Worldwide Best Practices of Circular Medical Devices, a dataset with over 346 products

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General Introduction

This dataset contains data collected through desk research at Delft University of Technology, as part of Tamara Hoveling's PhD Thesis. It is being made public both to act as supplementary data for publications and the PhD thesis of Tamara Hoveling and in order for other researchers to use this data in their own work.

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Purpose of collection

The intention of the inventory of best practices is to gain insights into possible circular design guidelines for digital health devices.

Methodology

The data was collected through desk research using the information available on distributers and manufacturers websites.

We started with mapping out all medical devices of two countries completely, namely Norway and Australia. Following this we set the following guidelines to perform the full research:

1. Select countries that are representative for a certain part of the world, based on their location, export of medical devices, and them being a high, middle or low-income country. Opt for variety. (see Table 1) (Medtronic and Philips were also included in the search due to them being two of the largest manufacturers in the world and not being located in the countries we chose)

2. For each country, pick a maximum of 10 medical device or health device manufacturers, and per manufacturer, aim to find maximum 10 devices that implement circular strategies. Are there more than 10 options available? Exclude examples that are similar. For USA, pick 20 companies (due to the size of the country and medical market).
3. Determine the MDR criticality classification of the device. If the device is not classified under the EU-MDR, use the original legislation document to determine what it would be classified as if it were to be classified under the MDR.
    a. The MDR classifications (from low risk to high risk: classes I, IIa, IIb, and III) are based on the « intended purpose of the devices and their inherent risks (MDR-EU745). Extremely summarized, they are determined based on a the healthcare situation (non-serious, serious, or critical patient situation or patient condition) and on the intended purpose of the device (low, medium, or high influence on or involvement in the diagnosis, therapy or clinical treatment). This definition is adapted from the explanation of Annex III of MDCG 2019-11 of the Medical Device Coordination Group (MDCG). For more information about risk classification rules, consult Annex VIII of the MDR-EU745. The following paper can be helpful in determining the classification of a device: (L. Peter, L. Hajek, P. Maresova, M. Augustynek, and M. Penhaker, "Medical Devices: Regulation, Risk Classification, and Open Innovation," J. Open Innov. Technol. Mark. Complex., vol. 6, no. 2, Art. no. 2, Jun. 2020, doi: 10.3390/joitmc6020042.).
4. Determine the criticality rating based on the point system (see Table 2) , and always let the final rating be peer-reviewed by another researcher

We also conducted triangulation of the data. This entailed some conversations with experts, a visit to a large trade fair related to healthcare, and a scan of the most relevant trade journals and graduation reports of the TU Delft Industrial Design master.

Table 1

	Included countries		Additionally, separately included companies
1	Norway	High Income > 12695	Philips
2	Australia	High Income > 12695	Medtronics
3	Mexico	Middle-Upper-income 4096-12695	
4	USA	High Income > 12695	
5	Germany	High Income > 12695	
6	India	Middle-lower income 1046-4095	
7	Switzerland	High Income > 12695	
8	China	Middle-Upper-income 4096-12695	
9	Japan	High Income > 12695	
10	South Africa	Middle-Upper-income 4096-12695	
11	Kenya	Middle-lower income 1046-4095	
12	Brazil	Middle-Upper-income 4096-12695	
13	Sweden	High Income > 12695	
14	United Kingdom	High Income > 12695	

Table 2

Circularity rating+J29:O40

STRATEGIES	DEFINITION (Examples)	PROCESS EXPLANATION	MAX SCORE	100% score is given when …	50% score is given when …
Refuse	Making a product redundant by abandoning its function or by offering the same function in a radically different, more sustainable device. (Example 1: “refusing” development or further production of a color treatment device as color treatment was proven to be uneffective for the intended purpose) (Example 2: “refusing” development or further production of certain hearing aids because that specific device can be replaced by a mobile application that amplifies sound.)	During the design process of a device, the added value of the device and its specific functions and components is reconsidered. In case the device function is vital, it is aimed to search for a more sustainable alternative to achieve the same purpose outcome with a different, significantly more sustainable device. For example, by abandoning electronics or adding to function to an already existing device. Additionally, users could make conscious decisions by opting for more sustainable alternatives to achieve the same outcomes.	7	The device eliminates the use of one or more devices and does so in a radically more environmentally sustainable way.	The device eliminates parts of medical devices and does so in radically more environmentally sustainable way

