

# Accounting for Diversity in Robot Design, Testbeds, and Safety Standardization

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Accepted: 7 February 2023 / Published online: 6 March 2023 © The Author(s) 2023

#### Abstract

Science has started highlighting the importance of integrating diversity considerations in medicine and healthcare. However, there is little research into how these considerations apply, affect, and should be integrated into concrete healthcare innovations such as rehabilitation robotics. Robot policy ecosystems are also oblivious to the vast landscape of gender identity understanding, often ignoring these considerations and failing to guide developers in integrating them to ensure they meet user needs. While this ignorance may be for the traditional heteronormative configuration of the medical, technical, and legal world, the ending result is the failure of roboticists to consider them in robot development. However, missing diversity, equity, and inclusion considerations can result in robotic systems that can compromise user safety, be discriminatory, and not respect their fundamental rights. This paper explores the impact of overlooking gender and sex considerations in robot design on users. We focus on the safety standard for personal care robots ISO 13482:2014 and zoom in on lower-limb exoskeletons. Our findings signal that ISO 13482:2014 has significant gaps concerning intersectional aspects like sex, gender, age, or health conditions and, because of that, developers are creating robot systems that, despite adherence to the standard, can still cause harm to users. In short, our observations show that robotic exoskeletons operate intimately with users' bodies, thus exemplifying how gender and medical conditions might introduce dissimilarities in human–robot interaction that, as long as they remain ignored in regulations, may compromise user safety. We conclude the article by putting forward particular recommendations to update ISO 13482:2014 to reflect better the broad diversity of users of personal care robots.

Keywords Exoskeletons  $\cdot$  Gender  $\cdot$  Diversity  $\cdot$  Intersectionality and technology  $\cdot$  Inclusive design  $\cdot$  Exclusion  $\cdot$  Access  $\cdot$  Discrimination

# 1 Introduction

Innovation in the healthcare domain promises to bring new tools with the unparalleled potential to assist people facing disabilities to become more independent and lessen the burden placed on healthcare professionals by automating particular tasks and processes. Robots can change the way healthcare is provided not only by changing the way experts provide medical assistance but also by directly supporting people during rehabilitation or letting them engage again in everyday activities [11, 106]. Those benefits are leading to the

Hadassah Drukarch h.g.drukarch@law.leidenuniv.nl growing development of robotic technologies, which increasingly feature in the most varied activities related to human care, including personal care, companionship, and rehabilitation 27.

Upper and lower-limb exoskeletons are among these technologies. Physical assistant robots help people with health impairments in their rehabilitation process, facilitating them in their journey towards regaining or becoming more independent [84]. Such devices aim to improve their standard of life by intimately intertwining with the user's limbs and supporting or enhancing their physical capabilities, enabling them to stand, walk, climb stairs and perform activities of daily living despite disabilities affecting their mobility, often even after many years of being in a wheelchair [35, 81]. As the users usually wear these devices (even *wearing the users* sometimes due to their active performance), they intertwine with them in physical and cognitive terms, typically sharing

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the control of functions between the user and the machines [69, 85].

Despite the promises of these robot developments, research suggests that the interaction between robots and humans introduces significant ethical, legal, and societal issues [34, 52, 53, 66]. Because exoskeleton users share an intimate connection, rehabilitation robots will likely impact them and their social environment considerably and in a particular manner compared to other robot types and raise specific questions about safety, responsibility, ableism, and identity [47, 60]62. One crucial yet underexplored concern is how the discussions around gender and sex arising in different communities, including the human–robot interaction one [75], impact specific robot types and how these affect users [79, 112].

In a healthcare context such as rehabilitation, gender and sex considerations are crucial because they affect individuals' health and disease differently, as well as their response to treatment [74]. However, most robots deployed in the healthcare context do not consider these aspects [19, 37, 89]. Missing these dimensions in robotics that interact with users and are used in sensitive contexts like healthcare is a huge concern, as neglecting these aspects will inevitably produce far from optimal results and harm patients, potentially generating liabilities. Although this critique is certainly not new [50], it has only recently been explored in robot design [80, 97]. Nevertheless, it remains unclear what exactly distinguishes users from one another, how such differences and accompanying risks impact robot designs, and, in our case, the rules according to these technologies are deemed safe.

While research often calls out developers and designers for failing to account for diversity, in this article, we contribute to the literature by focusing on how and to what extent existing lower limb exoskeletons, robot testbeds, regulations and standards account for users coming in different sizes, shapes, and medical conditions. More specifically, we focus on ISO 13482:2014, the leading standard setting out safety requirements for personal care robots (i.e., service robots increasing the standard of living of humans, excluding medical or industrial applications). We base our findings on observations following an extensive literature review and two weeks of experimentation within a robotic testbed developed under the H2020 EUROBENCH project for lower-limb exoskeletons in Los Madroños Hospital in Madrid (Spain).<sup>1</sup> We did those experiments in the context of PROPELLING, a Financial Support to Third Parties (FSTP) project within the H2020 EUROBENCH project, which aims to understand whether the standard regulates safety adequately and comprehensively.<sup>2</sup> Departing from these observations, we argue that the standard insufficiently accounts for differences between users, potentially compromising the safety of subjects whose features remain ignored.

Because robotic exoskeletons operate intimately with users' bodies [61], ignoring those conditions in robot design, test beds, policies, and technical standards might introduce dissimilarities in human-robot interaction, ultimately compromising user safety as it may hide important distinctions and risks excluding specific users (something highlighted theoretically by [98]. Following these lines of thought, our paper touches upon a mutual flaw in legal, engineering, and clinical settings: the accounting for gender and sex considerations in medicine, human-robot interaction, and the law. To do so, we give a first, ambitious look at existing technical challenges posed by rehabilitation robotics in the context of intersectional justice. Originating in Black feminism and Critical Race Theory, intersectionality has come to be considered "a method and a disposition, a heuristic and analytical tool" [17]. Crenshaw [23] introduced the term intersectionality in her landmark essay "Demarginalizing the Intersection of Race and Sex: A Black Feminist Critique of Antidiscrimination Doctrine, Feminist Theory, and Antiracist Politics," where she discussed the problematic consequence of the tendency to treat race and gender as mutually exclusive categories of experience and analysis and examines how this problem is sustained by a single-axis framework which has prevailed in antidiscrimination law, in feminist theory, and in antiracist politics. This analytical framework does not allow for an accurate reflection of the interaction between multiple personal characteristics and erases marginalized groups from the conceptualization, identification, and remediation of discrimination, as their experiences are not taken into consideration. As Crenshaw [23] highlights, the intersectional experience is greater than the sum of racism and sexism, and this necessarily means that in order to solve problems of exclusion, the analytical framework must be rethought and recast. Bearing this in mind, in this paper we refer to intersectionality when two or multiple personal characteristics (e.g., gender, sex, age, health condition) operate simultaneously and interact inextricably, producing distinct and specific forms of discrimination 21. Driven by this approach, we conclude the article by putting forward particular recommendations to update ISO 13482:2014 to better reflect the broad diversity of users of personal care robots.

# 2 Accounting for Diversity Through the Use of Science for Robot Policies

Wearable robots, among which exoskeletons, are emerging technologies that promise to return functionality to patients through rehabilitation or make physical work in an industry setting more efficient and safe. Thanks to their physical and cognitive intertwinement with the human body [84], these

<sup>&</sup>lt;sup>1</sup> See https://eurobench2020.eu/.

