

# Remanufacturing as a circular design strategy in healthcare: integrating socio-technical and environmental-economic assessments

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#### Abstract

This paper examines the role of remanufacturing in healthcare as a key circular design strategy, particularly for medical devices, assessing its socio-technical, environmental, and economic dimensions of sustainability. Through a detailed case of ultrasound catheters, it demonstrates how remanufacturing can lead to resource conservation, cost savings, and enhanced product lifecycles in health care without compromising quality and patient safety. The study argues for systemic changes in healthcare practices to fully integrate remanufacturing, underscoring its role beyond a technical solution.

Keywords: sustainability assessment, remanufacturing, medical device, design strategy, circular economy

### 1. Introduction

Changes are needed in our unsustainable world to reach the goals set forth in the Paris Agreement. We often tend to look at companies that have a very visible impact such as the heavy industry. However, when examining the impact of specific sectors, the healthcare sector in Denmark, which is the focus country in this paper, accounts for 6,3% of the national greenhouse gas (GHG) emissions (HCWH, 2014). It is therefore essential to begin exploring potential changes in the healthcare sector to lessen this climate change impact. Bearing in mind the ongoing expansion of the healthcare sector, and its ability to treat more patients, it is crucial to invest in sustainable infrastructure to meet the rising demand for health services. In Denmark, an aging population is anticipated to heighten the demand for healthcare services, consequently intensifying the sector's carbon footprint. This necessitates long-term financial planning and sustainable business models to manage resources effectively while reducing emissions. Single-use medical devices (SUD) play a significant role in the daily functioning of hospitals and come in a vast variety, ranging from syringes to diagnostic kits, each designed to ensure patient safety and prevent the spread of infection. Recently with the opposition to the unsustainable take-make-dispose linear economy and with the focus on waste stream reduction, SUD has received attention, for their noncircular lifetime/lifecycle and significant environmental impact. Medical devices are regulated with high requirements on performance and safety (European Council, 2017), which can also inhibit potential sustainable innovation. Many healthcare professionals in Europe favour SUD due to their reputation for sterility, which is perceived to enhance patient safety significantly. However, advancements in patient care and manufacturing technology are facilitating the adoption of remanufactured devices, thereby reducing their impact on climate change.

### 1.1. Remanufacturing as a design strategy for circular economy

Making environmentally sustainable change in the healthcare sector can be onerous, as this often is equated to reduced quality of care. Given that the quality of care is viewed as the cornerstone of social sustainability in the healthcare sector, it becomes difficult to introduce and integrate other dimensions of sustainability, such as the triple bottom line into the dialogue. The primary reason for this is the idea that improved environmental performance of hospitals necessarily will lead to poorer patient outcomes. However, as per Food and Drug Administration guidelines, the circular approach to the servitization of single use medical devices, making them 'multiple use', can be achieved by changing the current healthcare practices without disturbing the treatment approach (Weeda, 2021).

By embracing a circular economy (CE) model and adhering to the principles of the waste hierarchy, prioritizing reductions presents an optimal pathway to minimize areas of over consumption such as routine testing. Despite the potential value retention offered by reuse, as suggested in the waste hierarchy, this practice is not directly applicable to all medical instruments. At present, the practice of reusing equipment is mostly confined to basic medical devices in Danish hospitals (Statens Serum Institute, 2019). Moreover, current trends indicate a rise in the number of complex medical devices that are labelled as single use. This is because the Original Equipment Manufacturer (OEMs) can only be held accountable for the device's performance for one use-cycle if it is labelled as single use. If the OEM were to label the devices reusable, they should live up to a certain amount of servisation cycles, that could be conducted by the hospital's personnel. Following the waste hierarchy, the next strategy for CE is repair. As a result of the stringent hygiene requirements for devices, this approach is not practical for medical devices. That leads to the next step in the hierarchy: remanufacturing, which is the only end of life treatment, where products are reset before clearance for reuse, meaning they have performance and warranties equivalent to new products (Paterson et al., 2017). Remanufacturing is the most preferable option for SUD due to the challenges associated with direct reuse or repair. It is the only end-of-life strategy that returns the product to its original quality level, fulfilling the stringent requirements of hospitals that need assurance the product will not pose any risk to patients. However, remanufacturing requires a resource-intensive process that includes cleaning, sterilisation, and testing (Shulte et al., 2021). Consequently, the remanufacturing process requires personnel with specialized expertise to restore the devices. Thus, if remanufacturing is carried out on a larger scale with a larger mass flow involved, it might be possible to reduce the associated cost for the specialized personnel.

