Accessibility in Medical Devices: Proposal for a Conceptual Framework and Strategies for Universal Design

Mariana Ribeiro Brandão
Institute of Biomedical Engineering of Federal
University of Santa Catarina (IEB-UFSC) Florianópolis, Brazil
e-mail: marianaribeirobrandao@gmail.com

Monika Maria Möhring
Technische Hochschule Mittelhessen (THM) - University of Applied Sciences BliZ - Study Centre for Blind and Visually Impaired Students (THM) Gießen, Germany
e-mail: mmm@bliz.thm.de

Renato Garcia Ojeda
Institute of Biomedical Engineering of Federal University of Santa Catarina (IEB-UFSC) Florianópolis, Brazil
e-mail: renato.garcia.ojeda@ufsc.br

Abstract— **The lack of accessible medical devices is one of the factors that lead to disparities in healthcare services. Accessibility must be embedded throughout the entire lifecycle of Health Technology Management to meet the needs of a diverse patient population encompassing different abilities, limitations, genders, races, ethnicities, cultures, and geographical contexts. This work aims to realize a rapid review of the literature in search of evidence as well as provide proposal framework and strategies for inclusive design in medical devices. This research found a large number of accessibility problems involving different types of medical devices, as well as the lack of accessible technologies in healthcare environments. Different actions to provide a more inclusive and accessible health technology management throughout the life cycle were proposed, such as incorporating user-oriented development, training and development of standard operating procedures.**

Keywords-Accessibility; Medical Devices; Health Technology Management.

I. INTRODUCTION

Health technologies consist of medical devices, medications, vaccines, procedures, and systems, developed to solve a health problem and improve quality of life [1]. Considering accessibility aspects in the development of medical devices is essential to ensure inclusion and facilitate the safe use of technologies by a wide range of patients, from those with advanced technological skills to those with no aptitude at all [2]-[3]. Accessibility enables inclusion for people who may temporarily have some limitation or those who have a permanent one [4].

According to data from the World Health Organization, it is estimated that 1.3 billion people suffer from significant disabilities. This represents 16% of the world's population. This number is growing due to the increase in non-communicable chronic diseases and longer life expectancy. Alarming studies indicate that people with disabilities die earlier, have poorer health, and experience more limitations in daily functioning than others [5].

Accessibility, as defined by ABNT (Brazilian Association of Technical Standards) 17060:2022, consists of *"the extent to which products, systems, services, environments, and installations can be used by people from a population with the widest variety of characteristics and capabilities, to achieve a specific objective in a specific context of use"* [6]. The objective of accessibility is to expand the target population by ensuring that products, systems, services and environments are usable by a broader range of individuals across diverse contexts of use.

Accessibility aims to design products that meet the needs of a wide range of people, including those with physical, sensory, and cognitive disabilities, whether present from birth or acquired throughout life, as well as older adults with reduced capabilities, individuals with temporary impairments, among others. With the purpose of enabling the broadest possible access for users regardless of skill level, language, culture, environment, or disability, universal design becomes a framework to develop products to be used by all people, without the need for adaptation or specialized design [7]-[9].

Accessibility is determined by the ease of access to the necessary products to achieve the goal for people with the widest variety of abilities [10]-[11] and should be included as part of human-centered design, so that the population that can use technologies effectively, efficiently, and satisfactorily can be expanded, and consequently, usability for all users can be increased [10].

People with disabilities face barriers in all aspects of the healthcare system, such as: lack of knowledge, negative attitudes, and discriminatory practices among healthcare professionals; inaccessible health facilities and information; and lack of information or collection and analysis of data on disabilities contribute to the health inequalities faced by this group [5].

People with disabilities are more affected by health emergencies compared to people without disabilities, due to structural factors, social determinants, risk factors, and health systems, which include health technologies [12]. The global report on health equity for people with disabilities states that, due to systemic and persistent health inequalities, many people with disabilities are at risk of dying up to 20 years earlier than people without disabilities [5].

People with disabilities often do not have the opportunity to receive quality healthcare and sometimes have access to insufficient healthcare [13]. As technologies become increasingly present in the healthcare sector and are

incorporated to assist users in their safer and more reliable use, considering accessibility aspects in technological development becomes a fundamental requirement to achieve product usability [1]. The incorporation of principles that consider usability and accessibility should be strategic business objectives, as they are essential to optimising performance, minimising undesirable consequences for humans, maximising the well-being of the entire organisation, and improving customer relationships [10].

Recent studies in the field of medical devices have prioritized usability and safety as fundamental pillars of technology management, aiming to mitigate operational errors and ensure clinical efficacy. However, as demonstrated in a previous systematic review focused on the state of the art in accessibility, there is a critical scarcity of scientific evidence addressing the inclusion of users with physical, sensory, or cognitive disabilities in the design of this equipment. This methodological gap in the multidimensional analysis of accessibility underscores the need for new evaluation models, such as the use of Living Labs, to integrate the perspectives of diverse users into inclusive design [14].

