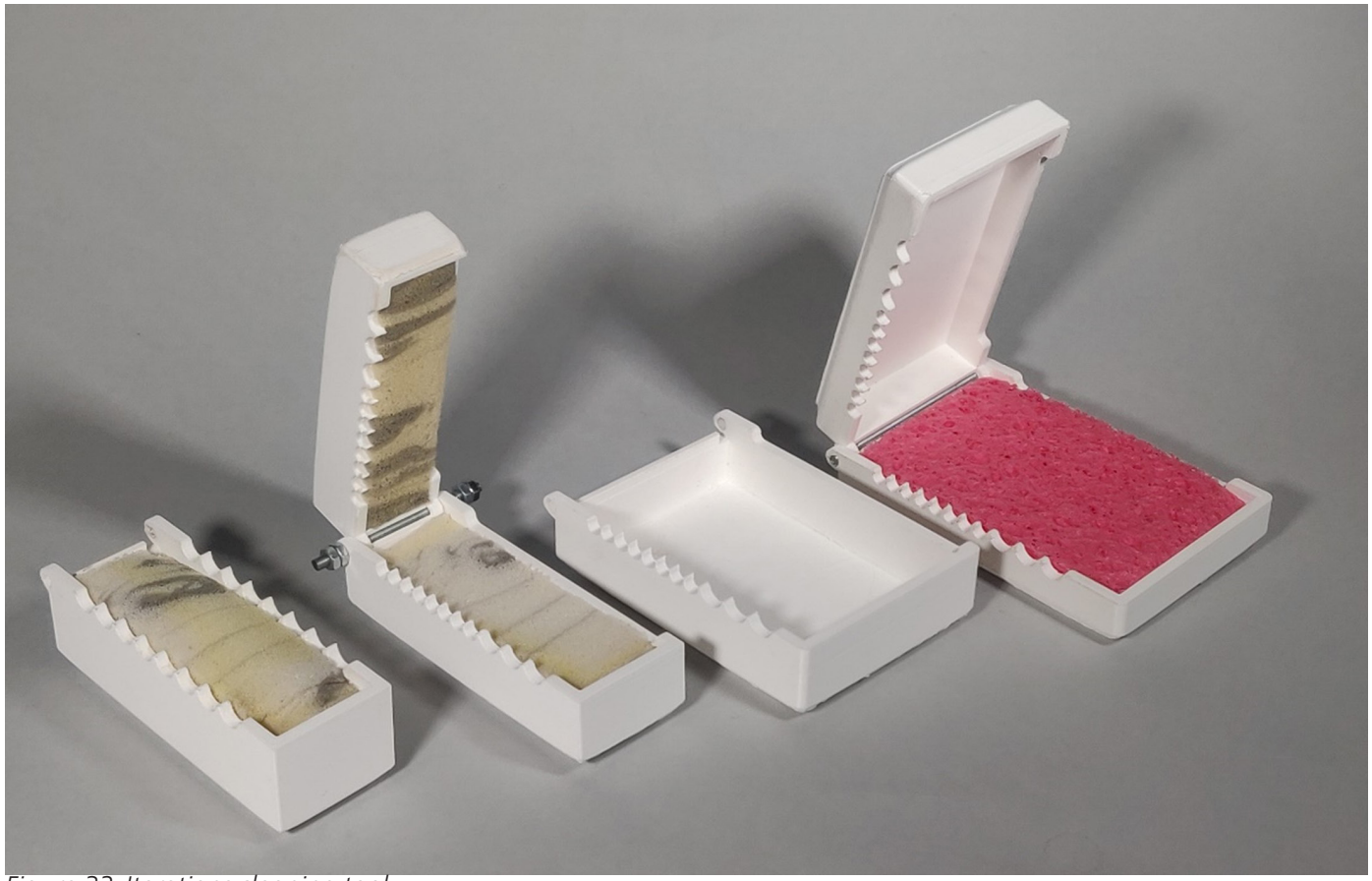


Figure 32: Iterations cleaning tool

4. EVALUATION AND VALIDATION OF THE CONCEPT

This chapter will describe how different parts of the concepts are validated. At this point of the project some validation¬¬s have not been done yet but are planned. The validation will be done on the 3 key areas described in chapter 2.3 (logistical, product level redesign, cleaning tool design) as well as a financial and LCA comparison to the current scenario.

