

# The Role of Artificial Intelligence and Machine Learning in Personalizing the Control of Robotic Lower Limb Prostheses



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**Abstract** The control of robotic lower limb prostheses is shifting from a “one-size-fits-all” paradigm to highly individualized approaches. This is because artificial intelligence, and particularly machine learning, now offer powerful tools to adapt how a prosthesis behaves to the unique needs of its user. Control algorithms capable of capturing each user’s specific locomotion patterns are making the initial post-operative rehabilitation phase after having a prosthesis fitted easier, ultimately improving the quality of life and comfort of individuals with lower limb amputations. Additionally, real-time intention detection and human-in-the-loop optimization are showing a great deal of promise as data-driven methods for aligning a prosthesis’s behavior with the user’s intentions. However, significant challenges remain. Accuracy, real-time responsiveness, efficient tuning, and adaptability to the learning curve of users are all issues that still need to be addressed. Legal compliance is posing additional hurdles, as coordination between the Medical Devices Regulation and the recently passed AI Act remains unclear. This regulatory ambiguity could hinder innovation and market access for robotic prostheses. Hence, this chapter presents advanced control strategies for robotic lower limb prostheses, with a particular focus on machine learning approaches. We discuss the opportunities and challenges associated with developing the next generation of assistive control algorithms and present potential pathways toward addressing regulatory requirements given Europe’s new legislation. Our goal is to promote both innovation and compliance in today’s rapidly evolving field of prosthetic control systems.

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## 1 Introduction

The purpose of a prosthesis is to restore the functionality of a missing limb. To this end, lower limb prostheses, such as prosthetic legs, not only compensate for an amputee's loss of mobility, they can also allow a person to reintegrate into society.<sup>1</sup> However, most of the commercial limb prosthetics that are currently available are passive systems; that is, they cannot generate net positive mechanical power, unlike the biological muscles of a leg. Unfortunately, using these passive systems often results in compensatory movements that lead to secondary complications such as chronic back pain and osteoporosis.<sup>2</sup> Alternatively, robotic or powered limbs are battery-powered mechatronic devices that can inject net positive power into the gait cycle. These systems have been designed to replace a human limb by mimicking its natural movement. Most often, they incorporate sensors, actuators, and control algorithms that inject energy at the right time in the gait cycle, giving the user dynamic adaptability to different walking conditions.<sup>3</sup>

Central to the functioning of a robotic prosthesis is the control framework that governs its operation. The primary aim of a controller is to manipulate the prosthesis' movement to achieve a seamless human-robot integration.<sup>4</sup> A key advancement in this field is the potential to personalize such control strategies according to the characteristics and preferences of the individual user as this generally makes the limbs far more effective. However, setting up these personalized control frameworks requires tuning the control parameters, which often involves long experimental procedures executed and overseen by trained personnel. Usually, the control parameters are selected manually through a heuristic approach based on trial-and-error. Moreover, the experiments often rely on pre-defined one-size-fits-all profiles. Subject-specific control strategies are, by definition, not generalizable to different users. This is why the main challenges with developing a prosthetic controller relate to its adaptability and its robustness to the variability in movements across many individuals.

Despite these hurdles, in recent years, machine learning has emerged as a promising strategy to accurately detect locomotive intentions via patient-specific physiological data. Thus, personalized, systematic parameter tuning has become possible.<sup>5</sup> Machine learning also offers the potential for subject-specific yet generalizable control architectures to increase the efficacy of robotic prostheses. For example, over the past few years, researchers have developed methods to automatically tune the actuators of robotic prostheses based on key performance indicators like symmetry or metabolic effort. These methods incorporate what they call "human-in-the-loop" optimization approaches. This involves acquiring performance metrics in real time

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<sup>1</sup> Miller et al. (2019).

<sup>2</sup> Gailey (2008).

<sup>3</sup> Fagioli et al. (2024).

<sup>4</sup> Goldfarb et al. (2013).

<sup>5</sup> Gehlhar et al. (2023).

and continuously modifying the control parameters so as to optimize a defined cost function.