Due to the importance of considering accessibility to ensure the inclusion of all people in the use of medical equipment, this work aims to realize a rapid review of the literature in search of evidence as well as provide proposal framework and strategies for inclusive design in medical devices.

The rest of the article is structured as follows. In Section II, we discuss the methodology used in the research. In Section III, the results are elucidated. In Section IV, we discuss the results found. Section V concludes the work with a summary and future research directions.

II. MATERIALS AND METHODS

This work was conducted in two stages. The first step consists in exploring accessibility in medical devices with a rapid literature review, which consists of a reliable and systematized methodology to synthesize knowledge. This approach is used when steps in the process of a systematic review are simplified to produce information from the selection of research that is available in the literature, and that is relevant to a study topic [15]. The constant increase in the amount of research carried out in the literature requires the implementation of an approach to evaluate published studies and contribute to decision-making, and thus provide an updated summary of the state of knowledge [16]. The conduct of this rapid review was based on the Methodological Guideline of the Ministry of Health for the preparation of systematic reviews [17], as well as on the PRISMA methodology of the University of Oxford, which consists of a set of evidence-based items that aim to assist in the presentation of research results. The guiding question of the rapid review research proposed for this case study was: **“What is the evidence of accessibility in medical devices?”**

To answer this question, the search strategy used was through the definition of keywords to identify publications that respond to this theme. The use of the logical operators “AND” and “OR” helped in the literature search. The search in the databases was executed using the union of keywords: (*"medical device"* OR *"medical equipment" OR "health technology”*) AND (*"accessibility"* OR *"disabled people"* OR *"disabled person"* OR *"disability"*) during March 2026. The search was implemented in the following electronic databases: IEEE *Xplore* and Pubmed, which were used systematically. To determine the choice of articles, inclusion and exclusion criteria were established, which included population parameters of the intended technology, the type of intervention used, the availability of the work, the date of publication and the type of evaluation of the results. After the initial search, the date of publication, the titles and abstracts were read, selecting a total of 15 publications. Table 1 explains the number of articles found per database using keywords.

TABLE I. NUMBER OF ARTICLES FOUND PER DATABASE.

Database	***("medical device*" OR "medical equipment*" OR "health technolog*")***	***("accessibility" OR "disabled people" OR "disabled person" OR "disability")***	***("medical device*" OR "medical equipment*" OR "health technolog*") AND ("accessibility" OR "disabled people" OR "disabled person" OR "disability")***
Pubmed	124,221	524,172	4,191
IEEE Xplore	18,086	36,081	315

The second stage of this work was to propose a conceptual framework about accessibility in medical devices categorized into different domains. Strategies for inclusive design were shown to improve the accessibility in medical devices for everyone.

III. RESULTS

The results obtained in the rapid literature review highlighted accessibility issues in different types of medical devices, such as examination tables [18]-[20], scales weight [21]-[22], nebulizers, glucometers [23-[24], positive airway pressure devices [25]-[26] neuromodulation devices, subcutaneous electrode that records the EEG [27] and mammograms [28]. The usability techniques applied to explore and investigate the problems were: questionnaires, interviews, focus groups, and usability tests.

In the studies analyzed, it was found that medical devices are often not accessible to the entire population. Story et al. highlighted the problems faced by patients with disabilities who experience difficulties in using different types of medical equipment [13]. The four main pieces of equipment with the most reported problems were tables, radiology equipment, rehabilitation and exercise equipment, and scales weight. Possible physical damage and incorrect reading of displayed values were the most recurring problems, followed by physical positioning and patient transfer in medical equipment [13]. In Table 2, a description

of accessibility issues in medical devices found during the conduct of the Rapid Literature Review is shown.

In the studies analyzed in the rapid review, a scarce amount of research highlighting accessibility issues in medical devices was found. No evidence was found that considers the perspectives of different actors and stakeholders on accessibility, nor evidence with a methodology for incorporating accessibility throughout the entire lifecycle of technologies, from the development phases to use and obsolescence, as will be presented in the next section. Medical devices are designed for the benefit of the population; however, they must be accessible to meet the diverse needs of the entire population, considering different ethnicities, races, genders, disabilities, as well as various contexts and locations. Due to the absence of an integrative definition in the current literature, this work proposes a Conceptual Framework for accessibility in medical devices, based on the convergence of 6 essential domains, shown in Figure 1.