4.1 Logistic

Validation on the logistical part of the concept is done in collaboration with logistic manager of Reinier de Graaf Gasthuis in Delft. This validation is done on the 21st of june 2024. Together with the logistic manager the storyboard was reviewed. The feedback was that the system could be implemented but that extra training for the quality tool would be required. An step by step guide should come with the tool to make it as simple as possible. Another point was that this testing tool could be placed at a different part of the logistical system. This would not create extra work because of the logistical system already going back and forward a lot to all other parts of the logistical system. Overall he could not point at critical failures of the system, when asked if he would be open to a pilot study the reaction was mildly enthusiastic. This should go via the innovation group at RdGG, as first more validation steps should be done.

4.2 Lead set redesign

To validate the lead set redesign iterations of different prototypes with different magnets and position of the magnets are made. The prototypes made give some good first impressions. Every prototype was a step in the right direction. Important criteria for this was the feel of the stability of the connection. With this the latest prototype is one with two stronger square magnets angled towards the electrode nip. This is the prototype seen on the right in figure 31. These prototypes are shown to a product manager at the R&D facilities in Boblingen, germany. The initial reaction is positive, but some concerns have been highlighted. The main concern is the stability of the connection. This stability is important for the quality of the signal. Movement of the connector on the electrode can cause signal artefacts that make the ECG measurement harder to read out. For the current design lead set a testing protocol has been implemented. This protocol has been shared with me to test this new design on. The precise angles and forces are confidential and so are not implemented in this report.

4.2.1 Test results

All prototypes are tested on the protocol. The grabber end in figure 33 yielded the best results. On a sideways force (0 degrees) this came up to 214% of the min force, but did not meet the specifications at max force at 118%.

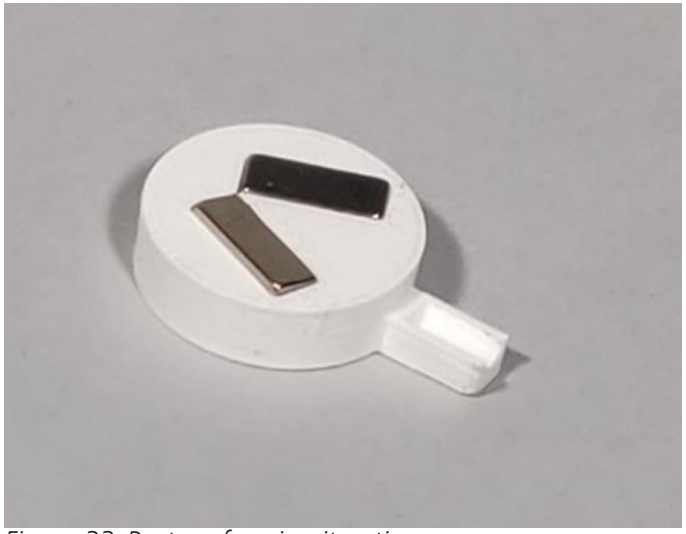


Figure 33: Best performing iteration

In a 45 degrees angle the iteration came up to 41% of the minimum force and did not exceed the maximum forced. And on a 90 degrees angle the iteration came up to 16% of the minimum force and did not exceed the maximum force. Full result of the 3 iterations tested can be found in appendix J.

The result do not meet the specifications jet but are promising. The retention on 90 degrees should be improved further. This can possibly be done by adding magnets on top of the electrode to keep it locked in to that direction better. This would be recommended to further do research and development on.