<sup>&</sup>lt;sup>2</sup> See https://www.laiden.org/projects/propelling-h2020-eurobench.

robots profoundly impact users' experience of their environment, others, and how they experience them [60]. As such, these technologies inevitably lead us to raise sometimes uncomfortable questions, some of which were recently explored in the Cost Action 16,116 on Wearable Robots for Augmentation, Assistance, or Substitution of Human Motor Functions.<sup>3</sup> For example, will exoskeletons protect workers' health or create unhealthy employee expectations. If we focus on restoring people's ability to walk, will we neglect those who cannot do so? Will wearable robots serve as a technology for the masses, or will they remain a luxury that is only accessible to the fortunate in society? If the use of an exoskeleton results in harm or injury to a user and his or her surroundings, who will be liable for such an occurrence? The human who controls the technology or the technology that has de facto caused the harm? These ethical, legal and societal concerns are significant to consider when the technology is already built and perhaps even more meaningful to raise in the development stage and process, which requires specific-sector guidance [61]. Indeed, it is at this stage that engineers and designers have the opportunity to shape future user experience with such technology if they can anticipate these reflections and incorporate them into their R&D process [99].

These reflections mostly happen within testbeds, where a prototype is tested against the requirements set by established standards. Industrial standards are generally developed to set out safety requirements that developers must comply with to ensure that robots are safe to use. Departing from those requirements, robot developers can then decide if and, if so, how they will continue the innovation process. As such, they have the choice to proceed in one of the following ways: (a) valorize if it is a fit; (b) developers may ask for clarification, permission, or assume negative if it is an unclear legal fit; (c) if there is no fit, then developers may decide to stop the innovation altogether, adapt it to the constraining legal liberty, lobby policymakers for a more permissive regulation, or ignore the recommendations and expose themselves to further liabilities [38].

The ISO 13482:2014 standard is the leading standard in service robots, i.e., robots that interact with users. It became a harmonized C-type standard under the Machinery Directive on 11 July 2014 (OJ C 220—11/07/2014). In practice, this means that the standard replaced any competing national standard, and, for those that can show compliance with the standard, the presumption of compliance was established that the safety criteria included in the corresponding EU legislation (Machinery Directive 2006/42/EC, Article 7(2)). There is no other standard beyond ISO 13482:2014 that covers specifications for design and information for use and verification and validations methods for lower-limb exoskeletons used

in everyday activities, which form the topic of study in this paper.

While this standard is the framework to follow to ensure safety compliance and eventually the CE marking that would allow the device's market entrance, the literature continuously highlights that ISO 13482:2014 fails to address user safety concerning the different human-robot interactions [5, 14, 34, 90, 92, 103]. For instance, under the project PRO-PELLING, we identified that travel instability measures do not apply to lower-limb exoskeletons, although balance loss can cause falls among older adults (ISO 13482:2014 Annex A.1 Hazard item 59). Collisions with safety-related objects, other robots, fragile objects, walls, and unmovable barriers such as stairs or walls also seem not to concern exoskeletons (ISO 13482:2014 Annex A.1 Hazard item 62–63). However, it is not hard to imagine that while wandering around with an exoskeleton, one may encounter obstacles in the way, especially in indoor environments. Cognitive hazards that may affect the user's psychological state, such as periods of confusion or the fear of falling (FoF), may affect user safety. However, these risks remain primarily underexplored, potentially because of the traditional understanding of safety, which refers to physical matters only [70]. On top of that, the standard lacks safeguards for specific categories of users, such as children, pregnant women, and older adults (as highlighted in the introduction of ISO 13482:2014). However, recognizing individuals' unique characteristics and providing adequate safeguards is essential for not only wearable robots' correct functioning but also for ensuring user safety and universal access [18, 36, 63, 67, 98, 113].

Though this may not be easily achieved, many disciplines support the narrative that integrating gender and sex factors in research makes better science [40, 95, 101]. However, while efforts are being taken in this direction [30, 44, 48] the EU policy only recently started compiling a comprehensive and cohesive framework for integrating diversity and inclusion in research and innovation. The European Commission assembled an expert group on Gendered Innovations in 2011 to address this problem under the framework program Horizon Europe. In 2013, the group issued a report entitled Gendered Innovations: How gender analysis contributes to research that was revised in 2020 [31]. The policy report furnishes investigators and designers with methodological mechanisms for analyzing sex, gender, and intersectionality in different clusters and missions, such as health, AI, and robotics, and others like climate change. Horizon 2020 was the first Framework program to set gender as an overarching matter concerning research and innovation. As one can imagine, these efforts take time to have an impact in practices and it is no surprise that other pieces of regulation, including private standards and regulation, have not been adapted to this public mandate [33].

<sup>&</sup>lt;sup>3</sup> See https://wearablerobots.eu/

This means that current standards and regulations do not frame technology development accurately and do not adequately capture all the issues technology poses, especially in light of diversity, equity, and inclusion, which ends with users being exposed to hazards that fall off the radar, and their rights being at stake. This mismatch between robot and regulatory framing is because the regulatory landscape for these devices include technology-neutral regulations, which impede their actual application to specific cases [13]. Also, codes of conduct for robot developers are on the rise, but they usually guide robot task performance more than how human action behind the technology should act [46]. Finally, the myriad of new regulatory measures, among which trustworthy ethical guidelines such as the ones from the High-Level Expert Group on AI [51] confuse the industry's traditional risk assessments and compliance mechanisms. That is because they lack the necessary empirical grounding to inform researchers, designers, and developers' practices, and consequently they fail to give appropriate guidance to robot developers, who often face the task of developing design measures to make robots fit those abstract values [72, 77, 94]. Beyond these complications, these regulations are not evidence-based and thus fail to adequately inform researchers, designers, and developers' practices [28]. Under this uncertainty and confusion, it is usual that both regulators, developers, and users, know what needs to be done to ensure user safety [38].

However, the difficulty of crafting fitting policies for new technologies should not be underestimated. For technologies such as assistive robotics, there may be insufficient or nonexistent data on risks and hazards, and it may be difficult to predict how the technology will evolve, including its impacts [76, 109]. The problem reaches far beyond this lack of sufficient information for lower-limb exoskeletons. The consequent risk is that products are certified as safe and released into the market, while they can be unsafe [8]. The lack of methods for collecting and using data for improving standards and policies limits these devices' safety levels and, consequently, puts users at risk [15]. Moreover, the ISO/TR 23,482–1:2020 technical report acknowledges that testing methods for care robots "have not been implemented or evaluated broadly." By affirming this, ISO reveals that although there may be standards for testbeds, these are not validated even, thereby questioning the validity and efficacy of the certifications based on those tests.

Reflections on the proper functioning of (robotic) systems usually occur in testing beds, where a robot is confronted with safety requirements of established standards [2, 110]. At PROPELLING, however, we believe these reflections could also help improve regulations, establish new safety requirements, reformulate existing criteria, or abandon specific provisions [15], as already started in Japan via the Tokku Zones [111]. However, what is currently lacking is a tool to link emerging technology to regulation and vice versa [38]. In this context, and bearing in mind that information can help estimate risks and harms, equip regulators with better means to understand novel technologies and help standard makers establish proper redressing mechanisms to safeguard the safety and other rights of users that the FSTP PROPELLING financed by the H2020 Eurobench project was born.<sup>4</sup>

PROPELLING stands for "Pushing forward RObot develoPmEnt for LawmakING" and investigates to what extent robot testing facilities can be used to advance robot regulation [15]. PROPELLING uses the EUROBENCH testing facilities, protocols, and data to frame emerging robotic technologies. To this end, PROPELLING focuses on a specific use case, that of lower-limb exoskeletons, in the context of the ISO 13482:2014 standard.

