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Review

Position paper on sustainability in cardiac pacing and electrophysiology from the Working Group of Cardiac Pacing and Electrophysiology of the French Society of Cardiology[☆]



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I N F O A R T I C L E

Historique de l'article :

Reçu le 9 octobre 2023

Reçu sous la forme révisée

le 19 novembre 2023

Accepté le 20 novembre 2023

Disponible sur Internet le 15 January 2024

Keywords :

Sustainability

Cardiac electrophysiology

Catheter ablation

Cardiac implantable electronic device

Reprocessing

A B S T R A C T

Sustainability in healthcare, particularly within the domain of cardiac electrophysiology, assumes paramount importance for the near future. The escalating environmental constraints encountered necessitate a proactive approach. This position paper aims to raise awareness among physicians, spark critical inquiry and identify potential solutions to enhance the sustainability of our practice. Reprocessing of single-use medical devices has emerged as a potential solution to mitigate the environmental impact of electrophysiology procedures, while also offering economic advantages. However, reprocessing remains unauthorized in certain countries. In regions where it is possible, stringent regulatory standards must be adhered to, to ensure patient safety. It is essential that healthcare professionals, policymakers and manufacturers collaborate to drive innovation, explore sustainable practices and ensure that patient care remains uncompromised in the face of environmental challenges. Ambitious national/international programmes of disease prevention should be the cornerstone of the strategy. It is equally vital to implement immediate actions, as delineated in this position paper, to bring about tangible change quickly.

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[☆] Tweet: Sustainability in healthcare, especially within the field of cardiac electrophysiology, is an essential consideration for the future. This position paper details proposals for improving the sustainability of our specialty.

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<https://doi.org/10.1016/j.acvd.2023.11.016>

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Abbreviations

AF	atrial fibrillation
CIED	cardiac implantable electronic device
CO ₂ -e	carbon dioxide equivalent
FDA	US Food and Drug Administration
MDR	Medical Device Regulation
NHS	National Health Service

1. Introduction

Sustainability is defined as “meeting the needs of the present without compromising the ability of future generations to meet their own needs.” Interest and research around this concept have grown exponentially in the last 5 years, reflecting an awareness of the increasing constraints towards which our world is rapidly heading. Some national healthcare organizations (such as the National Health Service [NHS] in the UK), hospitals and medical societies are already engaged in healthcare sustainability efforts, coordinated through organizations such as NoHarm (<https://noharm-europe.org/>) and Collectif d'éco-responsabilité en santé (<https://ceres-sante.fr/>). As cardiac electrophysiologists, we employ high-tech materials made from rare metals, semiconductors and other substances that may become scarce in the future. Thus, we sought to write this position paper to raise awareness among physicians, spark critical inquiry and identify potential solutions to enhance the sustainability of our practice. It is important to emphasize that each proposed solution must not compromise the effectiveness and safety of patient care. However, adaptation of our practices to future constraints is necessary.

2. Background

Constraints that affect healthcare sustainability can be broadly categorized into two types: downstream constraints and upstream constraints.

Downstream constraints correspond to the effects that result from our activities that could jeopardize the ability of future generations to fulfill their own needs. Whereas global warming stands as the most conspicuous and arguably critical of these effects, these constraints also encompass planetary limits that bring about irreversible alterations to our ecosystem. These downstream constraints already have a significant impact on human health [1]. The healthcare system contributes significantly to global warming, accounting for approximately 5% of greenhouse gas emissions [2]. To provide context, if the healthcare sector were a nation, it would rank as the world's fifth-largest greenhouse gas emitter.

Upstream constraints relate to our inability to sustain current practices as a result of physical, economic or political factors, and primarily encompass situations leading to inadequate access to medical professionals, medical devices or medication. These challenges pose a threat to our medical practice if left unaddressed. This discussion mainly focuses on the growing physical limitations of our environment, excluding economic and political dimensions, although these three facets are deeply interconnected.

When it comes to non-renewable resources, upstream and downstream constraints are often two sides of the same coin. Our current consumption results in downstream constraints through waste generation and pollution, while depleting these resources creates upstream constraints.

In healthcare, fossil fuels are omnipresent; they allow us to build the technical environments required for our activities, to transport patients and medical staff to the hospitals and to provide them with medication, food and heating during their stay. Of paramount

importance, fossil fuels are vital for manufacturing medical devices, contributing >20% to the healthcare sector's carbon footprint.

In cardiac electrophysiology, rare metals and rare-earth elements are crucial for manufacturing devices. The predicted availability of these resources must take into consideration global production and demand predictions, but also potential geopolitical issues that may hinder the availability of a locally unavailable and rare imported resource.

Another critical consideration is the intricate supply chain of a given product. Like numerous products in our globalized economy, medical devices are technical entities assembled from materials sourced worldwide (Fig. 1). This intricate network renders the supply chain vulnerable to multiple potential issues. Competitors often share common suppliers, increasing the risk of systemic failure instead of isolated shortages. This fragility has been evident over the past 3 years – semiconductor shortages have disrupted several medical device production lines. Furthermore, the sequential closure of ethylene oxide sterilization facilities has led to global shortages of catheters, sheaths and needles.