Technologically, these new AI techniques seemingly hold great promise for tailoring the assistance given to individual patients. Yet, from a regulatory perspective, much still needs to be determined. Starting from the very beginning, the way in which the manufacturer defines the intended purpose of an AI-driven prostheses determines which legal frameworks are even applicable. Moreover, as these highly personalized medical technologies approach commercialization, ensuring legal compliance becomes critical, particularly given the scope of the Medical Device Regulation (MDR)<sup>6</sup> and the newly passed Artificial Intelligence Act (AI Act).<sup>7</sup> For example, if the AI is framed primarily for safety, the hardware will be subject to the MDR (the physical prosthesis) while the AI Act will apply to the software (the control system). Alternatively, if the AI is intended for medical purposes, say, with the aim of alleviating a disability or compensating for an injury, both the MDR and the AI Act will apply to the whole prosthesis according to Article 2(1) of the MDR. Here, the software would be classified as “Software as a Medical Device”. This scenario presents a more complex legal landscape, as the prosthetics will need to comply with both regulatory regimes.

Thus, the aim of this chapter is to present an overview of the state-of-the-art in control strategies,<sup>8</sup> moving from the most common control methods like machine learning approaches<sup>9</sup> to the newest approaches based on human-in-the loop optimization.<sup>10</sup> Before concluding this chapter<sup>11</sup> this chapter, there will be a discussion on the preliminary outcomes of introducing AI into the field of robotic prostheses.<sup>12</sup>

## 2 Control Strategies

The control framework of robotic lower limb prostheses is often implemented as a hierarchical architecture, as illustrated in Fig. 1. A high-level controller receives information from a sensory system on the prosthesis or the subject and then tries to

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<sup>6</sup>Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and Repealing Council Directives 90/385/EEC and 93/42/EEC.

<sup>7</sup>Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 Laying down Harmonised Rules on Artificial Intelligence and Amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (Text with EEA Relevance) PE/24/2024/REV/1 OJ L, 2024/1689, 12.7.2024.

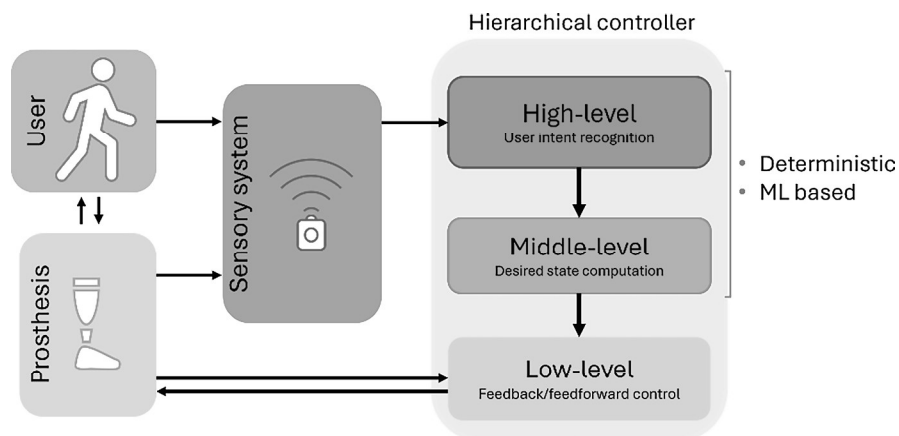
<sup>8</sup>See Sect. 2.

<sup>9</sup>See Sect. 3.

<sup>10</sup>See Sect. 4.

<sup>11</sup>See Sect. 6.

<sup>12</sup>See Sect. 5.



**Fig. 1** Hierarchical architecture of a robotic prosthesis controller. The figure illustrates the interactions between the user, the prosthesis, the sensory system, and the controller (Adapted from Tucker et al. (2015))

identify what the user wants to do—sit, stand, walk on a flat surface, ascend some stairs, and so on.<sup>13</sup> Typically, controllers are designed to identify the most common locomotion tasks, which include those just mentioned, plus walking on inclined surfaces, descending stairs, kneeling down, and others. The output from the high-level controller is then passed onto a middle-level controller, which computes the desired state of the device—this being the required position or torque to feed the device at the joint level. Generally, methods for predicting the intended locomotion task and setting the desired state of the prosthesis can be manually tuned once and then used for life. Alternatively, they can be implemented through data-driven learning techniques, such as those used in machine learning.<sup>14</sup> Lastly, a low-level controller implements the feedback and/or feedforward control loops to shift the device into the desired state.