4.3 Cleaning tool

The cleaning tool prototype is 3d printed and tested with two students at the faculty of industrial design. In the test they were asked to clean a lead set with towels and with the cleaning tool see figure 34. The first point of feedback was the misalignment of the indentation made and the beginning of the wires of the lead set, for this see figure 35. Multiple leads fall into 1 indentation which is not ideal. This is something easily adapted. Also, the indentations could be one sided. This would create less friction.
The second point was that the device was too thick in a vertical direction for small hands, this is easy solved by thinner sponges and therefore an overall thinner device.
A third point made is that the leads get stuck when closed too firmly, a stopper could easily fix this issue. In comparison to the cleaning method with towels this device took less time but took the participants some getting used to. The second and third time using the device went a lot faster than the first time.
The above findings are adapted in the iterations shown in chapter 3.3. The thinner tool and standardized sponges are a step in the right direction. The good alignment of the wires made the tool more intuitive and easier to use. Further user testing with this iteration is advised to optimize the process. A possibility for this would be the option to mound the tool to a workbench for cleaning at the central bed cleaning department. This would not work at the wards as here the lead set will stay connected to the monitor while cleaning.

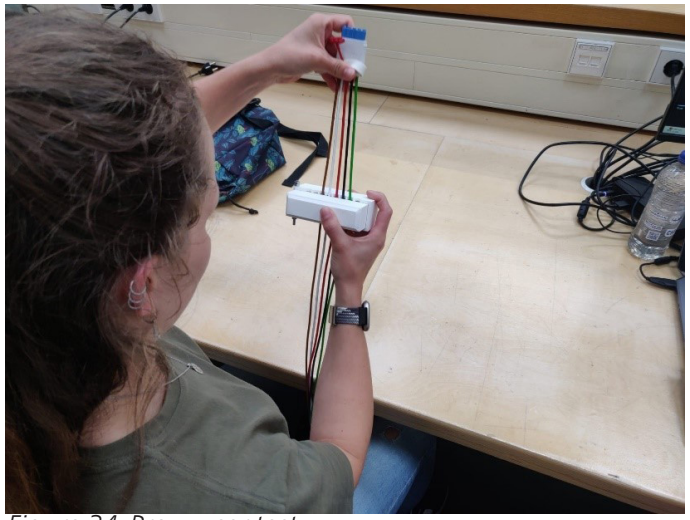


Figure 34: Proxy user test

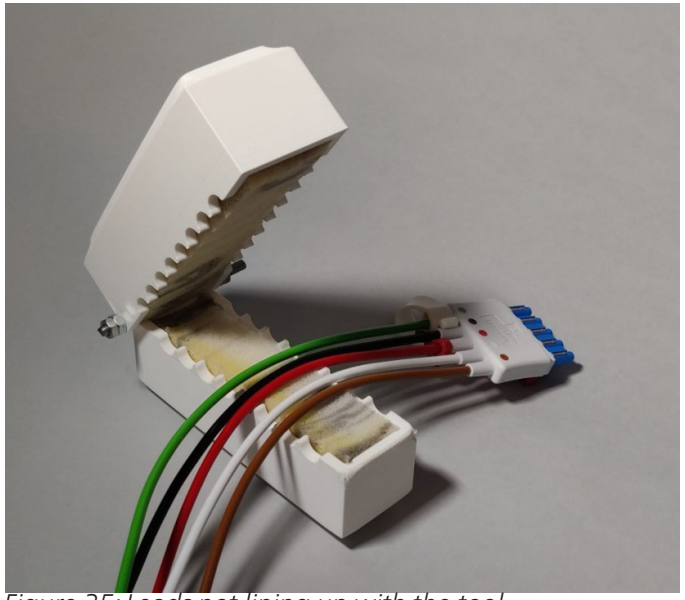


Figure 35: Leads not lining up with the tool

4.4 Financial

In this financial comparison there will be mainly looked at the hospital perspective. A rudimentary budgetary has been made which can be seen in appendix K. This resulted in a cost per FU of 265 euro for cleaning for the original system with wipes and of 272 euro of the new system. This slight increase in cost should not be the problem for implementation. What did come up was that the cost of personnel cleaning was the main contributor. The estimated time that could be saved with the cleaning tool has a big impact on this cost comparison and should be further researched.

