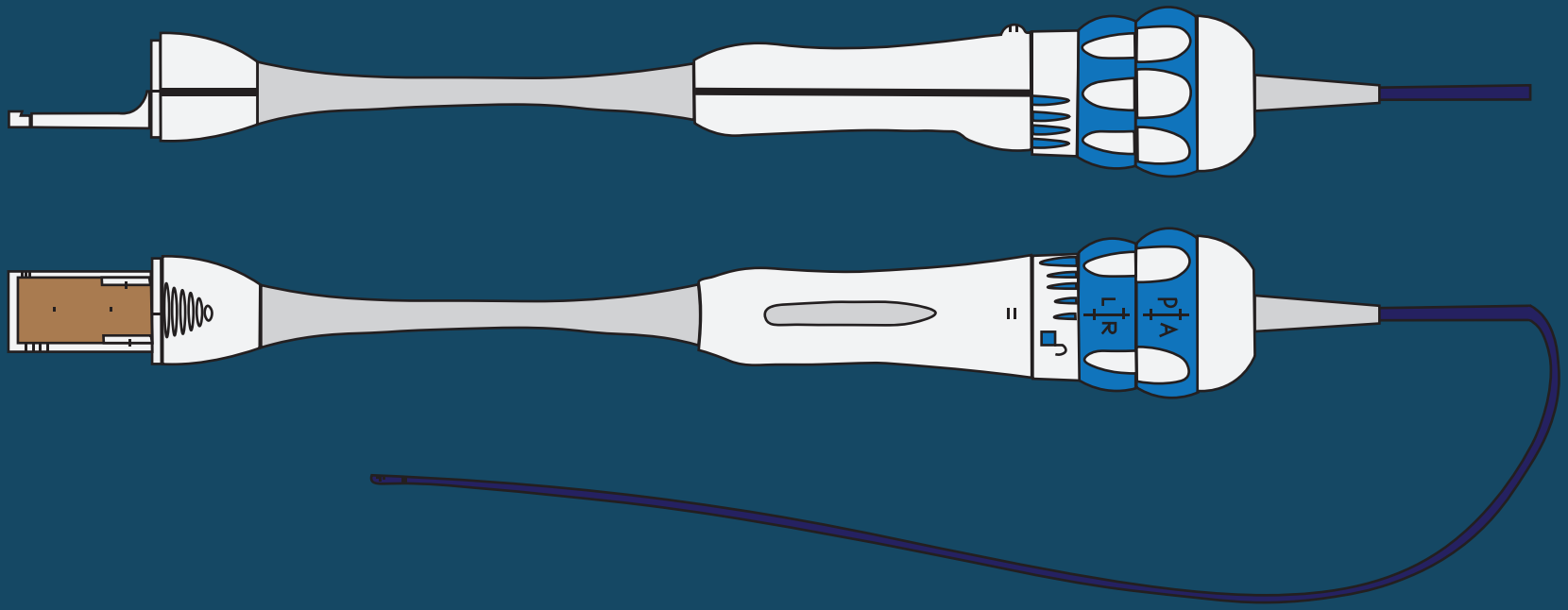
A case study of the environmental and economic sustainability of using remanufactured ultrasound catheters



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STUDENT REPORT

Abstract

Climate change has increasingly become the biggest issue of this century. This requires action in all sectors, to try and restore the planet back to a sustainable state. This also applies to the healthcare sector in Denmark.
This master's thesis wants to investigate how reductions in health care consumption and emissions can be achieved by deploying remanufacturing as a strategy for circular economy. Currently, the benefits of remanufacturing in healthcare are limited to a view of the economic benefits. Therefore, this master's thesis wants to pave the way for considering remanufacturing in healthcare for its environmental benefits. This is done by doing a case study of remanufacturing ultrasound catheters at Aarhus University Hospital. Through the case study, the environmental impact of remanufacturing single-use medical devices will be investigated by a life cycle analysis and the economic benefits of remanufacturing will be investigated by a Total Cost of Ownership analysis. Furthermore, actor-network theory will apply a socio-technical view on how a new system of remanufactured single-use medical devices could be introduced at Aarhus University Hospital.
Using remanufacturing of single-use ultrasound catheters is found to reduce climate impact compared to the current situation. Furthermore, previous findings of remanufacturing being economically beneficial are supported by the results found in this thesis. Lastly, multiple actors will need to be enrolled in the new network of remanufactured devices for it to be feasible. This will happen using the results of the analyses as a boundary object to interest the actors within their context. Furthermore, an open meeting will support the delivery of the results of the analysis to interest relevant actors in the further work for legalisation of remanufacturing single-use medical devices in Denmark.

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Preface

Thanks to Central Denmark Region, and especially Lærke Dahl Klausen and Rasmus Revsbeck, for all their time and willingness to create sustainable change and for always aiming higher – without the countless meetings and guiding this project would never have happened. A special thanks to Jensen, for the excellent tour at Heartlab 2 AUH and for answering our many questions. Moreover, we will also like to extend a thank you to Viola from Vanguard AG, she was an important help to collect needed data for the remanufacturing process and the ultrasound catheter. Additionally, a thank is owed to each of the persons, that was willing to engage in interviews, state their opinions and honestly sharing their thoughts of the project.

Last but not least, we would like to say a special thanks to our supervisors Monica Niero and Wendy Gunn, professors and researchers at Aalborg University CPH, for their guidance thoughout the duration of the project. Thanks for always making time to help with questions, to always be motivated during meeting and thank you for your sincere interest in the project, which helped us to stay motivated throughout.

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Glossery

ANT – Actor Network Theory
AMDR - Association of Medical Device Reprocessor
Aurikel – Is a closure of the left cardiac auricle by arterial fibrillation. It is a treatment used to prevent blood clots.
CE – Circular Economy
LCA – Life Cycle Assessment
PFO – Persistent foramen ovale, is a small hole in the partition between the two heart chambers.
OEM – Original Equipment Manufacture
TCO – Total Cost of Ownership

Association of Hygiene Nurses – Fagligt selskab for hygiejne sygeplejersker
Central Denmark Region - Region Midt
Central Unit for Infectious Diseases – central enhed for infektions hygiejne
Danish Association of patient - Patientforeningen
Danish Medicine Agency - Lægemiddelstyrelsen
Danish Society for Central Sterilization and Hospital Hygiene - Dansk selskab for central sterilisering sygehus hygiejne
Danish Society for Clinical Microbiology – Dansk selskab for klinisk mikrobiologi
Doctor's Association - Lægeforeningen
Doctors for Climate - Læger for klimaet
Heartlab2 – Hjertelab 2
The Agency for Patient Safety – Styrelsen for Patient sikkerhed

Remanufacturing – in some cases, such as quotes, the word "reprocessing" will be used to mean the same thing.
Resterilisation – the act of sterilising a device, different from remanufacturing as it is mainly done locally, cannot be done legally to single-use medical devices and does not ensure that the product lives up to the original manufacturer quality.

0.0

Introduction

What is the contribution of this thesis?

How we approach sustainability

In the Brundtland report (1987), the definition of sustainable development is: "*developments that meets the need of the present without compromising the ability of the future generations to meet their own needs*" (Brundtland, 1987, p. 15). This definition focuses on enabling future generations to gain utility from the same resources we have today. Furthermore, in 2015 the United Nations presented the sustainable development goals with 17 goals to: "*end poverty, protect the planet and ensure prosperity for all as part of a new sustainable agenda by 2030*" (Hauschild et al., 2018, p. 4). Acting on this agenda is not solely to preserve materials but also to include business opportunities and improve society worldwide, thereby including all three sustainability aspects (Environment, Society, Economy). Reaching these goals requires proactive decision-makers who take a system view of the challenges to avoid solely shifting the burden into one or another aspect of sustainability. For Sustainable Design Engineers (hereafter SDEs) sustainability is a core value when evaluating and developing systemic and technological change. SDEs believe that a holistic perspective is required when investigating the sustainability potential of the future, to ensure the creation of a genuinely sustainable solution.

Throughout this project, sustainability is defined and understood as a definition that encompasses social, economic, and environmental benefits. We argue that significant environmental sustainability changes can be implemented using tools that quantify the environmental impacts of a product or system's life cycle and the creation and implementation of strategies for a circular economy. However, in this study, the scope is narrowed into focusing on environmental and economic sustainability. This, as social sustainability if often the focus in the healthcare sector, resulting in much literature dedicated to this. Therefore, this thesis will investigate environmental and economic sustainability in the healthcare sector, as there is a great potential for improvement in those areas.

Our contribution to Sustainable Design Engineering

In this project, we aim to contribute to developing the research field within Sustainable Design Engineering.

We wish to contribute with a method to include economic sustainability in decision making. As SDEs, we often tend to focus on environmental and to some extent social sustainability, as these are the closest to observe and create an immediate change. Unfortunately, this often leaves economic sustainability overlooked. However, for actors in the status quo (in the current network) to support a solution, an economic incentive must be created, as this is the driving force of the status quo. Therefore, we try to add the total cost of ownership (hereafter TCO) as a tool to aid SDEs in positioning a new system or product in a network.

Furthermore, this master's thesis should help to qualify the potential of remanufacturing. Currently, remanufacturing as a circular economic strategy is overlooked, as it sits lower in the waste hierarchy as compared to other strategies for circular economy such as reuse.

Nonetheless, for products that are needed in the healthcare industry the circular strategy of reuse might currently be unachievable. This can lead to a stabilisation of the current use of medical products. We propose that instead of aiding the status quo, by letting an unsustainable practice continue, remanufacturing could be the middle-ground and help to start the transition towards more sustainable use of medical products overall.

Inherent in a circular economy is the preservation of resources. However, this Master's thesis also wanted to investigate the climate change impact of remanufacturing. Thereby, a full view of environmental sustainability is created considering both material depletion and CO_2-eq. emissions. This is done by including a life cycle assessment (hereafter LCA) and thoughts of circular economy in combination.

How sustainable design engineering contributes to the subject

The project clearly articulates how sustainability, design and engineering methods and approaches can be applied in unison to improve systems and envision transitions towards a society with sustainability at its core. In this project, we, as SDEs, have conducted a LCA study that has provided quantitative data on impact potentials thereby aiding with information of the impacts of choosing one system over another.

With our knowledge of sustainability, we have investigated the potential for increasing sustainability within the use of medical devices at Danish hospitals. As engineers, we have collected, validated and concluded upon data from the LCA and TCO. As designers, we have taken this information and transformed it, making it an interessement device. Finally, as SDEs, we have turned all the information and data into actionable steps, recommendations, and considerations for future improvements of the sustainability of using medical devices in Danish hospitals.

By focusing on the network of the healthcare sector, we have identified some obstacles to sustainable development that could be explored further and that are beneficial to be aware of when trying to implement a sustainable solution in the sector.

Introduction

Moving toward sustainable transitions in healthcare is increasingly becoming an important issue for healthcare workers, healthcare management, local and national government and policy makers. This parallels a need to accelerate the sustainable transition in wider societal systems to prevent most incoming disasters brought on by climate change. Consequently, changes are required in all sectors with a transition towards more sustainable use of resources.

Typically, the priority of the healthcare sector is ensuring patient safety by using the best quality medical devices and ensuring proper sterilisation. Medical instruments have been changing continuously since 1820 (Davis, 1978) due to this priority of patient safety with increasing focus upon infection risk. As a result, products that were previously made to be reused have been changed to single-use plastic versions that are said to be more sterile as they are newly produced. The unlimited use of resources, with the increasing use of medical devices with single-use labels, as well as the notion of ensuring patient safety above all, has led to the medical sector being responsible for 5% of GHG (greenhouse gas) emissions worldwide (Weeda, 2021) and 6% of GHG-emissions in Denmark specifically (Health Care Without Harm, 2019).

Case description

This master's thesis is a case study on remanufacturing of single-use medical devices in the hospital sector. The thesis studies the case of using remanufactured ultrasound catheters in Heartlab 2 at Aarhus University Hospital (Hereafter AUH) in Denmark. The project collaborates with the Central Denmark Region, which is interested in researching the

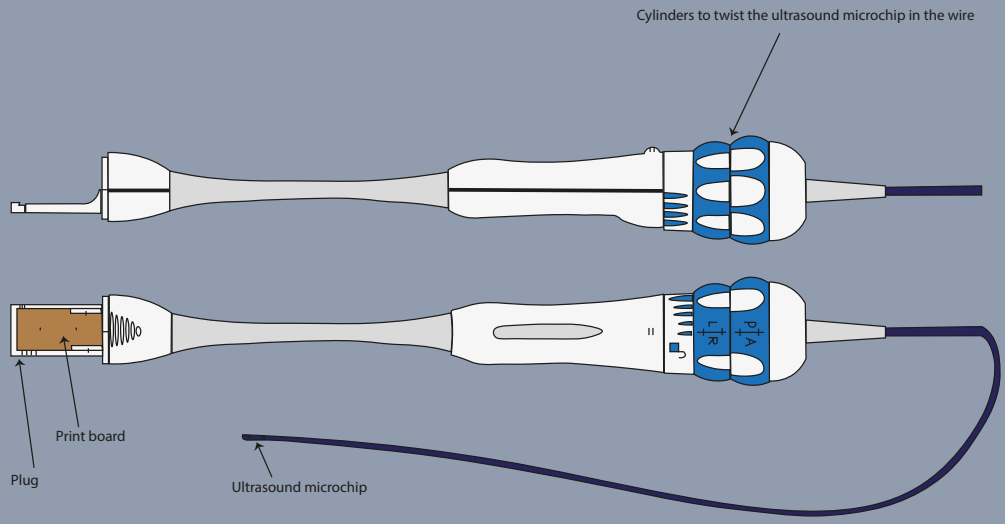


Figure 1. This figure illustrates the ultrasound catheter under investigation.

potential environmental and economic benefits of using remanufactured ultrasound catheters. The ultrasound catheters used for operation at AUH Heartlab 2 have previously been remanufactured in Germany by Vanguard AG. Ultrasound catheters are used in heart surgeries by being inserted through the groin and led by bloodstreams towards the heart. There, the ultrasound catheter provides ultrasound vision so that doctors can navigate inside the heart during operations. The ultrasound catheter consists of a handle with small cylinders which can be twisted (see blue part of Figure 1) to control the directions of the ultrasound microchip, which is placed at the tip of the wire. The wire is the part of the ultrasound catheter that goes inside the body of the patient. The catheter is connected to an ultrasound machine and projected onto a large screen, thereby allowing the doctor to navigate inside the patient's heart continuously (Keyhani et al., 2011). The materials of the ultrasound catheter are specified in section 4.

Research question and sub-questions

How can the Danish healthcare sector transition to using remanufactured single-use medical devices?

- Can remanufacturing of ultrasound catheters result in reduced climate change impact, resource consumption and cost at the AUH Heartlab 2?
- What could be done to improve the environmental sustainability of remanufacturing ultrasound catheters?
- How can remanufacturing of medical devices become an established alternative to using newly produced single-use devices at AUH Heartlab 2?

Approach to answering the research question

In this thesis, knowledge has been accumulated on the environmental challenges regarding the use of ultrasound catheters. This thesis has been written from the viewpoints of two SDEs (Valderrama Pineda & Niero, 2020), who view reality critically to impose and implement change from our relational standpoint. More about the viewpoints of SDEs can be read about in section 2. The thesis has contributed with an evaluation of two systems:

- The current system of using newly produced ultrasound catheters at Heartlab 2, AUH.
- A future system of using remanufactured ultrasound catheters at Heartlab 2, AUH.

Semi-structured interviews and desk research were used to gain knowledge of the interrelationships between actors and data for use in analyses. Combined with a literature review, historical analysis, and mapping of the two systems, this has contributed to understanding the challenges of the current system in terms of environmental impact and the challenges of implementing a future remanufacturing system.

By conducting a LCA, the environmental impacts of the two systems of ultrasound catheters were investigated. Moreover, the economic cost of the two systems were studied by conducting a TCO, and the socio-technical network of the current system was studied by deploying actor-network theory (ANT). Combining these analyses has allowed for a broad understanding of the current situation and identification of obstacles of the changes necessary to transition to a more sustainable system. The LCA has provided knowledge on the systems' contribution to climate change. The TCO has provided knowledge on whether there is an economic interest in doing a change. Finally, the ANT has provided an understanding of the relations that will need changing or redefining to allow a more sustainable system to enter the network.

The methods mentioned above have provided a framework for conducting the study, tackling identified challenges, and contributing knowledge on the environmental sustainability of remanufacturing single-use medical devices.

Sustainability in the healthcare sector

There exist multiple ways of reducing the CO_2-eq. emissions of the healthcare sector in Denmark. First and foremost, an approach could be to reduce the number of resources being used. This means reducing the materials used out of habit, contrary to medical need. Reducing the materials has been done at one surgical department in Central Denmark Region with good results, cutting away 1/3 of their waste flow (Strøh, 2021). However, this approach can only go as far as changing practices with redundant resource use. For example, some equipment is essential to perform specific surgeries, for which reason their use cannot be reduced.

Another alternative for hospitals to become more sustainable is to use more reusable products. However, most medical devices sold in Denmark are usually not reusable as the Danish hospital prioritises:

1. Patient safety - which is assumed to be more prevalent in single-use devices. Furthermore, sterilising reusable devices takes time and resources, something there is a general lack of in Danish hospitals.
2. Acquisition price - getting the most quality for the lowest price.

Subsequently, more complex medical devices are usually only sold as single-use as the original equipment manufacturer (hereafter OEM) can then avoid the liability connected to reusable products (read more about this in section 3). Thereby, an incentive has been created legally for the OEMs to continuously produce single-use devices. Therefore, it has been chosen not to investigate further how to implement more reusable devices in the healthcare sector, as that would be a project primarily engaged in creating legislative changes.

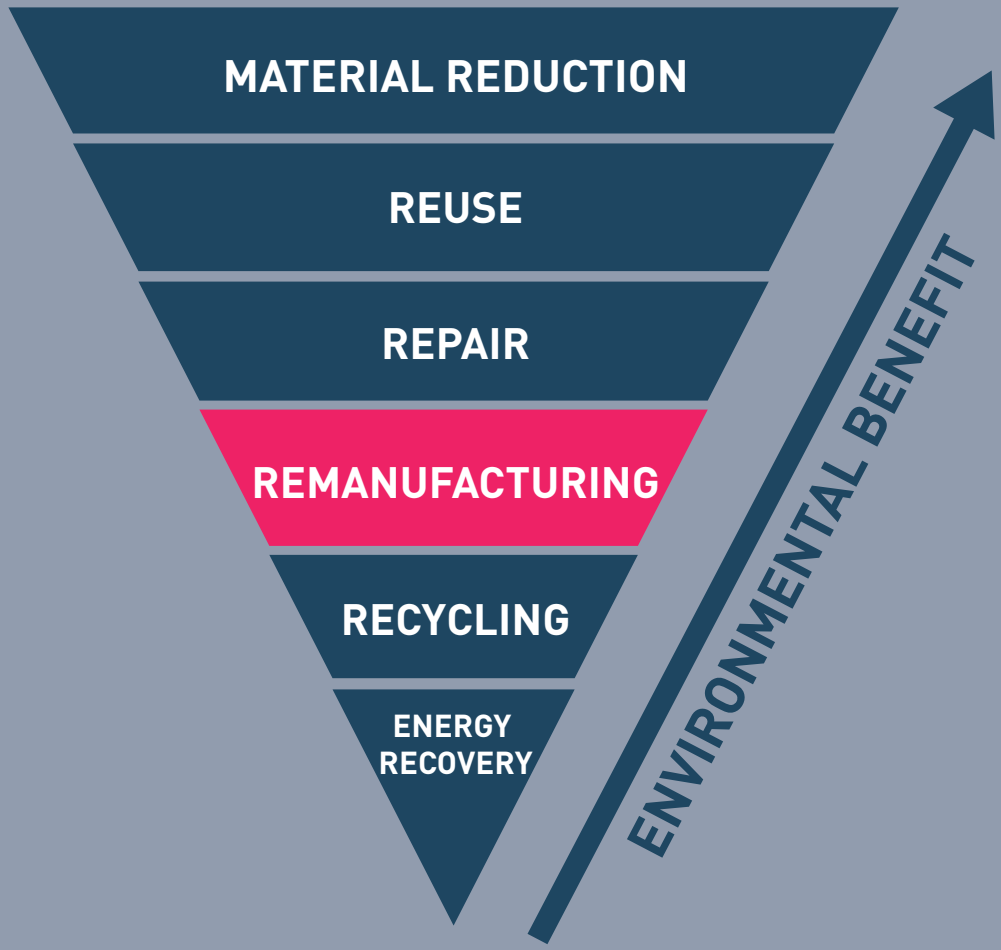


Figure 2. The possibilities for health care facilities to improve their environmental footprint. The figure is created with inspiration from Vanguard AG and the EU waste hierarchy.

According to the waste hierarchy (European Commission, 2008), see Figure 2, the next strategy to reduce emissions would be to introduce

repair. However, since the focus is on single-use medical devices, repair is not feasible. This leads to remanufacturing, which is a process of not only repairing but: "*the only end of life process where used products are brought at least to Original Equipment Manufacturer (OEM) performance specification from the customer's perspective and at the same time, are given warranties that are equal to those of equivalent new products"* (Paterson et al., 2017, p. 655). Some European hospitals sway to this strategy, as it results in the potential for saving costs. In 2020, Association of Medical Device Regulation (hereafter AMDR) members sold 31.683.256 remanufactured devices. Consequently, 5.426.851 kg of medical waste was avoided in 2021 alone (AMDR, 2022b).

Remanufacturing is not the highest environmentally beneficial end-of-life treatment of products in the waste hierarchy, as shown in Figure 2. However, it is the highest-ranked in the waste hierarchy for single-use medical devices, as they cannot legally be directly reused or repaired. Furthermore, remanufacturing is the only end-of-life strategy in the waste hierarchy that restores the product to its original quality. Having products that are the same quality as the original is the ultimate request of hospitals, as they need to be assured that the product will not harm the patients. However, remanufacturing is also a resource heavy process and requires many resources compared to the reuse of products. Furthermore, companies need to be highly specialised to restore the products. Therefore, it is rarely possible to find such a company locally adding a lot of transport to the product's life cycle.

Going further down in the waste hierarchy is presented the possibility of recycling medical waste. Currently, recycling is only done to a small degree at most hospitals. Many trials have been done to increase the amount of recycling in Danish hospitals (Godtsygehusbyggeri, 2021). However, recycling can be difficult for more complex medical devices because of many different materials and small parts, resulting in much time being put into a relatively small recycling mass flow (Schulte et al., 2021). Thus, recycling is not the most advantageous way to handle single-use medical devices. Furthermore, it is a strategy that holds a lower potential for circularity and environmental benefit than the other approaches placed higher in the waste hierarchy.

Legislation on single-use medical device remanufacturing

Germany has had national rules on remanufacturing since 2002, and in the Netherlands, it is permitted under certain conditions (Socialstyrelsen, 2020). As a result, Germany has remanufactured single-use medical devices for approximately 20 years.

Remanufacturing has previously been a grey area in Denmark because it was not specified in the Medical Device Directive (MDD). However, recently the EU implemented the Medical Device Regulation (MDR), which was introduced to try and make the market more regulated, following the wishes for more safety and better performance of medical devices. This resulted in the introduction of article 17, which states that for remanufacturing to be legal in member states, they will need to 'opt-in' by creating guidelines for safely doing it. This has effectively made remanufacturing illegal in most member states (except Germany) as of the 26th of May 2021 (Lægemiddelstyrelsen, 2021).
To make remanufacturing legal in Denmark, the Danish Medicine Agency has asked Central Denmark Region to prepare a joint appeal from

multiple regions. To create this appeal, they first need to convince other regions of the benefits of remanufacturing.

One benefit of remanufacturing would be its potential for reducing climate change impact, resource consumption and cost. To make this an argument that the Central Denmark Region can use in their interessement of other regions, the reduction in impact, resource consumption and cost will need to be proven and quantified. Therefore, a literature review has been performed to gain insight into the current knowledge on this.

Literatur Review

A literature review was conducted to map the current research on remanufacturing and sustainability in the healthcare sector.

Remanufacturing in the healthcare sector

Remanufacturing as an end-of-life process for single-use medical devices has been increasingly debated in recent years as a consequence of the introduction of article 17 in MDR. Some medical professionals have voiced concerns about patient safety and infection rates associated with using a remanufactured device (Vukelich, 2016). Nevertheless, the current research supports that remanufacturing single-use medical devices is safe (Socialstyrelsen, 2020; Thording, 2021; Vukelich, 2016; Weeda, 2021). Specifically, an FDA study states that single-use medical devices: "*can be collected, shipped, traced, cleaned, tested, disinfected/sterilised, repacked and returned to hospital for safe reuse*" (Weeda, 2021, p. 1). Moreover, Socialstyrelsen in Sweden has done an extensive literature review regarding the possibility of an increased infection rate in countries using remanufactured devices but has found no evidence that this should be the case (Socialstyrelsen, 2020). Nonetheless, as Eze et al. (2020) have pointed out, requirements should be established to ensure that the remanufactured medical devices are equal to newly produced devices in terms of performance and safety (Eze et al., 2020).

Numerous studies have investigated the advantages of utilizing remanufacturing at end-of-life (Fofou et al., 2021). One of the most mentioned benefits of remanufacturing is that of saving costs (Eze et al., 2020;

Oturu et al., 2021; Zhang et al., 2020). As mentioned by Bayrak & Soyly (2021): *"the main purpose of reusing medical devices is to reduce the cost of healthcare"* (Bayrak & Soylu, 2021, p. 1). Following, Thording et al. (2021) state that the lowered cost of medical devices can enable hospitals to improve care by hiring more nurses or afford more advanced technology for patient treatment (Thording, 2021). This is important as human resources and monetary resources are not limitless in healthcare (Antoniadou et al., 2021). The cost reduction enabled by remanufactured medical devices has been found to be an average of 40% compared to an equivalent newly produced device (Eze et al., 2020; Fofou et al., 2021; Socialstyrelsen, 2020; Weeda, 2021).

Disadvantages of remanufacturing

Even with the above indications of cost benefits of remanufacturing, some disadvantages also exist. One disadvantage of remanufacturing is the fact that the remanufacturing company's revenue is entirely dependent on the number of used products being sent and brought to their facilities (Lee et al., 2017). The remanufacturing company is thereby easily affected by changes happening further up in the supply chain, and they are therefore entirely reliant on others for their business to run steadily.

Another disadvantage of remanufacturing is the fact that most remanufacturing is currently happening in companies that are not the original equipment manufacturer (OEM). The OEM can easily change their products slightly, which will result in the remanufacturing company having to rebuild all their processes and do research on the best way to treat the product anew (Fofou et al., 2021). Therefore, the incentive for remanufacturing companies to expand their businesses is generally small, making them highly specialised.

Lastly, not many professionals in the healthcare sector are accepting of remanufactured products and will be sceptical about using the product, despite the heavy regulation and the cost reduction. Furthermore, because the healthcare professionals are not open to remanufacturing yet, it also implies minimal incentive for the OEMs to make their own take-back remanufacturing systems (Matsumoto et al., 2016), which elsewise would allow remanufacturing to be more effective. This, as the OEM has access to all data of the product and can easily add spare parts.

Remanufacturing as a strategy for circular economy

Multiple researchers suggest remanufacturing as an option to achieve a circular economy (Asif et al., 2021; Ellen MacArthur Foundation, 2015; Fofou et al., 2021; Oturu et al., 2021). This is, among others, presented by Asif et al. (2021), who criticise the current notion of a circular economy for rarely considering how to keep the value of a product over time (Asif et al., 2021). Instead, they perceive designing for multiple life cycles as the solution to keep the products' value long term, facilitated by utilising remanufacturing as an end-of-life method between each life cycle. By using remanufacturing on products designed for the remanufacturing method, it will be possible to exchange parts and otherwise optimise the product to prevent technical, emotional and especially technological obsolescence (Asif et al., 2021). Designing for multiple lifecycles thereby aligns with the design strategy presented by Bocken et al. (2016) of designing to prevent obsolescence (Bocken et al., 2016). The design strategies for a circular economy are detailed in the methods and theory chapter.

Remanufacturing is the only end-of-life solution that restores and adds value to the discarded product. Fofou et al. (2021) propose multiple ways to enhance remanufacturing to make it more effective and environmentally sustainable (Fofou et al., 2021). They suggest, among other things, a general digitalisation of remanufacturing processes, product-service systems and designing for remanufacturing. Designing for remanufacturing is similar to another design strategy for a circular economy, "design for dis- and reassembly", proposed by Bocken et al. (2016). Furthermore, Zhang et al. (2020) concludes that remanufacturing is an effective way to save resources, limit amounts of materials at landfills and energy savings (Zhang et al., 2020). Thereby, remanufacturing is a promising strategy for achieving a circular economy.

An overlooked benefit of remanufacturing

In recent years, environmental sustainability and medical waste has gained importance in the medical field – leading to an increased focus on how the healthcare sector can use more environmentally friendly solutions. Remanufacturing single-use medical devices remain one of the measures that contain the most promise for improving the overall sustainability of the healthcare sector without increasing costs. Remanufacturing is already in use in some countries, and no increased infection rates have been reported in connection with remanufactured devices. Moreover, the possibility of reducing cost has increased interest in deploying remanufacturing in countries that currently do not make use of it. Nonetheless, remanufacturing is not yet an optimised system and there are currently many uncertainties connected with being a company whose profits relies only on remanufacturing single-use medical products. Nonetheless, we argue that remanufacturing is a significant step towards a more circular consumption of materials, even if this benefit is not mentioned in most literature about medical device remanufacturing.