Rethink	Developing device use, function and its surrounding systems to help intensify the use of the device, due to which less devices are needed. (Example 1: “rethinking” the function of a wearable sensor by adding user profiles, making it shareable among multiple users instead of using one device per user) (Example 2: “rethinking” the use of an active surgical device by making it wireless, enabling usage at different locations rather than needed one device per location)	In design concept development states of a device, the service and system design, usage, and functionalities are re-evaluated to possibly intensify use, aiming to rather use few more valuable devices, than large numbers of less valuable ones. Rethinking often leads to innovations that for example let multiple users use the device at the same time, enable multiple functions in one device, and/or enabling the use of the device at locations where this was previously not possible.	**6**	Device is made to be used more intensively than its counterparts by using multiple strategies, such as : ● Being used by multiple users at a time; ● Providing multiple functions; ● Being able to be used at locations that previously was not possible.	Device is made to be used more intensively than its counterparts by using only one of the strategies presented for the 100% score.
Reduce	Minimizing the use of the device, the energy consumed during use, and/or of resources and materials used in the manufacturing processes. (Example 1: “reducing” the amount of electronics used in laparoscopic devices, as some laparoscopic procedures can be performed with manual tools without side effects) (Example 2: “reducing” the energy consumption of a chargeable blood pressure monitor by replacing its lithium-ion battery for an innovative alternative)	A conscious decision is made to minimize environmental impact in the manufacturing processes, device design, use stages, and circular treatments. This can be done by reducing or preventing certain materials to be used, resource consumption, energy use and waste generation during any step in the product life cycle. This involves for example design optimizations that include the reduction of excessive packaging materials and minimization of the transportation-related environmental impact.	**5**	Device reduces its environmental impact deliberately through both: ● Using less material or more innovative material that has a lower carbon footprint than equivalent devices ; ● Implementing either renewable energy sources or efficient energy use.	Device reduces its global warming potential in just one way of the strategies presented for the 100% score.
Reuse	Collection of the device or parts of the device (= partly reuse) after the use cycle to reuse it for its original purpose. (Example 1: “reusing” a personalized smart pill box repeatedly by enabling the user to return the device to the manufacturer, who cleans it and sends it to the next) (Example 2: “reusing” a health catheter partly, by removing infectious parts, cleaning, disinfecting and sterilizing the reusable parts, and preparing them for the next use)	After the use cycle, the product or parts of the product (= partly reuse) are collected and either directly reused or go through repair, restoration, decontamination, and/or maintenance. In healthcare, many reused devices go through a decontamination loop. In case of a complex and/or medium to high risk device, the device will likely need to be disassembled and go through a quality assessment prior to the initiation of the next use cycle.	**4**	Device is made with the purpose of being reused for the same purpose without reduction of performance or quality of patient care. Maintenance and repair of the device is part of the service to extend the devices life even further.	Only one part of the device can be reused while the rest is single use, or the reusable device does not have maintenance and repair services.

Repurpose	Collect the device or parts of the device (= partly repurpose) after the use cycle and find new applications for the device, or device parts to make it suitable to be used for a new function. This can be done by design or decided upon after use. (Example 1: “repurposing” an ECG monitor by updating its software to make it suitable to be used as a monitor or screen of any other type of device) (Example 2: “repurposing” an endoscope by, after using it on humans, changing its use setting to use the same device for veterinary purposes) (Example 3: “repurposing” an unreliable ultrasound probe by making a simple adjustment to the head that enables imaging at a different frequency with lower criteria)	After the use cycle, the product or parts of the product (= partly repurpose) are collected and either directly repurposed or go through repair, restoration, maintenance, or other processes that are needed to make the device suitable to be used for its new function. Additional processes that might be needed completely depend on the intended new function of the device. The device can be repurposed either in or not in a healthcare setting. However, in case the device will be repurposed in healthcare or other high-risk settings, it needs to be specifically designed to be repurposed and be accepted on the market based on a description of both the initial intended use and the repurposed intended use functions. The repurposed device can have the same function with different purposes (e.g. repurposing for training or in veterinary care). It can also have a completely different purpose that is used for a different application (for example, a click-on part that makes a surgical device suitable to be used in a different kind of surgery) or if the function is solely (or mostly) driven by software, it can be altered to change the function easily.	**3**	The entire discarded device is being reused for a different purpose or function. This may be intended by design or initiated by the user at EoL.	Only part of the discarded device is being reused for a different purpose or function. This may be intended by design or initiated by the user at EoL.
Remanufacture	Collect the device or parts of the device (= partly remanufacture) after the use cycle to test its function, disassemble it into components (if needed) to restore them in a new device (with used and new parts) with the same function. (Example 1: “remanufacturing” an auto-injector by testing, and disassembling the original components and producing a high quality device out of old and new parts) (Example 2: “remanufacturing” a pacemaker by after high level disinfection, testing functionality of all components, and fully restoring the device to better than new condition)	After the use cycle, the product or parts of the product (= partly remanufacture) are collected and disassembled into components (if needed). If they pass a quality check, the components go through the initial manufacturing process again resulting in a new product (with used and new parts) with the same function. In case parts of the initial product do not pass the quality assessment, new parts or spare parts (which have also resulted from incomplete devices) will be added to the assembly. Remanufactured products need to adhere to high quality standards, especially in a healthcare setting. The remanufactured product will go through repeated quality assessments to ensure that it meets or exceeds the quality requirements of a new product. The final remanufactured product is packaged again under a unique identification number, but with the mention of the number of times the device has been remanufactured.	**2**	At least 50% of the parts of the discarded device are brought back into manufacturing to develop a remanufactured device with the same function and a device quality that is similar or better than the original device.	Some, but less than half or the parts of the discarded devices are used in the remanufacturing cycle.