3. Environmental impact of cardiac electrophysiology

We will not discuss the environmental footprint of the hospital itself, but will focus on cardiac electrophysiology, which is an expanding field requiring high-tech single-use materials. Atrial fibrillation (AF) ablation, the foremost segment of electrophysiology, witnessed a two-fold increase from 2016 to 2021 in France (<https://www.scansante.fr/opendata/pmsi-mco/ccam>), with similar growth projected for the next decade. Consequently, a strategy to mitigate the growth's impact on resources is indispensable. To guide policy toward a sustainable system, assessing an industry's environmental impact requires an environmental audit. Studies have recently explored the environmental aspects of cardiac electrophysiology. For instance, Ditac et al. [3] conducted an ecoaudit of AF ablation to assess its carbon footprint. The findings revealed that each AF ablation procedure is responsible for the emission of approximately 77 kg of carbon dioxide equivalent (CO₂-e) into the environment (75 kg CO₂-e for paroxysmal AF and 88 kg for persistent AF). Notably, the electrophysiology procedure itself accounted for 75% of pollution, whereas anaesthesia contributed 25% (for procedures involving general anaesthesia), largely due to anaesthetic gases. In the realm of electrophysiology procedures, disposable medical devices played the most significant role in pollution. Material production and manufacturing constituted the most polluting phases, responsible for 71.3% (54.8 kg CO₂-e) and 17.0% (13.1 kg CO₂-e), respectively. Transport and product usage contributed merely 10.6% (8.1 kg CO₂-e) and 1.1% (0.9 kg CO₂-e), respectively, to greenhouse gas emissions.

Catheters, composed of precious materials such as gold or platinum and complex polymers, are the main contributors (40%) to the environmental footprint of an AF ablation. Anaesthesia set aside, this is over half of the carbon footprint related to the single-use devices. Additional devices, such as sheaths, needles, patches (mapping system and electrocardiogram monitoring) and cables containing copper, collectively contribute to 10% of the procedure's carbon footprint. The packaging of certain devices, particularly sheaths and needles, is oversized and contains a significant amount of plastic, paper or cardboard. In some instances, packaging may account for more than 80% of a product's carbon footprint (e.g. transeptal needle) (Fig. 2) [3].

Another aspect of the environmental impact is the caregiver's commute to work, as well as the field clinical specialists helping with three-dimensional mapping systems, who often have to travel long distances to support electrophysiology procedures in different hospitals.

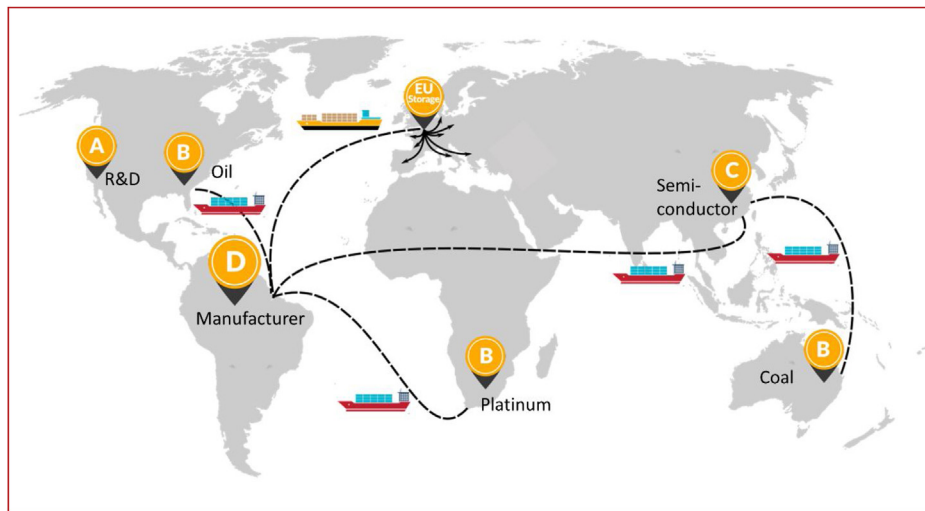


Fig. 1. Example of the supply chain of a cardiac electrophysiology catheter.

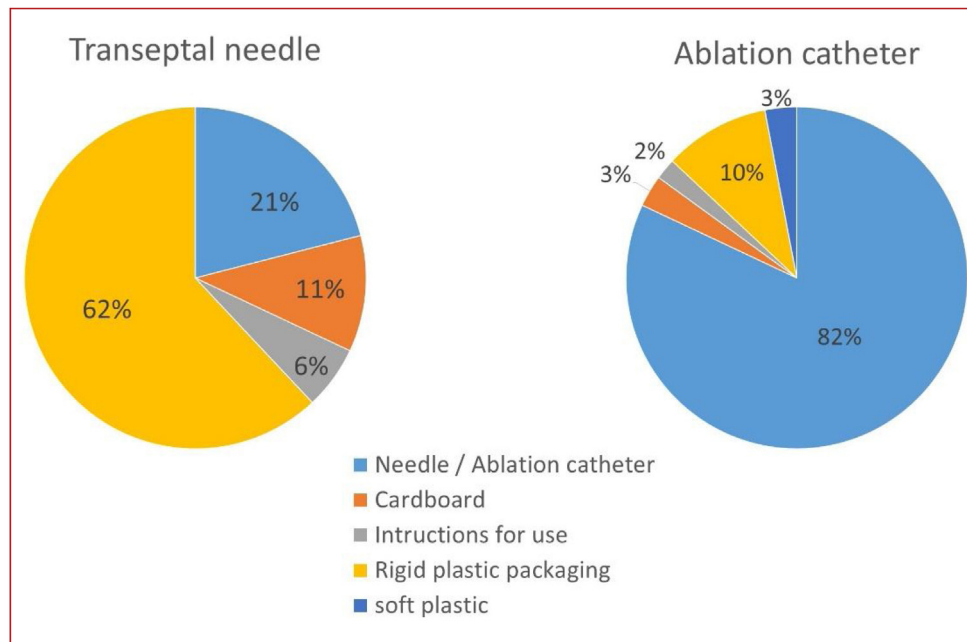


Fig. 2. Examples of the carbon footprints of different materials and their packaging used for cardiac electrophysiology procedures (based on Ditac et al. [3]).