Numerous studies have investigated the advantages of utilizing remanufacturing at end-of-life (Fofou et al., 2021). A frequently cited advantage of remanufacturing is the potential to achieve cost savings (Eze et al., 2020; Oturu et al., 2021; Zhang et al., 2020). In 2023, the UK National Health Services reported a significant projected saving of 1.2 million pounds if all their hospitals increased the remanufacturing of single-use medical devices (SUDs) (National Health Service, 2022). The Association of Medical Device Reprocessors (AMDR) stated that remanufacturing avoided 5,426.851 kg of medical waste in 2021 alone (AMDR, 2021). 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). A key point in the saving potential is that human and monetary resources are not limitless in healthcare (Antoniadou et al., 2021). Therefore, the saving creates the potential to pay for hiring more nurses or preforming more operations. Efforts to extend the lifecycle of ultrasound catheters, through remanufacturing and high-level disinfection can significantly reduce healthcare emissions and align with circular economy principles. Designing ultrasound catheters with longevity in mind and offering remanufacturing services can help preserve their value, reduce the need for new production, and minimize waste, contributing to sustainability in healthcare. Since remanufacturing offers a strategy that keeps the medical devices value over time, it is easier to implement into the current practices. Furthermore, multiple researchers suggest remanufacturing as an option to achieve a circular economy (Asif et al., 2021; Ellen MacArthur Foundation, 2013; Fofou et al., 2021; Oturu et al., 2021). To support decision-making regarding the use of remanufacturing in Denmark, a detailed case study was conducted during 2022, which validates the environmental and economic perspective in a combined sustainable assessment.

### 1.2. Aim of the study

This study applies an innovative methodology involving mixed methods research – Actor-Network Theory (ANT), Life Cycle Assessment (LCA) and Total Cost of Ownership (TCO) to perform a socio-technical and environmental-economic assessment. The goal is to create a framework for assessing the long-term sustainability of remanufacturing of ultrasound catheters and ensuring feasible implementation of findings (see Figure 1). The study outlined in this paper has two central aims:

- Designing how remanufacturing can be implemented as a circular strategy in the healthcare sector.
- Conduct a comprehensive sustainability assessment.

The first research aim was investigated by conducting a case study of remanufacturing ultrasound catheters used at Aarhus University Hospital (AUH) in Denmark. Before the implementation of the 2017 Medical Device Regulation, which rendered the remanufacturing of SUD illegal without established national guidelines, AUH employed remanufactured catheters on a limited scale. Therefore, Central Denmark Region, who is administrating the hospital, sought to legalize remanufacturing in Denmark but first needed to demonstrate its viability, as a circular and sustainable solution. Thus, it was required to carry out a full sustainability assessment to assist in the implementation of remanufacturing in the healthcare sector by providing supporting arguments. The full sustainability assessment was carried out using two quantitative methods, LCA and TCO, along with the qualitative socio-technical approach of ANT. This integrative framework brought together a multi-dimensional form of analysis. In the following sections, it will be detailed how the different methods were applied.

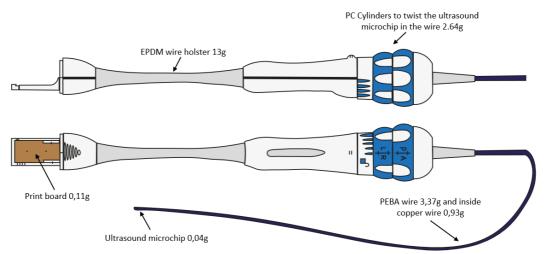


Figure 1. The ultrasound catheter investigated in this paper

## 2. Materials and methods

The integrative framework of LCA, TCO and ANT are used to guide the transition of the healthcare sector, where quantitative assessments of environmental impacts need to be performed to support sustainable decision making. Quantitative methods are essential, as they provide the data necessary to persuade decision-makers and healthcare professionals to adopt sustainable practices. Quantitative sustainability metrics supply reliable data needed to inform decisions that could steer the healthcare sector toward a more circular model. For making these assessments LCA and TCO can be applied. Quantitative measurements can be utilized to comprehend the present circumstances and to evaluate the consequences that alterations will have on future conditions. This can help in developing strategies for a sustainable transition, employing tools and methods from Industrial Ecology and Science and Technology Studies. Therefore, the aim of this study was to provide such data in a convincing manner, that could potentially drive decision makers and healthcare professionals into adopting and implementing new practices. The framework for integration of LCA, TCO and ANT is presented in Figure 2. ANT is employed to map out the regulatory terrain and identify various issues that must be tackled for the data to be influential. By fostering an understanding of the various agendas within this regulatory framework, ANT assists in the design and decision-making processes that shape the LCA and TCO findings into a full sustainability assessment.