#### 3 Methods

The H2020 EUROBENCH FSTP PROPELLING systematically sought to appraise safety gaps in regulations for lower-limb robotic exoskeletons. In particular, the goal was to identify areas for improvement in the ISO 13482:2014 standard that addresses safety concerns regarding service robots used for personal care. We conducted a literature review and identified regulatory gaps and legal inconsistencies to realize this objective. We built upon the recent work from the H2020 Cost Action 16,116 on Wearable Robots that mapped some of the central ethical, legal, and societal issues arising from the deployment of exoskeletons in society [60, 61, 62]. We completed this work with other literature in this realm [5, 34, 92, 103] and complemented these findings through a practical exploration of (some of) the identified limitations in the standard through two weeks of experimentation in the testbeds created by the H2020 EUROBENCH project in Hospital Los Madronos in Madrid.

The H2020 EUROBENCH project allowed the different FSTP projects to use an exoskeleton platform to conduct the experiments. The one available in the facilities was the Exo-H3 exoskeleton from the startup Technaid (see Fig. 1). The EUROBENCH project also provided FSTPs with two volunteers to do the experiments. The FSTP could complement that number by recruiting volunteers. Below, we explain the goals and aims of the experiments.

#### 3.1 First Week of Experimentation

The first week of experimentation aimed to tackle three types of regulatory issues. The first set of experiments focused on the fear of falling (FoF) with an exoskeleton and aimed to

<sup>&</sup>lt;sup>4</sup> See https://www.universiteitleiden.nl/en/research/research-projects/ law/propelling.



**Fig. 1** Exo-H3 will be the device with which PROPELLING carries out its experiments (The EUROBENCH Project has made Technaid's Exo-H3 exoskeleton available for testing at their facilities. The Exo-H3 is the third version of Technaid's lower limbs robotic exoskeleton. Because it has been designed as a research platform, it can be adapted to fit differences in users' height and width while being compatible with a range of control algorithms. It thus allows applying the findings to a variety of robots on the market or under development. For more information, *see* https://www.technaid.com/landing-exo-h3.)

determine to what extent a user that has not walked on an exoskeleton before is afraid of it and how such perception and fright could lead to a safety concern, instability or increased heart rate. The ultimate goal is to understand whether FoF and its involved risks should be included as a safety hazard within ISO 13482:2014. It also aimed at collecting empirical evidence to model the spiral of adaptation to lower-limb exoskeletons. To this end, PROPELLING assessed users' experience while wearing the exoskeleton and their ability to keep balance during pushes.

The second set of experiments focused on expanding the knowledge on protective stops and graceful collapsing. PRO-PELLING's objective was to specify the most suitable area to locate the red buttons triggering protective stops. PRO-PELLING also aims at defining in which scenarios protective stops should be activated and how to restart the exoskeleton after they have been triggered. The project described experiments determining users' stability in sitting-to-stand motion regarding these latter objectives.

The third set of experiments focused on instability due to a collision. Here, PROPELLING sought to specify whether instability due to the collision with an object or an animal should be included as a specific hazard in ISO 13482:2014 for lower-limb exoskeletons. It thus compared users' ability to keep balance and recover from pushes with and without having a lower-limb exoskeleton over their bodies to understand the need to include such a hazard that only exists for person carrier robots now.

Through these experiments, we aimed to answer the following research questions:

- Would the button's location in an unreachable part affect user acceptability, perceptibility, functionality and stress while wearing the exoskeleton?
- Would initiating a protective stop and graceful collapsing in scenarios with low control of gait stability increase the risk of falling?
- Would restarting an exoskeleton in different stages of a sit to stand movement decrease the user's stability?

During the first week of experimentation, PROPELLING followed the EXPERIENCE protocol developed under a previous H2020 EUROBENCH FSTP project.<sup>5</sup> Under this protocol, subjects walk assembled to the exoskeleton on a treadmill for around 6 min. The parameters evaluated are the subjects' heart, respiration rate, galvanic skin response, and heart rate variability. The goal is to extract different performance indicators using a method based on fuzzy logic approaches [102]. For our research most relevant are 'stress,' i.e., the situation of strain because of the perception of unfavorable scenarios, and 'energy expenditure,' i.e., the amount of energy necessary to walk with the device fastened. This protocol also involved a multi-factor questionnaire (H2020 EUROBENCH's multi-factor questionnaire), which builds upon the 'Unified Theory of Acceptance and Use of Technology' (UTAUT) [105] and applies considerations specific to the use of exoskeletons 82. The questionnaire includes four factors and different sub-factors, all measured on a 7point Likert scale: 1 meant 'strongly disagree' and 7 'strongly agree.' The factors are usability, functionality, perceptibility, and acceptability 15]. The first two indicators point to the ability to achieve specific goals and the perception of the exoskeleton regarding how reliable, flexible, and easy it is to learn using it. In contrast, acceptability and perceptibility point to the willingness to introduce the device to the user's everyday activities and how it influences the user's emotions. The sub-factors vary, including the perception of safety, perception of control over one's body, and satisfaction levels while using the exoskeleton.

In addition, we developed and conducted pre- and post-test questionnaires<sup>6</sup> with the subjects involved in the experiments we executed. These questionnaires aimed to obtain a more nuanced perspective of how users appraised their experience before interacting with the exoskeleton device and how they felt while they took part in the experiment connected to it.

<sup>5</sup> See https://github.com/eurobench/eurobench\_protocol.

- Pre-test questionnaire.
- Post-test questionnaire:
  - BENCH Protocol.
  - EUROBENCH and UDBenchmarking subproject Protocol.

<sup>&</sup>lt;sup>6</sup> Please find below the questionnaires used during week 1 of experimentation:

We analyzed the resulting performance indicators, considering what we observed during the tests and the outcomes of our surveys, and compared the results. Our current findings are based on three subjects. The first subject was a woman between 18 and 35 years old, weighing between 65 and 80 kg, and the second was a man between 70 and 75 years old, weighing between 70 and 90 kg. The third subject was a man between 45 and 60 years old, weighing 70–90 kg. The second subject has a disability that prevents him from walking. The subject reported having suffered a blood flow accident on the brain, resulting in one of his legs being paralyzed. As a result, he has been using a wheelchair for approximately eight years. Because of these factors, he is typically a person that could primarily benefit from the support offered by lower-limb exoskeletons in his everyday activities.

Although the other two subjects could stand and walk without the assistance of any device, they are also potential users of a lower-limb exoskeleton, mainly if it is a robot used to engage in everyday activities like walking in the house or climbing stairs. Since our goal was to understand how the exoskeleton device adapts to specific individuals given their particular physical traits, we wanted to have a representation of different sexes, ages, and health conditions. Despite being three subjects, involving three subjects with significantly different physical traits thus facilitated us in obtaining detailed observations on their experience while interacting with the device and how their unique attributes impacted the outcomes. Following the first week of experimentation, it became clear that future research on this topic should establish specific trends among categories of people involving a larger group of subjects to ensure adequate representability of the involved categories of people. This remark was taken into account during the second week of experimentation, as is elaborated in the following section.

