Integration of Sustainability in the Design Process of Medical Devices – Application to Dry Electrodes

Beerten Pieter
Industrial Systems Engineering and Product Design / BEAMS Department
Ghent University / Université libre de Bruxelles
Kortrijk, Belgium / Brussels, Belgium
Pieter.Beerten@ugent.be

Grandjean Victor-Paul
BEAMS Department
Université libre de Bruxelles
Brussels, Belgium
Victor-Paul.Grandjean@ulb.be

Decroly Gilles
BEAMS Department
Université libre de Bruxelles
Brussels, Belgium
Gilles.Decroly@ulb.be

Gaspard Nicolas
Department of Neurology
Erasme Hospital, ULB
Brussels, Belgium
nicolas.gaspard@hubruxelles.be

Delchambre Alain
BEAMS Department
Université libre de Bruxelles
Brussels, Belgium
Alain.Delchambre@ulb.be

Nonclercq Antoine
BEAMS Department
Université libre de Bruxelles
Brussels, Belgium
Antoine.Nonclercq@ulb.be

***Abstract*— The lack of design methodologies integrating sustainability into the design processes of medical devices has been identified as a hindrance in developing sustainable solutions. This research aims to overcome this by creating such a methodology, developed through a "Research through Design approach, incorporating Design for Sustainability (D4S) into the design process applied at the ULB BEAMS research group. As an illustration, this methodology was used in the development of electroencephalogram (EEG) dry electrodes. A simplified Life Cycle Assessment (LCA) was utilized to quantify the environmental impact of the final concepts. These calculations showed a significant reduction in CO_2 emissions of the final concept, a filled silicone electrode (at the embodiment design phase), compared to initially developed EEG electrodes, a coated silicone electrode (developed without the sustainable design methodology). Methodologically considering sustainability throughout the design process of medical devices can thus help achieve preferable outcomes. Further research is proposed to refine the methodology, explore variations in the implementation of medical device design processes, conduct additional case studies, and develop a new quantification tool to assess the full impact of medical devices. Overall, the paper highlights the importance of integrating sustainability into medical device design to effectively address environmental and potentially social challenges.**

Keywords*— *Design for Sustainability, EEG electrodes, LCA, Medical Device Design Methodologies

I. Introduction

Current environmental and socio-economic issues challenge the possibility of meeting present-day needs without compromising those of future generations [1]. The medical sector plays a crucial role, accounting for 5.4% of global greenhouse gas (GHG) emissions, with an annual five percent growth [2]. Approximately 20% hereof can directly be linked to the production, consumption, and use of medical devices [3]. In addition to the environmental impact caused by GHG emissions, medical devices can impact social equality by, for example, incorporating discriminatory biases [4]. These unsustainable environmental and social practices consequently negatively impact human health [5], [6], [7], creating a self-reinforcing feedback loop.

Approximately 80% of a product's environmental impact is locked in during the design phase [8], [9], highlighting the designer's significant influence and responsibility. However, integrating sustainability into medical device design is not yet standard practice [10]. A methodological integration of sustainability requirements is needed to achieve favorable outcomes [11]. Unfortunately, most existing sustainable design tools do not focus on this integration [12], [13], [14].

This work aims to establish a systematic methodology for integrating sustainability into all medical device design process phases. The methodology was applied to the development of dry EEG electrodes to illustrate the outcome.

II. State of the Art

A. Design process Medical Devices

The Medical Device design process is, in comparison to traditional design processes, highly controlled and standardized to ensure compliance with regulatory requirements and minimize costs [15]. Medical devices must comply with stringent regulations like the EU Medical Device Regulations (MDR) [16]. These regulations aim to ensure medical devices' safety, efficacy, and quality. The design process for medical devices must include activities to meet these regulatory requirements, such as performing animal and clinical testing, documenting risks, and obtaining necessary certifications.

Despite the design process of medical devices being highly standardized, variations exist that are mainly based on the traditional design methodologies: (I) Pahl&Beitz design, which is an iterative design engineering approach, and (II) the diverging/converging (exploring different possible ideas/narrowing down to the best option) Double Diamond approach [15], [17]. However, it is unclear how each company or designer implements their unique variant and how sustainability can be methodologically incorporated into these variations.