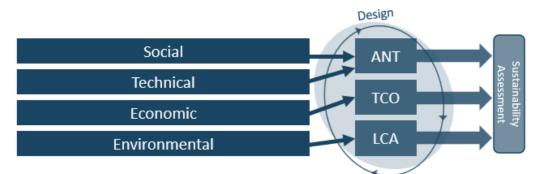


Figure 2. Correlation of methods: The four pillars are interconnected by involving quantitative (Life Cycle Assessment, LCA and Total Cost of Ownership, TCO) and qualitative (Actor-Network Theory, ANT) methods, which mutually reinforce each other through the application of design principles; By creating robust data metrics focused on sustainable transitions, these methods collectively form a comprehensive sustainability assessment framework unified through design

## 2.1. LCA

LCA is a method that can be used to assess the potential environmental impacts associated with all stages of a product or service's life cycle. The LCA in this paper follows the ISO 14040-44 standards (ISO, 2008), ensuring adherence to internationally recognized guidelines. LCA enables the comparison of environmental impacts of different options that serve the same purpose. LCA results can inform strategic or design decisions (Schulte et al., 2021).

The purpose of conducting an LCA in this research was to investigate the climate change impact of two alternatives that provides ultrasound imagery during heart surgery (i.e., single use ultrasound catheters vs remanufactured catheters) and to potentially propose design strategies for reducing the climate change impact. The functional unit for the comparative LCA was defined as "*having clear ultrasound visibility in aurikel and patent foramen ovale closing of the heart for one month at the Heartlab 2 of AUH, Denmark*". Consequently, the reference flows for each of the alternatives are:

- Alternative 1: 22 new ultrasound catheters delivered from Siemens Healthineers in Washington, US;
- Alternative 2: 12 new ultrasound catheters delivered from Siemens Healthineers in Washington, US, including 10 remanufactured ultrasound catheters from Vanguard AG in Berlin, Germany:

The reference flows were established based on the number of multiple life cycles the ultrasound catheters can safely be remanufactured (in this case three) and the number of ultrasound catheters that are ultimately discarded at the remanufacturing facility due to damages (the failure rate). Consequentially, there is an established failure rate of 48%. As shown in the Figure 3 below, 12 newly produced catheters are needed in the remanufacturing scenario to fulfil the functional unit.

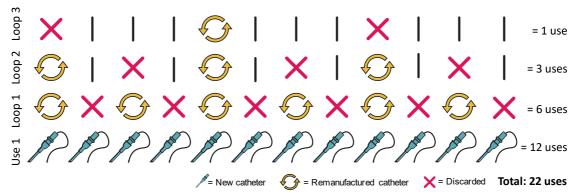


Figure 3. The calculation presented above demonstrates how many new and remanufactured catheters are needed in Alternative 2; It starts out with 12 new catheters; As a result of a failure rate of 48% when they reach remanufacturing, less catheter uses are available after each remanufacturing loop

To gather specific data to conduct the LCA on the ultrasound catheters, a used catheter was provided, and the data needed to compile the life cycle inventory (LCI) were therefore directly measured. Additionally, to gather data for the remanufacturing scenario, contact to a remanufacturing company was established. The Life Cycle Impact Assessment (LCIA) method chosen was IPCC 2021 GWP 100a (IPCC, 2021) and the LCA modelling was performed with SimaPro software version 9.3.0.3. Further details on the LCA can be found in Andersen and Sørensen (2022).