Conclusively, the literature has yet to address the sustainability potential of including remanufacturing as an end-of-life method in the healthcare sector. The only known case of investigating sustainability in remanufacturing of medical devices is that of Schulte et al. (2021). However, Schulte et al. take a one-to-one perspective of buying a remanufactured device contra buying a newly produced device, irrespectively of the fact that newly produced devices are needed to have remanufactured ones. Therefore, this master's thesis investigates the sustainability potential of remanufacturing in a longer-term scope, with a mixed input of both newly produced and remanufactured devices. Furthermore, this thesis will investigate the socio-technical changes needed for remanufacturing of single-use medical devices to be implemented in the hospital sector in Denmark.

1.0

Theory & Methods

In the following sections, our methodological standpoint will be presented, followed by a description of how the project has been managed. Furthermore, the selected theory and methods that have been applied throughout this project, to answer the research question, will be described. Additionally, it will be elaborated how the theory and methods were used and how they have influenced the outcome of this thesis.

Methodology

Where we position ourselves as researchers affects how we conduct and analyse information to create knowledge and ask questions (Burrell & Morgan, 1979). Regarding our methodological positioning, Burrel & Morgan (1979) express that one cannot operate simultaneously in more than one of the four social-political paradigms. The four paradigms are interpretivism, functionalism, radical humanism & radical structuralism (Burrell & Morgan, 1979).

We, as SDEs, are generally placed in the social-political paradigm of radical humanists. As radical humanists, we view reality from a critical perspective thereby seeing social reality as something subjective being independently interpreted by every person. This implies that to make changes, it is necessary to understand multiple understandings of reality. This can be done by qualitatively investigating each actor's opinions and relations, to be able to understand the socio-technical relations in between actors and artifacts. To do that, SDEs make extensive use of the sociological foundation of Actor-Network Theory. The socio-technical realm is: *"A narratology-inspired approach to science and technology studies, especially as practiced."* (Czarniawska, 2014, p. 57). This realm is the dominant narrative form of knowledge where the relationship between actors and non-human actors (such as technologies) becomes relevant to understanding the world.

Life Cycle Assessment

Life Cycle Assessment (LCA) is a method that can be applied to evaluate the potential environmental impacts of a product or service's life cycle. LCA can be conducted according to ISO-standards, which are also followed in the LCA study within this thesis. According to ISO 14040:2008 an LCA can be described as follows: *"LCA addresses the environmental aspects and potential environmental impact (e.g. use of resources and the environmental consequences of releases) throughout a product's life cycle from raw material acquisition through production, use, end-of-life treatment, recycling and final disposal (i.e. cradle-to-grave)."* (ISO, 2008, p. 16).

With LCA, it is possible to compare environmental impact of different alternatives fulfilling the same function. Furthermore, the results of an LCA can be used to make strategy or design decisions (Schulte et al., 2021). The purpose of conducting an LCA in this thesis is both to investigate the climate change impact of two alternatives and to propose strategies for reducing the climate change impact of a chosen alternative.

The LCA framework has four general phases that is gone through iteratively. Hence, each phase has been revisited as new information or results has come to light to better define the investigated system and strengthen assumptions and modelling choices.

Goal & Scope definition: The goal definition of the LCA is the first phase that indicates the study´s purpose. Depending on this, the LCA might

take different forms. Hence, it is essential to be precise. *"The scope definition determines what product systems are to be assessed and how this assessment should take place"* (Hauschild et al., 2018, p. 76). In the scoping, the boundaries of the product system will be drawn, ensuring adequate modelling in the following stages. It is also in this phase the functional unit will be defined, which determines the reference flows which are the systems to be modelled and compared.

Inventory analysis: In the inventory analysis, the information about the different flows within the system is collected. When collecting the data for the flows, it becomes clear what data is needed and what data might be missing. Furthermore, it clarifies the processes used in the impact assessment for documentation purposes. By use of the processes and flows detailed in the inventory analysis, an LCA software will be able to pick-up the elementary flows that result in an impact.

Impact assessment: In the impact assessment, the flows of the inventory are translated into impacts. Here, the impact categories are selected, and with the help of tools, different types of models of the impact are created. Furthermore, to create the impact assessment, a method needs to be chosen. Methods can be either single or multi-issue, and they are the ones that decide how the impact of different flows are calculated.

Interpretation: Continuously throughout the LCA study, the results and the models described in the impact assessment are assessed and interpreted. Furthermore, a contribution analysis and a sensitivity analysis is conducted to analyse possible weak assumptions of the inventory analysis. This way, the results become more robust, and ways to improve the study might appear (Hauschild et al., 2018).

Modelling frameworks

There are traditionally two main LCI modelling frameworks when conducting an LCA: consequential and attributional (Hauschild et al., 2018). The choice of LCI modelling framework will have consequences on the results of the LCA, as it impacts how, according to ISO, multifunctional processes should be handled and what type of processes should be used in the background system (average or marginal). Hence, it is essential that the modelling framework is established before starting the impact assessment.

Attributional LCI modelling investigates the product system in isolation from the surrounding technosphere and economic considerations. Generally, attributional modelling can be said to model according to: *"what environmental impact can be attributed to product X?" or "what environmental impact is product X responsible for?"*(Hauschild et al., 2018, p. 95). The Attributional LCI will usually include the processes from cradle to grave, including extraction of consumed materials, production of the product, transport, and waste management (Hauschild et al., 2018). When using attributional LCI modelling, the changes to background system will not be considered.

With consequential LCI modelling, the effects of introducing a new product system to the economy and general background processes are considered. Generally, it can be modelled according to: *"what are the environmental consequences of consuming X?"* (Hauschild et al., 2018, p. 95). Consequently, if a new product system results in the need for more electricity production, extra electricity production should be added to

the calculation to ensure the counting of all impacts that are a consequence of the new product system. This extra electricity will be based upon a marginal mix. Using a marginal mix means that the type of electricity inputs that will be added is based upon which technology would be employed to produce that extra electricity for the grid. Furthermore, it will in consequential modelling be considered if a product or service makes use of recycled products or ensure recycling. Hence, it considers the avoided burden of the product or service.

Functional unit

The functional unit is part of the scope definition. It is *"a quantitative description of the function or service for which the assessment is performed, and the basis of determining the reference flow of products that scales the data collection in the next LCA phase, the inventory analysis"* (Hauschild et al., 2018, p. 61). When conducting an LCA, it is necessary to support a fair and quantitative comparison of the alternatives that provide the same function. Furthermore, it should be specific enough to ensure that all alternatives live up to the same standard. The alternatives that each fulfil the functional unit are called reference flows. The reference flows need to be established to make the system boundaries of the LCI.

The SimaPro software v.9.3.0.3 has been used with the ecoinvent v.3.8 databases for this research.

Remanufacturing in LCA

When doing Life Cycle Assessment, it is namely important to include all phases of the lifecycle. This includes end-of-life which can often be tricky to include in products with multiple lifecycles. In general, end-of-life modelling of products with multiple lifecycles leads to a debate on how to allocate the impact of production of the original product when entering a second life cycle. This can lead to challenges when modelling remanufacturing, which is a type of end-of-life treatment that prepares the product for a second lifecycle. As the product is treated and resources are used to restore it to original quality, it needs to be decided on where to allocate the original impact of the production of the product. In this investigation, the end-of-life can be said to be both open and closed-loop. Open, as the medical product might not be returned to the same owner after use, and closed, as the product stays the same and returns with the same qualities as the original product.

Remanufacturing has only in a few cases been the item of investigation of LCAs. Peters (2016) only managed to find 13 articles that included remanufacturing (Peters, 2016). However, he did manage to find some similarities and differences in the way to approach it. He splits it into two different approaches: the supporter and the neutral perspective. Most of the articles identified have the supporter perspective, where the impact of the production of the product is allocated entirely to the first life cycle of the product (as in the case of Schulte et al. (2021)). Thereby, the remanufactured product only has the impact associated with the remanufacturing process, even if an original product is needed for remanufacturing to be possible. Contrarily, the neutral perspective splits the impact of production equally on the two life cycles. Thereby, the user

of the product on the second life cycle will not receive credit for choosing the remanufactured device. For this investigation, the neutral perspective has been chosen. However, since Central Denmark Region is both the ones to buy the newly produced catheter and the service of remanufacturing from Vanguard, having the impact of production only tied to the newly produced product would not do much difference as the impact would anyway be allocated to Central Denmark Region.

For the purpose of this thesis, the LCA has helped to create data on which to base decisions. It has allowed for comparing two alternative systems and further investigate how different redesigns of the systems affect the climate change impact of each. More broadly, the LCA has been essential in providing the argumentation needed by Central Denmark Region: that remanufacturing of single-use medical devices is more sustainable than the current system.

TCO

The concept of Total Cost of Ownership (TCO) is generally related to Life Cycle Costing (LCC), which is often used as a second parameter in assessing sustainability next to LCA. TCO is a less traditional concept to pair with an LCA as it done in this thesis. Both approaches have a notion of looking at the cost associated with a product/system from a long-term perspective, allowing for making more accurate purchases (Ferrin & Plank, 2002).

A TCO is a model that calculates the total cost of having the product/system as an owner. The product owner is viewed as the one utilising the product during its use phase. Additionally, the calculation generally includes the purchasing price and cost associated with use, maintenance and repair (Ellram & Siferd, 1993). In this thesis, the TCO is comparing two alternative systems, including working hours calculated in terms of costs, because the cost is studied from a business-level perspective.

The difference between TCO and LCC is the scope of the investigation. In TCO, only the costs related directly to the user are applied. In an LCC, the entire lifecycle cost and costs not directly affecting the user are included. TCO was chosen as preferable for the intended purpose of cost-calculations in this thesis. The TCO is perceived as preferable, as the intention of the analysis is to inform other Danish regions about the potential for reducing costs within their hospitals by implementing remanufactured devices. Furthermore, TCO is already a tool known to many public procurers (Udbudsportalen, 2022), thereby providing understandable results in their 'own language'.

The TCO has been a valuable tool to highlight the overall cost of the system, and to further document the savings of using remanufactured catheters. The TCO-data will be used as an object to interest and convince the procures from different regions, for how we envision the cost savings of the future system.

Circular economy

The notion of circular economy (hereafter CE) is currently one of the most well-known strategies for limiting resource consumption and increasing sustainability. This is evident by the focus of governing organisations such as the EU, with the action plan for Circular Economy, and the Danish government with the Strategy for Circular Economy (European Commission, 2020; Miljø- og fødevareministeriet & Erhvervsministeriet, 2018).

Inherent to CE is the focus on reducing waste generation and creating circular systems for resources (Ellen MacArthur Foundation, 2019). Moreover, CE creates business opportunities for companies working with the waste fractions of other actors. According to the European Commission, the circular economy transition *"can create 600 billion euros annual economic gains for the EU manufacturing sector alone"* (Korhonen et al., 2018, p. 37). As estimated by the MacArthur Foundation, *"applying circular economy principles in the EU could unlock value in business and society worth EUR 1.8 trillion a year in 2030"* (Ellen MacArthur Foundation, 2019, p. 8).

As shown in figure 3, there are multiple ways of achieving CE, which in general, mimics the first steps of the EU waste hierarchy.
All methods for a circular economy can be summed up into three different types: Slowing, Closing and Narrowing (Bocken et al., 2016). *Slowing* allows for products to be used longer by, among others, offering repair services. With *Narrowing* the focus is on reducing the amount of waste from the product system by recycling or putting less material into the

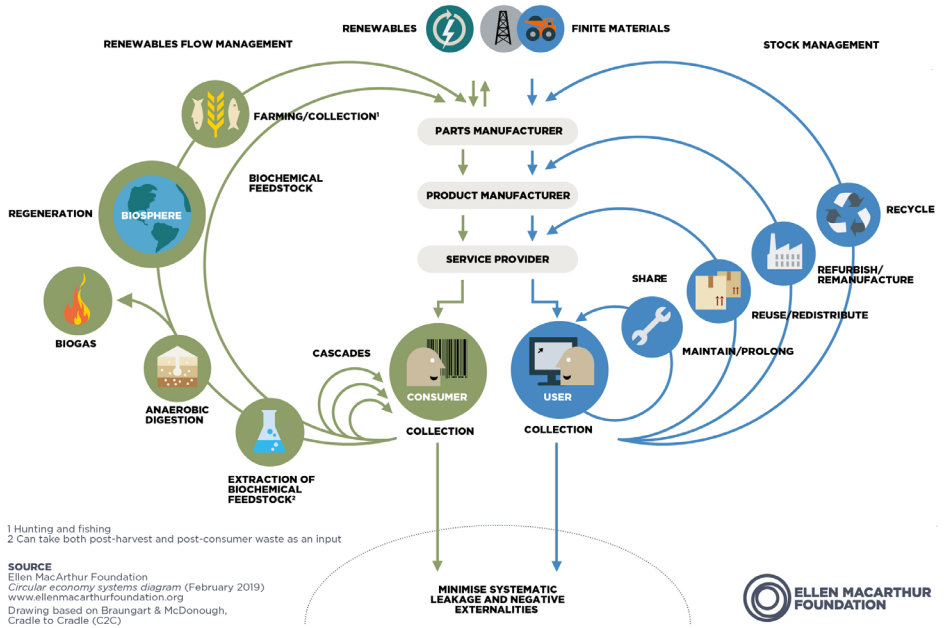


Figure 3. The Butterfly diagram illustrates the different ways to achieve circular economy, with two primary cycles of materials, referring to the technical cycle (where materials are continuedly used and do not become waste) and the biological cycle (where materials return to earth). The diagram is created by Ellen MacArthur Foundation (2015) with the inspiration of the Cradle-to-Cradle foundation by Braungart & McDonough, 2008.

product. Finally, *closing* is the only method of creating a complete circular economy. Here, no energy or materials 'leak' out of the system, ensuring that all materials are kept in the loop (Geissdoerfer et al., 2018).

Integrating circular economy concerns in the product's design phase is essential, since only minor changes can be done once the product is

designed (Bocken et al., 2016). In this project the notion of CE can be used as support for establishing a remanufacturing system and creating inspiration for future possibilities of improvement, both in terms of impact categories and preservation of resources and design choices. It can be said that this thesis is especially involved with design for product-life extension, as remanufacturing restores the product's qualities. Design for product-life extension is one of the design strategies for circular economy proposed by Bocken et al. (2016). It is a strategy for slowing the resource use by design, thereby also introducing strategies such as repair and remanufacturing which prolong the lifetime of products. Under designing for product-life extension is other strategies such as *"Design for ease of maintenance and repair, design for upgradability and adaptability, design for standardization and compatibility, design for dis- and reassembly"* (Bocken et al., 2016, p. 310). These strategies are all relevant when discussing remanufacturing.

As SDEs we work closely with the methods of circular economy. CE strategies have contributed with thoughts for how remanufacturing can be an improvement to the current system of using newly produced ultrasound catheters. Furthermore, CE has made it possible to put remanufacturing of single-use medical devices into perspective according to its potentials for lowering resource consumption.

Actor-network theory

In this thesis the authors have drawn upon Actor-Network Theory (hereafter ANT). ANT can be used as a tool for analysis which studies relations between different actors (human and non-human) and to design social technical systems. Key players in formulating ANT theory is Michel Callon, Bruno Latour and John Law. The theory has been expanded by multiple researchers contributing to the theory across many disciplines. As a tool, ANT is suitable for analysing and mapping the current situation in a network and investigating the relations between actors that define their positioning within the network. Within an actor-network are different actors with relations, discourses, concerns and practices in relation to human and non-human actors (Latour, 2004). The theory can be applied to uncover how the actors' interactions and concerns can shape or reshape the relations in the actor-network. It is essential to acknowledge that these networks, when represented, are of selected actors and constantly changing and will therefore never fully represent reality. Callon describes ANT as *"... an attempt to provide analytical tools for explaining the very process by which society is constantly reconfigured"* (Callon, 2001, p. 62). Since an actor-network is continuously redefining the actors' roles in the network, the current situation is changeable. When seeking to transform the network, the relations are of interest, especially the matters of concerns, because they are up to be negotiated. Different actors can be included in the network, which affects the symmetry of the network, and new entities can act to either stabilise or destabilise it.

Storni argues that *"... ANT worlds suggest that we look relationally and symmetrically: not at what entities are in isolation but rather what they*

become, do and produce when they are associated together." (Storni, 2015, p. 169) and Callon describe that "*an actor-world associates heterogeneous entities. It defines their identity, the roles they should play, the nature of the bonds that unite them, their respective sizes and the history in which they participate*." (Callon et al., 1986, p. 24). Therefore, when discussing actor-network, it is essential to be able to discuss the actors' places in the network and their potential for change. This can be done by using the four moments of translation introduced by Callon (1984). Translation is central to ANT and according to Callon (1984) translations occur when individuals formulate a network and their actions can be considered as an entity of its own rights. The four moments of translation are problematisation, interessement, enrollment and mobilisation, which cover how actors' positions and relations can be renegotiated.

Problematisation is the problem outline. In this phase, it is essential to define the problem so that the actors can agree, associate, or identify with it. Therefore, how the problem is defined can create alignment between the actors and the team working to create a change.

Within the *interessement* process, the actors develop an interest in the project. The interessement strengthens the links between different actors. The actors will desire to be part of the project because they are aware of how they can potentially benefit from it. Through the interessement process, the actors' roles in the network can be negotiated. To be able to work on the network and reconfigure it, it is necessary to understand what is at stake for each actor and navigate with varying opinions and concerns. Interessement can be achieved through the use of interessement devices.

Enrollment happens when the actor contributes to the project and accepts their role in a new network. The actors will work towards benefitting the networks' agenda and be aligned with it.

Mobilisation is when the enrolled actors act and speak on behalf of the project agenda. They will actively work on establishing the new network. Thereby, they are also able to spread awareness of the project and interest more actors in the problematization. They are then so-called spokespersons of the project/problematization.

Building upon the research of Callon (1984) and Storni (2015) has helped us to understand some of the relationships and matters of concerns of the actors in the current network of using ultrasound catheters and what matters of fact are hindering AUH from transitioning to a new network of remanufacturing single-use medical devices (Latour 2004; Storni 2015). An important part of the authors' roles as SDEs has been to reframe a diversity of concerns through ongoing interactions with relevant actors. Additionally, the translation process is iterative and ongoing, and will continue as the guidelines formed in this thesis are used even after the authors of this thesis leave the community of practitioners, that they have been collaborating with during this research project.

Boundary object

A boundary object is tangible and flexible enough to be adaptable to multiple actors differing viewpoints while maintaining some form of continuity across different sites of practice. At the same time boundary objects can help actors form different worlds to co-operate (Vinck, 2003). It was first introduced in 1989 by Star *"to describe how specific artifacts can fulfil a bridging function between different sociocultural sites."* (Terlouw, 2022, p. 26). Bowker and Star argue for the importance of flexibility and ambiguity of boundary objects whereby certain terms are open for multiple definitions across different social worlds (Bowker & Star, 1999, p. 324).

Boundary objects can be placed between actors and allow communication between actors within their own communities of practices and knowledge domains (Carlile, 2002). Furthermore, the boundary object can help to understand the needs and concerns of actors from their worldview by enabling the translation. Thereby, boundary objects can be a powerful tool for engaging actors in a specific problematization, as you will be able to convey the problematisation honestly and more precisely to them. A boundary object can consist of things, concepts, drawings, data and it has interpretive flexibility when displayed among actors (Star & Griesemer, 1989). Franco-Torres et al. (2020) have developed a framework to explain three ways of using a boundary object: *"(1) to build cooperation among conflicting worldviews without constraining diversity, (2) to articulate selection pressures, and (3) to concentrate resources to make transition possible."* (Franco-Torres et al., 2020, p. 35). In this thesis, boundary objects are utilised as a tool that brings added value to the articulation of data to actors, allowing interessement and other motions towards a new network of remanufacturing single-use medical devices.

Boundary objects have been especially important during this project when engaging with actors. This is especially the case when communicating with actors in the healthcare sector, who are acting in a paradigm which the authors of this thesis have limited knowledge about.

Semi-structred interviews

During this research, the most used method of studying the actors has been through semi-structured interviews. Semi-structured interviews are the middle ground between fully structured and very unstructured interviews. According to Drever (1995) the semi-structured interview is defined by having an informal approach while directing the focus of the interview, with a mixture of pre-planned and open ended questions organised by a thematic structuring. Adopting such an approach allows the interviewee more freedom to take the interview in directions that they find are important based upon their experiences related to the questions being asked. Hence, with this type of interview, something is often discovered that was not planned when the interview questions themselves were written.

Semi-structed interviews were used in all interviews of this thesis. The method allowed for flexibility and a more open conversation with the interviewee, which was important for the authors to gain valuable insights into a healthcare sector that they previously did not know much about.

Case study

This thesis project takes a case study approach to study the sustainability and actor interests regarding remanufacturing of single-use medical devices. The case study approach is convenient for obtaining an in-depth assessment of an area, event, or issue within the real-life context of the case. As explained by Yin (2009), case studies can describe, explain and help explore phenomena in the context in which it occurs (Yin, 2009). In a case study, it is the researcher's responsibility to distinguish the case's pre-defined boundary and scope and define an appropriate duration of the study. The case studies will be different in execution depending on the researcher's sociotechnical standpoint. Some of the approaches are *"...critical (questioning one's own and others' assumptions), interpretivist (trying to understand individual and shared social meanings) or positivist approach (orientating towards the criteria of natural sciences, such as focusing on generalisability considerations)"* (Crowe et al., 2011, p. 4). Frequently, a case study involves collecting data and evidence from multiple sources, covering both quantitative and qualitative techniques such as questionnaires, data, interviews, and observations. When the researcher is to make sense of and review the significant amounts of data for report findings, the analysis process occurs. Here the focus should be on providing contextual data to improve the readers' understanding of what the conclusions are based on and how they are reached.

As SDEs, we have made a case study on the ultrasound catheter and examined the case of a using either a new catheter and a remanufactured catheter for treatment at AUH Heartlab 2. Carrying out the study case has provided a deeper understanding of the entangled situation and different problems within remanufacturing of single-use medical devices.

Furthermore, by use of the case study, the authors aim towards a longer term objective of contributing to how other medical devices and systems could be remanufactured in the future.

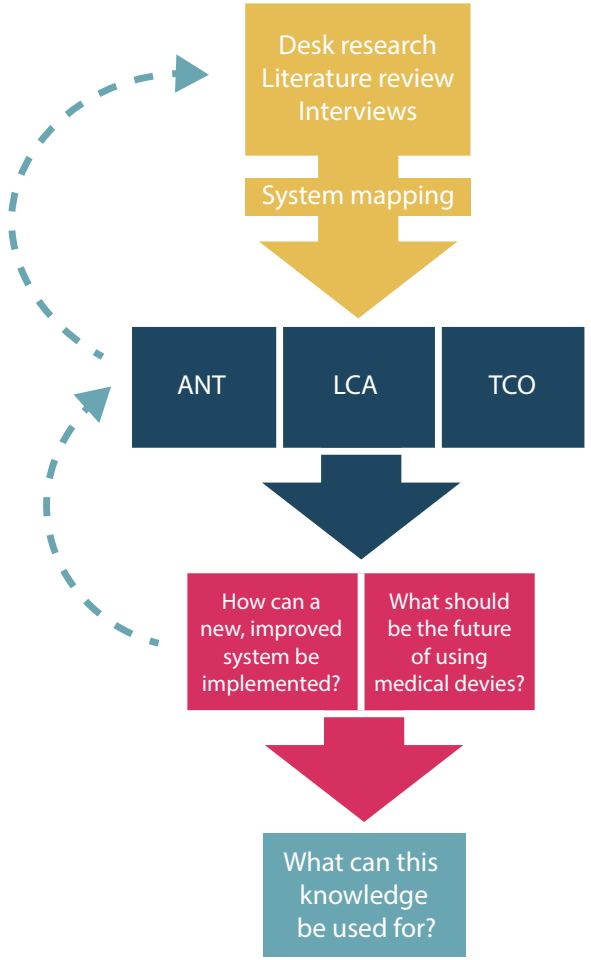


Figure 4 The different phases of this master's thesis. The sections of this report follows the same structure.

Research Design

The research has moved between different phases. The report is built according to these. These phases have been worked in iteratively when new information or lack of information has come up. In Figure 4, the overall process can be seen. The first step has consisted as reading up on relevant literature to understand the state of the art. Furthermore, it has included engaging with relevant actors to get a case-specific understanding of the issues and needs. The engagement with actors can be seen in Figure 5. This has all led to mapping the system at AUH in different ways, both in terms of processes and socio-technical systems.

Having an overview of the interconnections of actors and processes of the systems, it has been possible to do three different analyses. The analyses are ANT, LCA and TCO. These three analyses have helped investigate possible solutions and understand the relations of actors. Moreover, the analyses have created data to be used actively when investigating how to implement changes as seen marked with dark blue in figure 4.

Through the results of the analyses, it has been possible to create suggestions for how to implement a new system and how to optimise this system in the future. The suggestions have been created on two levels: what can be done now and what can be done in the future. This can be seen marked with pink in figure 4.

All of this case-specific knowledge has been used to make a general notion of the sustainability of remanufacturing single-use medical devices. Furthermore, some perspective on how this case-specific knowledge can be broadened and used to improve sustainability in the larger healthcare sector will be presented.

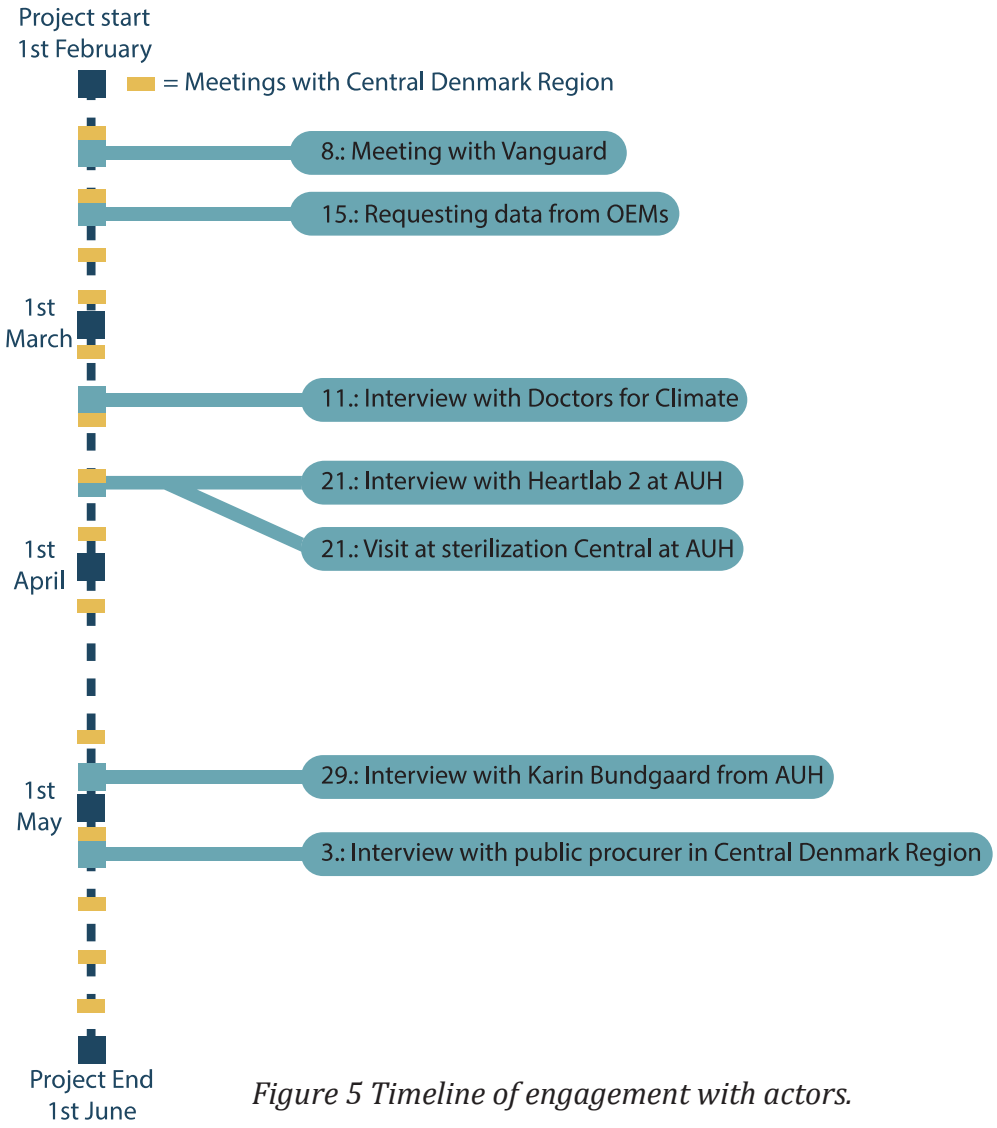


Figure 5 Timeline of engagement with actors.

There has been engagement with various actors during the project, as seen in Figure 5. The actors have each contributed with their understanding of the current system's issues and their concerns related to the implementation of a new system with remanufacturing.

2.0

Empirical Material

In this chapter, the area of investigation will be explained in more detail. Firstly, the history of regulation leading to the currently stabilised network of using single-use medical devices in Denmark will be explained. Followingly, the status on regulation in other countries will be presented. This is to show the current societal development regarding remanufacturing. Secondly, the current use of the ultrasound catheter and the most central actors of the investigation will be clarified, followed by an explanation of which actors have been contacted throughout the project. Lastly, the current system of ultrasound catheters will be shown in detail, and the remanufacturing system will be described. This chapter will present the foundation of empirical materials used in the later analyses.