4.5 LCA

When comparing the impact of the cleaning tool some assumptions have been made. To clean a FU 10 sponges are needed and alcohol is used as a cleaning agent. This resulted in a slightly bigger impact for the cleaning tool. But it is still a vast improvement over SPU lead sets. The results of the LCA comparison can be seen in figure 36.

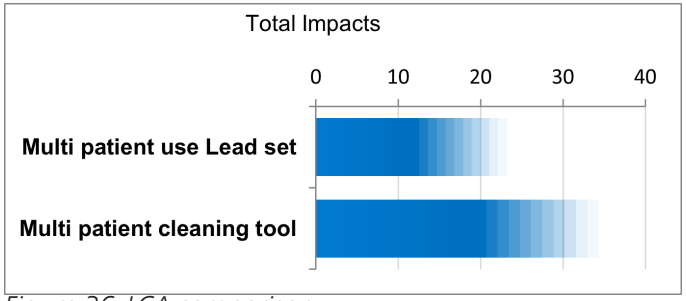


Figure 36: LCA comparison

PART III:

EVALUATION ON METHOD

This chapter will be used as an evaluation of the used methodologies within project. This is mainly focused on eco design methods and not on the more generic design methodologies. Starting with the methods used in the analysis phase of the design case study. An evaluation will be done on the fast track LCA and Circular product readiness method. How they compare and if the combination was perceived a logical one. During the analysis phase I came up with a method to combine barriers and opportunities and I will shortly discuss why this was not a valid method. The feedback on this came from my chair and mentor for this project.
During the ideation phase the CRF were used to ideate on, an evaluation on this will be included.
After this a section with recommendations from my learnings around circular methodology will be added.

1. Evaluation on fast-track LCA

The fast-track LCA gives detailed information of the amount of impact for a product. This is a blessing and a pitfall in one. From working earlier with LCA I knew the importance of the data used for the results. In this project it was hard to find the data but I believe the estimates to be in the right ballpark. Visiting the factory and hospitals to see production and use phases of the ECG lead set was essential for this. However even when asked face to face estimations on number where not given. This data secrecy is something that I did not expect and could hamper the future of LCA implementations in businesses. Another concern is that often the marketing experts do not understand the principles of LCA fully. This could result in false claims being made by businesses, within this project I (together with the LCA team) tried to explain this as good as possible to the involved stakeholders from the business side. For evaluation of SPU products vs MPU patient a problem with LCA lies in the cleaning methods used. From hospital to hospital this is done slightly different, which can have a big impact on the MPU LCA and so on the comparison of the impact. For example the use of warm or cold water can have a significant impact as shown in figure 37 where warm water is used instead of cold water. For further research this means that it is important to look at real world use scenarios and not only at the things said in the manuals of products.