## 2.2. TCO

The concept of TCO is closely linked to Life Cycle Costing (LCC), which is commonly used as a second parameter in evaluating sustainability alongside LCA. TCO is somewhat unconventional when paired with LCA, as demonstrated in the case study presented in this paper. Both LCC and TCO involve examining the costs related to a product or service from a long-term perspective, which aids in making more informed purchasing decisions (Ferrin and Plank, 2002). TCO specifically calculates the overall costs incurred by owning the product/system, considering the owner as the user during the products operational phase. This calculation typically encompasses this as well as the costs related to usage, maintenance, and repair (Ellram, 1995). In this paper's case study, the Total Cost of Ownership (TCO) assessment compares two alternative systems, considering the cost of working hours since the evaluation is from the standpoint of a hospital. To gather data for the TCO, the hospital staff who typically handle the transportation of medical equipment and restocking within the hospital were contacted. Additionally, an interview was conducted with a nurse to understand the routine use of an ultrasound catheter during surgeries, and the process of handling in post operation, with an emphasis on estimating the labour time involved. The TCO calculated the two following scenarios:

- The ultrasound catheter is disposed after a single use.
- The ultrasound catheter being cleaned, packed, and sent to remanufacturing.

The result of the TCO are the costs related to transporting, unpacking, using, potentially repacking and sending or throwing out the waste of one year's use of ultrasound catheters. All the data and processes were incorporated into an adjustable excel-model. This model facilitated discussions with various stakeholders about possible adjustments and helped identify which processes were the most cost intensive. Further details on the TCO calculations can be found in Andersen and Sørensen (2022).

### 2.3. ANT

Actor-Network Theory serves as an analytical tool that examines the relations between different actors (human and non-human), within the context of designing socio-technical systems (Callon, 2001). As an analytical instrument, ANT is well-suited for analysing and mapping relations in a socio-technical network, providing insights into the intricate relations and concerns that uphold the existing status quo. To promote sustainability in the healthcare sector, it is essential to address concerns about safety, hygiene, and market competition among the different actors in the network. Drawing insights from ANT, the concerns of various stakeholders within the health care sector were assessed. Through the involvement of ANT in the case study, it was possible to develop an understanding of the regulatory challenges and barriers hindering the widespread adoption of remanufacturing in healthcare. Figure 4 illustrates the various actors involved in the debate on remanufacturing within the healthcare sector, as well as in the broader discourse regarding its legislation.

Once mapped, it was possible to attach both positive and negative concerns to the actors. A shared positive concern among most actors was that they united in the aim to reduce the climate change impact of the hospitals by introducing remanufacturing. However, alongside these positive findings, concerns about patient safety and liability emerged as potential factors that could deter actors from using remanufactured devices.

The ANT mapping was essential to investigate the type of data that could be applied to facilitate consideration and potential legalization of remanufacturing of medical devices in Denmark. As a result, the researchers gained insights into what they needed to reframe to encourage stakeholders to embrace remanufacturing. By understanding the concerns of these stakeholders through ANT, the researchers could design ways to present results persuasively, making the quantitative data actionable for those

interested in transforming network relations. Furthermore, ANT assisted in mapping the systems for which TCO and LCA assessments were conducted. This ensured a suitable scope and consistent calculation background for both the economic and environmental assessments.

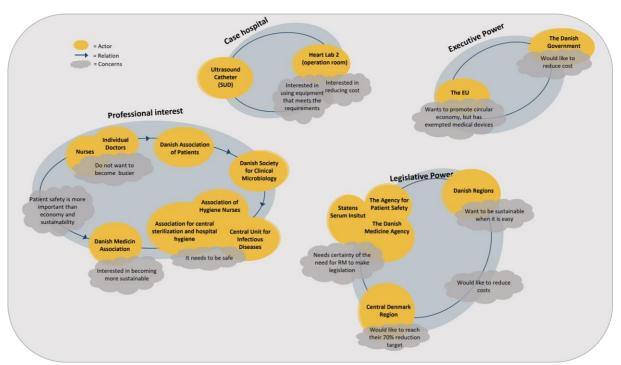


Figure 4. Actor-network illustration; The network depicts actors involved in remanufacturing, with their relations indicated by black lines and areas of concern highlighted by grey clouds; The actors are grouped according to their relation to remanufacturing within the healthcare sector

# 3. Results and discussion

In this section, the case-specific results will be presented, and it will be discussed, how these results can ultimately support each other in sustainable change.