In the next section, we focus on the high- and middle-level controllers, describing the most common strategies and newer approaches based on machine learning and human-in-the-loop optimization.

### 3 High- and Middle-Level Control Strategies

A common high-level control strategy used in commercial prostheses involves direct user input. By using a remote controller, an app, or simply by performing specific movements, the user directly sets the prosthesis into the correct control

<sup>13</sup>Tucker et al. (2015).

<sup>14</sup>Gehlhar et al. (2023).

mode for the upcoming locomotion task. While these methods can be highly accurate, they do require explicit actions from the user, resulting in an unnatural and cognitively demanding experience.<sup>15</sup>

More seamless intention decoding algorithms infer the locomotion task from signals collected by the sensory system inside the prosthesis or through sensors placed on the user's body. These methods offer a more natural integration between the prosthesis and the user, resulting in smoother locomotion. Common approaches to high-level control are based on finite-state machines, where the switch between different finite states often involves threshold-based rules applied to one or more signals from the sensory system.<sup>16</sup> Finite states could represent different fundamental activities: such as standing or walking<sup>17</sup>; different locomotion modes, such as sit-to-stand transitions,<sup>18</sup> or moving up and down stairs<sup>19</sup>; or discretely generic phases of locomotion, such as swing and stance.<sup>20</sup> Another approach to estimating the user's mode of locomotion involves using kinematic models. For example, Lenzi et al. proposed a three-segment planar model of the leg to estimate walking speed,<sup>21</sup> while Best et al. employed a double-pendulum model of human walking for the same purpose.<sup>22</sup>

Further, one of two main strategies is generally used to assess the evolution of a user's gait: a discrete segmentation algorithm or continuous phase estimation. Discrete segmentation algorithms (also referred to as FSMs) divide each locomotion activity into different subphases where specific control laws are applied. However, these algorithms may contain a large number of parameters that need to be tuned, especially as the number of subphases increases.<sup>23</sup> To simplify the control architecture, Culver et al. implemented a unified FSM with six states, defining a different sequence of states for each task.<sup>24</sup> Similarly, Tran et al. segmented different tasks into the same set of states.<sup>25</sup> Some studies have implemented adaptability—for example, using FSMs with varying thresholds to adapt to gait characteristics,<sup>26</sup> using adaptive control laws to ensure compliance with different stair heights, cadences, and gait patterns,<sup>27</sup> or using adaptability to avoid obstacles.<sup>28</sup>

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<sup>15</sup> Bhakta et al. (2020).

<sup>16</sup> Culver et al. (2018); Fluit et al. (2020).

<sup>17</sup> Flynn et al. (2018); Shultz et al. (2016).

<sup>18</sup> Li et al. (2018).

<sup>19</sup> Welker et al. (2022).

<sup>20</sup> Li et al. (2018).

<sup>21</sup> Lenzi et al. (2014).

<sup>22</sup> Best et al. (2021).

<sup>23</sup> Fluit et al. (2020).

<sup>24</sup> Culver et al. (2022).

<sup>25</sup> Tran et al. (2019).

<sup>26</sup> Katsumura et al. (2022).

<sup>27</sup> Hood et al. (2022).

<sup>28</sup> Gordon et al. (2019); Mendez et al. (2020).