#### 3.2 Second Week of Experimentation

The second week of experimentation aimed to understand better and clarify the safety-related hazards and implications, both physically and psychologically [91], concerning protective stops in the context of ISO 13482:2014. The literature and the first week's findings (in detail in the next section) of experimentation at the EUROBENCH facilities indicated that ISO 13482:2014 notably lacks detailed guidelines on protective stops and graceful collapsing mechanisms, or does it determine what should be done once a fall has occurred or is unavoidable. These stopping functions allow 'an orderly cessation of motion for safeguarding purposes' (ISO 13482:2014). However, exoskeleton robots work closely with users, and such a stop puts in danger the user wearing the robot, e.g., if the robot stops amidst operation climbing stairs or before a slope. As such, the standard falls short in guiding, more specifically, how the initiation, the duration, and the continuation following activation of such stop mechanisms may impact the user. Building upon these findings and using EUROBENCH's facilities and databases to this end, we decided to narrow down the focus of our experiment for our second week of testing to understand better and clarify:

- Under what conditions and circumstances protective stop and graceful collapsing mechanisms may (not) be activated;
- The physical and psychological implications perceived by users following the activation of a protective or emergency stop mechanisms;
- The extent to which time affects users' physical and psychological safety following the activation of protective or emergency stop mechanisms;
- The (a) actions to be taken after the protective stop and/or graceful collapsing mechanisms have been triggered and (b) whether these actions ensure user safety while wearing the exoskeleton; and
- The user experiences prior, during, and following the activation of protective stop and/or graceful collapsing mechanisms.

From the available EUROBENCH scenarios and the different parameters we wanted to cover, we chose to perform the following protocols<sup>7</sup>:

- Sit-to-Stand, Stand-to-Sit (BENCH Protocol): Sit-tostand (STS) is essential for assessing dynamic balance and lower limb coordination. STS help evaluate the implementation of lower-limb exoskeletons for aid and humanoid robots that emulate human movement. These protocols and the associated performance indicators aim to assess and standardize the STS gesture in healthy and non-healthy individuals, human/exoskeleton systems, and humanoid robots; and
- Ascending/descending slopes (EUROBENCH and UDBenchmarking subproject Protocol): The stability of bipedal locomotion is challenged when walking on an inclined surface. Changes in surface orientation require adequate adaptation to the new situation and therefore require enhanced fore-aft and lateral stability control. The gait stability of people using wearable robotic assistive devices can be quantified by assessing the control of gait stability and foot placement strategies.

<sup>&</sup>lt;sup>7</sup> The following information has been extracted from the "Description of the available benchmarking scenarios' available in the website of the H2020 Eurobench. http://eurobench2020.eu/wp-content/uploads/ 2020/09/EUROBENCH-benchmarking-scenarios-description\_v2.pdf; For the purposes of this paper we chose only those protocols that generated results relevant to the H3 exoskeleton.

These protocols were executed in combination with activating the protective stop via the tablet device accompanying the exoskeleton device, after which the protocol execution resumed. Subjects knew that the pushbutton would be triggered, but they did not know when or how. Executing these protocols helped us understand to what extent protective stop and graceful collapsing mechanisms call safety-related hazards and implications that need more attention and better detailing in regulation. More specifically, gaining a better insight in this regard was essential in light of our aim to investigate regulatory issues associated with protective stop and graceful collapsing mechanisms as identified in ISO 13482:2014 during our literature review.

In line with the first week of experimentation, we developed and conducted pre- and post-test questionnaires with the subjects involved in the experiments we executed. While the pre-test questionnaire measured the user's general assessment of exoskeletons and protective stops, the post-test questionnaire gathered information on users' experiences prior, during, and following exoskeleton use, particularly regarding the activation of protective stop and graceful collapsing mechanisms. Through this questionnaire, we sought to uncover users' opinions about the circumstances under which protective stops should (or should not) be activated and also the necessary safeguards to ensure user safety while using the exoskeleton, including when protective stops and emergency stops are activated (Fig. 2).

The subjects included stagiaires, master students, and researchers directly or indirectly involved in the H2020 Eurobench activities. Some participants were physiotherapy students interested in robot therapies. Here too, we analyzed the resulting performance indicators considering what we observed during the tests and the outcomes of our surveys and compared the results. During the second week of testing, we included different demographic questions geared toward understanding a bit more the diversity of our sample. In that sense, we asked our participants to identify their sex (understood as the sex assigned at birth, being male, female, intersex) and their gender (understood as their inner understanding of their gender identity), which play a major role in general but also in science [9, 24, 26, 41, 74, 87, 96]. The subjects were evenly spread in terms of sex-8 subjects reported to be male and eight subjects reported to be female. While most subjects identified with their sex assigned at birth, one subject reported being non-binary concerning their gender (Fig. 2):

While all the subjects answered the pre-test questionnaire, out of the 16 subjects, three subjects could not participate in the experiments for diversity and inclusion barriers (and thus did not conduct the experiment nor did they fill out the posttest questionnaire):

- Male subject identified as male with large physical completion: subject 7 had a large physical build and could not fit the exoskeleton: he was too big for it in terms of shoulders, back, and abdomen measurements.
- Female subject identified as non-binary with large breast region: subject 12 appeared to have 'average' measurements of shoulder width, wrist span, and knee height. However, one measurement not considered in the protocols nor in the exoskeleton design—breast size—presented an impediment to the subject wearing the exoskeleton. Her trunk was short (46 cm), and the breast area was too large for the exoskeleton to fit her and close properly. Other female subjects with similar breast sizes but larger trunks could fit the exoskeleton by putting the breast over the exoskeleton trunk to close appropriately. Not having the data from this subject means that our current article does not contain information over the experience that non-binary users have over exoskeletons.
- Female subject identified as female with small physical completion: Although sufficiently tall (160 cm), to fit the exoskeleton, subject 2 had a very small physical completion. Consequently the exoskeleton would not fit her body properly—she would slip through it -, and she was not able to take part in the experiments.

Whereas the first week of experimentation focused on gaining insights on the safety-related aspects of exoskeletons from a diverse group of subjects—male, female, and disabled persons (3 in total) -, the second week of testing focused on gaining more in-depth insights into the exoskeleton safetyrelated aspects by increasing the number of subjects involved in the envisioned experiments. During the second testing week, 13 subjects participated in PROPELLING's experiments using the H3 exoskeleton. The subjects included a wide variety of bodies, shapes, and sizes, as the following data shows:

# 4 Findings: Diversity Observations Concerning Lower-Limb Exoskeletons

Our efforts culminated in finding a wide array of areas for improvement, particularly concerning the role of psychological factors [91], gender and intersectionality considerations, and protective stops that play a crucial role in ensuring user safety [61, 70].