Data concerning the environmental impact of cardiac implantable electronic devices (CIEDs) are scarce or lacking. Nevertheless, it is likely that the production, manufacture and distribution of CIEDs and leads constitute the majority of the procedure’s carbon footprint.

4. Reprocessing: a quick win solution?

4.1. Definitions

Reprocessing is the practice of reusing medical devices originally labelled as single use after they are cleaned, tested and resterilized. This is different from recycling, which involves destroying the product, separating the components and using them for new products.

One should keep in mind that the “single use” marking of a device is affixed by the manufacturer. This marking corresponds to the use recommended by the company, depending on its ability

to demonstrate the possibility of reuse and its commercial strategy. Device properties only indirectly influence this labelling; therefore, many devices labelled as “single use” could potentially be reprocessed without issue. Reprocessing can be performed in the hospital where the device has been used (in-house reprocessing), a practice that was common in the early days of electrophysiology, and is still utilized in certain countries. As devices became more sophisticated, reprocessing began to be outsourced to specialized companies (Association of Medical Device Reprocessors <https://amdr.org/>). These entities have refined processes and can reprocess complex devices, including electrophysiology catheters with lumens. Ideally, manufacturers themselves should reprocess their own devices.

4.2. History of reprocessing and laws in Europe

In the early days of cardiac electrophysiology, catheters were commonly used multiple times and resterilized in hospital (in-

house reprocessing). This process minimized waste generation and was mostly motivated by cost-reduction goals. However, this practice began to shift in the 1990s, as a result of a confluence of factors that changed the landscape of medical device use in the field. One of the catalysts for this change was a series of health crises, including bovine spongiform encephalopathy and variant Creutzfeldt-Jakob disease outbreaks, the contaminated blood crisis (human immunodeficiency virus and hepatitis B transmission) and lawsuits for hospital-acquired infections in France. These events raised concerns about the safety and sterility of reusable medical devices, prompting a transition towards single-use devices in the interest of patient safety. Simultaneously, the development of the plastics industry allowed for the production of more affordable single-use devices, making them an increasingly attractive option for medical professionals. As a result, single-use devices have become the norm in cardiac electrophysiology, fostering a model deemed safer, but more expensive.

The practice of reprocessing persisted in some countries, resulting in heterogeneous practices across the globe. These practices mostly aimed to reduce costs, and concerns about the safety, efficacy and regulatory compliance of reprocessed devices remained. However, so far, there is no report of virus/prion transmission as a result of a reprocessed electrophysiology device. In recent years, regulatory agencies such as the US Food and Drug Administration (FDA) and the European Union, through its Medical Device Regulation (MDR), have explicitly allowed and set rules for reprocessing single-use devices (Regulation 2017/745 Of The European Parliament And Of The Council Of 5 April 2017 On Medical Devices [4]). Reprocessors of single-use devices are subject to regulatory requirements, which include obligations related to quality management systems, technical documentation and post-marketing surveillance; they also take legal responsibility for the reprocessed medical device. Moreover external reprocessors have to perform a new CE marking of the reprocessed device (article 17, paragraph 2) or by exception if national law authorizes it, certification by a notified body. Regulations such as the European Union's MDR impose stringent rules that are at least equivalent to those applied to the original devices. By following these strict guidelines, reprocessors must demonstrate that their products are safe, effective and of high quality, which should help to alleviate concerns about potential health risks.

However, in Europe, national law still prevails, leading to inconsistencies in the regulation and practice of reprocessing across the continent. Currently, reprocessing is allowed in some European countries (e.g. Belgium, Germany, Spain, The Netherlands) whereas it is illegal in other European countries (e.g. France, Greece, Italy, Poland) (Fig. 3). For example, in France, reprocessing is still banned, and this prohibition was further reinforced by a recent decree (n° 2022-582 du 20 avril 2022 [5]). The French ban on reprocessing is difficult to understand at a strictly rational level, given that numerous medical societies are in favour of the practice [6], which offers economic, environmental and strategic advantages.

4.3. Advantages of reprocessing

Reprocessing of certain single-use medical devices appears to be a solution for reducing supply tensions, limiting the environmental impact of medical devices (carbon footprint and reduction of raw material extraction) and lowering procedural cost [6–10].

4.3.1. Safety of supply

A national/continental network for reprocessing would contribute to the development of high-tech economic activity in our territories; it would limit the increase in new devices needed, whereas the growth of the market is estimated at 10%/year (<https://www.strategicmarketresearch.com/market-report/electro>

[physiology-market](#)), which may not be sustainable in terms of raw materials and the supply chain. Currently, the supply chain for electrophysiology catheters crosses the world (Fig. 1), with multiple points of weakness that could block supply. Finally, reprocessing at state/European level will allow at least part of a device to be available on the continent. In case of device shortage, this would enable us to continue treating our patients.

4.3.2. Environmental impact

Although some modification of our behaviour, such as reprocessing, can be safe and efficient for the care of patients, we must also be careful about the real environmental impact of our decisions. There is no one-size-fits-all answer for all types of medical devices. Therefore, life-cycle analyses have to be performed for different situations and different devices to ensure the environmental superiority of reprocessing for the different situations. Concerning electrophysiology, most studies point to a reduction (up to 50%) in the global warming impact by reprocessing, and a reduction (up to 30%) in abiotic resources for electrophysiology catheters [10] versus single use. Reprocessing also has an impact in terms of waste reduction.