Historical overview

Previous to the 80s the hospital sector in Denmark was reliant on reusable medical devices. Consequently, most medical devices were designed to be sterilised by easily cleanable designs and a selection of resistant materials such as stainless steel. However, this started to change in the early 80s, with the emergence of new, transmittable diseases, which resulted in fear of transmission through reusable tools at the hospitals. Correlatedly, medical devices became much more complex, which evolved into them being challenging to clean and sterilise properly. As the OEMs would not like to take responsibility for these new, complex devices being reusable, they adapted them to be single-use (European Commission, 2010).

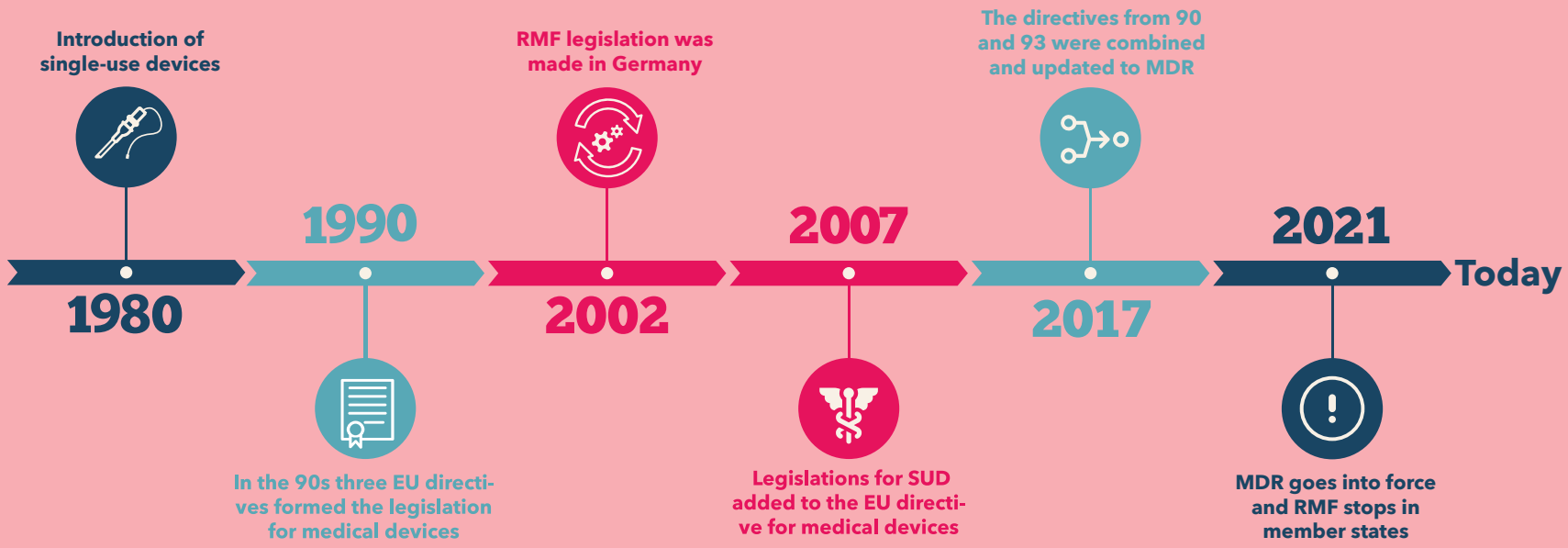


Figure 6 The timeline highlights the years when significant changes in regulation were made, from the 80s until today. (RMF=remanufacturing).

History of regulation

The wide application, and many medical devices entering the market, led to the European Commission implementing directives for medical devices to avoid safety issues. This led to the release of the following directives throughout the 90s as noted in figure 6: Directive 90/385/EEC on active implantable medical devices, Directive 93/42/EEC on medical devices and Directive 98/79/EC on in vitro diagnostic medical devices (IVDs). Especially relevant to this case is directive 93/42/EEC. There is no mention of whether remanufacturing can or cannot be used as an end-of-life method in this directive. This has left the door open to interpretation, with a different understanding of the legality of remanufacturing in member states.

Important to note in this directive is Annex I, Article 13.6(h). In this, multiple requirements and specifications are stated that OEMs should include to assure the safety of reusable devices, such as information regarding cleaning, disinfection, packaging and restrictions on numbers of reuses (European Council, 1993). However, there were not the same stringent criteria for single-use products, as these did not need to be sterilised and cleaned. Consequently, it was easier for OEMs to comply with the rules for single-use products than reusable ones, resulting in lowered cost of production for the OEMs. Hence, an economic incentive was created for OEMs to push their marketable products more towards single-use devices (Popp et al., 2010) than reusable devices. To restructure this unintended effect of directive 93/42/EEC, it was amended in 2007. Here, one of the additions were the following text to Annex I, Article 13.6(h): *"if the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used."* (European Council, 2007, p. 25).

Medical Device Regulation

As a result of the ambiguity regarding the legality of remanufacturing single-use medical devices, the EU commissioned a report to investigate the subject in 2010 as indicated in figure 6. This report supported a change to the directives (European Commission, 2010). Followingly, changes were made to the directives (MDDs), resulting in the medical device regulation (MDR) of 2017. The new regulation combined Directive 90/385/EEC on active implantable medical devices with Directive 93/42/EEC on medical devices. The one change from the MDDs to the MDR of specific interest is that of article 17. Article 17, pt. 1 states the following:

"Reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with this Article."(European Council, 2017, p. 30).

This was going to be implemented in May 2020 but was delayed due to the pandemic. Consequently, it went into force in May 2021, effectively stopping remanufacturing in most member states.

Danish regulation

In Denmark, the possibility for remanufacturing was mentioned in the "*Lov om videnskabsetisk behandling af kliniske afprøvninger af medicinsk udstyr m.v.*" on the 9th of December 2020. In this version, the following

has been added after §1d:" *reprocessing and continued use of single-use instruments must only occur if allowed according to rules created by Lægemiddelstyrelsen, and only in compliance with EU-regulation on reprocessing and reutilization of single-use instruments.[TRANSLATED]"* (Sundheds- og Ældreministeriet, 2020, p. 8).

Status on remanufacturing in other countries

In **Germany**, there has been national guidelines on remanufacturing single-use medical devices since 2002 (Commission on Hospital Hygiene and Infection Protection, 2012). These guidelines provide a minimum standard for remanufacturing in Germany. Several university hospitals have periodically hired external companies such as Vanguard AG to remanufacture catheters and other medical equipment (*Vahle, 2022*)*. The remanufacturing has provided lower costs of medical procedures for German citizens. The early creation of guidelines for remanufacturing has allowed an industry for remanufacturing to flourish in Germany, resulting in extensive use of these services in the past 20 years. This has further allowed remanufacturing companies to extend their practices to more products (Williamson, 2003).

In the US, FDA decided to allow remanufacturing in 2000 by classifying remanufacturers of single-use medical devices as OEMs (Socialstyrelsen, 2020; Vukelich, 2016). Hence, the remanufacturers must live up to the same stringent criteria as OEMs and some additional criteria that are only applicable to remanufacturers. According to AMDR-data, many FDA-cleared single-use medical devices could legally and safely be remanufactured, even if only a few are remanufactured currently. US hospitals are only now becoming aware of the significant benefits of using remanufactured medical devices, even though the US military already uses them in most of their facilities (Weeda, 2021).

Socialstyrelsen in **Sweden** established a commission in 2019 to investigate remanufacturing of single-use medical devices, addressing the primary challenges of product liability and patient safety (Socialstyrelsen, 2020). The commission conducted a literature review to collect knowledge regarding remanufacturing practices and developments in Europe and found that remanufacturing of medical devices had been used in Germany, and periodically in the Netherlands, Portugal, Latvia, Norway, Denmark, Finland, and Belgium. Based on a Swedish patient base of approximately 60.000 patients, the commission did not find any registered cases of complications due to using remanufactured medical devices from 2005 to 2019. Additionally, the commission surveyed Swedish hospital staff, concluding that 40% of all participants had used remanufactured equipment to some extent in the past (Socialstyrelsen, 2020).

** All reference to interviews will hereafter be put in italics like this to differentiate them from primary literature.*

Scope and boundaries

The scope of this research is restricted to the case study on the ultrasound catheter at AUH Heartlab 2. The ultrasound catheter has provided a case example of remanufacturing single-use medical devices.

The ultrasound catheter is shown in front of its' shelf at Heartlab 2, AUH, in Figure 7:

Figure 7. the AcuNav ICE ultrasound catheter from Simens Healtineers in front of the cabinet that it is stored in at AUH Heartlab 2

AUH, which is the case hospital we have been collaborating with, uses two different ultrasound catheters during operation. We have limited our investigation to focusing on just one of them, the AcuNav ICE from Siemens Healthineers. The AcuNav ICE from Siemens Healthineers was chosen since Vanguard AG shared a datasheet on this specific catheter, allowing us to use more precise data in our further investigation.

The ultrasound catheter consists of a plastic shell with a thread system within the wire, allowing bending of the tip, in which the ultrasound chip is placed as can be seen in Figure 8. This way, the doctor can readjust the ultrasound 'vision' while the wire is placed inside the patient.
The ultrasound catheter is used in operations of the aurikel and PFO-closing. The ultrasound catheter is inserted through an incision in

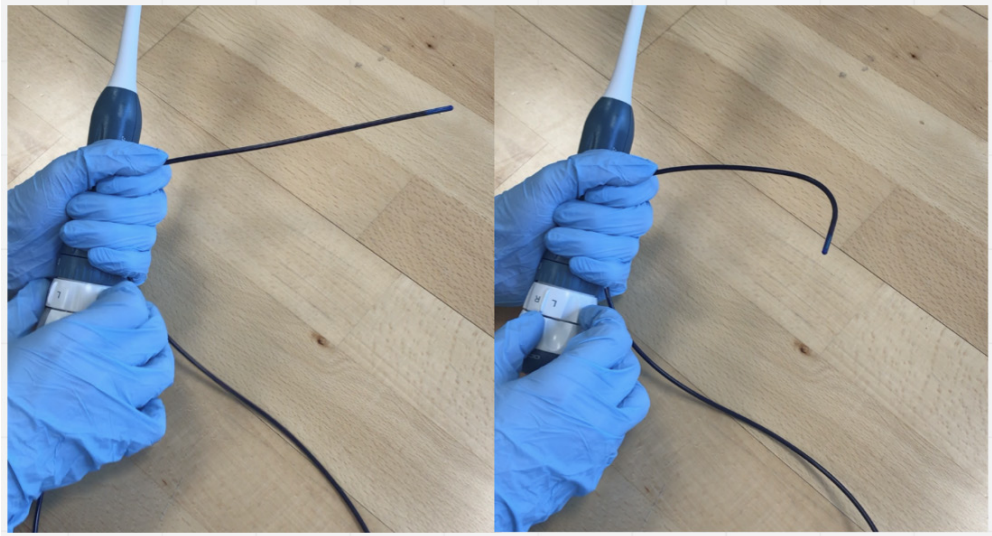


Figure 8. The picture shows how to rotate the handle to make the tip of the wire bend.

the groin and transferred through a vein into the heart. Typically, other tools are used simultaneously, inserted together with the ultrasound catheter *(Jensen, 2022).* In Denmark, only AUH and Odense University Hospital (OUH) perform this kind of surgery; hence in only these two places, the catheter is in use *(Klausen, 2022).* Central Denmark Region uses approximately 250-300 ultrasound catheters a year, all in Heartlab 2 at AUH *(Madsen 2022)*. According to Stryker Sustainability Solutions, the ultrasound catheter is relatively expensive, with a price of 2500 $ (Stryker Sustainability Solutions, 2017).

Central actors

To conduct the case study of using ultrasound catheters at Heartlab 2, AUH, multiple actors have been engaged in interviews and have provided information about their concerns, practices, and interests. The contact with the actors have been through interviews, email and one visit to AUH Heartlab 2. The obtained knowledge and a description of the actors will be elaborated below.

Central Denmark Region

This project is a collaboration with Central Denmark Region. They have requested an analysis examining the environmental and cost benefits of using remanufactured ultrasound catheters. They are interested in this case because AUH's Heartlab 2 has previously used remanufactured ultrasound catheters. Because of the MDR and thereby the outlawing of remanufacturing single-use medical devices without national guidelines, they would like to push for these national guidelines to be made, given that it is patient safe.

The collaboration with Central Denmark Region has consisted of weekly touch-base meetings between the authors of this thesis and Lærke Dahl Klausen and Rasmus Revsbeck, project manager in the Center for Sustainable Hospitals and Development consultant in the Regional Development section, respectively. Klausen and Revsbeck have facilitated contact with relevant actors in the Central Denmark Region, aided in collecting data for the LCA and TCO, and have contributed with their professional knowledge and guidance. Parallel to the research are two other groups. The first group consist of actors within Central Denmark Region who are researching and facilitating the work towards the legislation of remanufacturing. They have investigated the progress in creating the guidelines in other EU member states and collected experiences. The second group is a focus group consisting of experts in medical hygiene and sterilisation and medical associations. Klausen will, together with the focus group, prepare the appeal for the creation of the guidelines for remanufacturing single-use medical devices, which will be sent to the Danish Medicine Agency in October.

Mads Bräuner Madsen is the category manager in procurement and medico technique in Central Denmark Region. He is part of the focus group and has helped the authors of this thesis to understand public procurement and has assisted in data collection.

Mads explains that when making a tender, they will establish a working group, consisting of a purchaser, that must ensure that everything takes place in accordance with the public procurement act. The other part of the group will consist of doctors, that will provide knowledge for a requirement specification. When the agreement is for over 1,6 million DKK, it must be put out as a public tender. Moreover, a contact of using remanufactured catheters, is categorised as a service contract, which have some different requirement from a normal public tender.

Heartlab 2

Heartlab 2 is a laboratory department for heart diseases at AUH in Denmark. Heartlab 2 have used remanufactured ultrasound catheters for 1 ½ year and has expressed a desire to use them again. As part of this study, it was essential for the authors of this thesis to understand the practices and the use-case differences between a new ultrasound catheter and a remanufactured ultrasound catheter. Therefore, we contacted Jensen, a nurse at Heartlab 2, to plan a visit. Luckily, the operation room was not used on the day of the visit. This made it possible to walk around and physically see how the catheters are stored, used during operation and how they are, in the case of remanufacturing, cleaned and shipped.

Furthermore, Jensen provided two ultrasound catheters that have been used during operation and cleaned afterwards. Had we not received the ultrasound catheters they would have been thrown out with the general waste from the hospital, as per the current system. The given ultrasound catheters have been crucial in collecting data on the product materials, to be used in the LCA. Continuously through the project, Jensen has communicated with the authors of this thesis through email.

Vanguard AG

Vanguard AG has previously done remanufacturing on ultrasound catheters from Heartlab 2. Vanguard AG is one of the biggest remanufacturing companies in Europe and has over 20 years of experience (Vanguard, 2022). In this project, knowledge of the remanufacturing process was needed to assess the sustainability of the solution. Therefore, Viola Vahle has been contracted. Vahle is an international project manager in Vanguard AG and a board member of AMDR. Unfortunately, due to the corona restrictions in Germany, it was not possible to travel to their facilities and see the remanufacturing loop. Instead, an online meeting with Vahle was arranged where she carefully explained the remanufacturing steps. Furthermore, Vahle has answered countless emails, helping to collect the necessary LCA data.

Persons of interest

Sterilisation central

To investigate the possibilities of sterilisation locally, the sterilisation central at AUH was visited. Throughout a guided tour of the facility, it was the possible to ask questions to every sterilisation step. Furthermore, possibilities for sterilising the ultrasound catheter at the location was discussed. The knowledge of the sterilisation process was used in the work with the LCA.

Martin Schønemann-Lund

To examine the willingness of doctors to act on sustainability the organisation called Doctors for Climate was contacted. An interview with Martin Schønemann-Lund, the frontperson in Doctors for Climate, was established. Doctors for Climate wants to encourage, inform, and create interest in how healthcare professionals can engage in the climate debate (Læger for Klimaet, 2022). Through the interview, Schønemann-Lund contributed to the knowledge of why single-use medical devices are in use and the possibilities of change in the future. Furthermore, the reactions he experiences from other doctors when discussing sustainability issues and solutions were discussed.

Karin Bundgaard

Karin Bundgaard has a background as a nurse and has the past five years been engaged in the research field. She has investigated the advantages and disadvantages of sterilising reusable medical devices regarding hygiene. Currently, she is an Associated Professor at the Faculty of Medicine at Aalborg University Hospital and is also a member of Central Denmark Region's focus group. An interview with Bundgaard was conducted to obtain her knowledge on the barriers to remanufacturing associated with hygiene concerns and infection. Through an interview with Bundgaard, she has giving her vision on what kind of standards should be set in place and what investigations should be done to ensure the safety of remanufactured single-use devices.

Visit at Heartlab 2

To understand the journey of the ultrasound catheter through AUH, it was decided to discuss this with one of the nurses that have previously worked with the remanufactured ultrasound catheters. Therefore, a visit to AUH was arranged, located in the operation room of Heartlab 2. This way, it was possible to use the operation room as a boundary object to show and talk about the different systems.

The operation

The room is split into two sections during operation: an unsterile one and a sterile one. The doctor is on the sterile side with a nurse, and a second nurse is on the unsterile side. This allows for ensuring that all devices used are entirely sterile. When a tool has been used, the doctor hands it to the nurse on the unsterile side, who then disposes of the device. For example, in the case of ultrasound catheters sent to Vanguard, the nurse takes the ultrasound catheter to the sink and cleans it with leftover saltwater from the operation. Usually, the ultrasound catheter is first removed from the patient at the end of the surgery; whereafter it is cleaned with a sterile cloth and then handed to the nurses on the unsterile side of the room. This way, it is prevented that blood splatters around the room unnecessarily.

The ultrasound catheter is plugged into a socket next to the operation bed when it is in use, as seen in Figure 9. The socket is on the unsterile side of the room. For the ultrasound catheter investigated in this thesis, the bottom of the catheter is plugged into a reusable cable which is then plugged into the socket next to the bed. The reusable part of the cable is wrapped in sterile plastic packaging as it will cross from the unsterile to the sterile side of the room.

The catheter is plugged into a socket next to the surgery bed, allowing for an ultrasound machine to turn the ultrasound signal into a digital 2D image. The image is shown on a big screen in front of the doctor during operation, together with other relevant images such as x-ray.

See Figure 10 to see the catheter of investigation and the screen it is attached to.

Typically, the ultrasound catheter is used in unison with other tools inserted similarly. This, as the ultrasound catheter only provides the 'vision' inside the heart, other tools are needed to place items and perform the operation. Heartlab 2 has two different catheters which they use for each their purpose. The catheter by Siemens Healthineers is softer and often used in the right heart chamber. The catheter by St. Jude is a bit tougher and is generally used when they need to pass from one heart chamber to the other.

Figure 9 The operation bed with a yellow arrow indicating the socket for the plug of the ultrasound catheter.

Figure 10. The screens where the ultrasound image is shown and the mouse the doctor can use to navigate between the different image created.

Ordering Ultrasound Catheters

Devices are ordered through a BRIK-system at AUH, seen in figure 11. This system consists of small bricks on each device or product, which will be placed on a rack by the door when the operation room is about to run out.

The brick is scanned by the DKI-team, who will then order the device or product. The bricks come in two different colours, which indicate delivery times: blue and white. White bricks indicate that it is a storage item, and it can therefore be delivered tomorrow from the storage in Horsens. Blue bricks indicate that it is an 'ordered by demand'-item, which means that the DKI-team will order it from the producer, resulting in a delivery time of up to 5 days.

Figure 11 The BRIK-system. The yellow circle indicates the brick colour. Rows with green text are the bricks to be scanned and ordered. The ones one the rows with red text have been ordered and awaiting arrival.

The ultrasound catheters are a blue brick item. AUH gets 10 ultrasound catheters delivered at a time. Therefore, the nurses must be continuously aware of the stock of ultrasound catheters in the room to ensure they do not suddenly run out, as 5 days is long to wait if they have no more catheters. More about how the ultrasound catheter was physically moving between departments and made ready for remanufacturing will be described in the chapter 'system descriptions'.

System description

This section will map the two different journeys of ultrasound catheters at Heartlab 2. First, the mapping of the hospital loop will illustrate the journey of a newly produced ultrasound catheter. Next, the remanufacturing loop will be described, starting at the end of use of the catheter in operation. The system has been mapped to provide the base for the analyses and have a better understanding of the different actors that are in contact with the ultrasound catheter throughout its life cycle.

The hospital loop

To map the hospital loop, the description provided by Jensen from Heartlab 2 and emails exchanged with an employee from the Depot & BRIK team were used. The employee from the Depot & BRIK team explained how products move around the hospital, which helped to give a better understanding of the logistics. A detailed description of the steps within the hospital loop is shown in figure 12.

The nurse sees that they are running low on ultrasound catheters and therefore hangs a brick at the rack next to the door. Here, a depot employee comes to scan the brick, and the order is received at the DKI team.

The DKI team will confirm and place the order for 10 new ultrasound catheters at Johnson & Johnson. The delivery will take up to 5 days from then the depot employee scans the brick to the ultrasound catheters is delivered at Heartlab 2.

Johnson & Johnson have their production facility in Washington State; therefore, the ultrasound catheters will be delivery by air freight to a storage central in Belgium and from there they will be transported by truck to AUH.

The ultrasound catheters arrive in boxes and are placed into carts in the evening. Depending on the number of other products that are delivered, there will be about 250-300 carts filled with delivered products every day.
From the arrival area, the carts are driven to the ´landing zones´. There is a total of 87 'landing zones' evenly distributed across AUH.
At 5 a.m. every morning, a depot employee will come and distribute the products from the 'landing zones' to the OP departments. The ultrasound catheters are placed on their designated shelf at Heartlab 2. If any bricks are hanging on the rack by the door they will be scanned.

Before the operation a nurse will prepare the operation room and unpack the ultrasound catheter and place it ready for use.

After use the nurse will throw the used ultrasound catheter into general waste. During the day, depending on the waste production, the filled

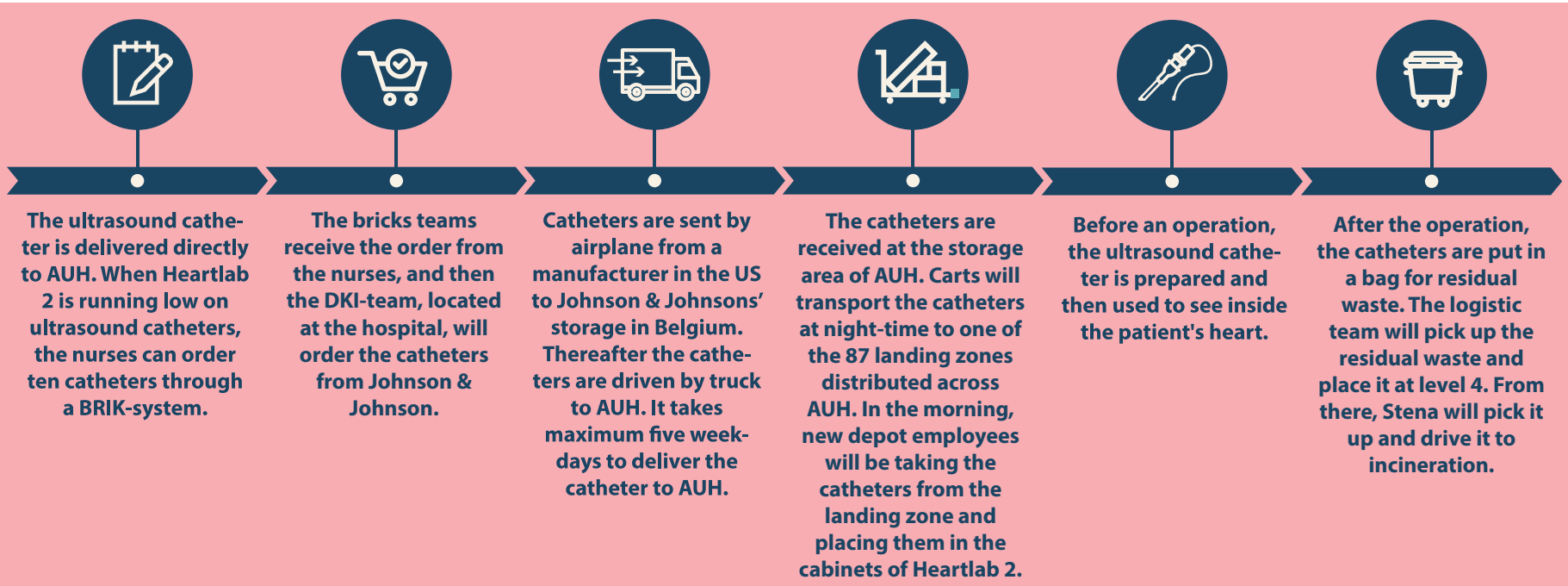


Figure 12. Shows a mapping of journey of the ultrasound catheter in the hospital loop.

bags of general waste are transported to the department's waste room. Here it will need to be stored for 24 hours before being transported to the waste central.
The residual waste is thrown into a container, where it is compressed and later picked up by Stena.

The remanufacturing loop

To map the remanufacturing loop, various data has been collected through an interview with Vahle from Vanguard AG and the interview with Jensen from Heartlab 2. The meeting with Vahle was conducted as an online semi-structured interview where an incomplete mapping of the remanufacturing loop was prepared to be used as a boundary object guiding the discussion. Vahle came well prepared by bringing a PowerPoint presentation of Vanguard AG, their facility, and a video that described the remanufacturing steps of catheters. Therefore, we agilely changed the scope of the meeting, by letting Viola tell us what she had planned, instead of using our boundary object. A step-by-step review of the remanufacturing loop of an ultrasound catheter can be seen in figure 14. Furthermore, a figure with real life pictures of the remanufacturing process at Vanguard AG's facilities can be seen in figure 13.
After the ultrasound catheters have been used at Heartlab 2, they need to be washed with water or salt water. Vanguard gives the hospitals strict instructions on not using any disinfection, chemicals or alcohol when cleaning the catheters before packing them for shipping. The catheters should ideally be packed when they are dry, but obviously, this takes time at the hospital. Therefore, the nurses can still pack the catheters in the plastic bag when they are a bit moist.

The used ultrasound catheters in the plastic bags are put into a blue box, that is certified to contain medical devices during shipment. Inside

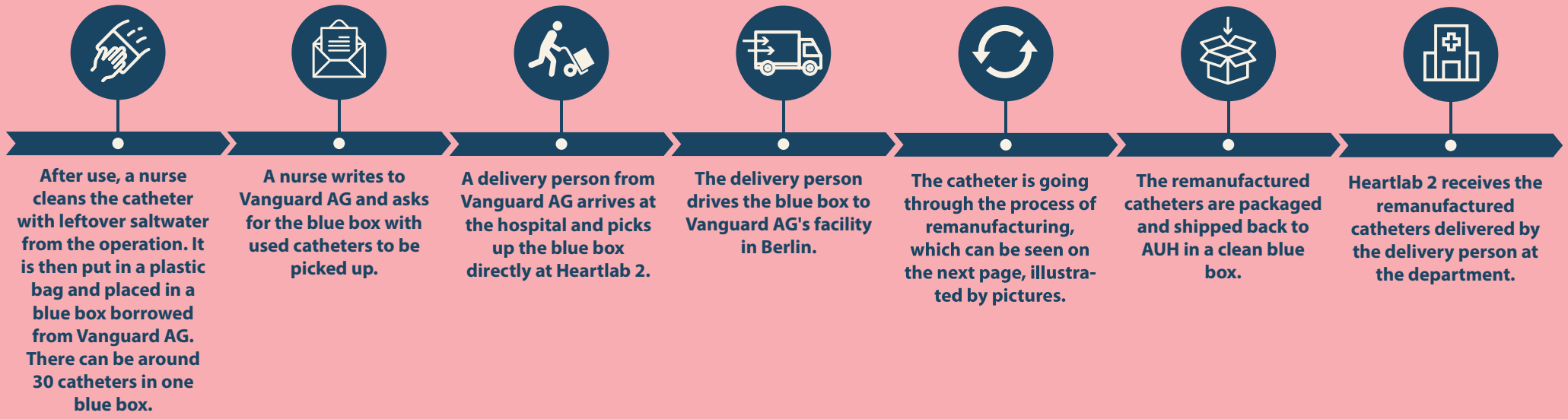


Figure 13. Shows the mapping of the remanufacturing process, that consists of many separate processes.