Diversity, inclusion, and intersectional considerations have been identified in the literature as potential access and discriminatory problems for 'non-average' body sizes, genders, and pediatric populations [18, 36, 42, 54, 98]. Persons differ considerably in size and body form, so accommodating robots to each potential user is a complicated task, yet there seems to be no alternative to embracing complexity and



Fig. 2 Subjects' reported sex and gender (Please, note that different scholars are pointing to many more gender identities, which we did not account for them all)

spurring developers to construct suitable alternatives. During our two weeks of experimentation, we came to a set of striking observations in this regard, which suggest that gender, sex, ableism, and age, and how these aspects intersect in each specific user, are not yet accounted for in exoskeleton design and ISO 13482:2014. Unfortunately, some observations already suggest that fitting specific types of users is not a premise for manufacturers but instead reflects preconceptions unsuitable for technologies assembled with each body [60], 62, 97, 98. The following subsections highlight some of these observations:

## 4.1 Intersectional Differences Such as Sex, Gender, Age, and Health Condition May be a Barrier in Exoskeleton Access and Usage

In general, more research is needed to understand the role diversity considerations play in exoskeleton development and safety. As a result of our findings, the lack of diversity and inclusion considerations manifest in the exoskeleton design, in the testing facilities configuration, in the standards governing these devices, and in the perceptions of the users. In general, the measurements to create lower-limb exoskeletons are typically femur size and hip width. However, our findings suggest that since lower-limb exoskeleton technology usually includes trunk support, they should account for other measurements to account for the biological differences between men and women. In particular, such measurements dot not do justice to female populations in two different ways:

- Women's pelvises are different from male and there are indications that current exoskeletons distress women in that respect;
- Women have breasts and an adjustable device is insufficient to accommodate this body part.

Not accounting for these fundamental differences may, at least, bother, if not harm, women. In this respect, exoskeletons should be re-designed considering these aspects, as mere adjustments will not do. A well-known example is bicycles for women: men created different frames to accommodate women's clothes, but they did not meet the wants of their anatomical differences until years later.<sup>8</sup>

During our experiments, diversity considerations prevented us from achieving our goals concerning expanding the knowledge on FoF and protective stop knowledge. The female subject in the first week had a poorer experience while connected to the exoskeleton than a male (and healthy) subject due to her body shape. Moreover, concerning the second subject, we observed that the exoskeleton and the testbed were not adequately prepared to accommodate his specific health-related characteristics and limitations. In line with these observations, the second week of experimentation confirmed that-depending on body shape and size-not all subjects could use the exoskeleton as envisioned or at all (see Table 1). More specifically, the diversity and inclusion barriers we noted during the weeks of experimentation include the ones described in Sect. 3.2 (male subject identified as male with large physical completion, Female subject identified as non-binary with large breast region; and female subject identified as female with small physical completion) and:

• Male subject with a health condition: 'non-healthy' subject could wear the exoskeleton even his large complexion, but could not do the experiments because the exoskeleton was not strong enough to support his condition. Moreover, the testbed largely lacked safeguards to ensure the user's robot-mediated task performance was safe.

Moreover, in line with what we noted during the first week of testing concerning female subjects, the device presented several remarkable aspects more generally. For instance, the device would operate while making bizarre sounds (indicating that the device did not fit the female subject's body correctly). The device proved to be extremely uncomfortable for female subjects with a wider hip and breast area, causing

<sup>&</sup>lt;sup>8</sup> See https://www.terrybicycles.com/About-Us.

Parameter (value in cm)	Subject number												
	1	2	3	4	5	6	7	8	9	10	11	12	13
Body height	167	160	183	174	174	170	181	181	166	173	167	168	171
Foot length	26.5	25.5	29	28	29	27	32	29	27	26	28	26	26.5
Shoulder height	139	132	152	144	147	143	147	155	135	139	136	141	140
Shoulder width	35	34	43	35	39	33	49	40	36	32	40	38	38
Elbow span	86	173	82	78	85	77	89	99	86	80	85	85	80
Arm span	132	120	148.5	133	138.5	125	182	181	165	161	174	132	133
Wrist span	170	156	187.5	171	177	157	144	147.5	131	127	135	163	165
Hip height	89	83	90	97	101	96	94	102	90	98	88	95	97.5
Hip width	25	30	34	29	26	28	28	29	23.5	27	25	25	30
Knee height	50	46.5	55	49	55	46	55	54	47	51	44	43	50
Ankle height	7.5	7.5	10.8	10	9	8	9	8	7	10	10	6	7

Table 1 Overview subjects and measurements second week of experimentation

pain at times (on which we elaborate more below). This is strongly in line with what we concluded following the first week of testing, namely that the device does not (sufficiently) account for the needs of female users.

Given our two weeks of findings, still unknown is how other intersectional aspects such as age, sexual orientation, race, or even religion and the interplay between them could play a role in influencing exoskeleton design. Research suggests that human morphology depends on factors such as age and nutrition [100]. Recent studies also indicate that racial considerations play a role. For instance, Edwards et al. [29] show that Chinese hips have significant differences compared to other racial groups: they present "more shallow and narrow acetabular sockets, reduced femoral head coverage, smaller femoral head diameter, and a lesser angle of alignment between the femoral neck and shaft" [29]. These findings indicate that race may play a role when determining the hip width and that this may have ulterior consequences on exoskeleton fitness and safety. Our research confirms the need for a more profound intersectional approach to exoskeleton research [98]. To our knowledge, no studies report the impact that reported gender has on exoskeleton experience and safety, this time being the first that one exoskeleton-related experiment includes non-binary subjects.

## 4.2 Adjustable Exoskeletons May Not Suffice for Accounting for Sex and Gender Differences

Based on observing two volunteers of different sex walking with an exoskeleton and a combination of performance indicators during the first week of experimentation, our findings indicate that women may experience being assembled to a robot differently in a way that goes beyond the mere adjustability of the device to different body size. There are different explanations for what we found. On the one hand, the device was not designed to fit a woman's body—despite the fact that the robot was adaptable to different sizes and shapes. On the other hand, there might be essential differences between men and women regarding control over one's own body, although ISO 13482:2014 does not account for these differences.

Our first findings were found on the stress levels, calculated based on the subject's heart rate, galvanic skin response, and respiration rate. The indicators show that the female subject experienced the highest possible stress levels shortly after starting the experiment. The subject's levels of energy expenditure also stayed at their maximum from the start and throughout the test. These levels were higher than those of the male subject. Indeed, the latter subject did not expend much energy or was as stressed as the woman user. The findings thus suggest that walking with the exoskeleton might be significantly more stressful and tiresome for women than for men. Our findings coincide with what the female subject reported in the pre- and post-test surveys. Although the female subject reported that she was not afraid of falling while connected to the exoskeleton in the pre-test questionnaire, she said the contrary after walking with the device. Notably, she highlighted the possibility of losing control of her gait, that the exoskeleton was too heavy for her, and that she would not be able to overpower it.

In line with those findings, the results of the multi-factor questionnaire indicate that the female subject disagreed that the exoskeleton features facilitated the performance of her tasks and could help her perform different functions. She also disagreed that the device was reliable and strongly disagreed that it was satisfactory to use. In contrast, the male subject agreed that the device was both functional and flexible enough to assist in performing other tasks and held a neutral view concerning the device's reliability and level of satisfaction. These results might suggest that women may be less confident to walk with a lower-limb exoskeleton and might be afraid of engaging in different activities while wearing the device. Still, no studies on exoskeletons have looked into these aspects on a large scale. At the same time, the lack of satisfaction on the part of the female subject while walking with the exoskeleton might also induce feelings of stress and anxiety, potentially increasing the FoF [78]. Based on previous correlations between anxiety and risk of falling [49], these observations could suggest that experienced anxiety and lack of ability to perform tasks of their daily living due to the use of an exoskeleton might present a higher risk of falling and predict future falls while wearing an exoskeleton, particularly among women [43, 49.

The findings indicate an essential difference between women and men in terms of (perceived) control over one's body. The female subject believed that she was not in control of her body while walking with the exoskeleton. This perceived lack of a sense of agency may induce FoF, as confirmed in earlier research [103]. These observations coincide with other studies pointing to a higher incidence of FoF among women. For instance, [71] reported a higher frequency among females and individuals living independently. Similarly, [83] found a higher ratio of FoF among females as compared to male participants, with previous research confirming their results [3, 43, 55, 65, 73, 114].