As an alternative to discretely detecting gait events, it is possible to continuously estimate the progression of periodic tasks from 0 to 100% of the gait cycle. This approach is typically subject-independent, requires a lower number of parameters to be tuned with respect to FSMs, and has the ability to adapt to changes in walking speed.<sup>29</sup> A common strategy for continuous gait phase estimation involves the use of phase variables derived from the position and velocity of the residual limb's segments.<sup>30</sup> In this context, it is essential to define a phase variable that is monotonic and capable of capturing the volitional intent of the user during a locomotion task. As an example, Thatte et al. used the information from hip, knee, and ankle joints in an extended Kalman filter to estimate the gait phase and phase velocity.<sup>31</sup>

Yet another method of continuous gait phase estimation involves adaptive oscillators,<sup>32</sup> which are dynamic systems that adapt their parameters to learn a quasi-periodic signal.<sup>33</sup> Information about the mode of locomotion and gait phase estimation (whether discrete or continuous) is then translated into a desired joint state by the middle-level controller. This is typically a reference position or a reference torque. Further, the desired state can be generated through various methods, including handcrafted trajectories, lookup tables that implement bio-inspired trajectories, polynomial fitting, or model-based trajectories.

Notably, an alternative approach to prosthesis control bypasses the high-level controller, eliminating the need to explicitly detect the locomotion modes or the gait phases. This approach, referred to as "unified control", consists of applying the same control strategy regardless of the locomotion activity. Unified controllers have been developed by exploiting the idea that the quasi-stiffness of the shank remains consistent across different tasks<sup>34</sup> and terrains.<sup>35</sup> Moreover, recent studies have leveraged inertial sensors to indirectly detect the user's residual limb movement, enabling adaptation to variable speeds, inclines, and uneven terrain.<sup>36</sup> For example, Cowan et al. introduced a controller based on electromyography (EMG) to power a knee prosthesis that allowed the user to walk on flat surfaces and negotiate stairs without explicitly classifying the activity.<sup>37</sup> Similarly, Hunt et al. used EMG signals to control a prosthesis through multiple locomotion tasks using shared neural control. More specifically, by detecting activations of the flexor and extensor muscles in the subject's residual limb, the controller could predict tasks such as standing up

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<sup>29</sup> Rezazadeh et al. (2019).

<sup>30</sup> Bartlett et al. (2022); Fu et al. (2021); Heins et al. (2018); Rezazadeh et al. (2019).

<sup>31</sup> Thatte et al. (2019).

<sup>32</sup> Heins et al. (2020); Mazarini et al. (2023); Xu et al. (2020a, 2020b).

<sup>33</sup> Ronsse et al. (2013).

<sup>34</sup> Bartlett et al. (2021).

<sup>35</sup> Shultz and Goldfarb (2018).

<sup>36</sup> Sullivan et al. (2023).

<sup>37</sup> Cowan et al. (2023).

and sitting down, lunging, squatting, and walking, allowing seamless transitions between these tasks without any explicit classification.<sup>38</sup>

All this said, these pioneering approaches still typically require many thresholds and control parameters to be manually tuned by expert personnel.<sup>39</sup> Machine learning classifiers are generally trained on pre-collected datasets containing locomotion movements, which help to classify the mode of locomotion, whether this be in a user-dependent or user-independent manner. The common approaches use linear or quadratic discriminant analysis,<sup>40</sup> support vector machines,<sup>41</sup> and neural networks,<sup>42</sup> based on kinematic and kinetic information gathered from sensors onboard the prosthesis. Some classifiers even incorporate feedback from EMG sensors,<sup>43</sup> which generally improves classification accuracy at the expense of increased complexity.<sup>44</sup> Moreover, the reliability of the EMG signals strongly depends on how accurate they are and the extent to which the limb has been amputated.

User-independent classifiers usually require a large amount of data from a diverse sample population to account for intra-subject and inter-subject variability.<sup>45</sup> Moreover, the accuracy of subject-independent models is usually limited,<sup>46</sup> specifically when movement patterns have a high variability, such as is the case with amputees walking, which can be affected by different subject-specific compensatory movements like hip hiking or circumduction.<sup>47</sup> In fact, multiple studies have shown that user-independent classifiers have significantly lower accuracy than user-dependent approaches.<sup>48</sup> For example, a classifier built from linear discriminant analysis with subject-dependent geometric measurements could recognize locomotion modes with an accuracy of over 95%.<sup>49</sup> That said, although machine learning methods in user-dependent settings typically provide better accuracy, extensive model training tends to be required for each new user.<sup>50</sup>

To overcome some of the limitations of both user-dependent and user-independent decoding strategies, hybrid decoding control algorithms have been proposed as a possible solution. Hybrid algorithms not only have the advantage of providing generalizability between different users, they also typically deliver relatively high accuracy with limited training data. For example, Le et al. applied transfer learning to a

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<sup>38</sup> Hunt et al. (2021).