TABLE II. SUMMARY OF ACCESSIBILITY ISSUES IN MEDICAL DEVICES FOUND IN THE RAPID LITERATURE REVIEW

Medical Device	Accessibility Issues	Effect
Diabetes Technologies	Screens and parts of the device with low contrast; absence of speech output; small screen and high levels of reflection	Erroneous administration of medications; imprecise diagnosis; hypoglycemia; hyperglycemia
Pulse Oximeter	Lower accuracy and greater bias in patients with dark skin, Asians, and Indigenous people, compared to white patients, increasing racial and ethnic disparity	Overestimation of oxygen saturation
Scale Weight	Absence of accessible scales; patient positioning, location and readability of the display, scale capacity; lack of color differentiation and absence of contrast	Healthcare professionals often ask patients to estimate their own weight, which can lead to health implications
Dental Unit (Dental Chair)	Difficulty in transfer; maintaining balance during the procedure; unable to support weight for obese patients; excessive height; intrusive arm position, lack of support devices, coating material, and lack of skill from the team in transfer and positioning process	Patient falls; discomfort; in some cases, chemical and/or physical restraints are used to ensure adherence and immobility
Imaging Diagnostic Equipment	Contact surfaces, transfer support, and positioning support; inability to bring wheelchairs or scooters into the MRI room (due to the magnetic field); equipment capacity	Inability to perform exams and not diagnose diseases; interruption in patient care
Woman Health Technology	Difficulty in maintaining positions during gynecological exams; examination tables and auxiliary components do not provide support to maintain proper positions; lack of adjustable height	Lower likelihood of undergoing preventive exams; patient fall

Beyond operational accessibility, there is also economic accessibility, which refers to the ability of individuals to afford healthcare without experiencing financial hardship. Social and cultural accessibility must also be considered, since factors such as language, age, gender, ethnicity, or religion may discourage the pursuit of healthcare services. Another dimension of accessibility is spatial, which assesses the distance or travel time between the user's location and the healthcare service, potentially affecting access to care. Geographic accessibility, such as in rural, remote, or conflict zones, poses additional challenges for users. Populations in these areas must cope with unique safety threats that may further obstruct physical access. Informational accessibility represents another dimension, defined as the dissemination of health information in a manner that is accessible and understandable to all users, enabling them to benefit from it and achieve their full health potential.

Therefore, accessibility in the context of medical devices could be defined as technologies that can be used, operated, accessed, and experienced by the greatest possible number of people, considering diverse abilities, cultures, characteristics, and geographic locations. In this project, accessibility will be characterized across six dimensions: operational, economic, sociocultural, infrastructural and spatial, informational and connectivity ad data, as shown in Figure 1.

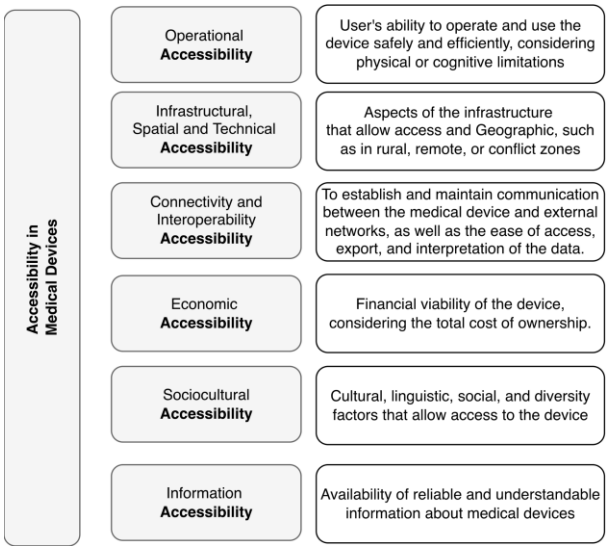

Figure 1. Dimensions of accessibility in medical devices.

Based on the proposed domains, we propose the following strategies for universal design of medical devices.