4.3.3. Cost

For a long time, reprocessing was carried out to reduce costs and to have enough devices to treat patients. Although reducing cost was reported in a European Heart Rhythm Association (EHRA) survey as the main motivation for reprocessing [11], the potential for savings depends on the device and the reprocessing circuit (in-hospital versus outsourcing). It has been estimated that the price of a reprocessed medical device is, on average, 60% of that of the original device [7]. In Canada, reprocessed SoundStar® catheters (intracardiac echocardiography) have been evaluated to save between \$239,000 and \$418,000 every year for 300 procedures per year (75 catheters were bought; 225 catheters were reprocessed) [12]. In another study [9], use of a remanufactured circular mapping catheter was compared with propensity-matched cases performed by the same operators using new devices. Using 100 remanufactured devices saved £30,444, without any complications.

CIED reprocessing is not done, except in low-income countries [13–16], where it appears to be safer than the risk of not implanting patients, as patients cannot afford new CIEDs. In India, where it is allowed, cardiologists wrote a consensus document [17] to homogenize reprocessing of CIEDs (pacemaker with no documented device malfunction and adequate remaining battery duration > 5 years).

4.4. What are the risks associated with reprocessing or reusing?

The main concerns that electrophysiologists have with reprocessing are contamination, quality aspect/loss of precision and persistence of chemical substances used [11].

Before the 2017 European regulation on reprocessing, Pitschner et al. [18] compared new and reprocessed (up to six times) diagnostic and ablation catheters. The devices were submitted to a certified reprocessing company, and the material properties, hygiene and functional capabilities of the devices were analysed. Catheters with any abnormality that could lead to an increased risk for the patient, the user or any third party were scrapped. This study showed that neither the material properties nor the functional characteristics of the devices were altered as a result of reprocessing. Moreover, the reprocessed catheters did not disadvantage patients or medical doctors. However, the authors pointed out that a high standard of quality management was needed from hospital and reprocessing companies to offer high-quality reprocessed material, comparable to the quality of the original equipment. The authors suggested that

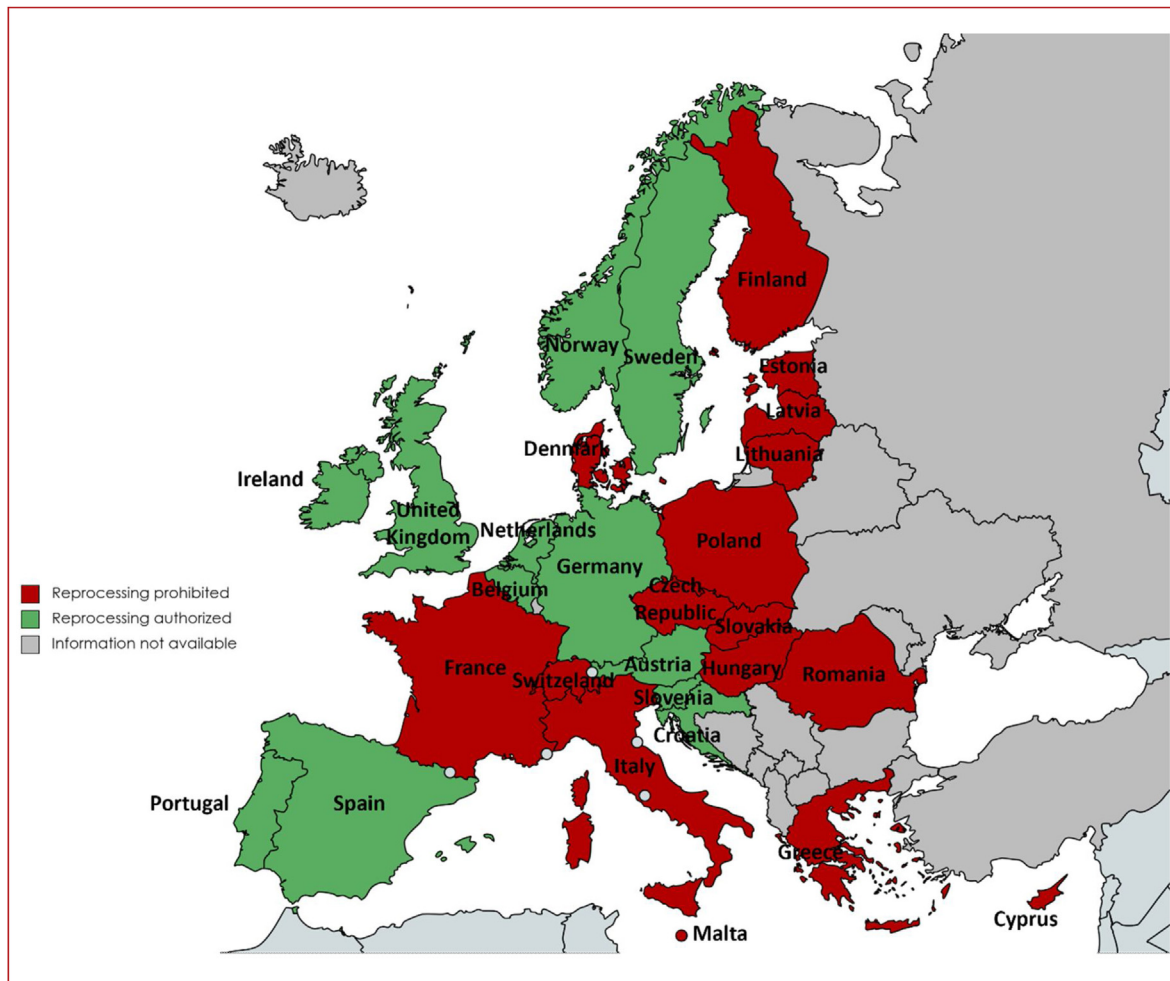


Fig. 3. European countries authorizing (green) or prohibiting (red) reprocessing of single-use devices on their territory in 2023 (created with mapchart.net) (https://health.ec.europa.eu/medical-devices-topics-interest/reprocessing-medical-devices/national-rules-reprocessing-single-use-devices_en).

the quality of reprocessing should be regulated and controlled by independent governmental institutions.