<sup>39</sup> Fluit et al. (2020).

<sup>40</sup> Leestma et al. (2021); Xu et al. (2018); Xu and Wang (2020).

<sup>41</sup> Mai et al. (2017).

<sup>42</sup> Bhakta et al. (2020, 2021); Xu and Wang (2019).

<sup>43</sup> Hussain et al. (2020).

<sup>44</sup> Hargrove et al. (2015).

<sup>45</sup> Lanotte et al. (2023).

<sup>46</sup> Hargrove et al. (2015).

<sup>47</sup> Murray et al. (2017).

<sup>48</sup> Bhakta et al. (2020); Hargrove et al. (2015).

<sup>49</sup> Leestma et al. (2021).

<sup>50</sup> Bhakta et al. (2020).

user-independent model, demonstrating improved accuracy when attempting to predict movement intentions with a group of new subjects.<sup>51</sup> Further, a study by Woodward et al. found that combining a user-independent classifier with real-time adaptation based on subject-dependent data produced error rates that were not significantly different from a user-dependent classifier. Thus, these authors eliminated the need for individual training sessions, while also reducing the time taken up with collecting data.<sup>52</sup>

Notably, machine learning algorithms can also be leveraged to detect both discrete gait events and continuous gait estimation. Additionally, machine learning techniques have also recently emerged that allow the control parameters to be tuned automatically. Moreover, neural networks,<sup>53</sup> fuzzy logic,<sup>54</sup> and online reinforcement learning<sup>55</sup> have all been used to iteratively tune a model's control parameters in real-time so as to reduce errors between the measured and desired profiles.

#### 4 Human-in-the-Loop Optimization

The aforementioned machine learning approaches rely on two distinct processes: an offline data-driven training phase and an online testing phase. During the offline training phase, an available dataset, either user-specific or generic, is used to set the algorithm's hyperparameters and tune all control parameters. In the subsequent online testing phase, the algorithm is validated with the user wearing the prosthesis, allowing for fine adjustments. However, dividing the training and fine-tuning phases may be lengthy and not the most efficient approach for identifying the optimal control parameters to enhance specific aspects of human-robot interaction. In truth, learning processes are essential in human-robot interaction. For example, users tend to naturally adjust the features of their gait pattern while walking with a prosthetic. This includes their gait cadence, symmetry, and loading phases, which typically become more physiological as the users familiarize themselves with their new limb.<sup>56</sup> Therefore, adapting the prosthesis behavior in real-time and determining the control parameters that optimize a specific cost function during actual use could significantly improve human-robot interaction.

Approaches where training and testing are continuously performed in real-time are called human-in-the-loop optimization algorithms (see Fig. 2).<sup>57</sup> This control paradigm inherently takes into account how users adapt, familiarize themselves, and

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<sup>51</sup> Le et al. (2022).

<sup>52</sup> Woodward et al. (2022).