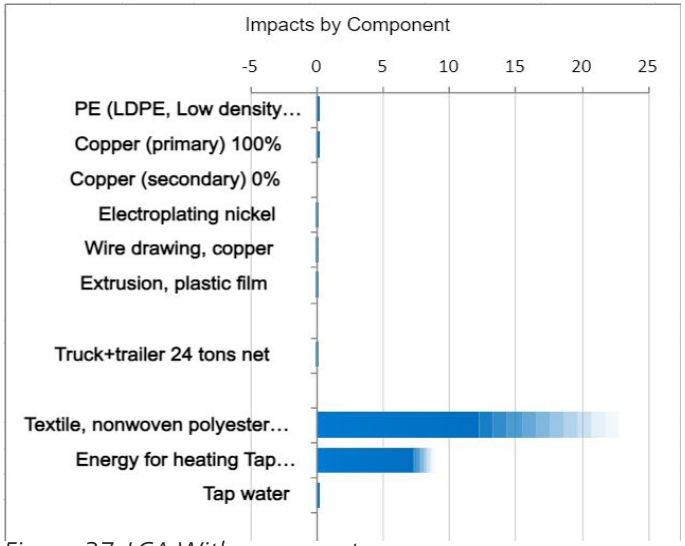


Figure 37: LCA With warm water

2. Evaluation on circular product readiness method

For this project, I feel the main value of this method lies in the integration of company and product assessments into a single framework. I believe that it could be a highly valuable tool to initiate a sustainability assessment and gain insights into the areas within a company or product line that require attention for a more thorough sustainability evaluation. Within Philips, a range of assessment tools for different business units is available, but none combines all aspects in the way this method does. With this reason I did send the publication about the method to the person responsible for sustainable assessment tools, which was received positive. A point of consideration is the treatment of scores deemed 'not relevant' or lacking data within the scoring system. It is not clear whether these should be included as 0 percent or should be fully disregarded. For now, they are implemented as 0%. Recommended would be to discuss with the industry experts that filled in the list of questions if it scores low or is not something that is normally applicable to the product (category). This should be done per each question that scores 0. This will give the most realistic view in the outcomes where problems/opportunities could be.

3. Evaluation on combination of LCA and circular product readiness method.

Due to the different scopes of the LCA and Circular product readiness method, I feel they make a strong combination. It feels that the LCA can pinpoint the area of the product life cycle with the most impact. The Circular product readiness model can then help to improve this area by showing lacking supporting systems as budget for sustainability within the company or knowledge about the lifecycle after point of sale. The combination of this information can strengthen both methods. I do believe they work on other levels within an organization. This can both be a strong point as well as a pitfall. I feel the circular product readiness method will speak more to the management part, while the LCA will speak more to the engineering staff. If combined this can put all noses in the same (hopefully right) direction. If the LCA and circular product readiness method are not checked upon each other it can create conflicting strategies within a company.

4. Evaluation on method ideation on CRF

Ideation on the CRF's made it easier to focus ideation on circular thinking. Unfortunately, from CRF 5 onward (Repurpose) ideating on the CRF did not spark a lot of strong valuable ideas. What did come up is that within the rethink flow all ideas were not within the 5 year scope of this project. Which resulted in the conclusion to mainly focus on the re-use flow. I feel using the CRF to ideate on works well but the ideas should be combined to get to concept directions with value.

5. Method development exercise

Apart from already existing methods a new methodology was tried out during the analysis phase. As it turned out to be a doubtful adaptation it has not been included in the final report.
The work process was based on mapping found barriers and opportunities for the ECG Lead set on the CRF's. This would then give an overview at what flows a lot of barriers could be seen and on which flows a lot of opportunities could be found. This then could be used as an indicator what CRF could be a valuable design direction. The huge problem with this approach is that one barrier could be more important than 10 opportunities. Furthermore, it is highly subjective which barriers and opportunities are connected to which CRF. As most of them do connect to multiple CRF's. In learning on circular design methodologies trying this work process has been a helpful step for this graduation process but it did not create valuable results to be implemented in the design case study. The list of barriers and opportunities can be seen in figure 38 and the mapping of these on CRF's in figure 39.

	Barrier	source
B1	Safety risks, infection contamination	Report 2.1, Interviews nurses
B2	Financial constraints	Report 2.1, Philips R&D
B3	Unsuitable device/material characteristics for circular strategies	Report 2.1, Philips R&D
B4	Time constraints	Report 2.1, Interview nurses
B5	Differences in device value (high value gets circular priority)	Report 2.1, Philips innovation and engineering
B6	Willingness to adapt to new processes	Interview sterilization department
B7	Regulations slowing down innovation	Interview Product mangager
B8	Unintended use scenarios	Interview nurses
B9	Trend of switching to single use	Literature research

	Opportunity	source
O1	System thinking & service concepts	Report 2.1, Philips innovation and engineering
O2	Circularity stimulating regulations, guidelines, and standardization	Report 2.1, Interview at sterilization department
O3	Increase and improve reuse/decontamination of the product	Report 2.1, Interview nurses
O4	Environmental benefits as a motivator	Report 2.1,
O5	Make use of existing collection methods	Report 2.1, interview sterilization department
O6	Intrinsic motivation of hospital staff	Interviews nurses and sterilization department
O7	Keeping backward compatibility	Interview Product manager
O8	Obtaining use data to push sustainable development	Literature research
O9	Integrating small healthcare electronics into the electronic recycling flow	Interview WeCycle Nederland Report 2.1