## 3.1. LCA results

The LCA provided the results of the two reference flows. Calculating with an extended scope of 12 impact categories, the scenario with remanufactured catheters showed lower values for all. Therefore, the focus remained on the climate change impact after having ensured that no burden shifting would happen. For the climate change impact there was a reduction of 33% monthly, as per the calculation according to the functional unit. The specific results from the calculation monthly can be seen in Table 1 below.

Table 1. The climate change impact of Alternative 1 and Alternative 2; There is a difference of33% between the two alternatives

Impact category	Unit	Alternative 1	Alternative 2	Difference
Climate change	kg CO2-eq	57	38	33%

The above saving was calculated based on a failure rate of 48% which is the standard failure rate when being sent to the specific remanufacturer investigated in this research. However, it seems that knowledge of how to treat the used catheters in the hospital before sending them to remanufacture can lower this failure rate. When looking at the reports sent back to AUH at the time when they were sending instruments to remanufacture, the failure rate seems to only be at 25%. Therefore, an additional case

was calculated with the 25% failure rate. This is called the AUH case and the results on climate change are reported in the Figure 5 below.

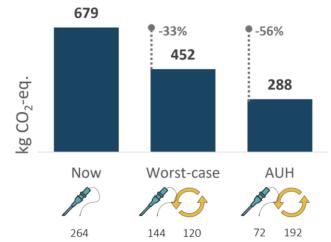


Figure 5. The LCA results on a yearly basis (12 times the functional unit); The "Now" scenario is equal to the current climate change impact with no remanufacturing; "Worst-case" is a case where 48% of ultrasound catheters are discarded when arriving at the remanufacturing facility; The "AUH-case" is the case where only 25% of catheters are discarded when arriving at the remanufacturing facility

This provided a great result for the actors that wished to implement remanufacturing, as it would allow the average ultrasound catheter use to be almost halved in terms of climate change impact. It would therefore be impactful in reaching the reduction targets set forth in different climate action plans.

### 3.2. TCO results

In terms of economic performances, the use of remanufactured ultrasound catheters seems to be advantageous with a potential saving of 1,2 MM DKK (160.000 euro) a year, even with the highest failure rate and an overestimated price for the remanufactured ultrasound catheter. For some actors a concern was that it would potentially take longer to clean the ultrasound catheter and pack it for distribution to the remanufacturing company. However, when looking at the overall saving, this could potentially lead to the employment of extra personnel providing more resources to the hospital department. Remanufacturing is not only limited to ultrasound catheters. Many other products at Aarhus University Hospital could similarly be remanufactured, with an equal percentage of saving. Therefore, there is great potential for making changes in hospital budgets if remanufacturing is implemented.

### 3.3. ANT results

To make use of the quantitative results from the LCA and TCO, the ANT mapping as a qualitative method was used as a tool to guide interpretation of the results. By applying the knowledge gained from ANT, it was obvious that the concerns that needed to be addressed were that of potentially making nurses busier and climate and cost reduction. Because of the results from the LCA and TCO that were in favour of remanufacturing, it was possible to interpret the data in a way, that would make Central Denmark Region able to interest the relevant actors. To address the concerns about nurses taking on additional work due to remanufacturing, the TCO results offered a means to evaluate the potential effects on the department's budget. The savings achieved by using remanufactured ultrasound catheters could be allocated to hiring additional staff in the hospital department, thereby easing the workload of current nurses. ANT also provided the idea of how to optimise a potential future remanufacturing system. Based on the concerns of the different actors, it was possible to investigate different scenarios for both the environmental and economic assessment. This was e.g., calculating on different transport scenarios, depending on where remanufacturing was done, showing the impact of packaging and the impact with more remanufacturing times (more life cycles per catheter). In this manner, ANT played a pivotal role in enhancing the potential for change stemming from the quantitative methods, ensuring that it would

result in sustainability improvements. Furthermore, ANT provided guidance to the researchers on how to provide Central Denmark Region with the necessary tools to initiate the transition towards adopting the new remanufacturing system.