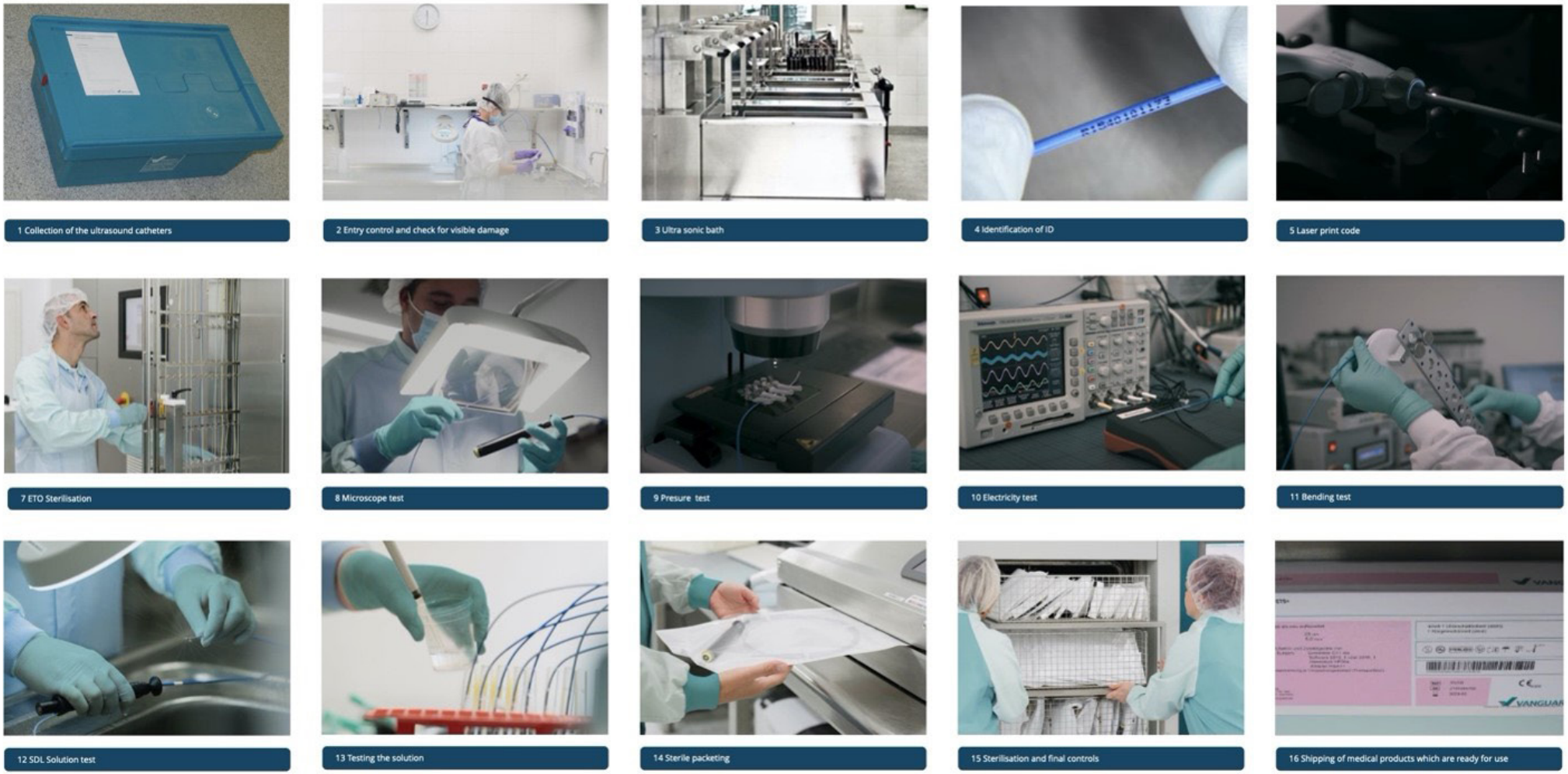


Figure 14. The pictures show the remanufacturing process at Vanguards AG´s facilities, when remanufacturing a ultrasound catheter.

the blue box, there needs to be a sheet with information of what the box contains, which hospital it has arrived from and so on. Outside the box is a sticker with more tracking information. This information is needed when the box goes through entry control upon arrival at Vanguard AG's facilities. A nurse will order pick up of the blue box when it is full.

Once the ultrasound catheter arrives at Vanguards facilities, they have a visibility check and pre-clean, where the device is checked for OEM label and lot number to identify the device before being placed in an ultrasonic bath. Then Vanguard AG prints a unique id-number on each device. This is done to have an overview of the product's remanufacturing cycles and be able to identify it if it returns to the facility. An ultrasound catheter can be remanufactured three times. For other devices, the number of cycles depends on the device.

The device arrives at the disinfection zone, where it goes into a disinfection machine, which Vanguard AG have developed themselves. The machine can disinfect up to 30 catheters in one hour. The next steps contain the drying process.

When the catheter is dry it goes through a function test. This is the most time consuming and challenging part of the remanufacturing process. Each individual catheter gets function tested. In the function test, the catheters get pressure tested, the electricity rate gets measured and the chip in the wire is inspected.

After the function test follows a mechanical test, where Vanguard AG checks if the catheters are bending correctly and clean it with a so-called SDL-solution. If a catheter does not get approved in just one of the functional tests it is discarded.
After all the testing, the ultrasound catheter gets packed into a peel pack and sterilised in an ETO steriliser.

Vanguard AG packs the ultrasound catheters in a box with a label that among other things specifies that the device is a single-use medical device.
The catheters are now ready to leave Vanguard AG's facilities and can be transported by truck back to Heartlab 2. The remanufactured ultrasound catheters are placed directly at the OP-department at Heartlab 2, and a nurse will place them on the designated shelf.

Sub-conclusion

All of this empirical knowledge has been necessary to create the base of knowledge upon which to analyse. The historical analysis of the legislation on remanufacturing single-use medical devices clarified how legislation have banned the use of remanufacturing devices for member states, that do not have their own legislation on the topic. Moreover, the historical analysis managed to explain the movements that have created the system of using single-use medical devices today.

The visit at AUH Heartlab 2 showed what a well working remanufacturing system, with cleaning and packaging, used to look like. This combined with the interview with Vahle, provided all the needed knowlegde to detail and map journeys of the ultrasound catheter trough the two systems. In the coming chapter this empirical knowledge will be referenced and used to analyse the actor-network of the ultrasound catheter.

3.0

Actor-Network

Actor-network on the debate of remanufacturing

There is a growing awareness of the sustainability issues connected to the heavy and reliant use of single-use medical devices. Moreover, concerns have been raised with the changes imposed by MDR, which results in the outlawing of remanufacturing in most member states. To resolve these sustainability issues and make way for the necessary changes to allow remanufacturing, it is essential to inspect the socio-technical network that is the status quo in this complex situation. Therefore, using actor-network theory, the actors' concerns have been analysed to identify which obstacles are intrinsically linked, how different actors shape the network and how certain actors hinder the introduction of a remanufactured ultrasound catheter in the network.

With the actor-network theory, the following will be investigated:

- Who or what is doing stabilisation work and who is trying to destabilise the network?
- Which relations are necessary to develop or change to foster the transition towards using remanufactured catheters?

To unfold the complexity of the current network, it has been chosen to portray the relations and concerns in a network illustration, see figure 15. The entanglement of actors in the network has been simplified and illustrated as grouped into five clusters. Each cluster represents actors that have a relation to each other. The actors are colour coded according to their role in the network: blue are actors related to producing the catheter, yellow are influential actors interested in the use of the catheter, and pink are actors concerned with legislation. The network has a focus on the Danish perspective on establishing future remanufacturing of single-use medical devices, but with an outlook to international relations when appropriate. This has the implication that the European context of the Danish network is included, as the motions at a European level severely affects the relations on a nationally Danish level. The represented actors have been chosen based on their strong influence or interest in the remanufacturing agenda. They each play a role in promoting sustainability, addressing concerns regarding hygiene risk, or contributing with an economic perspective.

Each actor's 'matters of concern' have been identified, analysed and placed on the network represented in the form of small grey clouds. According to Latour (2004) a 'matter of concern' presents the concerns from a diversity of actors' viewpoints. These viewpoints differ from matters of fact, as they have the potential to challenge embedded processes and practices that would have been unable to change if they were a matter of fact. As specified by Law (2016): *"Things never have to be the way they are."* (Law et al., 2016, p. 49). Thereby, attending to matters of concern leads to an ability to discuss reality and possibilities to enact changes.

Examining the actors' concerns presents what is at stake for each actor. Thereby also what can be used to interest each actor in changing the network.

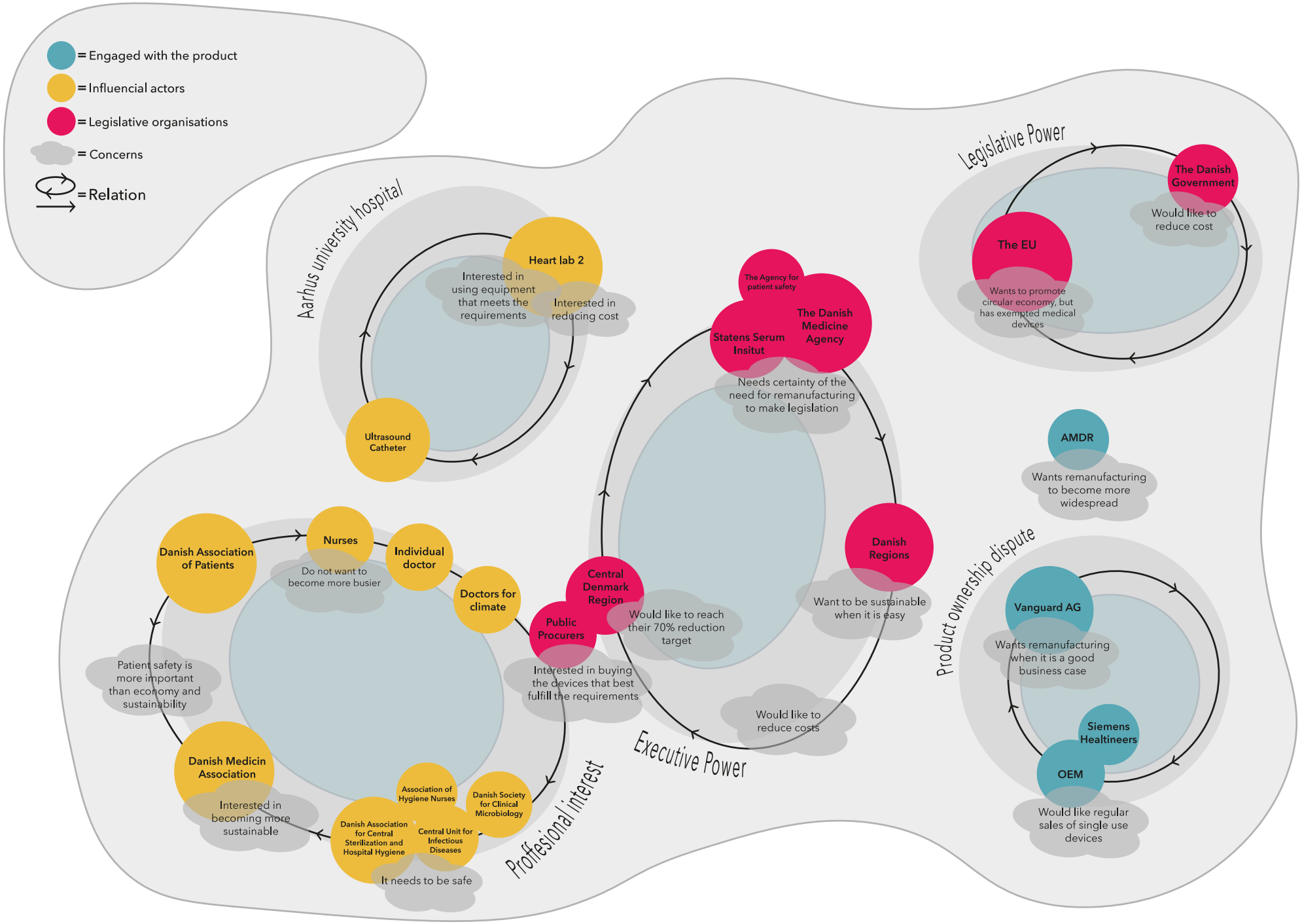
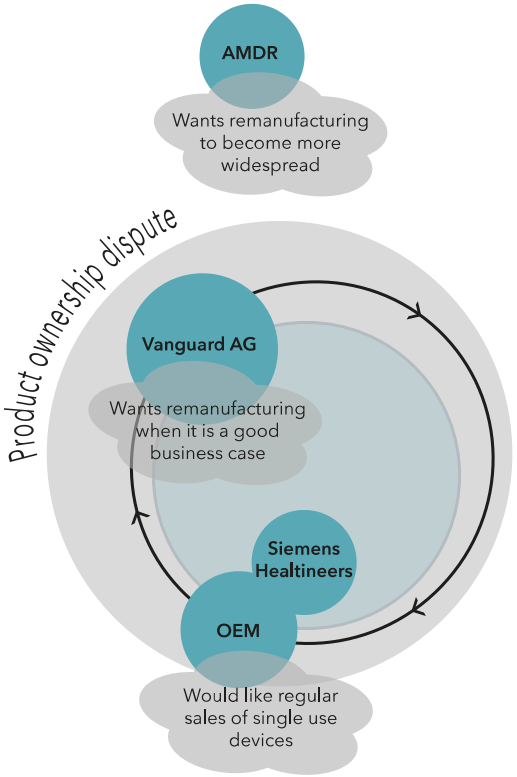


Figure 15 A simplified illustration of the actor-network with the most relevant actors to the case of switching to remanufactured ultrasound catheters. Many of the actors are only engaged in remanufacturing of single-use devices and not solely the ultrasound catheter. The grey clouds represent the matters of concern for each actor.

Product ownership dispute

Figure 16. Product ownership dispute of the actor-network



One of the more significant obstacles to changing the network is the dispute between OEMs and the remanufacturing companies. This dispute occurs because of internal cannibalisation when the customers of remanufactured devices and new devices overlap. These customers will overlap, as the newly produced and the remanufactured device deliver the same function and fulfil the same purpose. Resultingly, there will be a reduction of sales of new devices made by the OEM (in this case Siemens Healthineers) and corresponding sales in favour of the remanufacturing company (in this case Vanguard AG), as the OEM cannot compete on price. As stated by D'Adamo & Rosa (2016), this is considered an undesirable situation (D'Adamo & Rosa, 2016). It will lead to disagreements and tension between the two parties, potentially inhibiting the change.

Hence, the prevalence of remanufacturing could eventually deconstruct the OEMs' market share. However, the OEMs would like to continue their regular sale of single-use devices to continuously profit from every single device sold. Therefore, they are trying to stabilise the current network. Moreover, they have further incentive to prefer the production of single-use medical devices as they, as opposed to reusable devices, are not included in the EU WEEE-directive (European Council, 2018).

Association of Medical Device Repressors (AMDR) is placed between The European Commission and Vanguard AG in the network since AMDR's mission *"is to promote and protect the legal, regulatory and other trade interests of the commercial reprocessing industry"* (AMDR, 2022a). Hence, AMDR is interested in pushing for allowance and more widespread use of remanufacturing due to the environmental and economic savings. Eventually, AMDR's lobbying would benefit remanufacturing firms, such as Vanguard AG since it creates an opportunity to gain a more significant market share. Therefore, they are actively working on changing the current network.

Vanguard AG is interested in remanufacturing on a bigger scale and expanding its business if there is enough volume of a specific single-use medical product to make it economically feasible *(Vahle, 2022)*. Vanguard AG is currently remanufacturing the same ultrasound catheter as the

one investigated in this thesis. They have a relation to Heartlab 2 at AUH whom they have previously had an agreement with (*Jensen, 2022; Vahle, 2022*). When Vanguard AG remanufactures devices, they take full responsibility for the device. They remanufacture devices in accordance with the EU MDD and has submissions under the EU MDR for CE-certification of remanufactured products under article 17.2 *(Vahle, 2022).* This provides security for Central Denmark Region. Currently, Vanguard AG has no direct personal relation to OEMs, other than the conflict of product ownership, even if they take over the OEMs' products.

The product ownership dispute seen in Figure 14 holds potential for tensions, and the OEMs would be difficult to interest in the change.

Executive Power

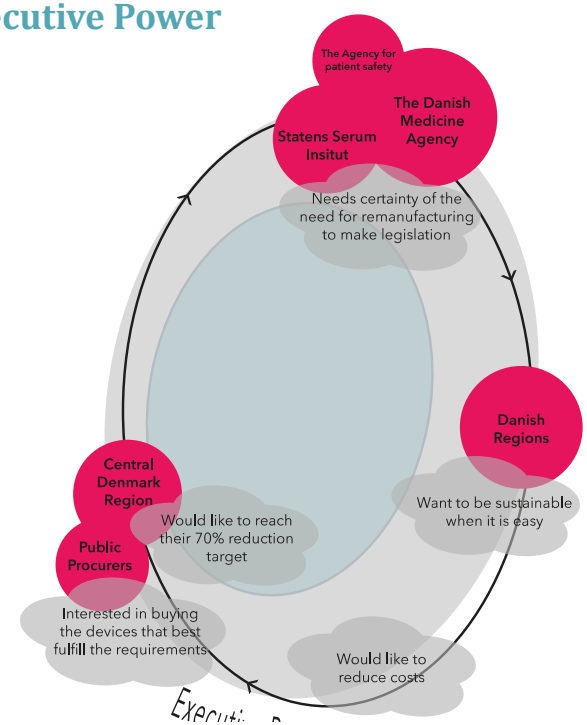


Figure 17, Executive Power of the actor-network

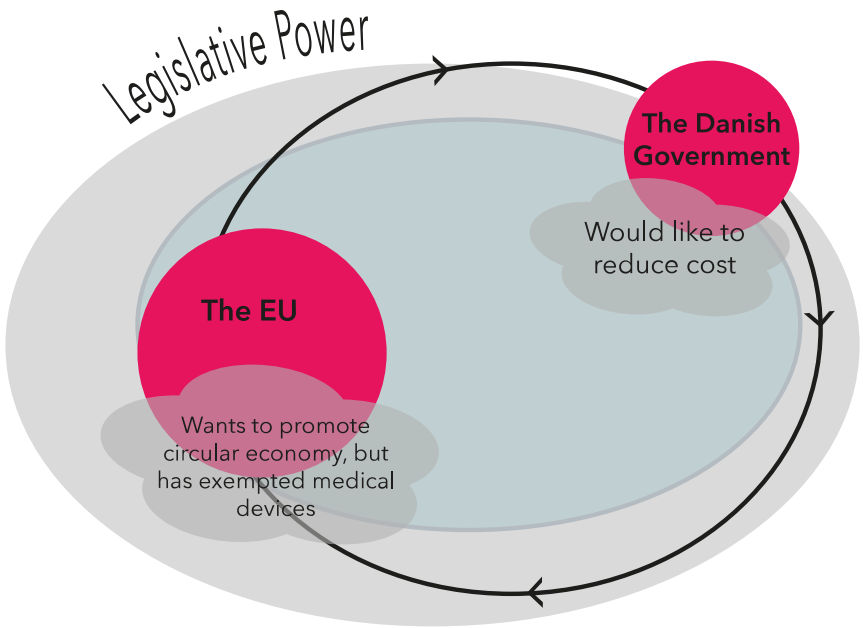
Central Denmark Region is a leading region in sustainability as they are the only region who currently has implemented the ´70% reduction before 2030´-goal in their strategy (Region Midt, 2021). Correspondingly, Central Denmark Region is ready to act and create the needed changes to transition to more sustainable healthcare. This makes them willing to use remanufactured products because of their hope of savings in both environmental impact and cost, given that it is patient safe. Therefore, Central Denmark Region has established a focus group, consisting of relevant actors such as patient and clinical associations, that will focus on providing insights into the appeal for remanufacturing.

Moreover, as stated in the strategy of Central Denmark Region, as a significant public company *"they must demand action and be part of the solution to the growing climate change [TRANSLATED]"* (Region Midt, 2021, p. 9). Therefore, Central Denmark Region is willing to engage in dialogues with the OEMs to resolve the conflict regarding the production of single-use devices. It is worth noting that as a significant public company, they could have the power to push OEMs in a new direction. Central Denmark region has mentioned that, according to the OEMs, the OEMs are currently making single-use devices because that is what is requested. Nonetheless, it can be discussed whether other incentives such as avoiding the WEEE-directive and the burden in terms of liability and inclusion of the instructions that is needed when producing reusable products are the real reason behind the continued production of single-use medical devices.

The Danish Medicine Agency has the responsibility for implementing the provisions in the MDR. Therefore, they, and **States Serums Institute** are the ones to create the guidelines that allow remanufacturing, as they make the national infection and hygiene guidelines. However, making these guidelines is not a cheap process and will demand the use of many resources. Therefore, they do not want to use these resources to create guidelines for remanufacturing if there is not sufficient need or support. Consequently, the Danish Medicine Agency takes on a passive role in the network, simply moving along with the direction set by the other actors.

Legislative Power

Figure 18, Lesgislative Power of the actor-network



The Danish Government is remaining passive in the network of the ultrasound catheter. The regulation states that The Danish Medicine Agency needs to create the guidelines for allowing remanufacturing, such as remanufacturing of ultrasound catheters. However, the Danish state aims to reduce emissions according to the Paris agreement and implement more circularity in society (Miljø- og fødevareministeriet & Erhvervsministeriet, 2018). Therefore, they should likely support actions that improve the nation's sustainability if it does not incur a higher cost or other negative consequences.

Furthermore, the Danish state is influenced by the legislation and regulation at **the EU** level. This, as the EU can propose goals that each member state should live up to. The EU is generally moving towards a more circular economy, as evident by the circular economy action plan (European Commission, 2020). This is a general plan that should be included in all regulations created by the EU. Furthermore, the European Commission recently proposed to include environmental sustainability requirements on more products (European Commission, 2022).

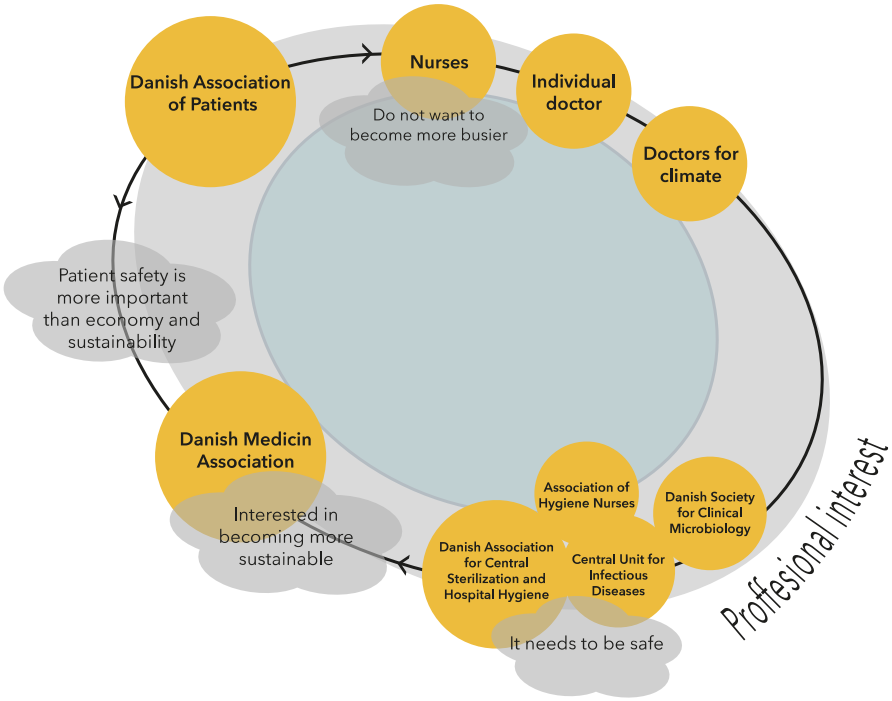
However, the EU is not a singular entity. Every time something should be decided, they will invite all interested actors to discuss what the regulation should contain. Therefore, the interest of these actors can affect the circularity and sustainability additions to regulations.

Currently, the sustainability agenda in the EU has not reached the regulation of medical devices. It seems that powers are making sure that exemptions are made for most medical devices. This is the case in the WEEE-directive, where single-use medical devices specifically are ex-

empted (European Council, 2018). For more sustainability to be implemented at an EU level, it will require an enrollment of actors from different organisations that have an interest in affecting the regulations within the medical sector. These could be OEMs, environmental organisations, and patient organisations. Nonetheless, with the MDR the EU has opened up for introducing more sustainable devices in the healthcare sector as they have allowed remanufacturing of single-use medical devices under national guidelines.

Professional Interest

Figure 19, Professional Interest of the actor-network



The Doctors' Association has recently released a new policy that equates sustainability with public health (Lægeforeningen, 2022). This marks a readiness for change towards more sustainability projects within healthcare. Hopefully, this new policy will persuade doctors to make sustainable changes in their daily work. However, this new strategy does not mention the option of remanufacturing and is not a clear indicator of whether the doctors would be ready to use remanufactured single-use medical devices. For remanufacturing to be an established method in the Danish healthcare system, the Doctors' Association must support remanufacturing and be part of the process to secure that remanufacturing can be done safely. The support from the Doctors' Association is essential to persuade the individual doctors since they can resist remanufacturing due to unpleasant experiences with reusable devices in the past – resulting in a restraint towards it because of a fear of a higher infection rate. The individual doctors and the Doctors' Association are intertwined and can affect each other. If either of them was to become more engaged in using remanufactured single-use devices, it would surely interest the other party.

Doctors for Climate are not specifically fighting for remanufactured products to enter the hospitals, but they are not against it either. They are generally ready to implement new measures if they are proven not to cause harm to patients *(Schønemann-Lund, 2022)*. Doctors for Climate have personal contact with doctors and can be a spokesperson for more sustainable use of medical devices, i.e., remanufactured devices. However, they have expressed that they sometimes have difficulty attracting older doctors to their organisation as these doctors are keen on keeping the status quo *(Schønemann-Lund, 2022)*.

The doctors operate within the network daily. Doctors will be ranging greatly on their readiness to transition to a new, more circular system of using remanufactured devices. However, an increasing amount of doctors seem to be engaged in sustainability issues *(Schønemann-Lund, 2022)*, although this does not necessarily mean that they are ready to use remanufactured products. Generally, the doctors work within the guidelines set by the Danish Medicine Agency (*Bundgaard, 2022*). Thereby, if the guidelines for remanufacturing were to be created, it could be assumed that most doctors would not be too critical. However, for the Danish Medicine Agency to create the guidelines, it is required that the Danish regions pronounce the need for the guidelines. For the Danish regions to pronounce this need, it is required that the doctors prioritise it, as they are part of the user-groups that helps to set the requirements specification in the tenders.

Consequently, it results in the currently stabilised network, but with a potential for change. However, the change will first come when the Danish Medicine Agency and the doctors stop awaiting the actions of the other party. Therefore, it is needed that some outside force starts to affect this part of the network and destabilise it.

Nurses are some of the actors most closely related to the medical devices used, just as the nurses at Heartlab 2 are the ones most closely related to the ultrasound catheter. Usually, the nurses are the ones to prepare the operation room and pack it down again after the operation. Hence, the nurses would be the ones that are required to make the most changes in their practice if a system of remanufacturing were to be implemented. Furthermore, the nurses are remarkably busy due to budget cuts, leaving only few resources available for managing various tasks. Therefore, the nurses would generally resist having another task to complete (which in the case of a new remanufacturing system would be having to clean the devices being sent to remanufacturing). Nonetheless, the nurses are also the ones to see the big amount of waste generated every day in the hospitals and they would therefore be more receptive of the problematization. However, some convincing would have to be done for them to fully support the implementation of remanufacturing.

The different **Danish regions** are generally ready for implementing sustainable solutions, as mentioned in their concern shown on figure 17. As stated by Rasmus Nielsen from Capital Denmark Region: "*we cannot achieve our climate goals without reducing consumption and extending the life of products [TRANSLATED]"* (Forum for Bæredygtige Indkøb, 2022) which is exactly what remanufacturing would be able to contribute with.

Nonetheless, the Danish regions are not one sole entity but an entire network consisting of many different departments with different objectives and opinions. Therefore, to interest the Danish regions are to interest the departments in the regions that are responsible for purchasing medical devices – which would be the public procurers.

Public procurers are the ones facilitating the formal buying process and documents the criteria which the products will be selected on. However, public procurers are not the ones determining which criteria, so called 'decision parameters', will be included in the procurement documents and published for the vendors to compete on *(Madsen, 2022)*. Instead,

a user-group composed of relevant healthcare professionals (doctors, nurses, or other relevant personnel for the specific procurement) would select the 'decision parameters' based on their needs, and hence the user group are the actual decision makers in the buying process of medical devices. Therefore, it becomes truly relevant to interest the user-group, since they hold the power over what criteria they asses are relevant.

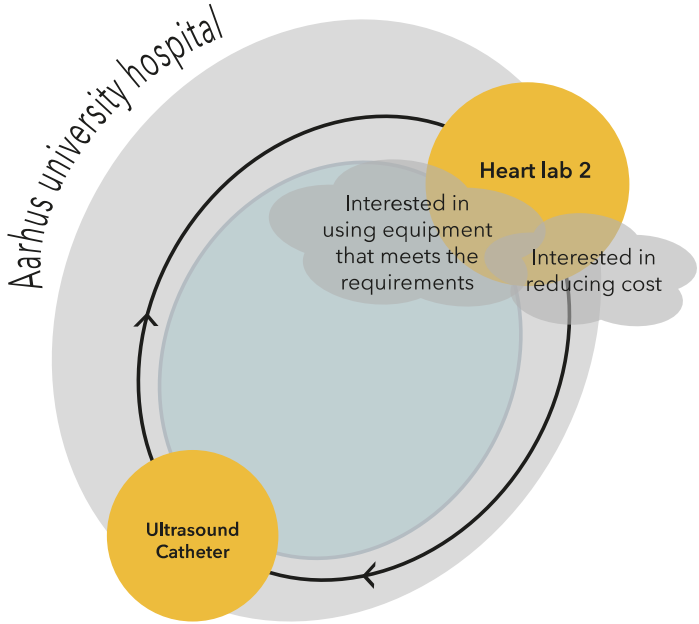
For the **Patient Association** the securement of infection hygiene and the perceived quality of care for a patient is essential. A concern shared among most patients and hygiene-related associations are how to be confident that a remanufactured device is washed/appropriately sterilised, which is also related to hygiene, accountability, and responsibility. This concern hinders the process of getting the patient associations on board to use remanufactured devices since their objective is to care for the interest of patients by giving them maximum influence in all matters of health and diseases (Patientforeningen, 2013). Therefore, there is a need to establish that *"the entire remanufacturing procedure and the remanufactured medical device do not jeopardise safety of a patients, user or third parties"* (Commission on Hospital Hygiene and Infection Protection, 2012, p. 3).