B. Design for Sustainability

Design for Sustainability (D4S) can be defined as the consideration and harmonization of ecological, economic, and social aspects in the design process [18], [19], [20]. To facilitate this, Life Cycle Thinking is applied [21], [22]. Other sustainable design methodologies, approaches, or tools simultaneously focus on one or two D4S aspects. For instance, Lifetime Extension focuses on technical aspects and consumer behavior to increase the lifespan of a product to lower the ecological impact [23], [24]. Others, like Life Cycle Assessments (LCAs), look at environmental [25] or social

[26] impact. Ecodesign focuses on the environmental and economic aspects [27]. None of them focuses on all aspects simultaneously to fully integrate sustainability. D4S can thus be seen as an overarching term incorporating these various facets [28].

Sustainable design outcomes can be divided into four levels of innovation: (I) incremental, (II) product redesign, (III) product alternatives, and (IV) design of sustainable societies [29]. Today, there is a need to focus on the highest level of innovation possible [30]. D4S aspects themselves can also be subdivided into five innovation levels - (I) material/component, (II) product, (III) product-service system, (IV) spatio-social, and (V) socio-technical system-, as introduced by Ceschin & Gaziulusoy [31], evolving from an insular/technocentric towards a systemic/human-centered focus. When D4S is applied in its totality, the designer must simultaneously consider the detailed material level and the broader socio-technical aspects, which can be very complex. This is without considering potential external factors that may hinder or enable the implementation of D4S, potentially explaining why there are few examples of sustainable medical devices.

C. *Sustainable Design of Medical Devices*

Limited work is performed on the holistic integration of sustainability in the medical design process. Previous works have been identified as incorporating LCAs, circular design, socio-economic analyses, and Ecodesign in the design process of medical devices [32], [33], [34], [35], [36]. Sousa et al. [33] further state that the absence of formal methodological guidelines for incorporating sustainability during the design stage of medical devices poses a major challenge in achieving this goal. This could explain the scarcity of sustainability innovation examples in medical devices or the difficulty of identifying them. Besides, from the few identified examples, these seem to be limited to level I and II innovations. These examples include the development of reusable endoscopes with a single-use end cap that could reduce infection transmission risk without discarding the entire endoscope after each use [37]. These endoscopes will have a similar environmental footprint as the general fully reusable endoscopes and will thus, from an environmental viewpoint, be preferable over single-use endoscopes. Another example that has been found is a reusable vacuum extractor developed for a low-resource setting [38].

Transdisciplinary conceptual research questioned the general sustainability of biomedical engineering practices [39]. Consequently, it developed a framework based on strong sustainability [40] with the added notion of "Clinical sustainability" as a component of Social Sustainability, as shown in Figure 1. Based on this framework, a set of guiding questions to evaluate the sustainability of a medical device was developed and applied to a case study. In conclusion from this exercise, there is a need to assess all aspects of sustainability and identify and quantify the trade-offs instead of focusing on one or two key indicators to have more relevant information to make better and more effective decisions. Practically, the guiding questions proposed in this work are the first step toward a multidisciplinary evaluation of the sustainability of medical devices and technologies. For future research perspectives, this research proposed the development of a semi-quantitative evaluation methodology that can be deployed to question projects at an early stage of development and evaluate established technologies.

In summary, the current state of the art lacks knowledge on the methodological integration of sustainability, specifically toward the development of medical devices. Therefore, this research initiates the development of a method to integrate sustainability into the design process of medical devices and applies it to a case study, dry electrodes.

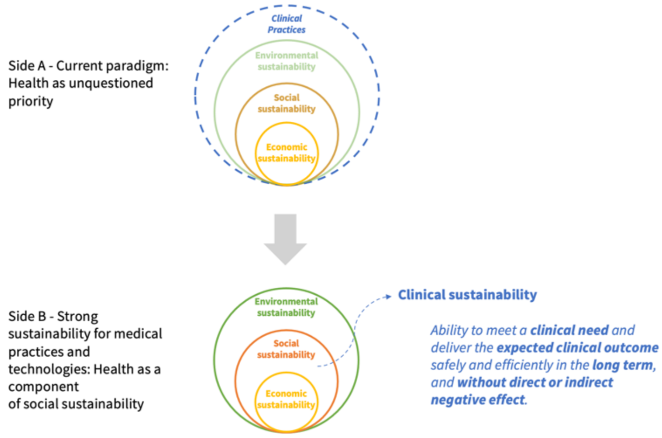

Figure 1 - Current paradigm of Clinical Practices as an unquestioned priority over sustainability, to a paradigm of Clinical Sustainability as a component of Social Sustainability.[39]

III. Methodology

A "Research through Design" approach was applied whereby the development of the methodology, the case study, and the final results contributed to scientific knowledge [41], [42], [43]. A four-step approach was applied: (1) Observing applied design processes, (2) Developing the sustainable design methodology, (3) Applying the developed methodology towards a case study, and (4) Evaluating the outcome by performing a simplified LCA approach. At this stage, the choice was made to limit this research scope to the processes applied at our research department and apply the sustainable design methodology toward only one case study, the development of EEG dry electrodes.