- **Operational Accessibility:** Inclusive Co-design, engaging multi stakeholders throughout the development process; Multimodal Interfaces, integration of auditory, tactile, and visual feedback; Assistive Technology Compatibility, ensuring seamless interaction with external assistive devices; Visual Ergonomics, contrast, font scaling, and display readability; Critical Action Redundancy, allowing essential tasks to be performed via multiple methods; Haptic Feedback, implementing tactile vibrations to confirm user actions or device status.
- **Economic Accessibility:** Cost-Benefit Optimization, Total Cost of Ownership Analysis, designing for essential functionality to ensure safety and reliability in resource-constrained settings; Reverse Logistics, implementing sustainable take-back and recycling programs for medical devices.
- **Infrastructure, Technical, and Spatial Accessibility:** Anthropometric Adaptation, designing for a wide range of body sizes and physical abilities; Versatile Portability, ensuring functionality across home care, clinical, remote, and conflict zone environments; Environmental Resilience, robust design protected against dust, water, humidity, and mechanical drops; Power Autonomy, ensuring device operation in areas with electrical instability or intermittent power; Spatial Optimization, compact footprints that do not obstruct emergency exit routes or clinical workflow; Universal Mounting, designing rails, brackets, and connectors compatible with international medical standards.
- **Connectivity and Interoperability Accessibility:** Standardized Protocols, adoption of interoperable communication standards (e.g., Health Level Seven International (HL7), Digital Imaging and Communications in Medicine (DICOM); Cybersecurity by Design, integrating data protection and encryption from the earliest stages of development; Workflow Integration, facilitating seamless data synchronization with Electronic Health Records (EHR); Offline-First Functionality, ensuring full device operation and local data storage during internet outages, with automated synchronization upon reconnection.
- **Informational Accessibility:** Inclusive User Manuals, providing instructions via audio-described videos, Braille, and plain language (Easy-to-Read); Digital Accessibility Compliance, ensuring apps and platforms follow global standards like Web Content Accessibility Guidelines (WCAG); Health and Digital Literacy, empowering users to understand and manage their health data effectively; Accessibility Education, promoting training and awareness regarding inclusive design in medical technology.
- **Sociocultural Accessibility:** Cultural and Linguistic Localization, adapting interfaces and terminology to local languages and social norms; Lifestyle Integration, adapting devices for daily activities, such as bathing, exercising, and social interaction; Stigma Mitigation, reducing the "clinical look" of devices through aesthetic design that resembles common accessories or clothing (Wearables); Algorithmic Equity: ensuring sensors perform accurately across different skin tones and body compositions, preventing technological bias.

VI. DISCUSSION

According to the account of one of the users in the research conducted by Story et al., "more than ramps are needed to solve the health crisis for people with disabilities" [13]. It is necessary to manage technologies focused on population diversity through user involvement. Accessibility must be incorporated into various phases of new technology, as well as in planning, acquisition, verification, training, use, decommissioning, and other activities throughout all life cycles, by applying Universal Design as a strategy and including people of all ages and abilities throughout the technology lifecycle. Universal design aims to create products in an accessible manner, in a simple and intuitive way, with equal possibilities of use [6].

In the pre-market, the lack of inclusion of user diversity in the design and validation of medical devices can result in performance issues for these devices for individuals of certain population profiles, thus perpetuating structural inequalities in healthcare. As presented by Jamali, the evidence highlights the need to include diverse patient populations in the design and validation of medical devices [29]. Biased data used in the development of medical technologies is a common cause of performance variation among racial and ethnic

groups [30]. Although design flaws may largely be unintentional, every effort should be made to identify, mitigate, and remove these biases so that they do not contribute to significant health disparities in minority groups [30]. Interdisciplinary involvement is also important in the process of incorporating new technologies, in order to ensure that the incorporated technology meets the diversity of the population.

To mitigate accessibility issues in medical devices, different stakeholders must be involved. Some actions and recommendations include: conducting continuous training to raise awareness among healthcare professionals about the accessibility issues faced by medical devices; improving regulatory requirements for devices; developing standard operating procedures considering accessibility at each stage of the technology lifecycle; and considering population diversity in the technological development process by applying the living lab methodology [31]. Therefore, developing user-centered technologies embedded in an interdisciplinary Living Lab, considering aspects of usability and accessibility, constitutes a recommended approach to explore problems and establish actions for improving the design and use of technologies.

It is necessary to develop technologies focused on population diversity through the involvement of users from the initial design process of medical equipment. Continuously carrying out training with the entire team and developing standard operating procedures are other strategies to be implemented by Clinical Engineering together with other actors in order to establish a more accessible healthcare environment. In the pre-market stage of medical device development, the lack of inclusion of user diversity in the design and validation of medical devices can result in performance problems of these devices for individuals from certain population profiles, thus perpetuating structural inequalities in medical care. As presented by Jamali, evidence highlights the need to include diverse patient populations in the design and validation of medical devices [30] as biased data used to develop medical technologies is a common root cause of performance variation between racial and ethnic groups [30]-[32].

V. Conclusion and Future Work

This work highlighted accessibility problems involving medical devices. Through a rapid review of the literature, it was found that most technologies are inaccessible and/or absent within healthcare environments. Accessibility must be embedded into the technological life cycle, beginning with the initial design phase. Furthermore, the limited existing literature on accessibility in medical devices highlights an urgent need for research that incorporates diverse user profiles to ensure inclusive medical devices. To address this evidence gap, the Institute of Biomedical Engineering (IEB-UFSC) plans to conduct future studies within its Living Lab ecosystem. By applying usability techniques, this initiative will foster an interdisciplinary and collaborative health ecosystem multi-stakeholders, engaging patients, healthcare providers, manufacturers, and clinical engineers, to identify accessibility challenges and develop strategies for more inclusive and human-centered medical devices.

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