Bundgaard conveys this concern on behalf of being a network spokesperson of associations such as: Association of Hygiene Nurses, Danish Society for Central Sterilization and Hospital Hygiene and Danish Society for Clinical Microbiology. She does so by referring to the need for adequate research of the utility of remanufactured devices to support the decision making. Specifically, she states that research must assure that remanufacturing single-use medical devices poses no hygiene risk when it is subsequently used. This in terms of an increasing infection rate, change in technical function properties of the device and the release of any chemicals *(Bundgaard, 2022)*.

The concerns regarding infection risk are essential to relieve for the remanufactured catheter to position itself in the network. For a good reason, patient safety is the most critical concern in hospitals (*Klausen, 2022)*. Nonetheless, this results in environmental issues, as single-use devices are perceived as being safer for patients than a resterilised device. This is, among others, expressed by Bundgaard, who was a nurse in the 1990s. She would experience devices being unclean after sterilisation and therefore welcomed the single-use devices with open arms during the 2000s *(Bundgaard, 2022)*. Moreover, by using single-use devices, no one in the hospital is liable for the product working correctly and safely.

Arhus University Hospital

Figure 20. Arhus University Hospital of the actor-network



The ultrasound catheter used in Heartlab 2 is imported from Siemens Healthineers. Heartlab 2 has a solid connection to the ultrasound catheter, having used them both as newly produced and remanufactured. After having used remanufactured catheters for a while, using them and ordering the pick-up is an established practice at Heartlab 2. In the current network, they are passive but eager for change to be implemented from 'the top'. They have previously used the ultrasound catheter, so they are not reluctant to implement it because of infection risk. However, they are interested in reducing costs, thereby being able to provide better treatment in other areas of their department (*Jensen, 2022*), making them eager for the change.

For the Central Denmark Region, Heartlab 2 can be used as a case study where Danish data on unintended occurrences (UTH'er) can be collected. With this data, they would be able to prove that using remanufactured single-use medical devices does not result in a higher rate of infections (*Klausen, 2022*). This could potentially be used in the appeal for the Danish Medicine Agency and to convince currently apprehensive actors.

Sub-conclusion

The EU is moving towards a future that accommodates the circular economy, leaving the door open to implementing circular strategies such as remanufacturing. At the moment, the EU regulation makes an unintended incentive for OEMs to continue to make single-use medical devices since that is less regulated than the production of reusable devices, and thereby easier to comply with. However, the prospective of circular change affects the course of medical device regulation, which will potentially affect the current market of OEMs if they do not start to implement circular strategies. The changes to the OEMs' market will start when other decision parameters are implemented in the tenders of the Danish regions. However, this step will first be possible once the guidelines for remanufacturing have been created, for which reason OEMs will likely fight the creation of the appeal for the Danish Medicine Agency.

Moreover, sustainability is becoming increasingly important to nurses, that through their everyday working practices, see the heavy use of single-use devices. However, there is still some resistance to using remanufactured single-use medical devices. Therefore, it is vital to prove that remanufacturing is safe and causes no harm to the patient, nurses

or the doctors handling the devices. Consequently, Central Denmark Region's role is to cover the potential of remanufacturing. Furthermore, an analysis of the infection rate of remanufacturing is crucial to submit the appeal to the Danish Medicine Agency. Central Denmark region plans to create the appeal in collaboration with the focus group, so it can be used to share knowledge between actors *(Klausen, 2022*) and be a potential interessement device as well as a boundary object.

4.0

Analysis of Environmental Sustainability & Economy

To aid the Central Denmark Region in their interessement work of actors, it is needed to provide data for both the environmental sustainability of remanufacturing and the economic possibilities. This interessement work is essential as general support from other Danish regions is needed for the appeal to the Danish Medicine Agency to be accepted.

A common goal in the Danish regions is to reduce CO_2 emissions of their activities and thereby also their healthcare-related activities (Danske Regioner, 2020). Therefore, an environmental analysis could assist the Central Denmark Region in persuading other regions to join the appeal. Additionally, an LCA study would be able to contribute to a rethinking of what a potential system for remanufacturing ultrasound catheters could look like. This could help to ensure that the system is not only becoming more circular because of the lifetime extension of the catheters but also that the system does not have environmental impacts that could cause harm.

Moreover, the healthcare sector is heavily influenced by what is possible from an economic perspective, placing sustainability as a lower priority. This results in the need for an economic perspective to ensure that the total cost of the proposed remanufacturing system is financially sustainable. Using the total cost of ownership, the authors can illustrate the possible costs of both systems to investigate which is the most feasible.

Life cycle Assessment

Description of the disassembly of the AcuNav Ultrasound Catheter

All the materials and their weights had to be defined and mapped for conducting the LCA. For determining the materials of the ultrasound catheters, it was disassembled in the E-Lab at Aalborg University CPH, which provided access to the needed tools. The ultrasound catheter components were separated, and the various parts were analysed and compared to a datasheet that defined most of the components' materials. Vanguard AG provided the datasheet.

The ultrasound catheters consist of a blue plastic body with a handle (see figure 21 and figure 23) that can be twisted to control the direction of the ultrasound microchip placed at the end of the wire. At the bottom of the catheter is a white rubber cable that leads to a hard plastic shell with the print board glued onto it, as can be seen in figure 21.

Inside the ultrasound catheter is a bearing where small stainless-steel sticks are placed, which can be seen in figure 22 and figure 24. The material of the sticks was defined by calculating the volume and weight to get the density and thereby compare it to a metal material sheet.

Attached to the bearing are white controlling strings. The strings start at the bearing and go to the tip of the wire. When the handle is twisted the strings are pulled, making the ultrasound chip at the top of the wire turn. The strings have not been included in the LCA data since they were not possible to weigh.

On the plug of the ultrasound catheter is placed a small print board, and from this runs a copper wire to the tip of the catheter. The ultrasound chip is exceedingly tiny and only weighs 0,04 g. Furthermore, the ultrasound catheter has some plastic rings to tighten assemblies.

The bill of materials can be seen in Table 1.

Inside handle black control ring	2,64 g	Polycarbonate (PC)
Inside handle white lock ring	3,04 g	Polyetherimide (PEI)
Soft white rubber wire holster	13 g	Polyethylene propylene diene rubber (EPDM)
Plastic wire	3,37 g	Polyether block amide (PEBA, e.g. PEBAX)
Copper inside wire	1,81 g	Copper
Copper wire from inside handle	0,93 g	Copper
Print board	0,11 g	Print board
White packing rings	0,65 g	TPU
Black packing ring	0,78 g	TPU
Metal rings	0,74 g	Stainless steel
Metal sticks	11,14 g	Stainless steel
Ultrasound chip	0,04 g	chip

Table 1. The table shows the bill of materials of the ultrasound catheter with the weight and material defined.

Figure 21. On the picture the full catheter can be seen with the plug and the handle to twist the wire

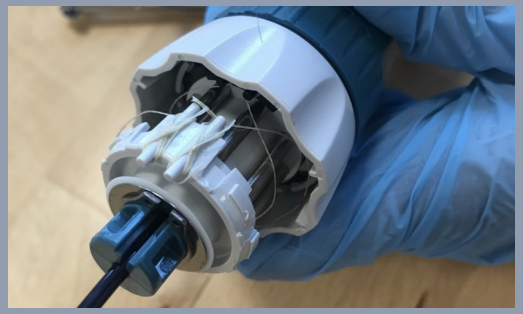


Figure 22. The picture shows how the strings is attached to the axis inside of the catheter.

Figure 23. The picture shows the blue plastic body of the catheter with the copper wire running through it.

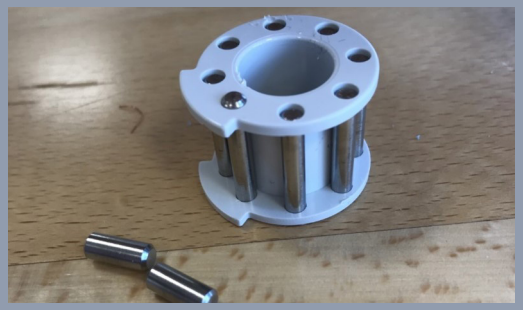


Figure 24. The picture shows the stainless steel metal sticks that are placed within the axis of the catheter.

Goal & Scope definition

The study intends to compare different alternatives for delivering the needed ultrasound vision of the heart. Alternative one is using a newly produced ultrasound catheter and sending it to incineration after use. Alternative two uses remanufactured ultrasound catheters, resulting in the need to buy fewer newly produced ones.

This study is intended to be used for the comparison of the two alternative systems. For this reason, some processes that are similar in both alternatives have been excluded from the study. Therefore, it is not possible to use any of the results to indicate the full impact of using an ultrasound catheter.

This study is based on possibilities in the status quo. Therefore, the results might not reflect reality if new technologies or changes to production are to happen in the future.

This study aims to provide the Central Denmark Region with a basis for taking the most sustainable decision in the future. Central Denmark Region wants to ensure that it is more sustainable to remanufacture the catheters rather than buy them newly produced before they push for legislation and implementation.

Following the decision tree, shown in figure 25, we have assessed that the decision to be made based on our LCA is that of situation B. Indeed, changing the system solely for ultrasound catheters will not have large-scale consequences. However, the hope is that by doing this LCA, Central Denmark Region will be able to interest other regions, thereby pushing for legislation to be made. If such legislation is made, it could result in a more considerable fraction of medical waste being diverted from incineration, thereby possibly having larger-scale consequences.

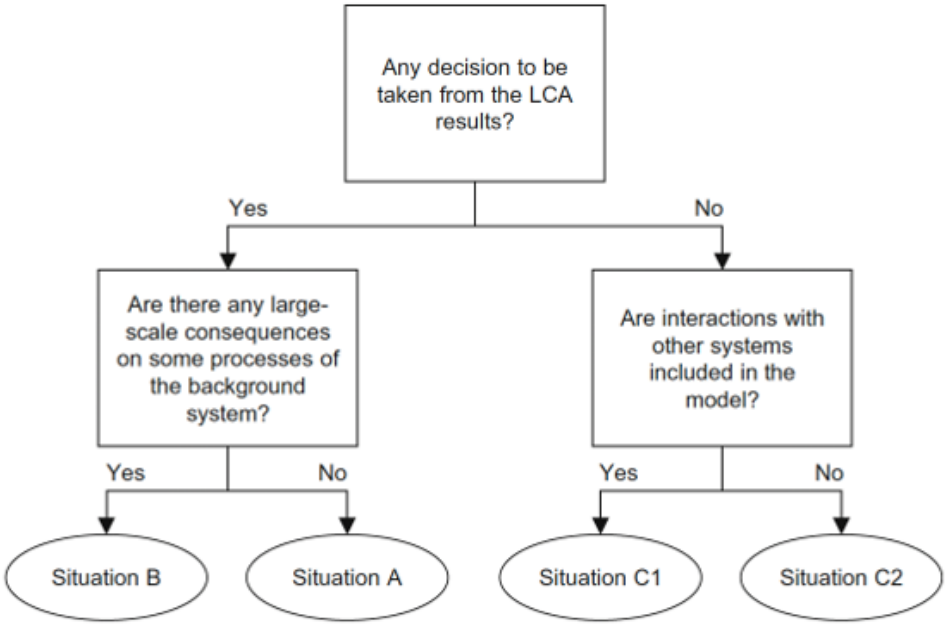


Figure 25. The decision tree from Hauschild et al. (2018).

This study has two primary audiences:

- Central Denmark Region's sustainability department
- Other Danish regions and other relevant actors

This study is not intended to be disclosed to the public.

The study is done as part of a master's thesis collaborating with the Central Denmark Region. Central Denmark region is interested in switching

from single-use ultrasound catheters to remanufactured ultrasound catheters to save costs and for sustainability measures. However, for the permission to switch to the remanufactured ultrasound catheters, Central Denmark Region will have to create a common appeal to the Danish Medicine Agency to make guidelines for remanufacturing. First when these guidelines are established remanufacturing will be a legal activity. As it must be a 'common appeal', Central Denmark Region will have to convince the other regions of the benefits of using remanufacturing. In order to interest the other regions, Central Denmark Region needs to prove that remanufacturing is economically beneficial, even when it requires more time of the personnel at the hospital. Furthermore, to have a stronger argument for why the other regions should support the request for the Danish Medicine Agency, the Centre for Sustainability in Central Denmark Region would like to prove the sustainability potentials of remanufacturing. This is where this master's thesis comes in: to prove that remanufacturing is a more sustainable solution with less climate change impacts than the current system of single-use ultrasound catheters. For this reason, this LCA analysis has, from the beginning, had a wish to prove sustainability of remanufacturing and might have a slight leaning towards remanufacturing as opposed to single-use. However, by applying a 'neutral' perspective as opposed to a 'supporter' perspective as described by Peters (2016), the LCA should provide a non-biased result.

As this study is only one analysis of the master's thesis, it will not be in as much detail and run as many iterations as a full LCA study. It is however a highly detailed hot-spot analysis to gain an overview of the possibilities and the main processes contributing to the climate change impact.

Deliverables

The life cycle inventory (LCI) and life cycle inventory assessment (LCIA) will be documented in the master's thesis and as an appendix and given to Central Denmark region. Two versions will be delivered:

- A comprehensive LCA with a sensitivity and contribution analysis to be delivered to Centre for Sustainability in Central Denmark Region.
- A short, easily readable document with a presentation of the primary results to be used with other Danish regions and further interested actors.

Object of the assessment

Function: Allowing clear visibility through ultrasound in operations of the heart.

Functional unit: Having clear ultrasound visibility in aurikel and PFO closing of the heart for one month at the Heartlab 2 of AUH in Aarhus, Denmark.

Reference flow - Alternative 1	Reference flow - Alternative 2
22 new ultrasound catheters delivered from Siemens Healthineers in Washington, US.	12 new ultrasound catheters delivered from Siemens Healthineers in Washington, US + 10 remanufactured ultrasound catheters from Vanguard AG in Berlin, Germany.

This LCA is modelled, assuming that the Heartlab 2 uses around 250-300 ultrasound catheters a year, making the monthly use 22 catheters *(Madsen, 2022)*. 'Clear' is subjectively defined by the doctor performing the surgery, and there is currently no definition for when something is clear enough for use. Aurikel and PFO closing are two different operations performed at Heartlab 2 at AUH.

In reference flow alternative 2 it is assumed that the remanufacturing system has a failure rate of 47,9%, with only 52,1% of the remanufactured catheters leaving the remanufacturing process ready to be used again. At Vanguard AG, all catheters are checked, and some will already here be discarded. However, others will be discarded later due to function failure. It has been chosen to use the failure rate used by Schulte et al. (2021), who investigated remanufacturing at Vanguard AG on electrophysiology catheters. This failure rate is a collection of failures happening at different times in the remanufacturing process. This is a high estimated failure rate since Jensen and Vahle estimate it to be approximately 25% (*Jensen 2022, Vahle 2022*).

Utilising this failure rate on the remanufactured catheters means that for a flow of 22 catheters, a mixture of 12 new and 10 remanufactured catheters will be used in a month. See the Figure 26 for an illustration of how many catheters divided on newly produced and remanufactured catheters are needed to fulfil the functional unit of 22 operations. It is assumed that the month of use under investigation is placed in a system where remanufacturing of catheters has been happening for a while. Therefore, there will continuously arrive remanufactured and new catheters to the Heartlab 2. This means that no start-up impacts of the remanufacturing system are included.

Figure 26 Visual explanation of alternative 2. It is seen that 12 new catheters are needed to provide 22 uses as some catheters are discarded after only some remanufacturing loops.

LCI modelling framework

Following the goal definition and decision context (situation B), this study uses consequential processes and modelling.

Figure 27 The system boundaries for alternative 1. The coloured processes are the ones that are included in the modelling of the system.

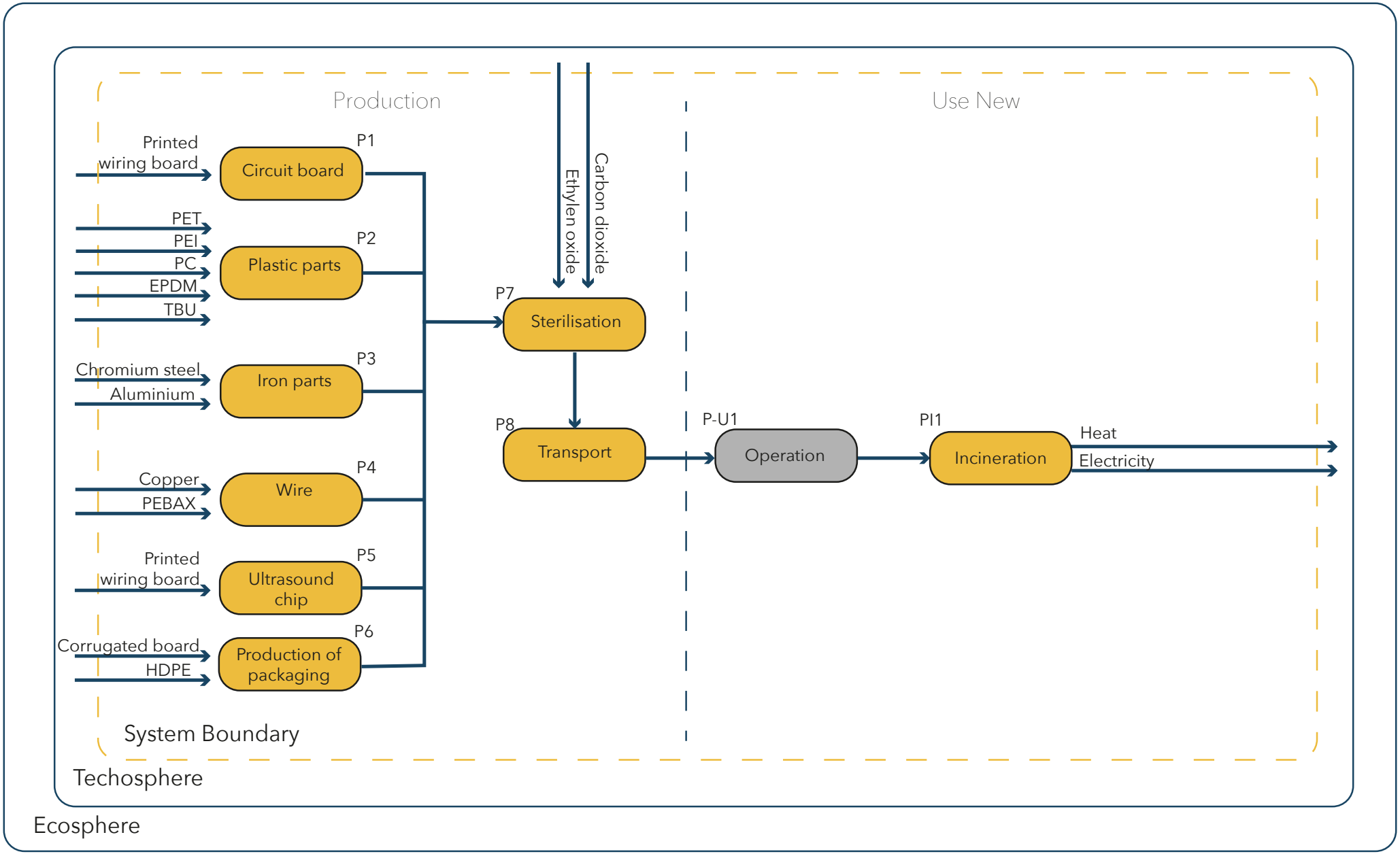
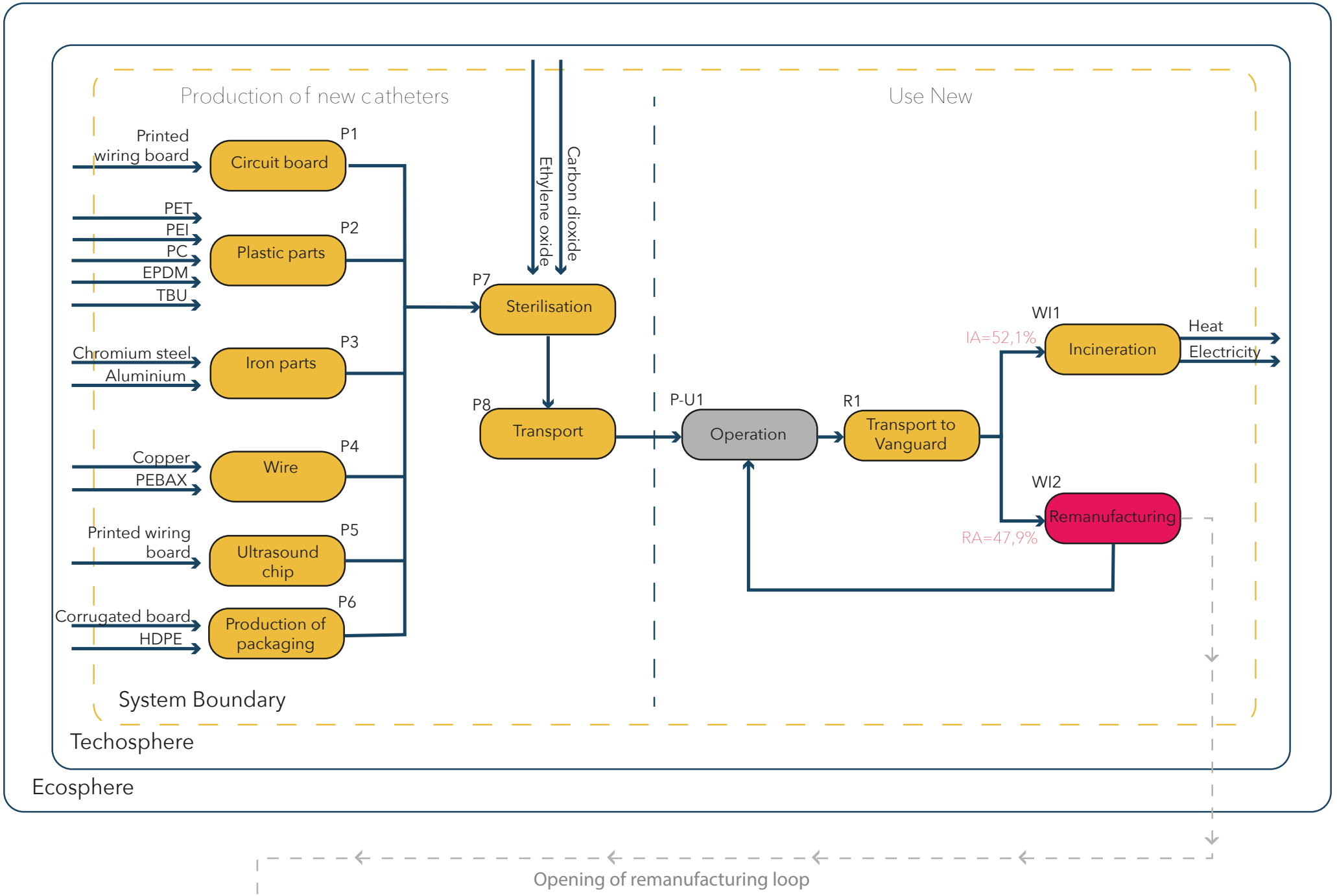


Figure 28 The system boundaries for alternative 2. The coloured processes are the ones that are included in the modelling of the system. The remanufacturing process that is part of alternative 2 will be presented in a second figure.



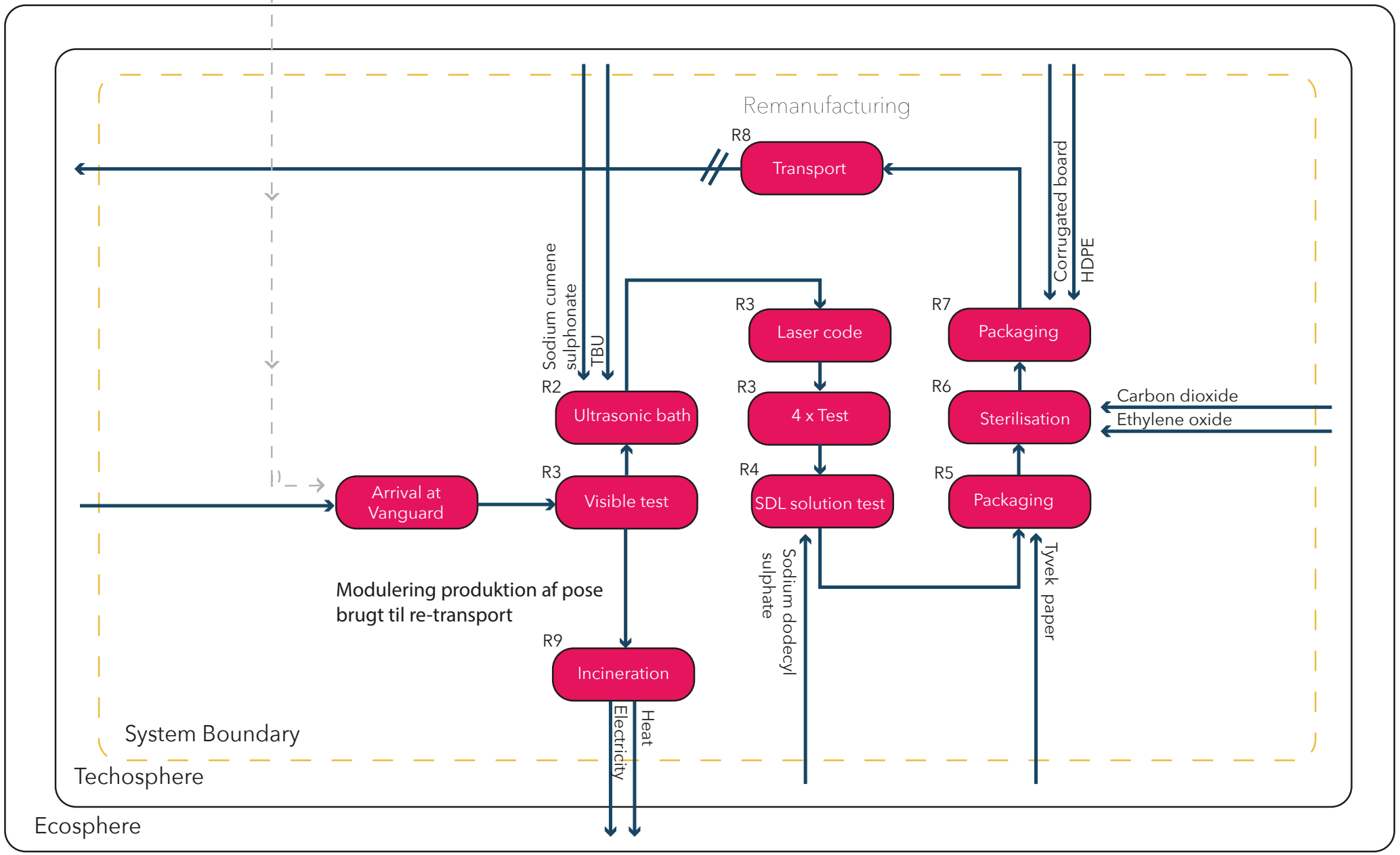


Figure 29 The remanufacturing part of alternative 2.. The coloured processes are the ones that are included in the modelling of the system. The system starts are the end of use of the catheter in the hospital and ends when the catheter returns and is in use in the hospital again.

Alternative 1

Alternative 1 consists of production phases of the different catheter parts, which are then assembled, packaged, and sterilised before shipping. Followingly, there is a transport phase and an excluded use phase, as this phase is relatively similar in both alternatives. Furthermore, personal protective equipment and electricity used for the operation have been excluded. After use, the catheter is thrown out and sent to incineration. As the catheter amounts to only a small amount of the waste mass from the hospital, the transport to the incineration with the entire waste mass has not been included.

Alternative 2

Alternative 2 consists of production phases of the different catheter parts, which are then assembled, packaged, and sterilised before shipping. Followingly, there is a transport phase and an excluded use phase, as this phase is relatively similar in both alternatives. Thereby, personal protective equipment and electricity used for the operation have been excluded. After use, the catheter can go one of two ways: Incineration or Remanufacturing. In alternative two, in 47,9% of cases, the catheter will go to incineration and in 52,1% of cases remanufacturing. If it enters the remanufacturing, it will go through the remanufacturing process and be reutilised in a new operation.

The basis for the LCIA

As a consequence of the intended purpose of the LCA, the results will be split in two.

- An analysis of all midpoint categories will be done, to ensure that the burden is not just shifting. A detailed analysis of climate change impact will be done with a contribution and sensitivity analysis, which will be delivered to Central Denmark Region in detail.
- An analysis of only climate change impact scores. These results will later be transformed into more intuitive units such as specific kilometres driven, hours of a turned-on light bulb or similar.

Two different methods will be used: ILCD 2011 Midpoint + to have a midpoint assessment and ensure that no burden-shifting occurs, and IPCC 2021 GWP 100a for a single-issue (here, climate change) assessment, which will be the main results used.

Life Cycle Inventory

The full LCI can be viewed in appendix 1 with explanations of assumptions and sources for the data.

The LCI data has been modelled in the SimaPro v.9.3.0.3 software in accordance with the system boundaries and with the ecoinvent v3.8 input processes specified in the LCI appendix document.