### 3.4. Integrating methods for a full-fledged sustainability assessment

Integrating ANT, LCA and TCO provided a foundation for proposing strategies that could assist with the implementation of sustainability measures. These strategies allow for an assessment that is not just environmentally focused but also encompasses social and economic dimensions of sustainability. Conducting a multi-dimensional analysis enabled the researchers to make an action plan for how and why Central Denmark Region should involve key stakeholders and convince them of changes necessary, for the sustainability measures to be successful. If remanufacturing was simply to be implemented from above, without understanding the social implications and power dynamics within the healthcare sector, the process would end up only becoming resource intensive, leading to no significant climate change reductions. The methods complemented each other, with the TCO and LCA providing data, and ANT making it actionable and amplifying the data's ability for change. In this study, ANT and TCO both gave results that supported change, which might not be the case always. As such, healthcare management were provided with a more robust and multidimensional set of data to inform their choices. At the same time, the researchers were able to understand the trade-offs between sustainability dimensions and deciding upon actions that can lead to improvements in sustainability performance. Integrating insights from ANT, LCA, and TCO can also assist policy makers in developing regulations that support sustainable practices within healthcare organizations.

A significant barrier to adopting remanufacturing practices for SUDs in healthcare is the concern over hygiene. Hygiene experts' express reservations about the safety implications of reintroducing remanufactured devices, fearing they might compromise patient safety. Nevertheless, it is arguable that the healthcare industry has escalated its hygiene standards to an almost exaggerated level, insisting on a hygiene level above required. Yet, pulling this back to the required and needed hygiene level could enhance sustainability efforts and, by extension, overall human health, given the long-term health threats posed by climate change. Stringent focus on hygiene is critical in the remanufacturing and reuse of healthcare equipment or components, which introduces new layers of complexity and potential risks to hygiene. We highlight the continued necessity of thorough research into various elements that could influence hygiene risks in healthcare settings. This includes evaluating the effectiveness of cleaning and sterilization methods during the remanufacturing process, identifying potential sources of contamination, and understanding how these processes may differ across various healthcare environments.

This case study focused on ultrasound catheters and may not be representative of all types of medical devices or contexts, which could limit the generalizability of the findings. Furthermore, the study might not fully account for the entire life cycle impacts of medical devices such as potential toxic waste generation or complete carbon footprint of the remanufacturing process. However, the results were assessed by using full LCA impact categories to ensure no burden shifting was occurring. The TCO may not include all costs related to implementation of the remanufacturing processes, nor long-term economic aspects of the healthcare sector. It is also worth noting that in a scenario where remanufacturing will be requested more than newly produced devices, the calculated results of both the TCO and LCA might be outdated. As outlined in section 1.2, the process of assessing the social impacts of implementing a circular design strategy through remanufacturing in healthcare, using an integrated framework that includes a multi-dimensional analysis, is in its initial stages. This suggests that some social consequences may not have been fully examined.

# 4. Conclusions

Remanufacturing has the potential to reshape the health care system, requiring practice changes to accommodate new approaches and serving as a circular design strategy. Two conclusions can be drawn based upon the previously introduced aims:

• In the context of healthcare, whether remanufacturing can be implemented or not, it has the potential to reshape the wider health care system. The thinking of allowing medical devices to

have multiple life cycles can overall improve the circularity of the health care sector. Furthermore, the study indicates that remanufacturing within the health care sector has the potential to lower the overall climate change impact of health care.

• Additionally, in a broader methodological context, ANT can enhance the value of LCA and TCO analyses by facilitating data transformation into actionable insights and emphasising the importance of providing relevant data for sustainability considerations. To implement the changes, data is needed, and it needs to be presented in an understandable manner, fitting the reality of the hospital personnel. In this case, ANT helped to transform the insights from LCA and TCO to fit this reality and make the two quantitative methods have change potential.

By highlighting the multifaceted benefits of remanufacturing in healthcare, this study contributes to a broader understanding of how circular design strategies can be effectively employed to achieve sustainable transition in the healthcare sector. The research presented in this paper has provided valuable support to the Central Denmark Region in their ongoing discussions aimed at establishing guidelines for the remanufacturing of SUD's in Denmark, with the goal of legalizing this practice.

The authors' acknowledgment of potential resistance to environmental-focused initiatives, due to concerns about safety and quality in healthcare, is important. However, to enhance the practical applicability of their research, it would be beneficial to explore the perspectives and contributions of OEMs more extensively. Future research could involve conducting in-depth interviews with OEMs to gain a deeper understanding of their willingness to engage in remanufacturing processes and the criteria they use to decide whether to discard products or components. Incorporating this additional perspective from OEMs would provide a more extensive view of the feasibility and challenges associated with implementing remanufacturing in the healthcare sector, thereby strengthening the paper's findings and recommendations.

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