A. *Observation design process BEAMS research group*

The design process generally applied at the BEAMS research group was reconstructed and visualized by observing previous and currently ongoing projects.

B. *Development 1st version methodology*

Based on this reconstruction, a new methodology was developed to integrate sustainability in each phase.

C. *Application on EEG dry electrodes*

This newly developed methodology was consequently applied to an ongoing project, the development of EEG dry electrodes. An initial concept, polydimethylsiloxane (PDMS) silicone electrodes coated with an electrically conductive substance, was already developed without the sustainable design methodology. This concept was used as a benchmark to compare the newly developed electrodes.

D. *Evaluation simplified LCA*

The LCA was initiated during the development of the EEG electrodes. Given that design processes, especially initial design stages, are characterized by uncertainty and unavailability of data necessary for performing full-scale

LCAs, a simplified LCA approach was chosen [44]. For this, the SimaPro database was utilized to gather data on the A1-A3 phases, which cover raw material acquisition to production. However, this simplified assessment did not incorporate considerations for the use phase (B1-B7) or end-of-life stages (C1-C4), nor did it assess the potential benefits or costs associated with reuse (D). On top of these limitations, the assessment focused on quantifying CO2 equivalent (CO_2e) emissions only, offering a preliminary insight into the environmental performance of the EEG dry electrodes at this developmental stage.

IV. Results and Discussion

A. *BEAMS design process*

As shown in Figure 2, the design process applied in the BEAMS research group consists of 9 iterative phases: (I) Medical & technical state of the art, to diverge the designer's view, looking at what previous work has done to solve the problem. (II) Medical & technical requirements: a converging phase in which the requirements for the to-be-developed device will be determined. (III) Conceptual design: in this diverging phase, the designer ideates and explores potential solutions. (IV) Embodiment design: the best concept(s) will be further developed during this phase. (V) Failure mode & effects analysis: this phase aims to identify all possible failures in a design. (VI) Detailed design: at this phase, the concept is refined into a finalized product. (VII) Specifications & verification: Verify if the final design has met the preset medical and technical requirements. (VIII) Validation: in this phase, the device will be tested and validated to check if it resolves the intended issue. (IX) Design improvements: issues identified during the previous phases will be resolved.

B. *Development Sustainable Design Methodology*

A new methodology was developed to integrate sustainability in each phase. As can be seen in Figure 3, the developed proof of concept of the sustainable design methodology starts with an exploration of the potential sustainability opportunities for the product by a guiding questionnaire, which consequently helps set the Sustainability requirements in the next phase that determine which Design for Sustainability approaches and quantification tools should be applied in the following design phases. Lastly, a full LCA should be performed based on a framework specific to medical devices.