Life Cycle Impact Assessment

When comparing the two alternatives according to their climate change impact using the IPCC 2021 GWP 100a method, a big difference in im-

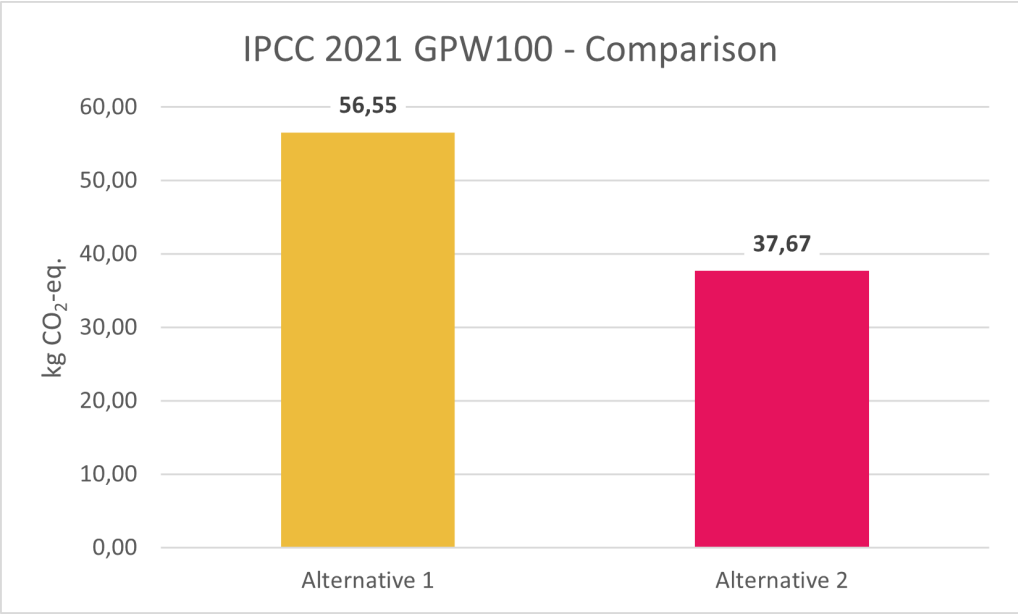


Figure 30 Comparison of the climate change impact of the two alternatives. Alternative 2 has a lower impact than alternative 1

pact score becomes visible as seen in Figure 30.
To make sure that the impact burden has not just been shifted to another impact category, the distribution of impact on the different midpoint categories was tested. This was done by using the ILCD 2011 Midpoint+ method. The results can be seen in Figure 31.

It can be seen that alternative 2 is overall better, with a saving of around 40% for all categories. This means that a focus on only climate change impact will not shift the burden unto another impact category, as the most prominent impacts all show the same pattern – that there are fewer impact potentials in alternative 2 than in alternative 1.

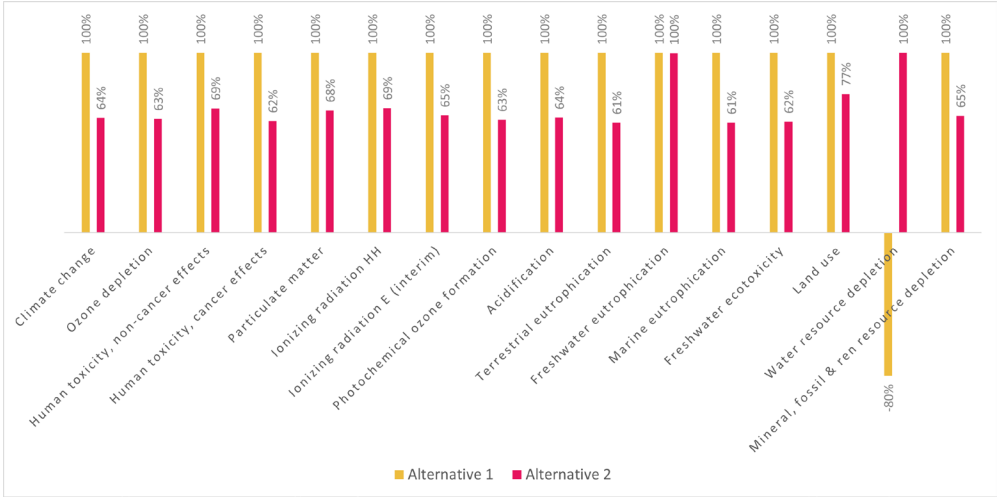


Figure 31 Comparison of the two alternatives in midpoint categories. By use of ILCD 2011 Midpoint+ method.

Looking more detailed at the results, it shows the following impact in Table 2:

Impact category	Unit	Alternative 1	Alternative 2	Difference
Climate change	kg CO_2-eq.	56,55	37,67	36%

Table 2 Overview of climate change impact of the two alternatives

This clearly indicates that alternative 2 is a more sustainable solution when looking solely at climate change impact.

In the following section, the main contributors to the climate change impact in both alternative 1 and alternative 2 will be investigated.

Contribution analysis

To calculate climate change, ILCD 2011 midpoint + is using IPCC 2007. However, it is not updated according to the latest IPCC-report (European Commission & Joint Research Centre, 2012). For this reason, the IPCC 2021 GWP 100a as a single-issue method has been used to investigate the climate change impact.

Climate change is calculated in kg CO_2-eq., having characterised the potency of various greenhouse gasses such as methane and nitrous oxide to arrive at a single impact category equivalent to kg CO_2.

In Table 3 the most impactful processes in alternative 1 can be seen:

No	Process	Alternative 1
-	Total of all processes	56,55
-	Remaining processes	8,59
1	Transport, freight, aircraft, long haul {GLO}| transport, freight, aircraft, belly-freight, long haul	12,96
2	Transport, freight, aircraft, long haul {GLO}| transport, freight, aircraft, dedicated freight, long haul	10,77
3	Polycarbonate {RoW}| production	8,83
4	Waste polyethylene terephtalate {DK} SELF-MADE| treatment of waste polyethylene terephthalate, municipal incineration	4,90
5	Polycarbonate {RER}| production	4,36
6	Transport, freight, lorry 3.5-7.5 metric ton, EURO6 {RER}| transport, freight, lorry 3.5-7.5 metric ton	1,58
7	Kerosene {RoW}| kerosene production, petroleum refinery operation	1,09
8	Heat, district or industrial, other than natural gas {RoW}| heat and power co-generation, lignite	0,97
9	Ethylene {RoW}| ethylene production, average	0,51
10	Nylon 6 {RoW}| production	0,49
11	Propylene {RoW}| production	0,45
12	Sweet gas, burned in gas turbine {RoW}| processing	0,40
13	Heat, district or industrial, other than natural gas {RU}| heat and power co-generation, hard coal	0,38
14	Containerboard, linerboard {RoW}| containerboard production, linerboard, kraftliner	0,31
15	Electricity, high voltage {SERC}| electricity production, natural gas, combined cycle power plant	0,30
16	Electricity, high voltage {CA-ON}| electricity production, natural gas, combined cycle power plant	0,29

Table 3 Contribution of processes to climate change impact in alternative 1. All processes that contribute less than 0,5% are excluded from the table. All results are in kg CO_2-eq.

In alternative 1 the plane freight process is the most impacting process on climate change. The plane freight processes contribute to 42% of the total impact on climate change from alternative 1. Most other contributions consist of the production of plastics and incineration of those. This makes sense, as the biggest material input is that of plastic, specifically that of polycarbonate.

In alternative 2 the plane freight process is also the most impacting process; however, in this alternative, it only accounts for 35% of the impact. This would result from the decreased number of flights needed to fulfil the functional unit. In alternative 2 only half of the catheters have a flight process, as the other half is being transported from Germany by truck.

The contribution of the polycarbonate process in alternative two has about halved, however, the transport with truck fills more in the calculation. This is because of the increased travel of the catheter when it goes to remanufacturing in the alternative, which happens to all 22 catheters that are needed to fulfil the functional unit.

Generally, the most contributing processes are all related to the production and transportation of the newly produced catheter in both alternatives. Hence, the remanufacturing part of alternative 2 (apart from the transportation to Vanguard AG) does not seem to be very impactful.

In Table 4 the most impactful processes in alternative 2 can be seen:

Table 4 Contribution of processes to climate change impact in alternative 2. All processes that contribute less than 0,5% are excluded from the table. All results are in kg CO_2*-eq.*

No	Process	Alternative 2
-	Total of all processes	37,67
-	Remaining processes	7,60
1	Transport, freight, aircraft, long haul {GLO}| transport, freight, aircraft, belly-freight, long haul	7,07
2	Transport, freight, aircraft, long haul {GLO}| transport, freight, aircraft, dedicated freight, long haul	5,88
3	Polycarbonate {RoW}| production	4,82
4	Waste polyethylene terephtalate {DK} SELF-MADE| treatment of waste polyethylene terephthalate, municipal incineration	3,20
5	Transport, freight, lorry 3.5-7.5 metric ton, EURO6 {RER}| transport, freight, lorry 3.5-7.5 metric ton	2,58
6	Polycarbonate {RER}| production	2,38
7	Ethylene {RER}| ethylene production, average	0,98
8	Heat, district or industrial, other than natural gas {RoW}| heat and power co-generation, lignite	0,88
9	Kerosene {RoW}| kerosene production, petroleum refinery operation	0,60
10	Containerboard, linerboard {RoW}| containerboard production, linerboard, kraftliner	0,35
11	Heat, district or industrial, other than natural gas {RU}| heat and power co-generation, hard coal	0,34
12	Ethylene {RoW}| ethylene production, average	0,30
13	Nylon 6 {RoW}| production	0,27
14	Sweet gas, burned in gas turbine {RoW}| processing	0,26
15	Electricity, high voltage {DE}| electricity production, natural gas, combined cycle power plant	0,25
16	Propylene {RoW}| production	0,25
17	Heat, district or industrial, other than natural gas {RU}| heat and power co-generation, lignite	0,21
18	Diesel, low-sulfur {Europe without Switzerland}| diesel production, low-sulfur, petroleum refinery operation	0,21

Alternative 1 – sub-processes

The points of the contribution analysis in the previous section can also be seen when inspecting sub-parts of the system as shown in Figure 32. For example, the transport scores higher than any of the other sub-processes, corresponding to the plane freight process being the most impactful of the included processes.

Alternative 2 – sub-processes

In alternative 2 the process with the most climate change impact is the production of the new catheter as seen in Figure 33. In climate change, the remanufacturing process and the incineration process are similar in impact scores. However, it is essential to note that every time a remanufacturing process is added, the impact associated with producing a new catheter is saved. Therefore, even if it seems that there would be no difference in the two ”end-of-life”-processes of remanufacturing and incineration in terms of impact, this would not be a correct assessment.

Biggest contributor in the production processes of catheter

To see improvement potentials in the production of the ultrasound catheter, it has been investigated which materials have the highest climate change impact. Generally, it can be said that the production of the catheter itself is not the most impactful compared to the transportation of the catheter. As seen in Figure 34 the plastic parts are the biggest contributor to the climate change impact. However, plastic is also the most used material and contributes most to the weight of the catheter. Comparably, the iron parts of the catheter have a much higher impact as compared to their weight. Nonetheless, there is quite a high uncertainty with these results as the materials’ production methods and extraction locations are unknown. However, since the catheter has been separated manually the weights are certain as well as the type of material since this was given in a datasheet from Vanguard AG who is the remanufacturer.

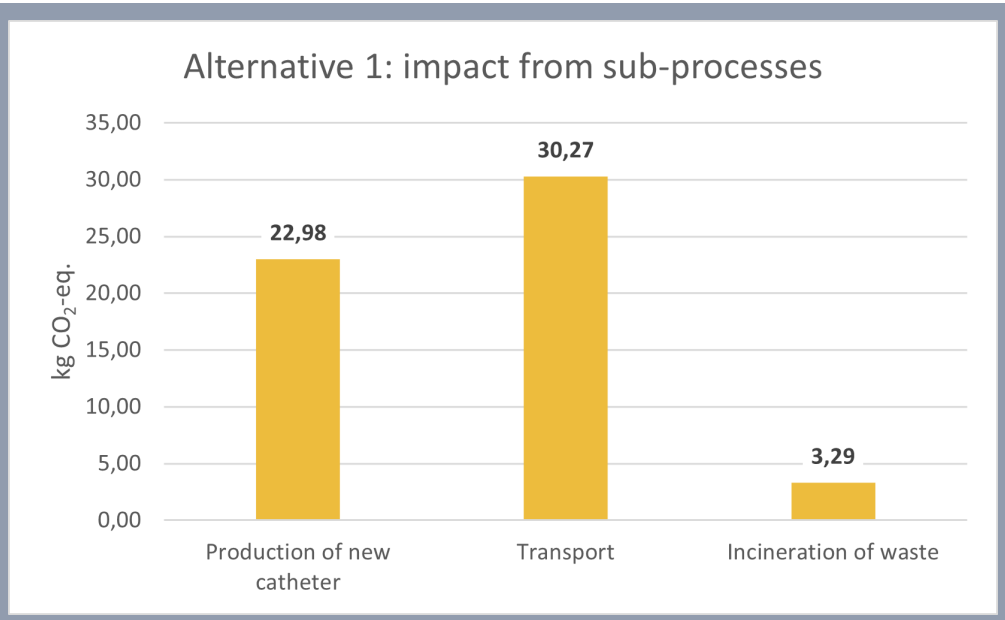


Figure 32 the impact of the three sub-processes in alternative 1.

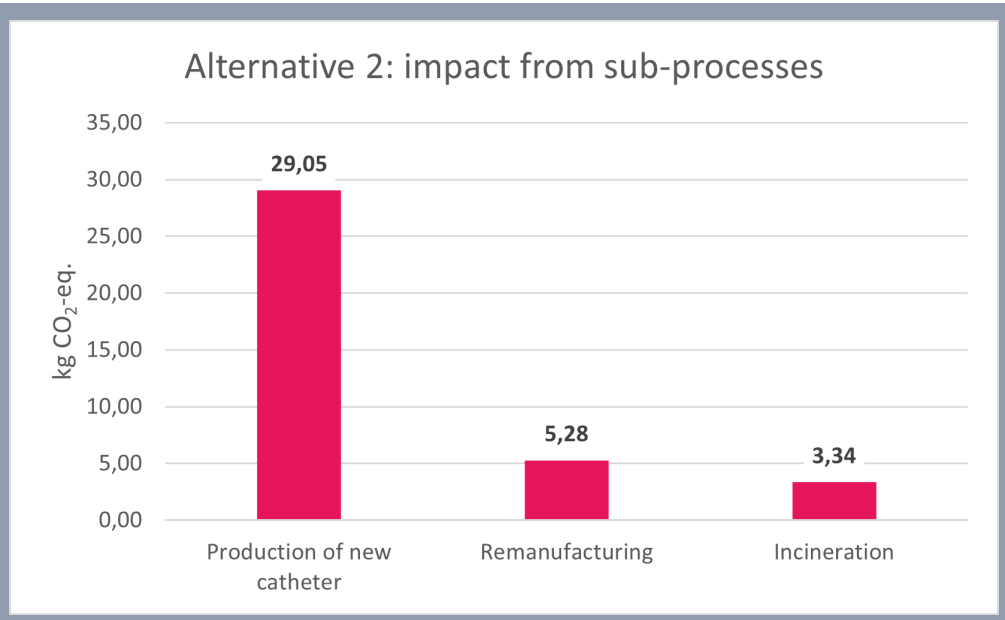


Figure 33 the impact of the three sub-processes in alternative 2.

Biggest contributor in the remanufacturing process of the catheter

On Figure 35 the climate change impacts of the remanufacturing process can be seen. It becomes clear that the secondary packaging of the ultrasound catheter has the highest impact score. However, when looking at the impact of packaging as compared to packaging in the production process (section above), the impact score is the same at 0,14 kg CO_2-eq. per process. The second most impacting process is that of transport to and from Vanguard AG. The impact is slightly higher in the transport to Vanguard AG as a plastic bag is added. The peel pack that the remanufactured catheter is wrapped in when being sent back to the hospital has its own process in the remanufacturing loop (primary packaging), thereby not adding impact to the process of 'Transport to hospital'.

It has been modelled that all catheters that will be discarded are first discarded when arriving at Vanguard AG. However, this is not the entire truth as they are primarily discarded at arrival, but some percentage points are discarded once they have completed a few steps of the remanufacturing process. It was not possible to model this as it was only possible to obtain a single value for electricity, even if all the individual processes use electricity. As seen in the results, it could affect the results slightly if the catheters were modelled to be discarded at different stages of the remanufacturing process. However, with the electricity use split over multiple processes, none of the 'middle'-stages of the remanufacturing process would be significant and they would thereby not significantly change the result.

Concludingly, the most effective way of lowering the climate change impact of the remanufacturing process would be to limit the amount of transport.

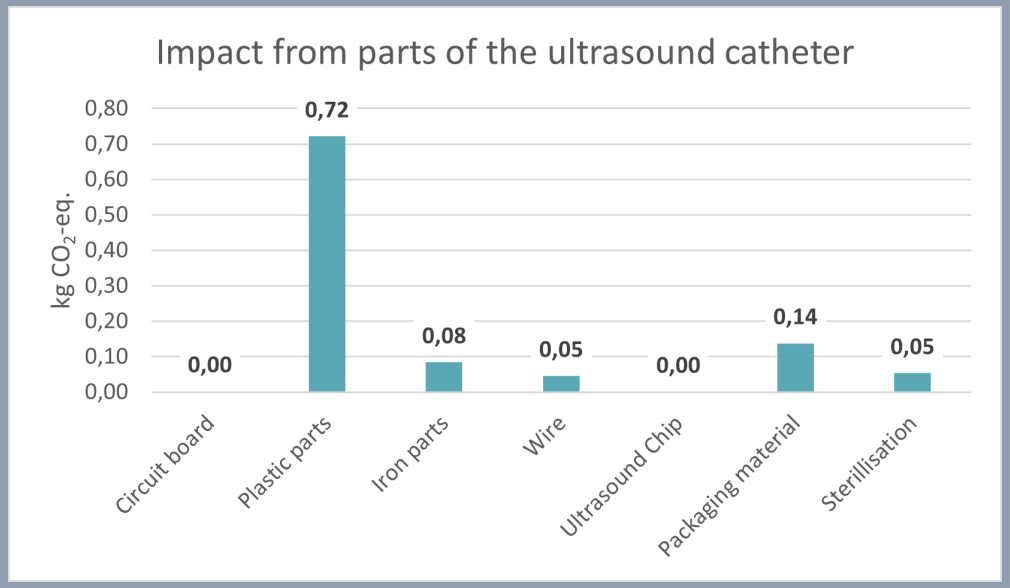


Figure 34 The impacts of the different parts of the ultrasound catheter can be seen in this figure. No assembly or transport of the final product is included.

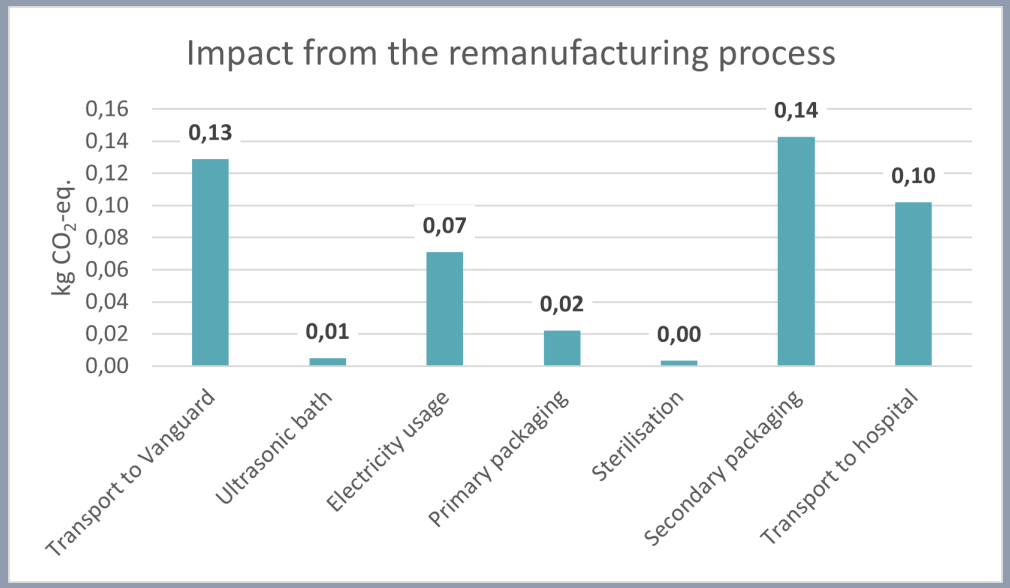
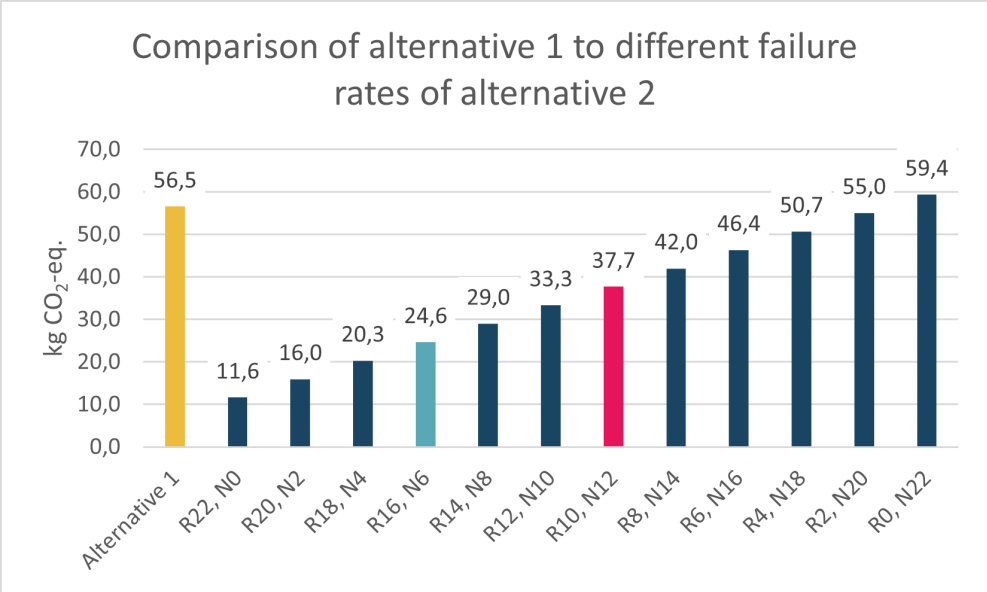


Figure 35 The impacts from the different sub-processes of the remanufacturing process. The transport to Vanguard AG is assumed a sub-process of the remanufacturing process.

Sensitivity analysis

Figure 36 Comparison of alternative 1 against alternative 2 with various failure rates. The number behind "R" indicates the number of remanufactured catheters in the alternative and "N" the number of new catheters.



Currently, it is assumed that 47,9% of the catheters are discarded when arriving at Vanguard AG's facilities, as noted by Schulte et al. (2021). However, according to Vahle and Jensen (*Vahle, 2022; Jensen, 2022*) the percentage of discarded catheters at Vanguard specifically from AUH is around 25%. Therefore, it has been investigated what impact a failure rate of 25% would have on the results.

On Figure 36 can be seen the impact of alternative 2 (marked with pink) with a failure rate of 47,9%. Marked with light blue is an alternative with a failure rate of around 25%. Essential for understanding the results is that it is calculated in whole catheters. The amounts are not set by a percentage but are rounded to complete catheters. This means that for a failure rate of 47,9%, there are 10 remanufactured and 12 new catheters to fulfil the functional unit. However, for a failure rate of 25%, this amounts to the pillar of 16 remanufactured and 6 new catheters (R16, N6).

The impact of 10 remanufactured catheters and 12 new catheters (corresponding to alternative 2) shows an impact score of 37,7 kg CO_2-eq as shown in Figure 36. The development in climate change impact in accordance with the input of newly produced and remanufactured catheters can be seen in figure 37.

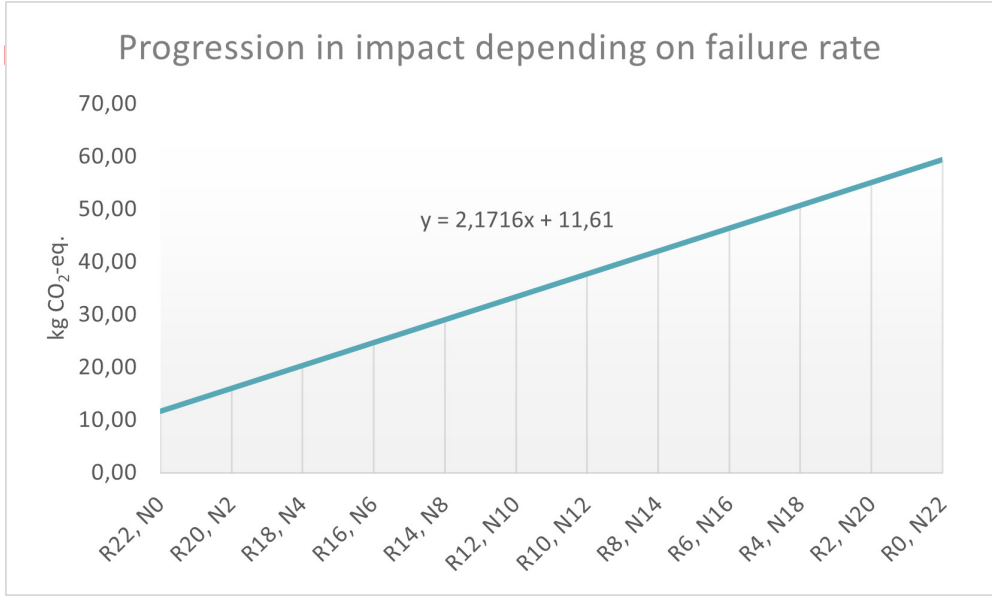


Figure 37 Curve of the change in climate change impact as a function of number of new catheters input in the system. The input of new catheters will result in fewer remanufactured catheters to provide the functional unit of 22 uses.

The formula for the development in climate change impact is the following:

Climate Change impact (x)=2,1716x+11,16
Where x = amount of newly produced catheters

By having a lowered failure rate at 25%, which amounts to the need of 6 whole newly produced catheters, corresponding to the need for 16 remanufactured catheters, the saving in impact potential would be:

Climate Change impact (25% failure rate)=2,1716*6+11,16

Which equals to 24,6 kg CO_2-eq. Compared to alternative 1, which has an impact of 56,5 kg CO_2-eq. this is a saving of 31,9 kg CO_2-eq. According to the function, it can be said that every time a new catheter is replaced by a remanufactured one, there is a saving of 2,17 kg CO_2-eq per month.

It is worth noting that it is technically not possible to have a failure rate below 25%. This is a result of the fact that the ultrasound catheter is currently only remanufactured 3 times, giving each catheter a life of 4 uses before it is discarded. Thereby, the system investigated here can be said to be the most effective system possible with current machinery.

Conclusion

Alternative 2 is a less impactful system for providing the functional unit when looking at climate change impact. Therefore, it would make sense for Central Denmark Region to go towards that solution.

Furthermore, it does not seem that Alternative 2 results in burden shifting between midpoint impact categories.

Alternative 2 becomes an even better solution when accounting for the failure rate proposed by the relevant actors of 25%.

Because of the scope of the investigation, it can be concluded that alternative 2 of utilising remanufacturing for the ultrasound catheters is a more sustainable alternative than alternative 1 in terms of climate change impact. However, it cannot be concluded that alternative 2 is the overall most sustainable alternative for providing the ultrasound vision, as there might be other solutions to doing that which has not been included in this study.

Assumptions

The data used for the calculation of failure rate in the specific case of AUH has been based on a quick assessment by relevant actors. It has not been measured or calculated and can thereby not be supported by specific data. This could result in the alternative 2 specific to AUH having a higher impact than indicated in the study. Furthermore, the assumed average failure rate (47,9%) could be misleading as this is the failure rate used by Schulte et al. (2021) who did an analysis of electrophysiology catheters that are different from ultrasound catheters.

It has not been possible to gain information regarding the production of the catheter. It has been assumed that it is produced in the US, and most material production has been modelled to be a global average. This could affect the result of the production of the catheter, but since the production processes are part of both alternatives, it would not affect the result.

Total Cost of Ownership

Purpose

This total cost of ownership (TCO) calculator was created to convey various costs of using a remanufactured ultrasound catheter as opposed to a newly produced ultrasound catheter. The purpose of the TCO is to define the actual cost of the system by using different cost inputs such as procurement cost and work-hour cost.

A TCO provides a more systemic overview of the total costs related to a product. Hence, it can help to avoid situations where a cheaper product in procurement ends up being much more expensive long term because of recurring maintenance, repair, or consumption of materials. Total cost of ownership is good for assessing economic sustainability, as it takes into account the same life cycle perspective as an assessment of environmental sustainability would usually do. Evaluation of economic sustainability within the healthcare sector can lead to cost reductions while subsequently optimising the use of resources, thereby also improving the circularity of the healthcare sector by narrowing their consumption (Pereno & Eriksson, 2020). Thereby, this TCO of remanufactured and newly produced catheters is optimal for evaluating long-term economic sustainability.

Data	Data source
Purchase of 10 catheters pr. delivery	*Jensen, 2022*
Delivery & systems operation	Depot & BRIK Team employee
Price on nurse	From Central Denmark Region. "Solsikkepapiret".
Price on Technical employee	The salary is stated by employee from Depot & BRIK team at AUH
Price on newly produced catheter	Based on flyer from Stryker Sustainability Solutions
Price on remanufactured catheter	Based on the price of new catheter with savings indicated by Weeda, 2021. (40% savings). This value can be changed manually in the calculator
Number of catheters in blue box	30, given by *Jensen 2022*
Incineration of the catheters	Depot & BRIK Team employee
Ordering pickup of remanufactured catheter	*Jensen, 2022*
Pick-up of incineration of by Stena	Depot & BRIK Team employee

Table 5 Collection of used data and sources.