An alternative explanation could be that the exoskeleton did not correctly fit the female user, especially in the hip area. The device was apparently designed with a male pelvis in mind and thus was unable to sufficiently adjust to fit a woman's pelvis, which is different. That issue has also been highlighted in earlier studies which have revealed that female athletes are more susceptible to injuries of the anterior cruciate ligaments than men, owing to the difference in pelvis position [57]. These observations contrast with the technical information provided on the Exo-H3 exoskeleton, stating that the device offers the 'ability to adapt to different sizes'.<sup>9</sup> Consequently, the female subject reported that the device felt tight on her hips and caused her slight pain, even though she was not overweight and the exoskeleton was put to its maximum width capacity.

Additionally, the exoskeleton made a shrieking sound while she was walking. These circumstances could explain why the female subject was comparatively more stressed, spent more energy walking with the exoskeleton, and experienced the device differently than the male subjects, raising concerns about whether the device was about to break. These observations were not made in the case of the healthy male subject, even though he was taller and heavier than the female subject.

Based on these observations, there might be significant differences between users that cannot be accounted for by simply allowing a robotic device to be adjustable. While differences between male and female anatomy have informed the design of, for instance, bikes with proportional geometry and properly sized components for riders of different sexes, these considerations still need to be implemented in exoskeleton design.

## 4.3 Accounting for Age, Health Conditions, and Psychological Aspects in Exoskeleton Development

Before the experiment in relation to protective stops took place during the second week of experimentation, most subjects indicated that the protective stop made them feel uncomfortable. After the experiment, subjects indicated that they would be concerned with the protective stop activation under the following conditions:

- While walking (6 subjects);
- While sitting and standing (6 subjects);
- In structured scenarios (6 subjects);
- In public spaces (7 subjects);
- During social gatherings (5 subjects);
- During activities of daily living (5 subjects);
- In no situations and under no circumstances (1 subject).

The results provided here are very close to the results provided in the pre-test questionnaire when asked the same question. Regarding subjects' perception of falling risk, especially following protective stop activation, subjects generally indicated not to feel any such risk (6 subjects). In comparison, four subjects indicated to be uncertain in this regard. What we found out over the two weeks of experiments is that the particular health condition of a subject, age, and psychological aspects play a significant role in how they experience their interaction with an exoskeleton [60, 62, 91]. A review of the literature on social robots has shown that people with disabilities are portrayed as having defective abilities that the robot is called on to fix [107].

The observations we developed during the two weeks of experimentation confirm these considerations, suggesting that the particular characteristics of the involved 'nonhealthy' subject represented an enormous barrier to the successful execution of the experiments. For instance, during the first week of experimentation it was noted that half of the second subject's body was paralyzed, making it impossible to use the crutches that support the exoskeleton movement.

<sup>&</sup>lt;sup>9</sup> "EXO-H3—Technical Specifications (EN)." [Online]. Available: https://www.technaid.com/wp-content/uploads/2021/06/ Specifications-Exo-H3\_2020.pdf.

Since the second subject was a wheelchair user, the reported periods of disorientation and FoF affected his overall perception of safety and made him more vulnerable to the risk of falling while using the lower-limb exoskeleton. Furthermore, the results of the multi-factor questionnaire following the experimentation indicate that the subject believed that he would be unable to deal with simple tasks like walking with the robotic exoskeleton. The subject disagreed with the robot's usability, perceptibility, acceptability, and functionality more than any other test subject. Despite being highly motivated to use the exoskeleton, he strongly disagreed that using the lower-limb exoskeleton was comfortable and safe, indicating that he would not feel confident engaging in different activities of daily living while assembled with the device. Similarly to the female subject, he reported not feeling in control of his body while using the robot. Those findings reveal that the experience of using the exoskeleton was negative for an elderly subjects more than for younger participants. Those negative feelings might translate into anxiety, activity avoidance, and, thus, an increased FoF with the potential of actual falls occurring in the future. The subject reported finding it difficult to learn how to use the exoskeleton, whereas the other subjects held a neutral view and agreed that it was easy to use the robot. In line with this observation, it might take longer for elderly users to get used to a robotic exoskeleton. These differences may arise because the exoskeleton was designed without considering subjects' specific needs and limitations. For instance, the elderly and disabled subject complained that the device pressed on his groin, making him feel uncomfortable, and he could not follow the exoskeleton's predefined gait pattern.

Even though the subject with those conditions could be upright, walking with the device was frightening and uncomfortable. Moreover, the subject's energy expenditure and self-efficacy levels suggest a higher probability of avoiding activities of daily living or feeling more anxious, suggesting an increased FoF. In this sense, it is important to note that different investigations correlate an increased level of FoF with the risk of actually falling [43]. For instance, Delbaere et al. [25] found correlations between the avoidance of activities as a result of one's fear of performing them and the actual physical performance, muscular power, and control of the posture. Such correlations, found among elderly living in a community, suggest that activity avoidance because of fear may anticipate falls in the future. Cumming et al. 22 reached a similar conclusion by correlating subjects' self-efficacy related to falls,-i.e., how they perceived their capabilities to participate in everyday activities while avoiding falls-with falls that occurred during a set time. They concluded that those with low self-efficacy encountered a higher risk of falling [1]. The meta-analytic review of findings from previous studies [49] also suggests that clinical anxiety may be associated with future falls.

Moreover, during the second week of experimentation, age, health conditions and psychological aspects were taken as a point of departure in noting the instrumental importance of advancing the knowledge on protective stops' inner workings and their consequences on subjects in preparing the terrain for future applications. The currently available data from PROPELLING only concerns what the H2020 EUROBENCH project calls "healthy subjects." However, the experiments ought to include subjects with a particular health condition (or non-healthy subjects as named by the H2020 Eurobench project) if the technology strives to meet the needs of persons with disabilities. In this respect, including these subjects is essential, but what remains an open question is *how* and *when* they should be included and what expertise will be required to accommodate them adequately.

Based on these views, our observations suggest that elderly users, users who have a medical condition, or those who walk again after having been in a wheelchair for an extended period of time, might find it more challenging to adapt to an exoskeleton, and this may lead them to experience a higher safety risks (e.g. the risk of future falls). These observations are particularly relevant concerning exoskeleton technologies, as these technologies are meant to assist users while walking and performing activities of daily living.

## 4.4 Diversity Considerations Should be Accounted in Test Beds

During our two weeks of testing, we also observed that the testbed was not designed to accommodate unhealthy or impaired individuals. As already established during the first week of experimentation, all of the subjects received the assistance of technical experts. The technical personnel also stayed around during the tests to intervene if needed, although they did not assist the subjects. A tether would hold subjects 1 and 2 to prevent falls as an additional measure. The subjects were aware of these features before and throughout the test. However, subject 2 received further assistance from technical experts and a physiotherapist. These helped him to remain standing during the trial. His family would also stay close to provide moral support. We did this because of his medical condition, which implied that he required help to remain standing. As such, the facilities were unprepared to accommodate this subject. The second week of testing did not change this conclusion. While the facilities have been renewed and the amount of space within the facility has dramatically increased, additional safeguards and means of assistance for impaired or unhealthy individuals remain scarce.