Figure 38: Barriers and opportunities

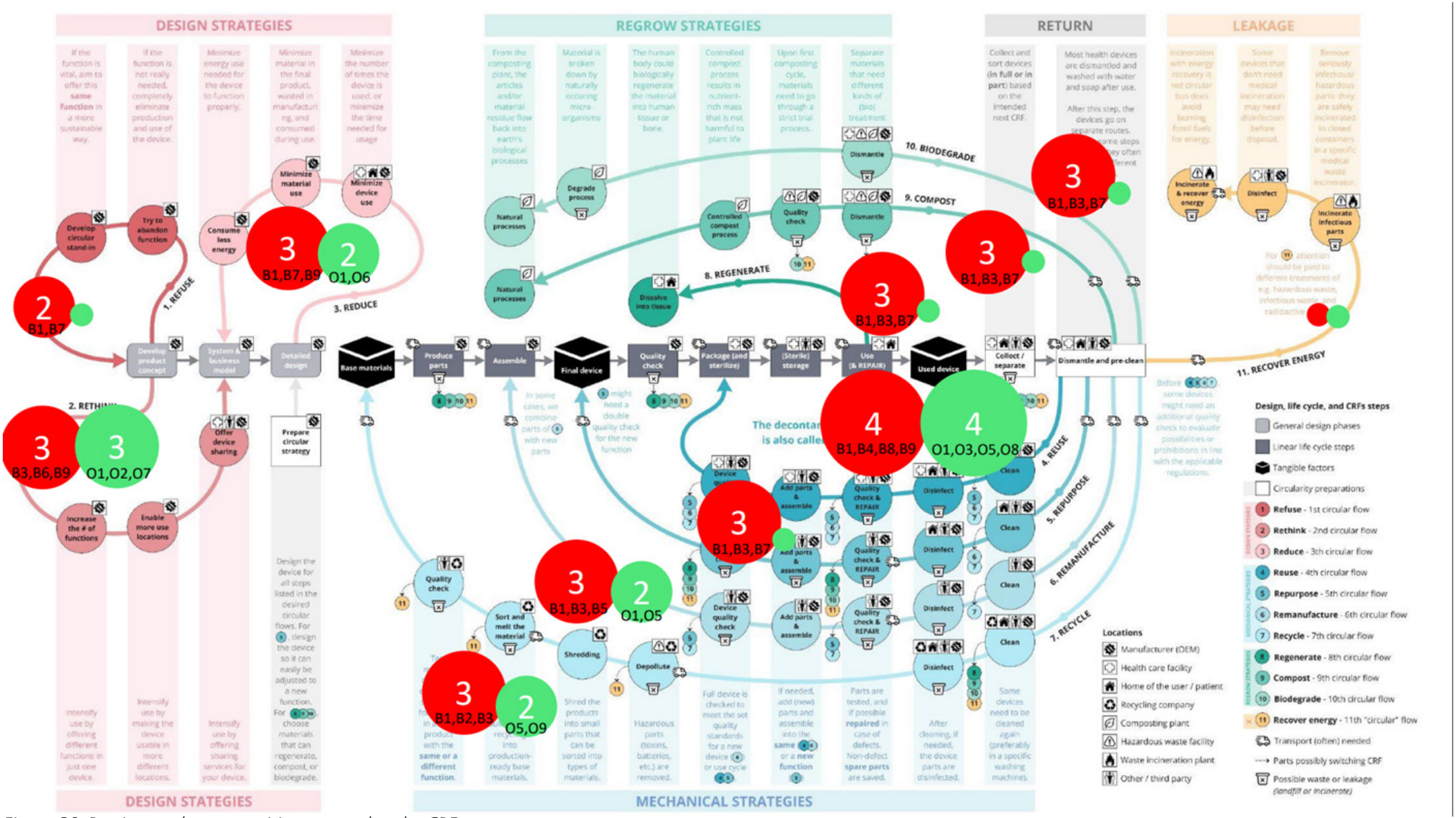


Figure 39: Barriers and opportunities mapped at the CRF

PART IV:

CONCLUSIONS AND RECOMMENDATIONS

This chapter will recap on the findings within the design proposal and methodologies used. Further limitations and recommendations regarding the project and a personal reflection are included as well.