Another fear is the risk of infectious agent transmission. Indeed, besides the quality of the devices, potential risk of infection is one of the main obstacles to reprocessing. A protocol for reuse of non-irrigated electrophysiology catheters was validated in a Brazilian hospital [19]. The number of reuses was settled at a maximum of seven for electrophysiology catheters with a handle and ten for electrophysiology catheters without a handle. With their protocol, no organic material was detected by HemoCheck-S® (Minerva Stericlean Ltd., Calne, UK) at the surface of the electrophysiology catheters. Assays for sterility were negative, and assays of ethylene oxide (used for sterilization) residuals and endotoxins showed levels below established standards. Thus, according to this protocol, reuse of electrophysiology catheters was considered safe for patients. However, some electrophysiological devices are equipped with lumens (sheaths, irrigated catheters, needles), and precautions should be taken because some areas can be difficult to reach. Cleaning and sterilizing the lumens as well as checking that there is no obstruction or leak are essential. Thus, medical devices with lumens should probably only be reprocessed by facilities with dedicated expertise.

5. What are the other potential solutions?

One positive aspect is that 62% of electrophysiologists expressed interest in transitioning to more sustainable practices, as revealed by an EHRA/LIRYC (*Institut des maladies du rythme cardiaque*) survey on sustainability in cardiac electrophysiology [20]. The reuse of mapping and ablation catheters emerged as the solution mentioned most frequently by physicians. To effect a shift in practices, the willingness of participants is crucial, underscoring the importance of information dissemination.

The proposed solutions (Table 1) will be depicted in this section along with the principles of the circular economy (“reduce, reuse, recycle”) to prompt a rethinking of practices [21]. Actions will rely on the implication of all the entities involved in healthcare, from countries (national regulation) to medical companies (manufacturing, distribution), medical societies (guidelines, education, information) and healthcare providers/physicians (practice, material choice). Importantly, the underlying principle should prioritize adapting practices to provide optimal patient care while minimizing environmental impact. All the proposals listed below need to be assessed from a global perspective. Uncertainties remain about the real impact of certain proposals.

Table 1
Proposal to improve healthcare sustainability, with a focus on cardiac electrophysiology.

Level of action	Action
Europe/state	Ambitious and effective disease prevention programme Healthcare carbon reduction programme (such as the NHS carbon footprint programme) Authorization for reprocessing of selected medical devices labelled as single use Mandate life-cycle analysis of medical device Enforce stringent rule for single-use device mark and ban forced single-use tools (such as chipset to block electrophysiology catheters) Promotion of interoperability among controllers of CIEDs, remote monitoring systems, catheter connectors and electrophysiology mapping systems of the different companies (such as the DICOM format in radiology and lead connectors) Facilitation of remote monitoring
Manufacturer	Optimization of manufacturing processes (e.g. ecodesign, water and energy conservation, efficient transportation, reduction of unnecessary packaging, elimination of instructions for users) Development of interoperability standards for CIEDs, remote monitoring systems, electrophysiology mapping systems, catheter connectors (such as the DICOM format in radiology and lead connectors) Implementation of reprocessing of their used catheters
Medical society	Education initiatives targeting the medical community Establishment of dedicated working groups/networks to tailor sustainability proposals to each medical specialty (e.g. SFAR GREEN) Grant to support project on sustainability in their area of expertise
Hospital/physician	Assessment of the carbon footprint associated with scientific meetings Development of an ecolabel for healthcare institutions, focusing on reducing energy consumption, improving waste management and incorporating environmental criteria into purchasing policies Integration of environmental criteria, such as life-cycle analysis, into the selection of medical devices Recycling materials when reusing/reprocessing is not feasible Limiting the number of on-site meetings per year and promoting hybrid formats, particularly for overseas meetings requiring air transportation

CIED: cardiac implantable electronic device; DICOM: Digital Imaging and Communications in Medicine; NHS: National Health Service; SFAR: *Société française d'anesthésie et de réanimation* (French Society of Anaesthesia and Intensive Care).

5.1. Reduce

National/international prevention programmes must be the cornerstone to decrease diseases and then limit the need for intervention. For instance, in the context of AF, it is not possible to prevent the aging of the population; however, it has been demonstrated that beyond AF ablation, the management of risk factors such as weight, blood pressure and sleep apnoea syndromes can reduce the occurrence of these arrhythmias [22]. Disease prevention programmes should be driven at state level as well as by medical societies. In the context of cardiac electrophysiology, several aspects warrant exploration, particularly as the electrophysiology market in the USA is projected to triple between 2020 and 2030 (<https://www.strategicmarketresearch.com/market-report/electrophysiology-market>). Initiatives include avoiding unnecessary procedures and seeking more effective approaches for managing complex arrhythmias, particularly persistent AF, in order to reduce recurrence rates and subsequent reinterventions. This would allow redo cases to be limited, and therefore there would be fewer procedures per patient. Whenever possible, reducing the number of materials/catheters used per procedure to what is strictly needed would help, if this does not alter the efficacy/safety of the procedure. Limiting waste by avoiding what is not necessary (instructions that come with each catheter and are never read), reusing some part of the material (detailed below) and better sorting of the remaining waste should not be neglected as these steps can be implemented quickly and easily. Remote monitoring of CIED and telehealth can be leveraged in countries with large geographical distances between patients and specialists, mitigating the need for extensive patient transportation and enabling specialized care from a distance. This approach has also demonstrated the potential to reduce greenhouse gas emissions [23].