In this vein, specific attention was also paid to the accessibility of the device to unhealthy or impaired individuals. Subjects noted that impaired subjects would generally either be unable to handle the protective stop activation of the exoskeleton or would need prior instruction. This perception is also in line with what we found during the first week of testing: the unhealthy subject could not walk with the exoskeleton. The technical personnel helped him take a few steps from the wheelchair to the treadmill, with the exoskeleton in compliant mode,—that is, following the user's gait pattern. Once the user was on the treadmill, the technical personnel set the device in active mode. The exoskeleton replicates a pre-defined gait pattern through six actuated joints in the sagittal plane. Then, the subject tried to take a step with his right foot. However, the subject reported an unusual pattern and could not continue walking. Consequently, the experiment could only be carried out with the subject standing upright and not as initially planned.

From our experiments, we understand that it is not only a matter of having the exoskeleton meet user needs but also the test bed. If the test bed cannot accommodate 'non-healthy users' and the tests cannot be performed with users with a health condition, then there is little room for understanding whether wearable robotics will be helpful in this particularly vulnerable category of users. More work should be done to understand what additional safeguards are needed to ensure the safety of operations concerning a user with a health condition wearing a lower-limb exoskeleton. Some measures could range from hooks in the ceiling or hanging from frames surrounding the device to having bars where the user could hold herself or including an airbag [108].

#### 4.5 When Standards Fail To account for Diversity

The ISO 13482:2013 standard itself leaves unanswered the question of users' unique characteristics—including height, weight, and health condition. It acknowledges this flaw by stating in its introduction the commitment to update the standard with tailored provisions for different kinds of users and specific types of robots. Moreover, it obliges developers to factor in the 'conformity to the human anatomy and its variability' when identifying hazards (ISO 13482:2014). However, it says nothing about which are the design choices needed to meet that conformity while accounting for users with different bodies.

In line with these findings, most subjects involved in the two weeks of experimentation believed that ISO standards do not include specific guidelines on different types of users, such as children, the elderly, or pregnant women. Those who believed that ISO standards establish guidelines for specific users in their framework highlighted that the aspects included were age, health status, ethnicity, physical and cognitive abilities, pregnancy status, or height and weight. Although ISO 13482:2014, for instance, stated back in 2014 that while future editions would include specific requirements for different categories of people, this reality is still to be seen [15]. In addition to the lack of requirements, those considerations are restricted to anatomy. Relatedly, ISO 13482:2014 only advises considering typical body sizes of the intended user population to ensure easy operation. It, therefore, lacks detailed provisions for people who might have diverse body shapes, ages, and health conditions, demanding specific adaptations. Other aspects such as sex or gender thus remain ignored.

In general, because ISO 13482:2014 provides no further guidance, it remains up to manufacturers to decide whether and how they should tackle the differences among end-users. That lack of requirements and data seems particularly important for wearable robots because they seamlessly intertwine their operation with users to help them perform tasks that would otherwise be impossible or difficult for them to do. This dependency challenges how users experience themselves and their bodies [10, 60, 62].

Design choices oblivious to differences between users, including intersectional aspects such as age, health condition, or gender, are likely to produce and design robots that do not fit their users [36]. ISO 13482:2014 should therefore consider any special safety requirements broadly understood as measures to avoid unacceptable harm for different types of users [70]. Otherwise, missing such considerations may contribute to having robots deemed safe because they comply with the standard (which is user-neutral) but are unsafe for different users, which at the end of the day are who should remain at all times safe. This leads to uncertainty as to the protected scope of the framework in relation to different user types and raises the question to what extent diversity and inclusion are sufficiently taken into consideration [68, 98, 112].

# 5 Including Diversity Considerations in ISO 13482:2014 on Personal Care Robots

By not including the unique characteristics and features of subjects, exoskeletons risk not serving the purpose for which they were conceived in the first place. Moreover, the conditions of the robot might be such that people with different characteristics might end up 'dis-abled' [45] from using them if their characteristics and features are not or insufficiently reflected in standardization. The various tests suggest the lack of specific device requirements for women, which may subsequently introduce safety hazards for women.

Moreover, the physical-cognitive interaction with robots highlights how certified safety and perceived safety differ from each other, which, despite not necessarily qualifying as a consideration in relation to inclusion, still reveals that users may perceive the robot and its safety differently. Perceived safety is 'the user's perception of the level of danger when interacting with a robot, and the user's comfort level during the interaction' [4]. Indeed, 'a certified robot might be considered safe objectively, but a (non-expert) user may still perceive it as unsafe or scary' [90]. Fear for the device, for example, has shown to affect the adequate performance of the device and the user. Depending on the user's condition or position, the user's perception of the device's overall safety may consequently be impacted. In a 2017 resolution, the European Parliament stressed that it is permissible for users to make use of a robot without risk or fear of physical or psychological harm.' Because exoskeletons are used in close proximity to users and physical and cognitive aspects are inevitably at play at the same time [60, 60], special attention should be paid to both sides to ensure the safety of these devices. This all reinforces the need to re-evaluate how safety is conceived of in relation to robots, especially considering advances in design safeguards and also differences among users [70].

Our observations show that a one-size-fits-all approach for protective stops may not work and that personalization strategies on top of complying with a minimum safeguard baseline may achieve better-perceived safety results. Our tests indicate that lower-limb exoskeletons might not suit the elderly, subjects with medical conditions, or those who start walking again after having been wheelchair-bound for a long(er) period. Also, women report, beyond discomfort and even hurt, higher stress levels and energy expenditure levels. These observations might suggest that some categories of users would be inclined to avoid different activities in daily life or underestimate their ability to engage in them, thus increasing their risk of falling. However, more information is needed to understand what, when, and how such personalization would increase perceived safety and certified safety levels.

Concerning those problems, ISO 13482:2014 recognizes those difficulties by stating in its introduction the need to update the standard with provisions and data on specific technologies and the varied characteristics of users interacting with them. Nevertheless, typical body sizes of the intended user population are suggested for consideration to avoid demanding postures or ensure easy operation (Clause 5.9.2.1); it lacks specific requisites for varying body shapes and sizes or introducing specific adaptations; and it does not have safety requirements to inform users of the targeted population on whether the robot fits different categories of people (Clause 5.9.2.5). It also lacks guidelines on the extent to which devices could be adjusted for safe use [7]. If the user feels discomfort, she might adjust the robot. However, it is unclear how doing that does not compromise her safety. These problems bring about uncertainties regarding the protected scope of the framework for various subjects, and challenging us to think about how good intentions are not necessarily sufficient to ensure that design processes and practices become tools for liberation and the prevention of reproduction of existing inequalities [20]. All this being said, exoskeleton safety cannot be compromised by business decisions concerning device personalization [34]. For instance, the project EXO-LEGS divided the exoskeletons based on their mobility functionalities and depending on their characteristics and capabilities [88]: (See Table 2).

However, the price of the devices could compromise safety. The deluxe version as described in the table above includes the function of uneven and slippery terrain, which is included in the other versions. Especially where a ground qualifies as "deluxe," the user's safety may be compromised while they may not be able to control the circumstances that have caused this [34]. In this respect, user safety should not depend on the device's price. On the contrary, it should be safe by design, and all exoskeletons should respect that minimum baseline. Companies should strive to ensure that perceived safety is also met and that there is no price discrimination for safety-related operations.