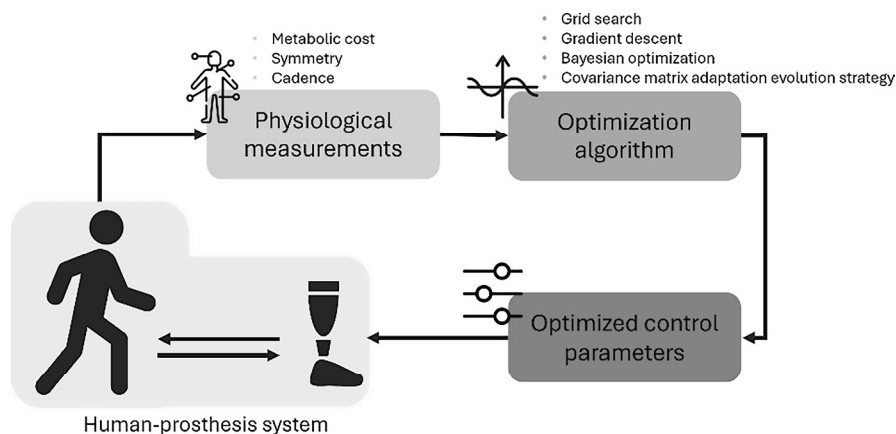
<sup>53</sup> Li et al. (2022).

<sup>54</sup> Huang et al. (2016).

<sup>55</sup> Wen et al. (2020).

<sup>56</sup> Huang et al. (2021); Poggensee and Collins (2021).

<sup>57</sup> Ding et al. (2018); Kim et al. (2017); Zhang et al. (2017).



**Fig. 2** A typical human-in-the-loop optimization framework. By directly observing the evolution of physiological variables of the user, an optimization algorithm iteratively produces a new set of control parameters for the prosthesis to minimize a specific cost function

learn to use a device by means of either statistical techniques or machine learning methods.<sup>58</sup> Recently, this kind of approach to control has gained more interest since it can embed machine learning to process human feedback and optimize how the device functions in real time. In human-in-the-loop approaches, optimizing the algorithm ends when it converges on the minimum of a defined cost function. Usually, the cost functions of human-in-the-loop algorithms consider physiological variables, such as the metabolic cost of walking for the user,<sup>59</sup> or some kind of kinematic measure. The most popular method of assessing the metabolic cost of walking is through indirect calorimetry, which measures oxygen inflows and carbon dioxide production. From these measurements of gas exchange, the Brockway equation can produce an estimate of the instantaneous metabolic cost of the given activity—in this case, walking.<sup>60</sup> However, the metabolic cost also includes slow adaptation components and history dependence. Indeed, respiratory measurements are usually meant for long testing and steady-state conditions, and they typically need at least 3 min to stabilize. Additionally, the recordings may contain high amounts of noise, and cardiopulmonary drift can occur if the tuning takes too much time.<sup>61</sup> Most of the time, optimizing the control parameters requires more than 15 min of continuous walking. Additionally, gas exchanges are typically measured through a face mask, which may be uncomfortable for the user. Some alternatives to indirect calorimetry for estimating user effort include EMG, which can be used to measure muscle activation and heart rates. However, although heart rates can be used to estimate the

<sup>58</sup> Díaz et al. (2023).

<sup>59</sup> Zhang et al. (2017).

<sup>60</sup> Brockway (1987).

<sup>61</sup> R Koller et al. (2016).

so-called “physiological cost index” as an approximation of metabolic expenditure, it still usually takes a lengthy testing session to obtain a steady-state reading.<sup>62</sup> As such, EMG signals may provide a faster response, but their use in an unstructured environment can be problematic due to the need for long setup times as skin is prepared and electrodes are placed.

In general, cost functions related to the energy cost of walking require relatively long optimization procedures as each set of control parameters should ideally be tested for a few minutes, and testing various combinations in real time may require more than 20–30 min of continuous walking. That said, other cost functions with shorter adaptation periods can be used, such as temporal or spatial symmetry<sup>63</sup> or cadence.<sup>64</sup> Then, once a cost function is defined, it can be assessed by measuring a physiological variable. The optimal set of control parameters is typically defined by an algorithm that looks for the minimum solution to the cost function. Here, different algorithms can be used depending on the cost function’s complexity. The simplest solution is a grid search, which evaluates the cost function by iteratively changing the set of parameters through random sampling. The results are then interpolated to find a relationship between the control parameters and the observed measurements with the optimal parameters being the ones that correspond to the minimum value for the cost function. However, this approach can only be used in low-dimensionality problems. This is because performance can exponentially decrease as the number of parameters increases due to the curse of high dimensionality, which means the search will become more and more time-consuming and computationally expensive as the problem becomes more complex.