5.2. Reuse

Reuse is not limited to reprocessing, which was largely discussed in section 5; it also concerns many fields where single use is

Table 2
Barriers to and factors facilitating reprocessing (modified from [8]).

Barrier	Facilitation factor
Manufacturers' use tactics of forced obsolescence	Potential cost savings
Perception of decreased functionality of reprocessed medical devices	Resilient supply chain
Lack of infrastructure for reprocessing	Culture of sustainability
Physician preferences	
Variable staff knowledge and beliefs	

present, e.g. in an operating theatre (scrubs, surgical caps, anaesthesia trays, laryngoscopic blades, etc). It could also refer to unused devices that have passed their shelf life. However, for each product, this raises questions about cost, cycle of life analysis and whether it is feasible to come back from single use at an institutional level. Some institutions have lost their capacity to sterilize devices or wash clothes on a much larger scale, and therefore cannot avoid single use without major investment in dedicated structure.

Interestingly, even in countries authorizing reprocessing, only a small portion of these devices is reprocessed. It is therefore important to identify what limits or facilitates reprocessing [8], to favour it whenever possible (Table 2). Reprocessing authorization in countries using a large number of these devices would help companies to develop sustainable business models. Reprocessing of devices by their own manufacturers could certainly help to accelerate and improve the processes and disseminate this strategy. Interestingly, a major medical device company manufacturing electrophysiology devices has recently bought a reprocessor company.

5.3. Recycle

Recycling plays a vital role, but should not supersede reuse, which was well illustrated by Stahel [24], who proposed the concept of “reuse when you can, recycle when you can't reuse”.

In the context of CIEDs, even if reuse has been shown to be feasible [14–16], CIEDs need to be recycled, at least when the battery is empty.

Electrophysiology procedures require multiple mapping and ablation catheters, sheaths, needles and patches. Single use translates into plastics, metals, rare metals, printed circuit boards and microchips being discarded directly after the procedure. When reprocessing is unfeasible for technical or regulatory reasons, recycling becomes imperative. However, recycling complex medical devices poses challenges, including product knowledge, component separation and an on-site recycling capacity. Precious metals (platinum and gold) from catheter electrodes should be systematically recycled when the catheter cannot be reprocessed, given that they are scarce resources with highly polluting extraction methods. This action can be quickly and easily implemented. There are companies specialized in recycling precious metals that can collect them directly from hospitals. Additional materials, such as copper from cables and patches, should also be recycled whenever possible. General recycling practices (paper, plastic) should be mandatory within healthcare institutions.

5.4. Rethink

Ambitious national programmes aimed at reducing healthcare's environmental impact, akin to the NHS Carbon Footprint programme targeting net zero emissions by 2040, should be developed. Similar discussions are unfolding in the USA [25]. States should implement a national strategy to secure the supply of critical medical devices, as well as drugs, as we have more and more shortages of sheaths, catheters and drugs (antibiotics, quinidine and, more recently, flecainid and nadolol).

National regulatory institutions need to think about how we can move away from the pay-per-act/pay-per-device model towards a service-based economy, which is – in many ways – more in line with current practices (technical support, with field engineers to help with navigation systems, for example). In this setting, reprocessing can be seen as a means of encouraging industrials to change their business model towards this service-based economy. At state level, the next step after reprocessing authorization with stringent safety regulations, as mentioned by the FDA and the European MDR [4], would be to designate medical devices as reusable, except for duly justified exceptions. Measures such as forced obsolescence, such as microchips that deactivate catheters after 24 hours, should be prohibited. Such practices waste resources without enhancing device efficacy, and can contribute to shortages. Regulatory requirements, such as life-cycle analysis for complex single-use medical devices (e.g. electrophysiology devices), could be incorporated into authorization processes at state and European levels. Decision-makers (legislative and administrative) should also be sensitized to these themes. Moreover, the relevance of pacing and electrophysiology activities as a whole, and the incentives created by the reimbursement system should be evaluated. It is interesting to note that the number of procedures per million inhabitants differs from one country to another, partly as a result of the reimbursement system.

Medical societies should raise awareness and educate the medical community about healthcare sustainability, mirroring efforts such as those during the 2023 European Heart Rhythm Association meeting; they could also allocate research grants dedicated to sustainability within their respective specialties. Integration of

sustainability themes into medical and surgical training is also crucial. Medical practice should evolve towards a more comprehensive approach to healthcare, in which intervention constitutes only a part of patient management, and may be contingent upon comprehensive care.