The tests we have conducted provide many valuable insights that, with the support of more numeric data on how intersectional aspects play a role in exoskeleton safety, could be considered as areas for improvement in ISO 13482:2014. We anticipate some of those here:

- The standard should include a clause stating that standard users shall be cautious in applying safety requirements and the hazard lists to different categories of people (e.g., women, elderly, impaired users).
- The design of the personal care robots should take into account different body anatomies, including those of women. The objective shall be to ensure proper fit and avoid uncomfortable postures, changes in position, FoF, lack of agency, and other cognitive hazards, and ensure safe and easy operation of the robot (Clause 5.9.2.1).

 Table 2 Mobility Functionalities for Basic, Standard, and Deluxe exoskeletons

Basic	Standard	Deluxe
Quiet standing Straight walking on flat ground Sit-to-stand and vice-versa Crouching with support	Basic plus: walking/turning flat ground Bending down Walk up/down stairs Stepping over objects Walking on ramps Crouching without support	Standard plus: Speed walking on flat ground Walking on uneven ground Walking on slippery ground Exercising Leg to open/close door Bio-monitoring Other support functions Navigation Alarms

- The design of the personal care robot shall take into account the body shapes of women to ensure proper fit. (cf. ISO 13482:2014 Sect. 5.9.2.1)
- Robot design should consider the unique needs of the elderly, subjects with a range of medical conditions, or those who walk with the robot after being in a wheelchair (Clause 5.9.2.1).
- The design of the testbeds should take into account the unique needs of the elderly, subjects with a range of medical conditions, or those who walk with the robot after being in a wheelchair.
- The information for use should contain a list of the range of users that could safely use the robot (Clause 5.9.2.4).
- Annex A.1 of the ISO standard should be updated with a specific list of significant hazards to particular types of users, like women and non-healthy subjects.
- Consider differences in stress and perceptibility between women and men and different categories of subjects when determining how emergency and protective stops should be provided (see ISO 13482:2014 Sect. 6.2.2.2. Emergency stop).

More research is needed to understand the role diversity considerations play in exoskeleton development and safety. These include the subjective, cultural and emotional aspects that are traditionally linked to gender stereotypes and ignored by regulation and technology but that are very much elementary to the analysis of the role ISO 13482:2014 could play in further protecting intersectionality and diversity. As a result of our findings, the lack of diversity and inclusion considerations manifest in the exoskeleton design, the testing facilities configuration, the standards governing these devices, and the perceptions of the users. Being oblivious to these considerations may give way to the development of robots that not only fall short of fitting everyone or underperform but compromise the safety of those whose features are disregarded [6, 39]. In this respect, various levels of diversity need to be met before we can say that, in this case, exoskeletons are safe to use for users (see Fig. 3).

This article has just covered three of these diversity levels, mainly how robot design, testbed configuration, and laws should be more inclusive. However, other layers are essential in ensuring these devices are safe. First, researchers and developers (including manufacturers and firms) should be equipped with multidisciplinary education since they may not be able to see the broader implications of their work otherwise. Having some educational modules on intersectionality and using the Responsible Research & Innovation framework could be an excellent start to reflect on how their practices are diverse [92]. Connected to it, and secondly, the team must also be diverse. Diversity improves group thinking and is optimal when market-fueled anxieties and time constraints are present. Having a multidisciplinary team with



Fig. 3 Levels for Diversity, Equity, and Inclusion for Robot Safety

different backgrounds but also representing different communities would help ensure all the steps have been taken, for instance, when carrying out ethical, legal, and societal aspect-related exercises [61].

With this knowledge and diversity, teams are better prepared to design robot technology that, at least, tries to account for diversity, equity, and inclusion considerations. However, these design considerations need also to be expanded and translated into the testbeds since if the testing zone where safety is being ensured does not accommodate these aspects; then there will be no possibility for developers to integrate them adequately. Therefore, developers and manufacturers will need to ensure that these facilities can account for different user categories with different unique characteristics. Finally, and potentially more time-consuming and, at times, disheartening, developers and manufacturers could join standardization activities or expert groups at the EU level to help shape the future of standards and frameworks governing robotics so the community of roboticists can benefit from safeguards and guidelines that are more straightforward and that account for all of these aspects that have ulterior consequences, including safety.

# **6** Conclusions

Robots in medical care and rehabilitation are becoming increasingly prevalent. They promise to meet patients' needs by personalizing physical and social interactions with users. However, tailoring robots to users is not only about making the robot adjustable or personalized to the users' tastes. It is also about ensuring design justice (i.e. a design theory which rethinks design processes, places marginalized groups at the center of the design process, and exploits collaborative, creative practices to to overcome exclusion challenges [20] and understanding how inclusive robot design is to interact with the user in a natural, non-discriminatory way. This article explored the role of intersectionality within (rehabilitation) robot design, testbed, and standards. Being oblivious to these considerations may give way to the development of robots that fall short of fitting everyone or underperform and compromise the safety of those whose features are disregarded [7].

This article has reported several diversity observations based on our work in the H2020 EUROBENCH FSTP PRO-PELLING project. This endeavor may be the first to explore in more detail diversity considerations highlighted in the literature in real-life robot testing zones and reported directly to exoskeleton developers and the scientific community [15]. Our observations represent a step forward in engaging in conversations with the startup Technaid and positively influence the exoskeleton device for its updated version (H-4 exoskeleton from Technaid).

Since the standard ISO 13482:2014 was developed, ISO has acknowledged the need to specify safety standards for robots and the broad range of people interacting with them, like children or the elderly, but it still failed to do so in its revision in 2020. However, in our experiments, we have observed many unique characteristics concerning female, elderly and disabled users that are safety-critical and that, if disregarded by robot designs, can cause harm to users. Moreover, our research suggests that subjects perceive rehabilitation robots and their related safety differently, something in line with previous research [90]. These findings suggest that a more holistic, user-centered approach toward robot safety should be taken. This approach and effort should understand how considerations such as gender, age, sex, and disability interconnect them in physical assistant robots and affect user safety. In our understanding, the issues that arise from those intersectional differences cannot be tackled simply by making those devices adjustable. Instead, they require an account for intersectionality considerations to the broadest extent possible, not only as an afterthought during the postdevelopment/pre-market phase but from the design phase directly, onward, and throughout each iteration of the device, also considering the testbed to ensure adequate grounds to ensure reliable, inclusive and safe technology applications. Moreover, more efforts should be made to translate these considerations into safety safeguards enshrined in standards.

Accommodating robots to each potential user is a complicated task, as it is to write more inclusive laws that account for intersectionality. However, we want to believe that there is an alternative geared toward embracing complexity and spurring developers to construct suitable alternatives and testbeds, as well as more understanding policy framing [15, 92].

Acknowledgements The authors would like to thank Carlos Calleja for his contribution to early drafts of this work. Carlos Calleja was a

research assistant to the PROPELLING project for the first months of the project and the first week of testing.

Author contribution EF-V: Conceptualization, Methodology, Investigation, Writing—Original Draft, Project administration, Project administration; Writing—Review & Editing. HD: Methodology, Investigation, Writing—Original Draft, Visualization, Writing—Review & Editing.

**Funding** This paper is part of the PROPELLING project, an FSTP that has received funding from the European Union's Horizon 2020 research and innovation program, via an Open Call issued and executed under Project EUROBENCH (Grant Agreement No. 779963). The funding institution had no role in the study design, data collection and analysis, publication decision, or manuscript preparation.

Data availability The data that support the findings is publicly available.

#### Declarations

**Conflict of interest** The authors declare that they have no conflict of interest.

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