1. Conclusion

The ECG measurement is a widely adopted diagnostic tool. For the ECG measurements the Lead set plays an important role. The ECG Lead set served as a case study to evaluate circular design methods within the medical sector. The original assignment for this project was the following:

Develop and evaluate a circular design method with the multi-use lead set for Philips as a case study in hospital settings.

Circular design methodologies are used to create a concept that decreases the impact of the ECG Lead set system. For this concept it has been important to not only look at the product level impact but also at system factors. An important factor was the trend of the medical sector switching from multi patient use (MPU) lead sets to single patient use (SPU) lead sets. To decrease impact the core of the concept laid on developing the MPU lead set in a way that the MPU lead set would be more widely adopted again. This is done by optimizing the logistic flow, product design and cleaning process.

2. Limitations and recommendations

In any research limitations do occur. This chapter describes the limitations and recommendations from this graduation project.

2.1 Recycle flow

Within this project the main focus has been on the Reuse CRF. Other flows have been in consideration and a valuable opportunity was found within the recycle flow. I have had an interview with a project manager from stichting Open, the main organization behind WeCycle. WeCycle organizes the electronic waste recycling in the Netherlands (Wecycle, 2024). In this interview we discussed the possibility of adding healthcare electronic waste to recycling flows. The main limitation for this was the amount of waste. If enough waste was coming from hospitals cleaning would only deduct roughly 10% of the value, which still could provide a profitable scenario. With the increase in electronics used in healthcare setting up this recycling flow could become feasible opportunity. As this would be a big project to sort out it is not included within this graduation project. I did include this scenario in the storyboards as the ideal end of life scenario. Due to the uncertainties, it is not included in the LCA calculations.

2.2 Change management

The concept presented within this thesis requires a systematic change of the healthcare system around ECG lead sets. Even when the solutions found work perfectly in the first implementation (and even though the concepts are validated it will be doubtful) people need to be guided and convinced to adapt. Within this graduation an interview with a change manager within the Philips consultancy group has been conducted. This gave insight in how complicated this area can be. For this reason I did not proceed with implementation of change management within this thesis. Research or knowledge on how to implement this within this concept should be adapted in future implementation.

2.3 Business focus

This project started off with a focus on circular design using a case study to develop these methodologies. With the location of the research mainly done at Philips and personal interest in solution focused working than being more focused on the methodologies used, the scope early in the project shifted to the case study. This means that this thesis will give more input on a business level than on an academic level.

2.4 Local observations

Situated in the Netherlands observations at hospitals are done in the Netherlands. This creates a bias to the Dutch hospital system. It is hard to check literature findings without visiting hospitals. For further research the logistical concept should be checked in other European hospitals as well. To have some input from other countries interviews with product managers from other countries have been conducted. But as these are not situated at the hospitals it gives limited information.

3. Personal reflection

This graduation project has been a great opportunity to combine working within a big healthcare company as Philips and working on something that lays close to heart, sustainability. This subject area is after this graduation still what I would like to start my early career in.

3.1 Methodology vs design project

The scope of this project regarding design methodology has been switched from the start of the project towards the middle. This can be explained by the working environment within Philps where it was mostly solution focused in combination with a personal interest. This worked really well for me and I believe it played more on my strengths than going deeper into the methodological direction.

3.2 LCA Methodology

From my earlier experiences and learnings from the first half of this project I felt enthusiastic about the LCA methodology. For this reason, I joined a LCA training within Philips to learn more. This enthusiasm has been tempered by the struggles to get data from companies working for Philips. And without strong data LCA is a far less valuable tool. It is promising to see that there are big data management projects that could result in the data being more available in future projects.

FINAL WORDS

Overall I loved working on this project and felt hugely supported from my coaches from the TU Delft as well as within Philips. It was motivating that anyone I contacted was willing to help and share information. I have had a huge array of meetings with a lot of stakeholders which helped a lot. I hope this project can help to take a small step into a more sustainable healthcare system.

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