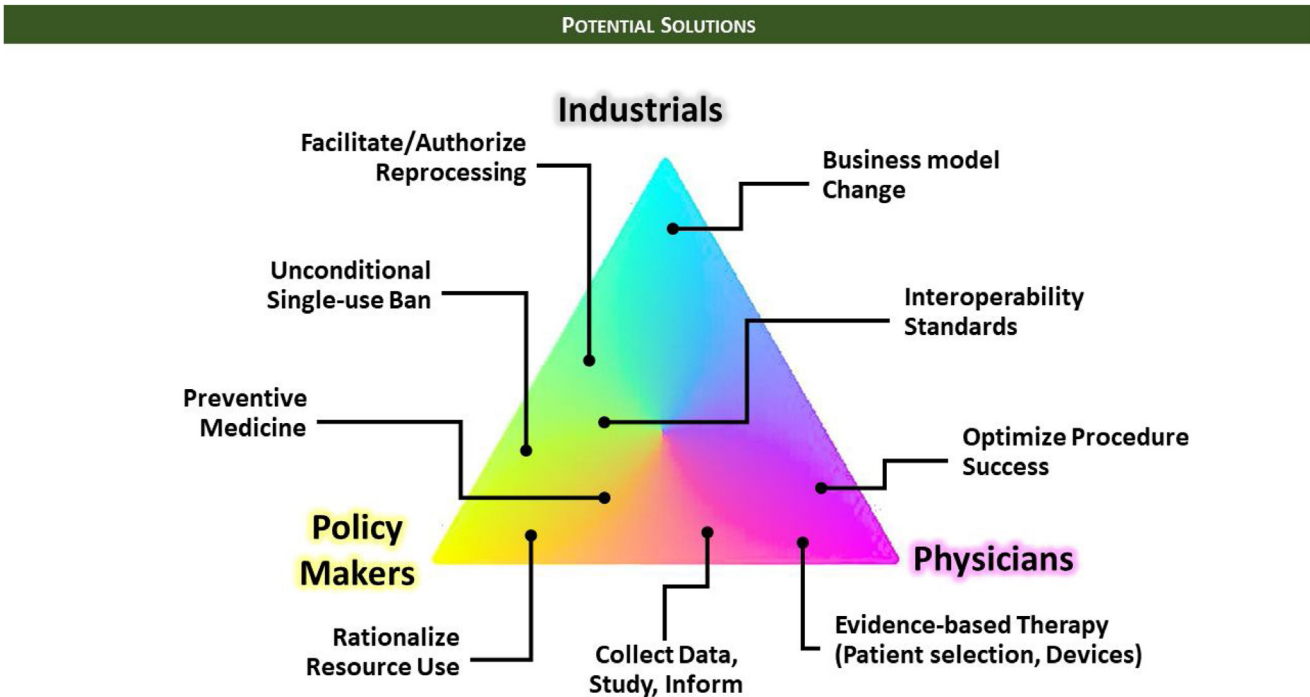
Facilitating exchange and shared experiences across societies and hospitals is another important feature (<https://noharm-europe.org/>; <https://ceres-sante.fr/>; <https://Sfar.Org/Comites/Developpement-Durable/Fiches-Pratiques/Sfar-Green/>). The creation of networks comprising healthcare professionals committed to sustainability can foster change. Efforts to reduce the environmental impact of transportation and meeting attendance warrant consideration. Scientific meetings can integrate sustainability into their organization, encouraging low-carbon transport options. A hybrid or on-site format with recorded sessions for viewing later should be considered, particularly for international meetings requiring air travel. However, in-person participation remains essential for fostering collaboration and ambitious projects. Rationalizing the frequency of on-site conferences may also be worth exploring.

Manufacturers have a pivotal role to play, by integrating sustainability into their processes, encompassing device creation (ecodesign, resource efficiency), packaging and distribution (reducing packaging, reusable options, optimized transportation) and end-of-life management (e.g. reusing remote monitoring systems) [26]. Standardizing interoperability across medical devices, such as pacemaker controllers, remote monitoring systems, electrophysiology systems, navigation systems, ablation devices and connectors, is an avenue for improvement (akin to radiology's Digital Imaging and Communications in Medicine [DICOM] format and pacemaker leads). Manufacturers should also disclose the carbon footprint of their products in each country, providing clear information for users and an additional criterion for choice when deciding between two similar products. In a different field, exploring new business models incorporating device reprocessing would also be of importance.

Finally, healthcare institutions and physicians can also contribute through practice adaptations, energy-efficient infrastructure and selective waste sorting. Sustainability criteria should be considered when selecting similar medical devices, a practice already being adopted in some institutions. Emerging ecolabels for healthcare institutions facilitate collaboration between administration and motivated healthcare professionals, while providing information to the public.

6. Conclusions

Sustainability in healthcare, especially within the field of cardiac electrophysiology, is an essential consideration for the future. The increasing environmental constraints we face, both upstream and downstream, necessitate a proactive approach. Reprocessing of single-use medical devices has emerged as a potential solution to mitigate the environmental impact of electrophysiology procedures, while also offering economic advantages. However, the implementation of reprocessing must adhere to stringent regulatory standards to ensure patient safety. It is essential that healthcare professionals, policymakers and manufacturers collaborate to drive innovation, explore sustainable practices and ensure that patient care remains uncompromised in the face of environmental challenges (Central Illustration).



Central Illustration. Potential solutions to improve sustainability in cardiac electrophysiology.

Funding

None.

Disclosure of interest

The authors declare that they have no competing interest.

Références

[1] Watts N, Amann M, Arnell N, Ayeb-Karlsson S, Belesova K, Boykoff M, et al. The 2019 report of The Lancet Countdown on health and climate change: ensuring that the health of a child born today is not defined by a changing climate. *Lancet* 2019;394:1836–78.

[2] Pichler P-P, Jaccard IS, Weisz U, Weisz H. International comparison of health care carbon footprints. *Environ Res Lett* 2019;14:064004.

[3] Ditac G, Cottinet PJ, Quyen Le M, Grinberg D, Duchateau J, Gardey K, et al. Carbon footprint of atrial fibrillation catheter ablation. *Europace* 2023;25:331–40.