Collection of data and modelling choices

The collected data is based on different data sources. However, most of it is provided by the Central Denmark Region. Additionally, the system for the two catheters is created based on information from multiple actors from Central Denmark Region with whom we have been in contact through email and interviews. When calculating the total cost of a device, a TCO typically includes implementation cost, maintenance expenses (services), expected lifetime, residual value/disposal price and administrative expenses (Forum for Bæredygtige Indkøb, 2018). Consequently, only studying the procurement price would be to only look at the tip of the iceberg. Additionally, the TCO-calculator is modelled to demonstrate the total cost of a system running continuously, which means that all start-up costs are excluded, for example, the time used for the introduction on how to clean and package the catheters to be sent to Vanguard AG correctly is excluded.

In the TCO, water used in operation is excluded, since the used water is excess water from the operation. Therefore, it is not included in the total cost. An assumption is made concerning the time it takes to perform the different tasks. There have been collected data on how the system operates through mail correspondences with the BRIK-team from AUH. Therefore, the sequence of tasks is correct, but it has not been possible to qualify how long it takes to complete each task. Therefore, the time in the TCO is based on an assumption. However, those who will use TCO in the future, have the possibility to change the amount of time used based on a qualitative assessment. Nonetheless, this assumption will affect the data in this report.

In the TCO, the user has the choice of selecting between two employee groups to perform the task. An example of this is that in the column of ´throwing out of catheter´, it can be chosen to calculate with either the price of nurse or technical personnel. It should be noted that the technical personnel group are a mix of different employees at the hospital. This has been done to simplify the TCO and make it easier to use, as the logistics system has multiple steps with different types of employees connected to each step. Additionally, this makes it easier to use the TCO-calculator in a future scenario, where there might have been changes to the steps of the logistics chain.

The choice of having both the nurses and the technical personnel has been included to accommodate the lack of nurses in the departments. As Lisbeth Lintz (member of the board in the Doctor's Association) states in an article by Dagens Medicin regarding an investigation of the bustle in the hospitals: "we have a big need of resources. This applies to both financial and human resources" (Krabbe, 2021). Therefore, *Revsbeck (2022)* suggested to implement the choice of personnel group to handle the different actions needed for the system to work. Thereby, the TCO was created to be adapted to future scenarios of the systems. By allowing the user to input more different options, the TCO can be used as a decision tool for quantifying the difference in cost of future changes to the system.

In the TCO-calculator, the user can type the correct price of the catheter. This is selected since the price can differ vastly among the procurement agreements. Various sources state that the remanufactured single-use medical devices cost 30-40% less than the newly produced ones (Weeda,

2021).

The modelled systems

This section describes the two systems of using newly produced ultrasound catheters and remanufactured ultrasound catheters to explain what elements the TCO-calculator contains.

For the newly produced catheters, all costs from when the catheters are being ordered until the catheters leave the hospitals as waste is included. See Figure 38 which illustrates the steps within the TCO.

For the remanufactured catheters, all the cost is included from when the catheters are being ordered from Vanguard AG, the transport, delivery, preparation before an operation, cleaning after use and ordering of pick-up when the transport box is filled up. See Figure 39 for a detailed illustration of all the steps. Furthermore, since the cost of the different processes of remanufacturing at Vanguard AG does not affect the total cost of ownership for the Central Denmark Region, it has been excluded from the TCO.

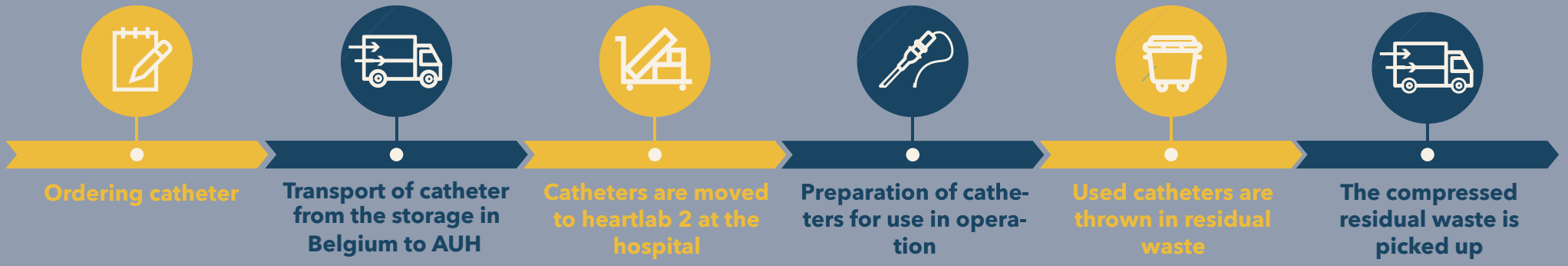


Figure 39. The figure illustrates the journey of a newly produced catheter used at Heartlab 2 AUH.

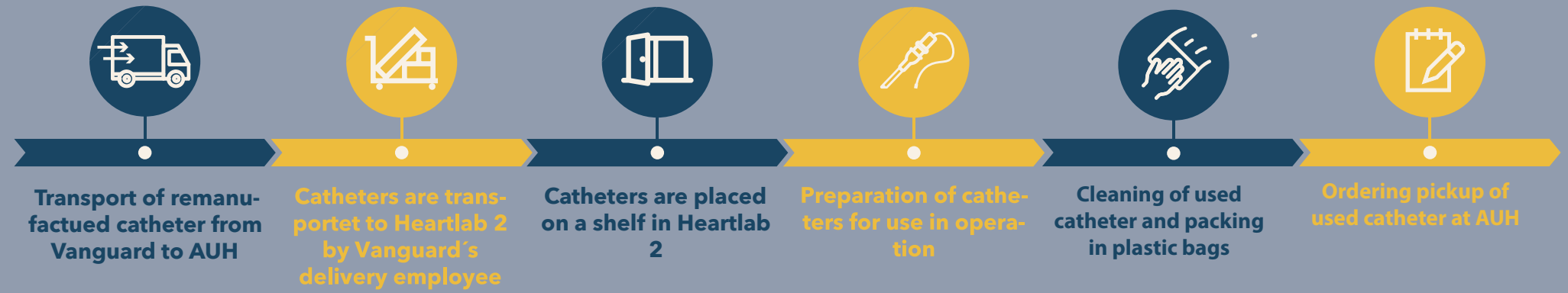


Figure 38. The figure illustrates the journey of a remanufactured catheter used at Heartlab 2 AUH.

Results

The TCO-calculator can be seen on Figure 40. On the figure, the categories of what to consider in the two systems are shown. The TCO follows the same order as the life cycle figure illustrated in the previous section, for the two systems. This has been done to make it more intuitive for the user of the calculator.

Proces	Nuværende system	Mængde	Enhed	Pris	Remanufacturing	Mængde	Enhed	Pris
Indkøb	*Antal katetre købt*	1	stk	**17000,00** kr	*Antal katetre købt*	1	stk	**10200,00** kr
Bestilling af kateter	*Tid brugt*	2	min.	**0,84** kr	*ikke relevant - da kateterne sendes tilbage efter genbehandling og ikke behøves at blive bestilt*	-		
Levering	*Er levering inkluderet?*	inkl.			*Er levering inkluderet?*	inkl.		
	Indtast pris	0	kr	**0,00** kr	*Indtast pris*	0	kr	**0,00**
Fra modtagelse til placeret på stuen	*Hvem sætter katetret på plads?*	Sygeplejerske			*Hvem sætter katetret på plads?*	Teknisk personale		
	Tid i minutter (anbefalet tid 5 min)	5	min.	**20,92** kr	*Tid i minutter (anbefalet tid 2 min)*	2	min.	**5,99** kr
Klargøring af kateter på stuen	*Hvem gør klar til operation*	Sygeplejerske			*Hvem gør klar til operation*	Sygeplejerske		
	Tid i minutter? Af sygeplejeske (anbefalet tid 2 min)	2	min.	**8,37** kr	*Tid i minutter? Af sygeplejeske (anbefalet tid 2 min)*	2	min.	**8,37** kr
Bestilling af afhentning	*ikke relevant*	-			*Hvem bestiller afhentning?*	Sygeplejerske		
					Tid brugt på bestilling af afhentning pr. afhentningsgang	30	min	**17,50** kr
Afskaffelse af kateter	*Udsmidning (anbefalet tid 1 min)*	Sygeplejerske 1	min	**4,18** kr	*Rengøring og nedpakning*	Teknisk personale		
					(anbefalet tid 3 min)	3	min	**8,98** kr
Afhentning af affald	*Hvem afhenter affaldet på stuen?: (Anbefaling: ekskluderes da den smides ud sammen med meget andet affald.)*	Sygeplejerske						
	Hvor lang tid tager det? (anbefalet tid 0)	0	min	**0,00** kr	*Ikke relevant*	-		
RESULTAT				**17034 kr**				**10241 kr**

Figure 40. Displays an image of the interface of the TCO calculator. On the image are estimated the minutes it takes to do the task and the price difference with 40% difference in procurement cost.

As seen in figure 41, the price of a newly produced catheter is 17.034 DKK and the price of a remanufactured catheter is 10.241 DKK. The biggest expense would be the cost of buying the catheters for both systems, see Figure 41. On the graph the cost of all the work tasks within both systems are significantly minor compared to the cost of buying a catheter.

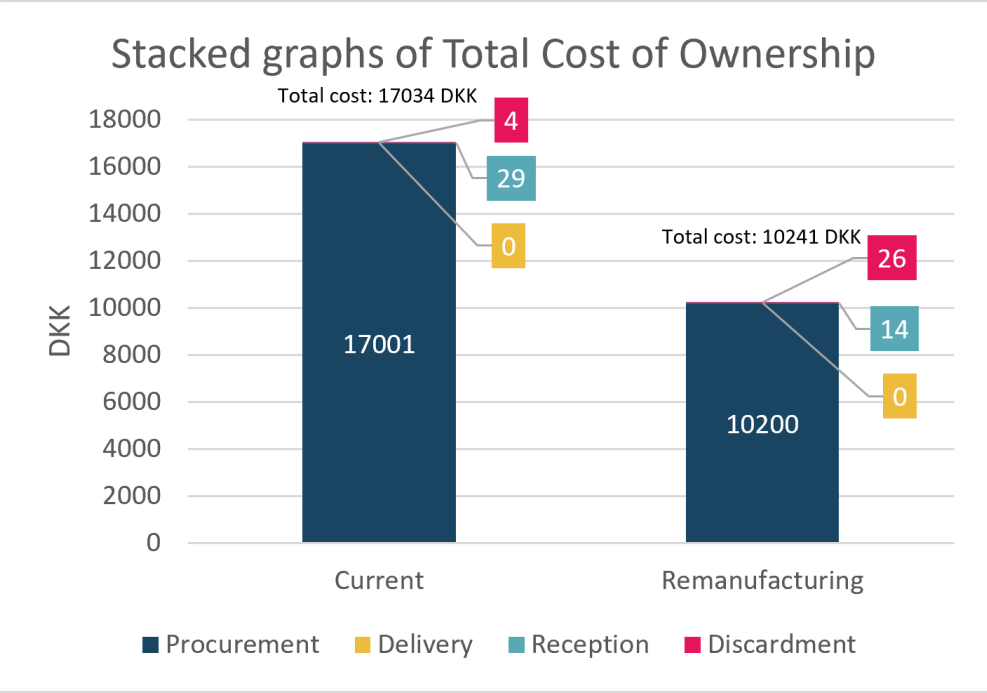


Figure 41 Shows the variation in the cost for procurement (indkøb), delivery (levering), reception (modtagelse) and discardment (afskaffelse) for both the current system and the remanufacturing system.

By comparing the total price of ownership for the two systems, the total saving by using a remanufactured catheter would be 6.793 DKK. This is a significant saving. It was chosen to look at the total saving for one month, where the use is 22 catheters, and to look at one year, with 264 catheters.

Looking at the line in Figure 42, it is seen that the total cost of using only remanufactured catheters for one month gives a total saving of 149.456 DKK and approx. 1,8 million DKK a year as compared to only using newly produced ones. It is essential to point out that a system containing only the use of remanufactured catheters is not technically feasible, as there will always be a need for new catheters to be included in the system.

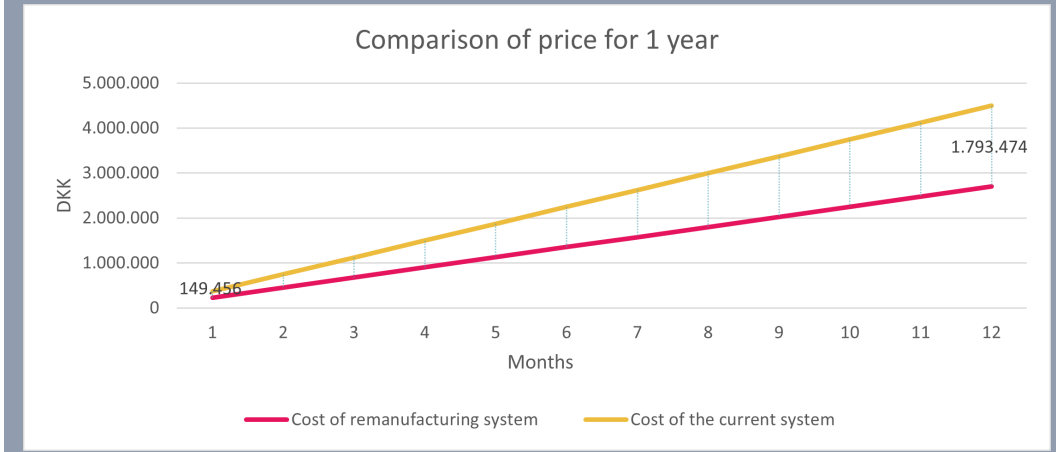


Figure 42 Shows a comparison of the price for the current system compared to the price of the remanufactured system. Assumed that the remanufactured price is 40% less than a new catheter.

Consequently, it would be suitable to look at our case-example from the LCA with a price difference for one month's use of 22 catheters with a 47,9% failure rate (12 newly produced and 10 remanufactured catheters in a system for one month). As shown in Figure 34 the saving would be 67.935 DKK and for a year the savings would be 815.216 DKK.

Since the case-example from the LCA has a high failure rate, it would give a more realistic saving by looking at the AUH-case, that has a failure rate of 25% (equivalent to 6 newly produced and 16 remanufactured catheters). In Figure 35, is showed a comparison of the current system and the AUH-case. The difference in price between the two systems is 108.695 DKK for a month, equaling a saving of 1,3 million DKK a year.

The regions in Denmark have a shared strategy for 2025 to make green procurement the norm (Danske Regioner, 2020). Furthermore, the strategy sets a goal to save 1 billion DKK by 2025 (Danske Regioner, 2020). This makes the potential saving of using remanufactured devices of interest for Danish regions. Locally on the Heartlab 2, the potential saving in cost of procurement would make it possible to treat more patients from the waiting list or provide better care *(Jensen, 2022)*.

If remanufactured devices were to become more widespread in the hospital, this could put a strain on another resource, which is the hours of the nurses. The cleaning of the devices after use, the packaging and the ordering of pick-up only takes a few minutes now, but if it were to

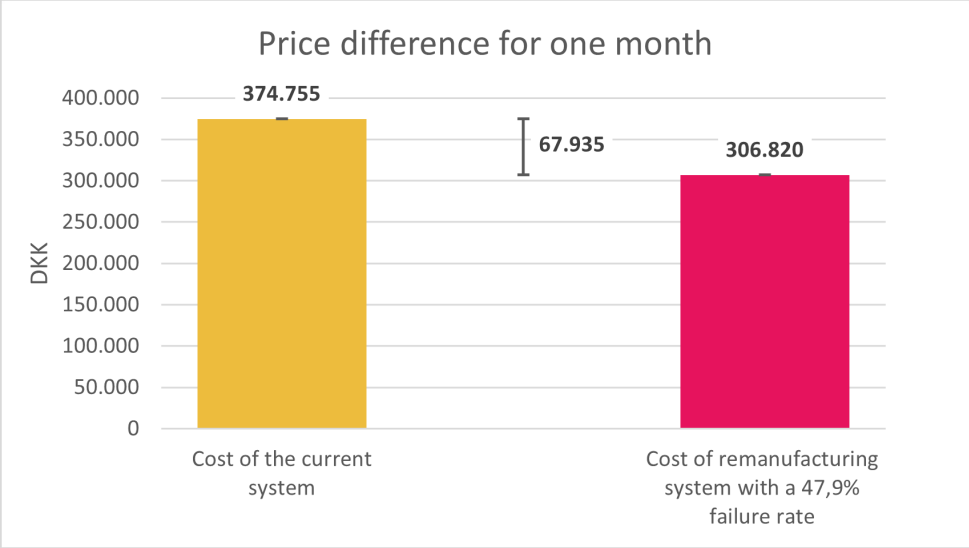


Figure 43 Shows a comparison of the price for the current system using 22 newly produced catheters for a month and the price for using 10 remanufactured catheters and 12 newly produced catheters, which is equivalent to the failure rate of 47,9%.

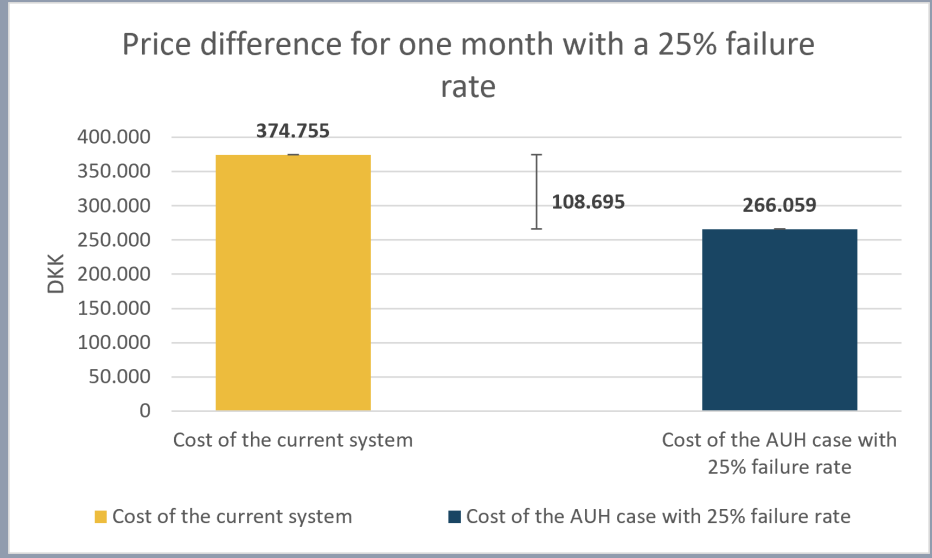


Figure 45 Shows a comparison of the price for the current system using 22 newly produced catheters for a month compared to the price of the AUH-case of using 16 remanufactured catheters and 6 newly produced catheters, which is equivalent to the failure rate at 25%

happen on multiple devices, the time used would go up. These dynamics needs to be assessed when using the TCO-calculator and the results. The reason for the freedoms of choice in the TCO is to try and make these dynamics visible.

In the next section, it will be further analysed how these savings can be made into objects that can be used to interest and translate actors of the network. Moreover, ideas for how to make the current system more sustainable will be analysed.

Sub-conclusion

In the previous section it was studied how remanufacturing of the ultrasound catheter can result in a reduced climate change impact by looking at the climate change impacts of a month of using either solely newly produced catheters or using a mixture of newly produced and remanufactured catheters. Furthermore, a total cost of ownership study showcases the potential cost reductions of using remanufactured catheters.

The main takeaways are:

- Using a mix of remanufactured and newly produced catheters, with a failure rate of 47,9% for remanufactured catheters at the Heartlab 2 AUH, will provide a potential climate change saving of 36% CO_2-eq. The impact of the system per month can be said to have the potential saving of 2,17 kg CO_2-eq. every time a newly produced catheter is replaced by a remanufactured one.
- The total cost saving of using a mix of newly produced and remanufactured catheters with a failure rate of 25%, would provide a cost saving of 1,3 million DKK, with a price difference of 40% between a newly produced catheter and a remanufactured catheter.

5.0

Implementing the remanufacturing system

The above section illustrated how a new remanufacturing system could create environmental and economic savings in the healthcare sector. Multiple actors need to be interested and support the change for remanufacturing to be implemented as a circular strategy for limiting the climate change impact of single-use medical devices in the healthcare sector. For this reason, it is vital to consider how these actors can be interested. This section will clarify how actors can be translated into the new network of remanufacturing and what interessement devices will be needed. Furthermore, it will be investigated what changes to the remanufacturing system can be done to make it more sustainable once it is implemented.

Interessement of actors

Nurses

Over the years, budget cuts have resulted in fewer resources in the healthcare sector. This has, among others, resulted in fewer, more pressured nurses in the hospital. The shortage of nurses causes not only busyness and fewer hospital beds, but as stated in an article by Danish Nursing Council, it also affects the quality of nursing and patient safety (Brandi, 2022). A solution to this problem of busyness and lowered quality of nursing could be to have the finances to hire more nurses. However, it is not easy to find money in a system which is already cut to the bone. Therefore, it makes sense to start looking at where money can be saved in the procurement of materials, so savings no longer affects the number of employees.

A way to interest the nurses in using remanufactured devices could be to express the amount of money saved every month in the procurement of materials if remanufacturing was to be used. This could directly translate into hiring more nurses in the department. In the AUH-case example, with a 25% failure rate, the department could save 108.935 DKK a month. This would result in a total savings of 1,3 million DKK a year. If one department saves 1,3 million DKK a year, it would be equivalent to them being able to cover the salary of two full-time nurses, given that the average salary of nurses at AUH is 481.885 DKK a year (Vestergaard, 2021). This would be of interest to the nurses, as hiring more of them would help to alleviate some of the hurriedness at the departments.

A concern from the nurses is that remanufactured devices are more time-consuming, as they will have to wash and pack them in plastic bags after the operation. Furthermore, they will also need a nurse to order the pick-up of used catheters every month. As *Mikkelsen (2022)* expressed, she and other colleagues have experienced it being time-consuming using resterilised devices. This leads them to worry about the time they will need to put into using remanufactured devices. If remanufactured devices could free money to hire more nurses, this could be used as an interessement device potentially getting more nurses ready for the change. Many departments (other than Heartlab 2) are using devices that can be remanufactured. If these departments were to also use remanufactured devices, it could be expected that they would have a similar saving.

The annual saving by using remanufactured devices equals:

1,3 million

Just from the heartlab 2 at AUH

=

+2 Nurses

The Danish Regions

For the transition to using remanufactured single-use medical devices, particularly remanufactured ultrasound catheters, the support and documentation of the need from the other Danish Regions is needed. To interest the Danish regions, they could be shown a quantification of the potential savings they could have if they were using remanufactured devices. This quantification of the cost would come from the TCO-calculator. The quantification would be able to interest the regions as they have set the goal for saving 1 billion DKK before 2025 (Danske Regioner, 2020).

Revsbeck (2022) expressed that a reduction in costs would free up resources to be used for green initiatives. Furthermore, the Danish regions, as described in the ANT, are interested in being sustainable when it is easy and does not result in further expenses. Therefore, the saving could be seen by them as an opportunity for creating new pilot projects in sustainability, ultimately accelerating the transition towards more sustainable healthcare in each region.

To further interest them in remanufacturing, they could be shown the possible reductions in CO_2-eq. emissions that the use of remanufactured devices could bring about if implemented. To interest the Danish regions, CO_2-eq. reduction is important, as this is the factor they consider with their current strategy for sustainability. Especially a percentage reduction of CO_2-eq. would be able to interest them to at least look more into remanufacturing possibilities. The reduction in CO_2-eq. can be seen on Figure 46.

Furthermore, the interest could be done by taking the results of the LCA and displaying them in understandable units. An understandable unit to show the reduction in impact could be to convert the difference in CO_2-eq. of alternative 1 (the current use of ultrasound catheters) and the AUH-case (with a mixture of newly produced and remanufactured catheters and a failure rate of 25%) into an equivalent number of kilometres driven. This can be seen on the next page.

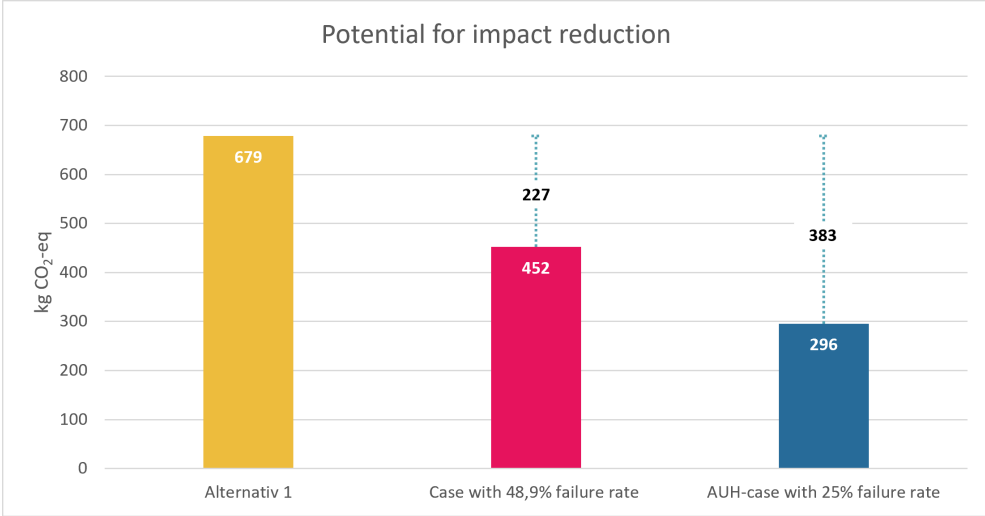


Figure 46 The differences in climate change impact in three different cases: The current use of ultrasound catheters, the use of remanufactured catheters with a failure rate of 47,9% and the specific AUH-case with remanufactured catheters and a failure rate of 25%

The savings between alternative 1 and the AUH case in km driven

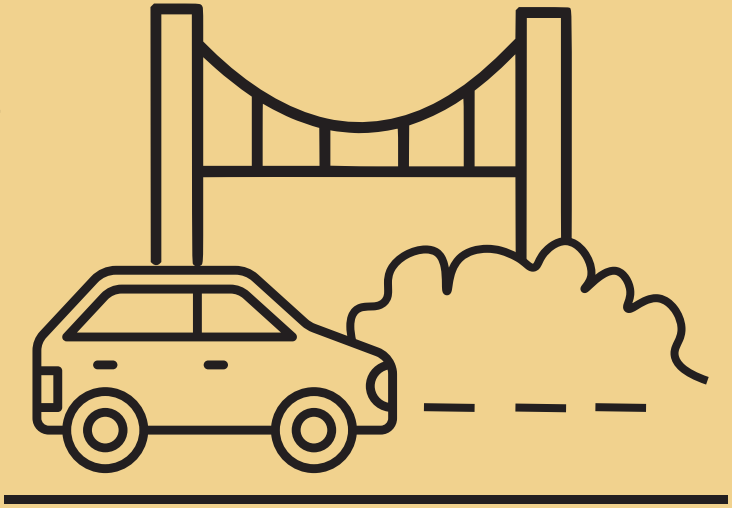
Case with 47,9% failure rate, it is equivalent to driving

3

5

AUH-case with 25% failure rate, it is equivalent to driving

Times **back and forth**, over the bridges, from **AUH to Christiansborg**



The doctors

The doctors will be more challenging to interest. Most of them are not directly seeing the impact of throwing the devices out (*Schønemann-Lund, 2022*), and many can thereby be unaware of the significant waste flows going out from the hospitals. The aspect of most importance to the doctors is that the remanufactured devices are of the same quality as the ones they currently use. However, this should not be an issue with the remanufactured catheters, as they live up to the specifications of newly produced devices in Germany.

To get the doctors interested in the change, it will be necessary to make them aware of the possibilities. As explained previously, they have high power to select the devices based on the parameters they help set for the tenders. Therefore, for the hospitals to use remanufactured devices, the doctors must express sustainability wishes when setting the tenders. This interessement could be started by mobilising Doctors for Climate and making them spokespersons of a new system of using remanufactured devices. Doctors for Climate could be provided with the appeal prepared for

the Danish Medicine Agency, which should already work as a boundary object to share knowledge between other relevant actors, to interest more doctors in the change. Furthermore, since The Doctor's Association has their new strategy (Lægeforeningen, 2022), they would likely be interested in looking into using remanufactured catheters if they were made aware of the possibilities of climate change reduction.

Nonetheless, if the doctors are made aware of the opportunity of using remanufactured devices and the Danish Medicine Agency creates the guidelines, they will be likely to be enrolled in the new network. This as they are generally followers of the guidelines presented from the Danish Medicine Agency.

Hygiene organisations

For the translation of the hygiene organisation to succeed, it is essential to provide data and evidence-based research that expresses that there are no higher infection rates when using remanufactured devices. A convincing argument would be to use AUH Heartlab 2 as a case example, showing their unintended occurances (UTH'er) during the 1 1/2 years they have used remanufactured devices. This is to state that it has not increased UTH'er. Remanufacturing has been used since 2002 in Germany. Comparing Germany's reported infection rate to the Danish infection rate could provide another argument. In 2019 Socialstyrelsen in Sweden set down a research group to document the use of remanufactured devices and map the infection rate in multiple countries using these. They concluded that the use of remanufactured devices causes no risk to the patient, which could be another argument to interest the hygiene organisations. Furthermore, another specific action that can be taken to interest the hygiene organisations is to set down a research group to study whether the remanufacturing processes change the material quality.

OEMs

The increased demand for remanufactured devices in the healthcare industry would disrupt the market, thereby influencing the OEMs. Therefore, it is essential to investigate the possibility of a future business model by having a dialogue with the OEMs. As mentioned before, the OEMs are not delighted by the fact that other companies are making remanufacturing on their original devices. However, the market is starting to move in new, more sustainable directions that their current single-use medical devices do not fit into.