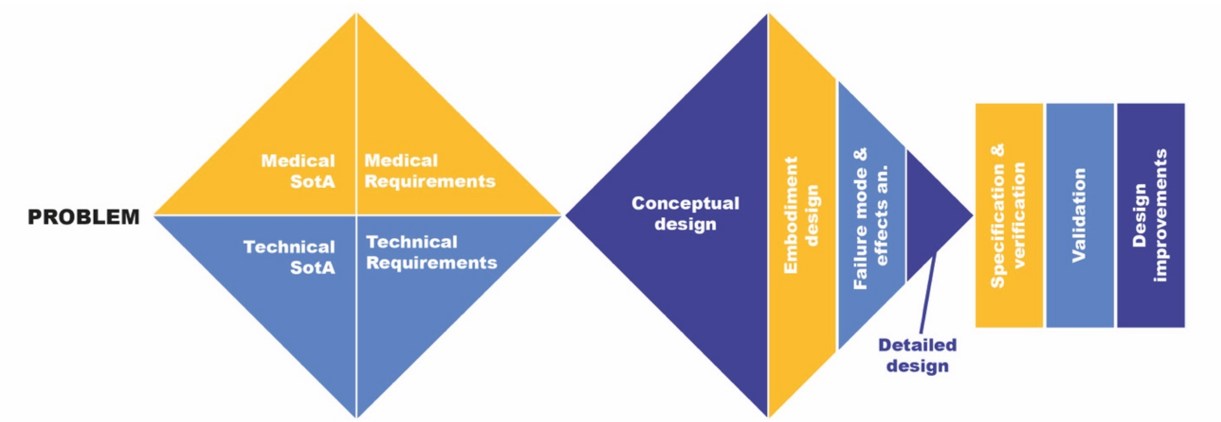

Figure 2 - BEAMS design process

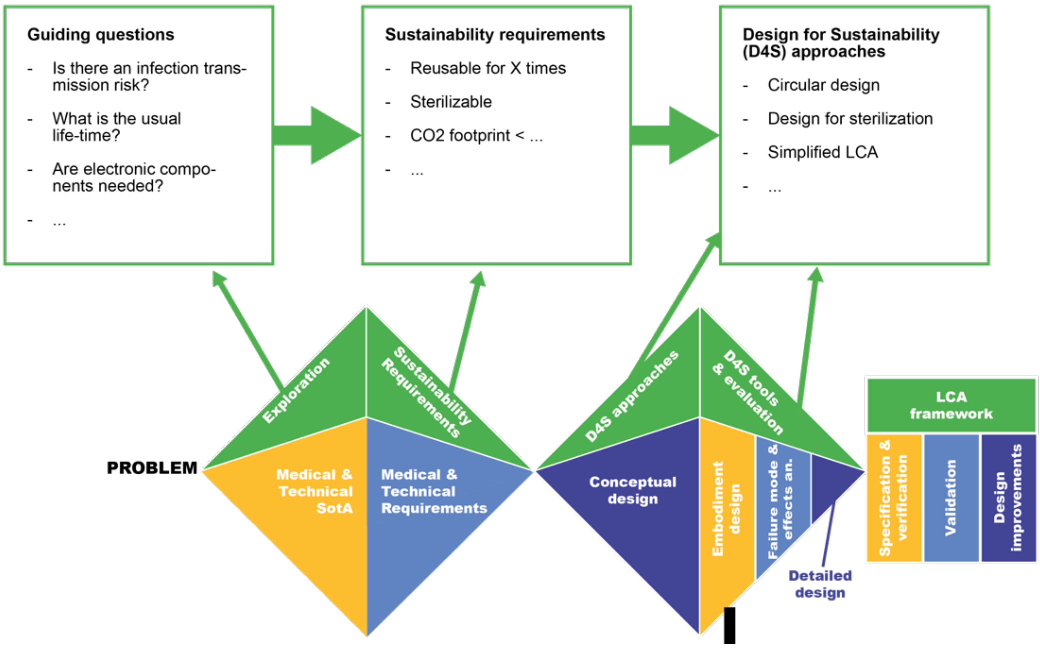

Figure 3 - Proof of Concept of the sustainable design methodology based on the BEAMS design process

C. Application on EEG dry electrodes

As the guiding questionnaire was not developed when the methodology was applied to the development of the case study, an alternative approach was used to explore sustainability opportunities. A search was done for previous examples of sustainable EEG electrodes, of which no examples were found, and an expert (NG) was questioned about the systematic requirements for the sustainable electrode to be developed. As a result of these actions, the following sustainability criteria were determined:

- The electrodes should be technically reusable (e.g., should not lose conductivity after repeated use) and systemically reusable (e.g., should be washable with aseptic solutions).
- The electrodes should be (at least chemically) recyclable.
- The electrodes should have the lowest CO_2e footprint possible.

Besides these environmental requirements, the previously determined technical requirements (e.g., minimum electric conductivity) must still be met.

On top of the already developed (I) Coated Silicone Electrode (without the sustainable design methodology), two new concepts were created: (II) Filled Silicone Electrode and (III) Biobased Electrode. Concept II is, similarly to concept I, a PDMS silicone electrode, but it has an electrically conductive filler instead of a conductive coating. For concept III, biomaterials were considered as an option. Biomaterials and biopolymers generally have a lower environmental impact [45]. By performing a literature study, multiple biocompatible biomaterials that could readily be used in medical applications were identified [46]. Therefore, biomaterials were assumed to be a suitable alternative for the silicone rubber variants to meet the preset medical requirements. On the technical requirements, however, no suitable biomaterials that would meet the requirements in terms of conductivity were identified. A prior case study [47] investigating the potential use of biomaterials in medical sensors (including EEG sensors) came to the same finding. Therefore, the decision was made to no longer consider this concept. Only two concepts remained (I and II), both at the embodiment design phase. These were compared to each other with a simplified LCA approach.