[4] Regulation 2017/745 of the European parliament and of the Council of 5 April 2017 on medical devices. Available at: <https://www.medical-device-regulation.eu/download-mdr/>.

[5] Ordonnance n° 2022-582 du 20 avril 2022 portant adaptation du droit français au règlement (UE) 2017/745 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux. Available at: <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000045614779>.

[6] Tribune : face aux pénuries de dispositifs médicaux, le retraitement est une nécessité pour continuer de soigner nos patients. *Monde* 2022. Available at: https://www.lemonde.fr/idees/article/2022/12/07/face-aux-penuries-de-dispositifs-medicaux-le-retraitement-est-une-necessite-pour-continuer-de-soigner-nos-patients_6153316_3232.html.

[7] Chouvel R, Goeury D. La prohibition du retraitement des dispositifs médicaux à usage unique en France. *RDS* 2023;112:206–17.

[8] Hennein R, Goddard E, Sherman JD. Stakeholder perspectives on scaling up medical device reprocessing: a qualitative study. *PLoS One* 2022;17:e0279808.

[9] Leung LW, Evranos B, Grimster A, Li A, Norman M, Bajpai A, et al. Remanufactured circular mapping catheters: safety, effectiveness and cost. *J Interv Card Electrophysiol* 2019;56:205–11.

[10] Schulte A, Maga D, Thonemann N. Combining life cycle assessment and circularity assessment to analyze environmental impacts of the medical remanufacturing of electrophysiology catheters. *Sustainability* 2021;13:1–23.

[11] Duncker D, Svetlosak M, Guerra F, Nagy KV, Vanduyhoven P, Mikhaylov EN, et al. Reprocessing of electrophysiology material in EHRA countries: an EHRA Young EP survey. *Europace* 2021;23:479–85.

[12] CIUSS de l'Estrie/CHU de Sherbrooke. Réutilisation des cathéters en électrophysiologie : une analyse contextuelle; 2015. Available at:

<https://www.santeestrie.qc.ca/clients/SanteEstrie/Professionnels/UETMISSS/2015/Rapport.Reutilisation.Catheters.UETMIS.20151023.pdf>.

[13] Baman TS, Kirkpatrick JN, Romero J, Gakenheimer L, Romero A, Lange DC, et al. Pacemaker reuse: an initiative to alleviate the burden of symptomatic bradyarrhythmia in impoverished nations around the world. *Circulation* 2010;122:1649–56.

[14] Enache B, Sosdean R, Macarie R, Dodinot B, Pescariu S. Assessing the safety of implantable cardioverter-defibrillator reuse – a retrospective case-control study. *Pacing Clin Electrophysiol* 2019;42:1095–8.

[15] Kantharia BK, Patel SS, Kulkarni G, Shah AN, Lokhandwala Y, Mascarenhas E, et al. Reuse of explanted permanent pacemakers donated by funeral homes. *Am J Cardiol* 2012;109:238–40.

[16] Khairy TF, Lupien MA, Nava S, Baez FV, Ovalle FS, Ochoa NEL, et al. Infections associated with resterilized pacemakers and defibrillators. *N Engl J Med* 2020;382:1823–31.

[17] Kapoor A, Vora A, Nataraj G, Mishra S, Kerkar P, Manjunath CN. Guidance on reuse of cardiovascular catheters and devices in India: a consensus document. *Indian Heart J* 2017;69:357–63.

[18] Pitschner HF, Reinesch P, Bahavar H, Jung U, Haßdenteufel H, Kunis M, et al. Using reprocessed devices does not impair patient safety, nor does it affect the course of the procedure or success rates – a report of quality management. *Eur Cardiovasc Dis* 2007;3(1):83–8.

[19] Leichsenring ML, Psaltikidis EM, de Oliveira Figueiredo MJ, Moretti ML, Trabasso P. Conception and validation of a protocol for reuse of non-irrigated electrophysiology catheters in a Brazilian teaching hospital. *J Interv Card Electrophysiol* 2018;51:45–50.

[20] Boussuge-Roze J, Boveda S, Mahida S, Anic A, Conte G, Chun JKR, et al. Current practices and expectations to reduce environmental impact of electrophysiology catheters: results from an EHRA/LIRYC European physician survey. *Europace* 2022;24:1300–6.

[21] Boussuge-Roze J, Duchateau J, Bessiere F, Sacher F, Jais P. Environmental sustainability in cardiology: reducing the carbon footprint of the catheterization laboratory. *Nat Rev Cardiol* 2023;20:69–70.

[22] Elliott AD, Middeldorp ME, Van Gelder IC, Albert CM, Sanders P. Epidemiology and modifiable risk factors for atrial fibrillation. *Nat Rev Cardiol* 2023;20:404–17.

[23] Bawa D, Ahmed A, Darden D, Kabra R, Garg J, Bansal S, et al. Impact of remote cardiac monitoring on greenhouse gas emissions: global cardiovascular carbon footprint project. *JACC Adv* 2023;2:100286.

[24] Stahel WR. The circular economy. *Nature* 2016;531:435–8.

[25] Rabin AS, Pinsky EG. Reducing health care's climate impact – mission critical or extra credit? *N Engl J Med* 2023;389:583–5.

[26] Chaffin Z. L'industrie pharmaceutique interpellée sur la lente « révolution verte » du médicament. *Monde* 2023. Available at: https://www.lemonde.fr/economie/article/2023/08/17/l-industrie-pharmaceutique-interpellee-sur-la-lente-revolution-verte-du-medicament_6185626_3234.html.