The OEMs could be proposed a new business model of them selling a service rather than products. This would be of great interest to the regions, who would gladly leave the responsibility for end-of-life (whether that be recycling or remanufacturing) to the OEMs (*Klausen, 2022*). Furthermore, by selling a service, the OEMs would remain owners of their products and be able to develop remanufacturing of their own devices. They would also maintain the continuous flow of profits they have by selling single-use devices, as they would be able to repeatedly sell the service. Consequently, OEMs would keep their market share and products, relieving the tension of the product-owner dispute. Additionally, remanufacturing at the OEMs would be a better business than current remanufacturing companies, as the OEMs have all the needed data. It could open for the OEMs to produce better products designed for remanufacturing, making remanufacturing an even more sustainable solution than currently.
It can be discussed if it is the responsibility of the regions to initiate the

discussion of business models with the OEMs. However, the change of the OEMs is inevitable if they want to keep their market share, as the requirements of the specification in the tenders of the regions are likely to change if the appeal is accepted and the guidelines for remanufacturing in Denmark are created (*Klausen, 2022*).

How can the remanufacturing system's impact be lowered?

In this section, different actions that can be taken, or ideas for redesigning the system of using remanufacturing, will be discussed. Furthermore, it will be investigated what significance these changes could have on the environmental impact of the system and the actors influenced by it.

Collective remanufacturing in Denmark

A suggestion for lowering the environmental impact of remanufacturing could be to have the remanufacturing closer to the user (in this case, AUH). This could be in the form of a collective remanufacturing central for all Danish Regions, placed in the most optimal location for all the regions to reach. The idea behind this central is that the impact of the transportation in remanufacturing would be lowered when fewer kilometres are to be driven. Limiting the transport has been of interest as the transportation of the catheters is the process with the highest climate change impact in the remanufacturing loop.

A case example could be to have a remanufacturing central located at Funen. In this example, the new remanufacturing central is assumed to be located at Odense University Hospital (Hereafter OUH) instead of Germany. This could provide a saving of 2,5 kg CO_2-eq in the AUH case. See Figure 47.

Nonetheless, the saving in impact could be even more significant for other hospitals as the distance would be reduced even more in their cases. This could be for hospitals such as Rigshospitalet in Copenhagen and OUH.

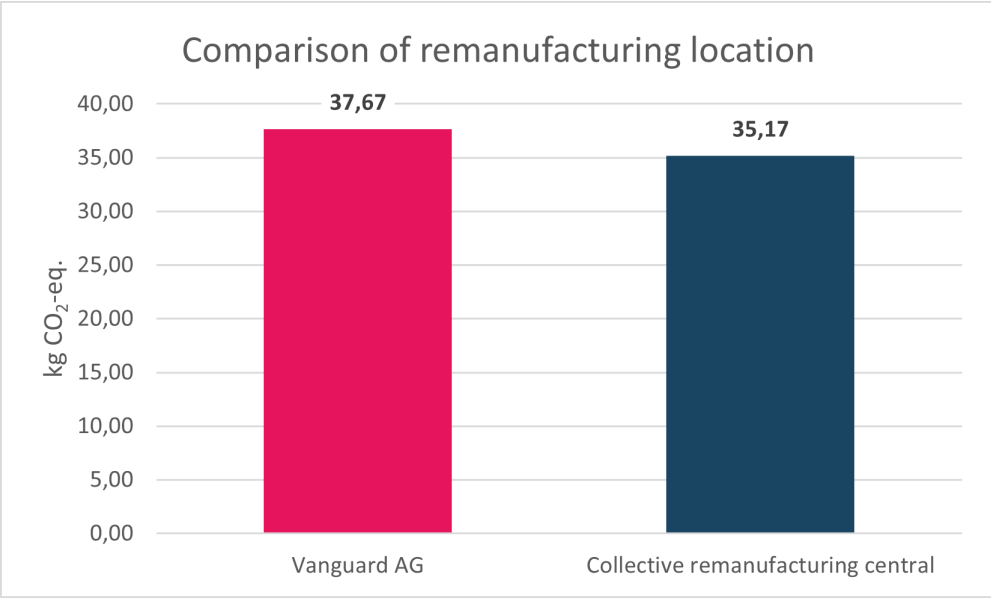


Figure 47 The table shows a comparison of different locations for the remanufacturing facility, which gives a saving in CO_2-eq. With the transport from AUH to Vanguard AG: 37.67 kg CO_2-eq pr. Transport. And the transport from AUH to OUH at Fyn: 35.17 kg CO_2-eq pr. Transport. In the calculation has been added a Danish electricity mix.

Furthermore, the saving would be correlatedly increased if more devices were remanufactured. It is worth noting that there already is transportation of other equipment between the hospitals (*Revsbeck, 2022*). Therefore, it would not be too much of a change to the system to bring along some more materials (which in this case would be single-use medical devices for remanufacturing).

Changing the delivery method of the ultrasound catheters

One of the more considerable climate change impacts of the new catheters, which are needed in both alternatives for providing the ultrasound picture, is that of air freight. The reason for using air freight delivery is that the ultrasound catheters only have a shelf-life of 12 months. Therefore, a long journey would mean that the OEMs could only sell relatively short shelf-life products to the Danish hospitals. Moreover, in some rare cases, the catheters were not used before the expiration date. Consequently, they need to be thrown out due to health concerns.

Furthermore, due to regulation, it is not permitted to remanufacture them if they are past the expiration date. This means that within one year of production, the catheter will need to be transported to Europe, wait to be sold, transported to the buyer, used and then sent to Vanguard. Therefore, it could make sense to extend the shelf-life of the catheters to allow for both slower transportation from the US to Belgium, and less risk of catheters going past their expiration date in both hospitals and before they reach Vanguard AG. Prolonging the shelf-life could be done by introducing an extra dust cover to the packaging. The dust cover is put around the device in the peel pack, sealed and should, according to producers, extend the shelf-life of the product for 6 months. In the AUH-case example, if the transport is changed from air freight to ship freight and a dust bag for prolonging the shelf-life is added, it would save 14,68 kg CO_2-eq., see Figure 48. In this example, it is assumed that the weight of the dust bag is the same as the weight of the transportation bag that Vanguard AG uses in alternative 2.

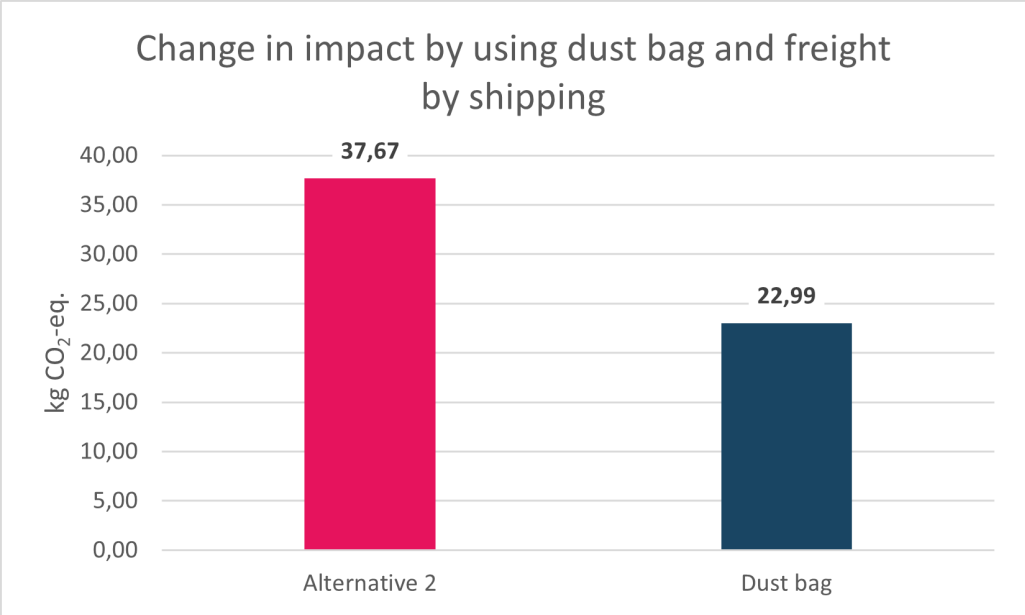


Figure 48 The table shows the alternative 2 with a catheter being transported by freight to Belgium and later with truck to AUH. In the Dust bag example, the catheters are being transported by ship and later truck to AUH with a dust bag to prolong the shelf-life

Nonetheless, a solution to this issue could also be better planning of how many ultrasound catheters are sold and used and produce accordingly. Thereby, no ultrasound catheters would end up staying at the producer long after production, which would result in them having a short shelf-life when they arrive at the hospital. At AUH they are currently only purchasing 10 catheters at a time, and it, therefore, seems unlikely that they would be able to improve that. However, it might make all the steps of the catheter more feasible to do within a year, if the box was to be sent to Vanguard more often than the current cycle of every 1,5 months. Nonetheless, the impact per remanufactured catheter would then go up as the box would be less full each shipping. This could be solved by looking into options for remanufacturing other devices at AUH, which could be packed in the same box resulting in the box being picked up more frequently. This would result in the dust bag that is added in figure 48 to be spared.

Recycling of discarded catheters

Another way to limit the impact of ultrasound catheters is by ensuring proper waste handling. In the remanufacturing system (alternative 2), the catheters are thrown out into regular waste when discarded at Vanguard AG. If Vanguard AG were to send the catheters to an electronics recycling facility, it would be possible to lower the climate change impact of the system.

If this is done, it could potentially reduce the climate change impact with 5,0 kg CO_2-eq. a month, as seen in Figure 49.

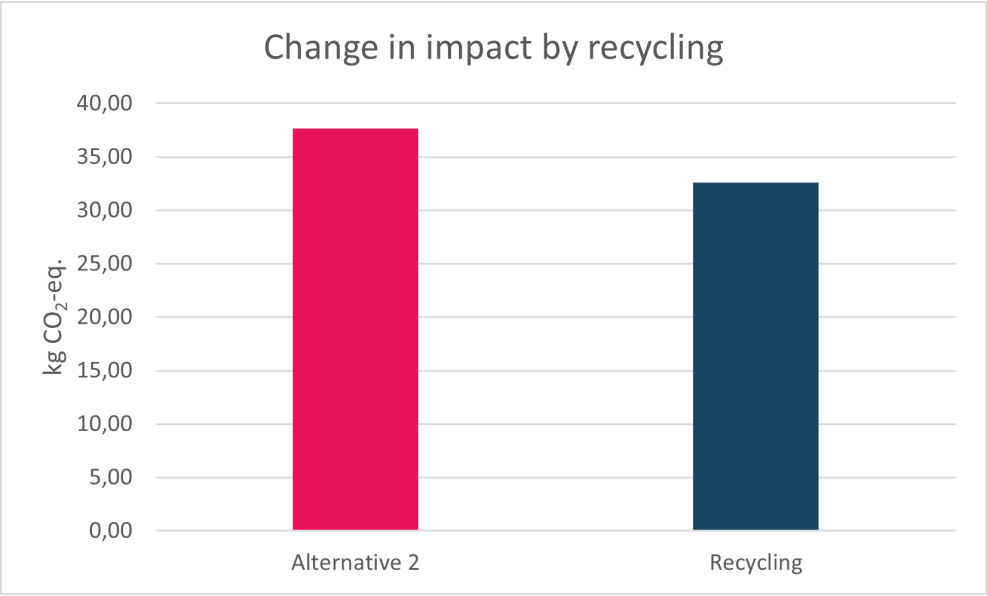


Figure 49 The table shows the different in kg CO_2-eq for Alternative 2, where the catheters are thrown out as general waste at Vanguard AG compared to being recycled when it is discarded at Vanguard AG.

Design for remanufacturing

A strategic way to optimise the current remanufacturing system would be to design products to be remanufactured. If it is designed to be remanufactured, it would be fair to conclude that the device could go through the remanufacturing process more times than currently. If the catheter could last for more remanufacturing cycles, it could influence the climate change impact of the system. Design for remanufacturing could be evident in the choice of materials as well as design for dis- and reassembly. As stated in the circular economy action plan from the EU commission 2020, up to 80% of the products environmental impact will be determined in the design phase (European Commission, 2020).

However, a way to extend the lifetime of the devices without the need for a redesign would be to take even better care of them. An investigation of remanufacturing of single-use medical devices from Socialstyrelsen in Sweden has concluded that remanufactured devices, if following a validated protocol, can undergo more life cycles: *"... there is a large number of published studies, showing that remanufacturing is possible between 5-10 times without risking patient safety"* (Socialstyrelsen, 2020, p. 33). Thereby, suppose the catheters are washed properly and packaged for shipping correctly. In that case, it could be feasible to remanufacture them more times without the need for other system changes. Furthermore, it is essential to ensure that the catheter's wire does not bend extensively during shipping, as it could cause harm to the device. If the wire is bent too much, it will likely be discarded when arriving at the remanufacturing company, limiting the number of times devices are remanufactured on average.

As seen in Figure 50, if the catheters are remanufactured more times than the current limit of 3, the impact of the system could be lowered. Optimally, if no limit were put on how many remanufacturing cycles could be done, the impact of the system would be at 11,6 kg CO_2-eq. per 22 ultrasound catheter uses as per the functional unit. If remanufacturing is possible 10 times per catheter, it would be equivalent to the pillar called R20, N2 with a climate change impact of 16,0 kg CO_2-eq. per 22 uses of ultrasound catheters.

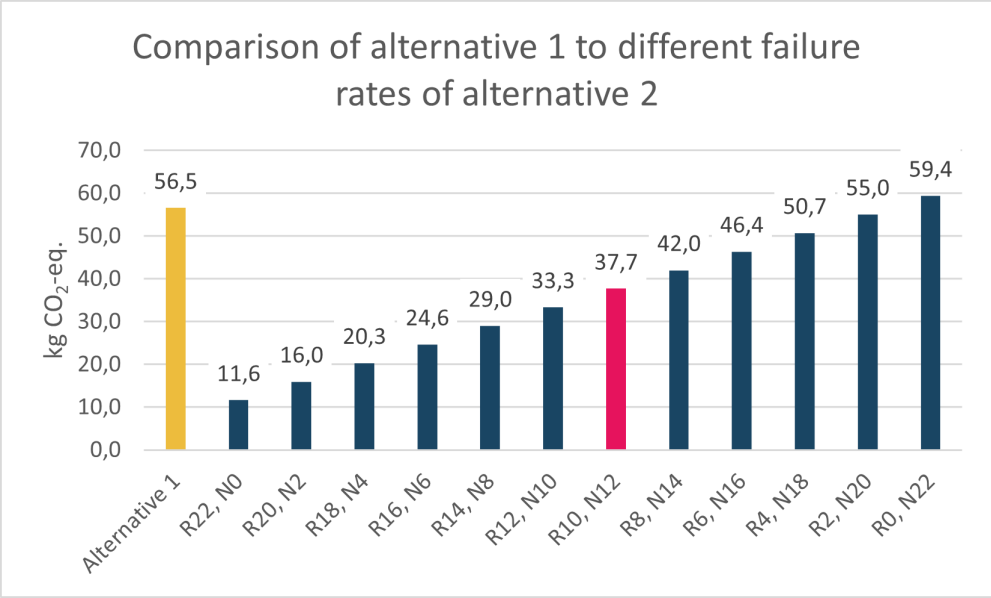


Figure 50 Development in climate change impact depending on the amount of remanufactured and amount of new catheters input. Each step indicates a change of two new catheters being input, thereby eliminating 2 remanufactured catheters.

Seen from the view of a single ultrasound catheter, its climate change impact per use time would change according to Figure 51.

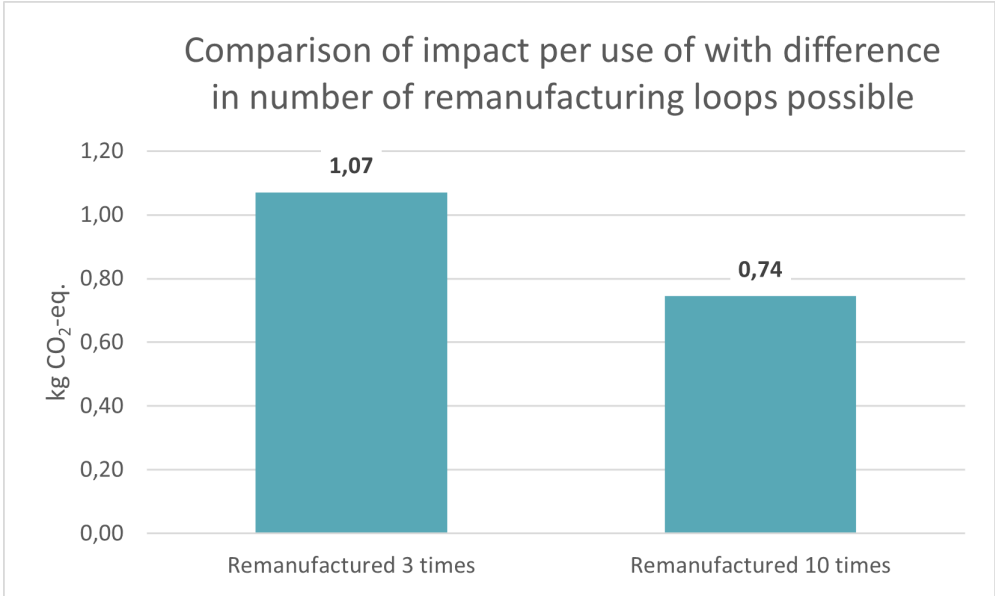


Figure 51 The climate change impact related to the use of catheters depending on the amount of times the catheter can be remanufactured.

How could more sustainable use of medical devices be ensured?

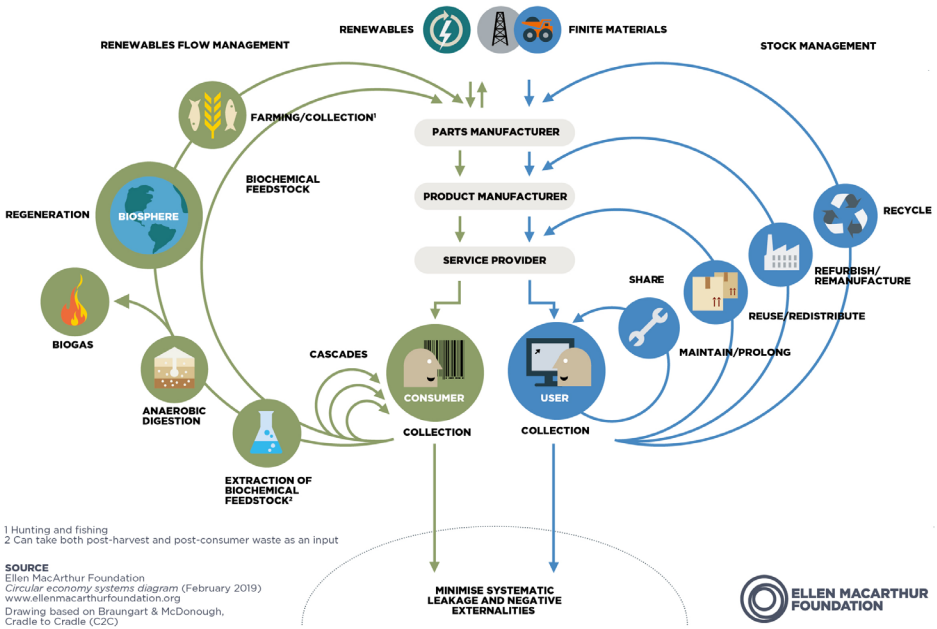


Figure 52. The butterfly model by the Ellen MacArthur foundation.

As seen on the butterfly model for a circular economy by the Ellen MacArthur Foundation, it would be possible to make smaller loops and create more sustainable healthcare if other circular economic principles were applied.

One way to improve the overall sustainability of the healthcare sector is to make products that are reusable and can be disassembled to be sterilised. The disassembly is critical to include, as with complicated medical devices, it would be needed to disassemble them thoroughly to get them appropriately sterilised. Currently, primarily simple medical devices are resterilised, but by applying design for dis- and reassembly (Bocken et al., 2016), it would be possible to expand the sterilisation service to more complicated products. This would enquire that OEMs are liable for their product for multiple life cycles, which is currently not their priority. However, with the sustainability discourse in society, it can be hoped that the incentive to produce single-use medical products will be removed, resulting in the OEMs needing to adapt and make more sustainable devices such as reusable devices.

Generally, for the chance for hospitals to use medical devices more sustainably, OEMs would need to change their business models. A way to change could be to aim at a product-service system, as mentioned previously. By implementing a product-service system, they would be able to include CE strategies such as extending the lifetime of the product (slowing the loop) or creating more efficient products and using less material (narrowing the loop) (Bocken et al., 2016). With product service systems, the ownership would remain with the producers, and only the device's function would be bought. This would give the incentive for the OEMs to introduce better products and greater possibilities for repair and maintenance. The product-service systems are the two inner loops of the technical cycles in Figure 52.

How to hand over the project

To ensure that the knowledge produced from the TCO and LCA analysis will make a lasting change, it needs to be handed over appropriately. First and foremost, Central Denmark Region is already a spokesperson for the new remanufacturing system. Therefore, it would be conspicuous to equip them with the materials to continuously enroll actors in the network of remanufacturing single-use medical devices. This would require that they build an actionable plan for how to continue the project. It will, however, not be possible to 'design' the transition all the way to the end, hence the first few steps to continue the enrollment would be the most essential.

Furthermore, the objects of knowledge and the data within this project will be handed to Central Denmark Region. It will consist of a small slidebook that summarises the results of this master's thesis that they can use to interest actors with whom they are not physically in touch with. The point of the slidebook is to be short and visual, efficiently communicating the benefits of remanufacturing to interest actors in engaging in a new network. It is imperative that it is precise and visual since Central Denmark Region has the experience that a more comprehensive report does not interest certain actors due to the time-consuming reading before getting to the point (*Klausen, 2022*).

Additionally, it will be possible to enroll more actors at the upcoming open meeting on the 24th of June, 2022. Central Denmark Region is preparing to have an open meeting with multiple actors from various disciplines, all of which are related to the single-use medical device agenda. Here, the authors of this thesis will participate. Furthermore, many actors from the ANT will participate and they will surely comment, and debate based on their matters of concern. It can be said that all actors of the ANT are interested in the new system. However, not all their interest might be positive. This would be the case for the OEMs who will participate in the meeting but are expected to present an argument as to why the appeal to the Danish Medicine Agency should not be made. Therefore, the idea of the meeting is to interest all actors to engage in a negotiation space where concerns can be discussed, and a common problematization can be created.

For the Central Denmark Region, it is essential that all these actors are enrolled when the writing and editing/commenting on the appeal for The Danish Medicine Agency will start. Once this appeal has fallen in place, it will be needed to interest the head of procurement in the different regions, which will have to sign their acceptance before the appeal can be sent to the Danish Medicine Agency. A significant argument to interest the head of procurements from the different regions is the cost reductions related to using remanufactured devices. Furthermore, the Heads of procurement should be interested as they are responsible for making green purchases in the regions. Once the meeting has been completed, the appeal will finally be sent, and the Danish Medicine Agency will start creating the guidelines, possibly with guidance from different relevant actors.

As can be seen, there are still quite a few steps before remanufacturing of single-use medical devices is legal in Denmark. However, it is believed that the evidence provided by this master's thesis on climate change impact reduction and the reduced cost of remanufacturing will be more likely to create the needed arguments for realising the guidelines of remanufacturing.

Intended content of the slidebook

The slidebook is intended to include the most important findings for supporting a change to using remanufactured devices, by use of a case study on ultrasound catheters. The slidebook is intended to be a PowerPoint that can be exchanged by Central Denmark Region to multiple actors to interest them.

The slidebook will include a brief description of the relevance of this project and why it has been investigated. Furthermore, the slidebook will entail a description of the savings in climate change impact if remanufacturing was to be implemented. It will furthermore discuss how remanufacturing can contribute to the Danish regions' goal of reducing their impact by 70%. Additionally, the overall cost reduction enabled by implementing remanufacturing for Heartlab 2 will be detailed and it will be shown how that money could be used for new nurses or new sustainability projects. Moreover, text is intended to be in an easy understandable language and all the data from the LCA and TCO will be illustrated simply and with more intuitive examples showing the reductions in different ways, that will help people that are not familiar with the methods to comprehend it.

All of this will work as an interessement device with convincing arguments for why the different actors support is needed. If they Regions' Heads of Procurement are not aligned with this agenda, it would mean that they are opposing strategies that work towards their reduction goal of 70%.

Note for the creation of guidelines on remanufacturing

As a final note, the authors of this thesis would like to mention, that when the guidelines for remanufacturing are created, they should try to mimic the guidelines of other member states. Currently, it would take a lot of capital to create a remanufacturing company in Denmark. The amounts of devices of a similar type used in hospitals are simply not big enough to make it profitable for a Danish company to invest in the specific machines needed for each type of medical device. Therefore, it would currently be needed that the guidelines are so similar to the German ones that single-use medical devices can be remanufactured there without too much of a hassle.

Moreover, if the OEMs would start taking back their products, it would still be needed that the Danish guidelines are similar to those of other EU member states. It would be a blocker for OEMs to pick up remanufacturing of their products if needed to do so differently for each member state. Therefore, they might refuse to make a take-back system in Denmark if the guidelines are too different from other countries, as the flow of devices from Denmark is relatively small.

6.0

Conclusion

Conclusion

The LCA shows that the climate change impact can be lowered at the Heartlab 2 AUH by using remanufactured ultrasound catheters. Moreover, as fewer catheters will need to be produced if remanufacturing is deployed large scale, the resource consumption will be reduced. Furthermore, as shown in the TCO, there is a potential for reducing costs by 29% if remanufactured ultrasound catheters are used. Thereby, it can be concluded that remanufacturing would reduce climate change impact, resource consumption, and cost for single-use ultrasound catheters at AUH.

Multiple changes could be made to improve the overall sustainability of the remanufacturing of single-use medical devices. Firstly, being that the catheters are designed to be used only once causes a constraint in the practicality of remanufacturing them. This causes a reduction in remanufacturing cycles of every single ultrasound catheter and an extra cost as it becomes more complicated to clean appropriately. Therefore, remanufacturing of ultrasound catheters could become more environmentally sustainable if the catheters were designed to be remanufactured.

Even if the process of extraction of the materials for the ultrasound catheter is still unclear, it could be beneficial in terms of climate change impact to ensure production in Europe. This, as the ultrasound catheters are on a long journey before reaching AUH, and this journey accounts for around 42% of the climate change impact of the system. Even with a remanufacturing system with an estimated 47,9% failure rate, where fewer flights from the US to Europe is needed, the transportation of the newly produced catheters that are needed continuously accounts for around 35% of the climate change impact.

Furthermore, in the remanufacturing process itself, the transport from the hospital to the remanufacturing facility, which in this case study is Vanguard AG, accounts for most of the impact. This means that approximately half of the impact of remanufacturing the catheters (not considering the newly produced catheters needed) is not associated with the process of remanufacturing itself but rather with the processes to get it to a remanufacturing facility. Therefore, it would be valuable to investigate how remanufacturing might be done more locally. Moreover, adequate recycling of discarded catheters could help lower the impact of remanufacturing ultrasound catheters marginally.

For Heartlab 2 to use remanufactured ultrasound catheters, it is needed that Central Denmark Region sends an appeal to the Danish Medicine Agency together with the other Danish Regions. Once this appeal is received, the process of creating the Danish guidelines for remanufacturing will begin, allowing Heartlab 2 to start using remanufactured ultrasound catheters.

However, to get to the point of sending the appeal, multiple actors need to be interested in the problematisation and support the change to a system of remanufacturing single-use medical devices. The results from the TCO and LCA clearly indicate that remanufacturing single-use medical devices is an excellent solution to reduce climate change impact and cost. Therefore, the TCO and LCA results could be used as an interessement device when communicating with the actors. For the results to work optimally in the translation, they should be tailored to address the concerns of the

individual actor. For example, for the other Danish Regions, the results should be tailored to show how they can help the regions reach their 70% goals.

The case study has allowed assessment of the potential of utilising remanufacturing as an end-of-life method for handling single-use medical devices. It is believed that if the guidelines for remanufacturing were to be made, Danish regions and departments of hospitals would be quick to investigate the potential of including remanufactured devices in their practices. However, for the practical implementation in hospitals, it will be needed to convince the sceptical actors by providing evidence that addresses their concerns.

The legalisation of remanufacturing will be the first step in a sustainable transition in the healthcare sector in Denmark. However, to achieve even more significant benefits, it would be needed to increase the use of resuable devices, as these would result in a greater environmental benefit in terms of both material consumption and climate change impact.

Perspectivation

This case study can be used as inspiration for remanufacturing many other single-use medical devices and holds the potential for expanding remanufacturing from the ultrasound catheters to include other single-use medical devices used in the hospitals. Furthermore, many of the observations done in this study will be applicable to countless other devices which are currently single-use. Already, Vanguard AG remanufactures up to 985 different medical devices, some of which are used in the Danish regions (*Klausen, 2022*). Thus, there is great potential for remanufacturing even more medical devices than just ultrasound catheters.

This master's thesis should inspire environmentally sustainable development in hospitals and should serve as proof of the environmental improvements that can be achieved by remanufacturing. Furthermore, it can be used as an additional argument within EU member states when discussing whether to 'opt-in' to article 17 by giving an argument of sustainability.

However, remanufacturing might not be the most sustainable option for hospitals in the long term. To further develop sustainability in the healthcare sector, EU regulation will need to change, and incentives should be put in place to limit production of single-use medical devices.

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