D. Simplified LCA

The material composition is confidential and can thus not be communicated in this paper, but details can be provided on request. All the electrode-constituting materials were searched in the SimaPro database. No full compositions of the PDMS silicone, coating, or filler could be obtained. Therefore, per component, the following assumptions were made based on the available information:

- The database contained information on PDMS silicone, assumed to represent the silicone used in the prototypes.
- Based on the Safety DataSheet (SDS) of the coating, a maximum of 78% of the dried-up weight consists of one metallic element. The assumption was made that this one component represents the entire environmental impact of the coating (CO_2e coating = CO_2e known component x % dried-up weight known component (78%)).

-	**Raw material**	**(I) Coated Silicone Electrode**		**(II) Filled Silicone Electrode**	
	Impact (CO_2e/kg)	*Weight in elec. (g)*	*Impact (CO_2e/elec.)*	*Weight in elec. (g)*	*Impact (CO_2e/elec.)*
Silicone	1.7	3	0.005	2	0.003
Coating	335.4	0.4	0.134	NA	NA
Filler	50	NA	NA	1	0.05
Total		3.4	0.139	3	0.053

Table 1 - Calculations of the environmental impact of each concept

- It was assumed that the electrically conductive filler consists of 100% out of one organic compound.

During quantification, common LCA issues like unavailable data, complex assumptions, and lack of standardization [48], [49] were encountered.

Calculations of the environmental impact of each concept are shown in Table 1. The final calculations showed that concept I (Coated Silicone Electrodes) had an environmental impact of 0,139 CO_2e/electrode. For the second concept, concept II Filled Silicone Electrode, this environmental impact was approximately 62% lower, equalling 0.0534 CO_2e/electrode, as seen in Table 1.

As previously mentioned, this calculation did not take into account factors related to the use phase (B1-B7), end-of-life stages (C1-C4), or potential benefits or costs associated with reuse (D). It is assumed that Concept II would perform better in these categories since:

- the impacts of the use phase and end-of-life stages are equal for both concepts,
- Concept II is expected to perform better regarding the potential benefits of reuse as the coating is suspected to deteriorate more from the disinfection process compared to the filler. This is under the assumption that the reuse cost is lower than the reuse benefit.

V. Future Research

While this work presents a first step towards a sustainable design methodology for medical devices, further research is crucial to refine it and enable its universal applicability. Three key areas have been identified that require further exploration:

1. The current lack of clarity regarding individual variations in implementing medical device design processes hinders the methodology's universal adaptation. Observational research aimed at understanding these variations would be valuable. Such insights could inform the reiteration of the proposed methodology.
2. This work was illustrated on a single case study, limiting the generalizability of its findings. Conducting additional case studies across different medical device contexts would allow for robust validation of the proposed methodology.
3. Lastly, as LCAs suffer from various previously discussed limitations, these raise a fundamental question: Is LCA the most suitable tool for guiding the entire design process, or should a new tool be developed to quantify a product's (potential) impact, addressing uncertainties in the early stages and overcoming the drawbacks of LCAs? While other measurement tools exist to quantify specific aspects or provide early-stage insights [50], such as eco-design checklists, environmental indicators, and pre-LCA tools, none comprehensively quantify the full

(potential) impact throughout the entire design process. Therefore, future research could target the development of such a tool.

VI. Conclusion

The medical device sector plays an important role in the current environmental crisis, yet few solutions and examples exist addressing its impact. The lack of methodological integration of sustainability in the design process of medical devices has been identified as a main barrier. There is a need for further integration of sustainability requirements in the development process of medical devices.

As a response, this work addresses this issue by proposing a novel methodology, based on the design process applied at our research group. This methodology aims to integrate Design for Sustainability (D4S) in the design process of medical devices. The methodology was partially applied to the development of dry EEG electrodes to demonstrate its efficacy. The results showed much promise as the newly developed Sustainable Design Methodology successfully guided the design process, creating a novel EEG electrode concept with a 62% reduction in CO_2e GHG emissions compared to the baseline. The methodology demonstrated its efficacity, enabled us to look at the problem from another standpoint, to consider other design possibilities, and to discriminate between them based on their environmental impacts.

To conclude, this research proposes multiple future research perspectives, such as the further development of the proposed methodology and the development of a novel quantification tool to assess the full impact of the device under development from an early design stage on out.

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