Recycle	Collect and sort the device or parts of the device after the use cycle to process materials such as paper, glass, plastic, and metal in such a way that they can once again be used as (recycled) base materials in the manufacturing process of the same or a different device or product.	After the use cycle, the product or parts of the product (= partly recycle) are collected by disassembling and/or shredding it. All kinds of material are separated and are directly recycled or go through depollution and decontamination processes before they can be melted into recycled material streams. The final recycled material additionally goes through a quality check to determine whether the granulate can be used in the production process of a similar product with the same function or can be "downcycled" to be used in the production process of a different product and function, potentially out of the healthcare setting. Alternatively, to the described process, a chemical recycling process can be followed, although this method is still in earlier development phases.	**1**	The device is made to be easily recyclable. There is a recycling program in place.	The device is made for easy recycling. There is no a recycling program, but recycling is encouraged with detailed instructions.
Regrow	During or after use (depending or how the use phase is defined), the material is dissolved into nature through tissue regeneration. This applies to regenerative medicin, and is currently not applicable to electronic components in itself. Example 1: "regenerating" the staples of a medical stapler into tissue to prevent hospital readmission and additional surgery, and thus reduce environmental impact) **OR** Collect the device or parts of the device (=partly compost/biodegrade) after the use cycle to process compostable/degradable materials through controlled composting processes into nutrient-rich mass that is not harmful to plant life (Example 1: "composting" the lid of a smart pillbox by making it of PLA, removing the electronics after use, and letting it biodegrade in days at a composting plant)	For materials that are implanted into the human body, during the detailing design phase, select a material that is suitable for tissue regeneration. During use, the human body can biologically break down the material while 'regenerating' it into human tissue or bone. Although this CRF is (currently) not applicable to electronic components and thus digital health devices, it may lessen the need to use those kinds of devices or the environmental burden that typically comes with their use. **OR** After the use cycle, the device or parts of the device are collected and separated. Through controlled composting processes organic materials are converted into nutrient-rich mass. These processes must always comply with the applying industrial composting standards, and shall thus biodegrade and disintegrate within 90 days without leaving any harmful residue. The compost can be applied to soil for various purposes, such as enhancing soil fertility, improving water retention and promoting plant growth. Biodegrade is similar to compost but differentiates itself by the absence of time limits and specific standards or regulations for biodegrade processes. Despite these absences, it is always aimed to minimize the time needed for biodegradation and disintegration, and to prevent harmful residue as much as possible.	**1**	At least 50% of the parts are suitable for (tissue) regeneration, composting, or biodegradation and has a regrow program in place.	Device parts are suitable for regrow strategies, but this is only true for less than 50% of all materials and/or there is no regrow program in place.

Recover energy	Devices or parts that cannot possibly go through any other CRF, are incinerated with the aim of harvesting energy. (Example 1: “recovering energy” from a laparoscopic device by capturing energy while burning non-infectious and non-hazardous parts (excluding batteries)) (Example 2: “recovering energy from a wearable sensor by removing the battery and capturing energy while burning the other, non-hazardous parts)	After the use cycle, the device or parts of the device are collected after separation of the battery and other hazardous components that may not be incinerated. First, medical incineration is performed on (potentially) infectious components. The resulting components can be brought to a standard, non-medical incineration plant. Incineration is a process where waste materials are burned at high temperatures. Specialized equipment and technologies capture and convert wasted energy during the incineration into a usable form, such as electricity, heat, or mechanical power. Energy recovery is however currently not applicable for medical incineration, which happens at much higher temperatures.	**0**	Device is thrown at landfill or incinerated upon EoL.	Not applicable
More than one			Total points = total from categories + 1 point* (number categories-1)		