An alternative to the grid search is the gradient descent algorithm, which evaluates only a subset of all the possible solutions by following the gradient of the objective function. At each step, a new set of parameters is defined by following the descending gradient of the cost function. However, this algorithm requires an explicit definition of the cost function, which is not always feasible, so it may get stuck in a local minimum and not actually provide the global optimum as is the case with non-convex problems. Human-in-the-loop optimization problems typically present a non-convex, unknown cost function to be evaluated and analytically described, due to the intrinsic intersubject variability of physiological measurements. In general, one of two well-known machine learning algorithms are used to solve non-convex optimization problems: Bayesian optimization<sup>65</sup> and covariance matrix adaptation evolution strategies (CMA-ES).<sup>66</sup> Bayesian optimization is a sequential model-based approach to finding the global maximum or minimum of an unknown objective function. It relies on surrogate models like Gaussian processes. A prior probabilistic model is set first, and then sequentially refined through

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<sup>62</sup> Brunelli et al. (2019); Chin et al. (1999); Hagberg et al. (2007).

<sup>63</sup> Feng et al. (2022); Li et al. (2023).

<sup>64</sup> Felt et al. (2015).

<sup>65</sup> Shahriari et al. (2016).

<sup>66</sup> Hansen (2006).

observations to build a posterior updated model that better reflects the objective function. A new set of candidate points (i.e., a new set of parameters) is extracted at each iteration from the updated model and tested to evaluate the system's response.

Conversely, CMA-ES is used to minimize a cost function by analyzing the covariance matrix of the prior probabilistic model set. New query points are obtained by sampling a multi-variate normal distribution. Then, a new mean and covariance matrix are estimated and updated until a stop condition is met. Moreover, different implementations of human-in-the-loop optimization have been undertaken to determine whether the metabolic cost of walking can be reduced with the majority of experiments involving ankle exoskeletons and transtibial lower limb prostheses. Here, assisting the ankle has shown promise for reducing walking effort since this is the joint generating most of the push-off power.<sup>67</sup> Along these lines, Zhang et al. conducted a study where four different parameters were tuned to provide subject-optimized torque profiles of the ankle.<sup>68</sup> Healthy subjects were able to reduce the metabolic cost of walking by an average of 24% compared to the no-torque control condition. Moreover, the walking patterns varied widely between participants; hence, the authors were able to confirm the benefits of customization, finding that this type of adaptation could also facilitate motor learning.

Feng et al. also applied human-in-the-loop optimization to control a robotic ankle-foot prosthesis while walking.<sup>69</sup> The algorithm was designed to minimize gait symmetry using the vertical ground reaction force recorded on both feet. The optimization was conducted using an instrumented treadmill, lasting only 9 mins on average. Unilateral amputees were able to improve their gait symmetry by 21%, while also reducing the metabolic cost of walking by 9%. This work demonstrates a correlation between gait symmetry and metabolic cost, and that by changing the cost function under analysis, the control parameters can be optimized within much shorter tuning times. These studies show promising preliminary results on how human-in-the-loop approaches can tailor control strategies to the specifics of individual users, ultimately realizing the promise of personalized rehabilitation and maximizing rehabilitative outcomes.

## **5 The Legal Frameworks Governing Robotic Prostheses and Their Control Algorithms: A First Look**

The legal compliance associated with robotic lower limb prostheses will become increasingly complex in the near future, as multiple legal frameworks have come into force that each apply differently. The main legal frameworks include the

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<sup>67</sup>Sawicki et al. (2009).

<sup>68</sup>Zhang et al. (2017).

<sup>69</sup>Feng et al. (2022).

GDPR<sup>70</sup> since active lower limb prostheses collect personal and health-related data<sup>71</sup> and the MDR, which governs medical devices as defined in Article 2(1). Additionally, the AI Act outlines a very broad definition of an ‘AI system’, which refers to any:

machine-based system designed to operate with varying levels of autonomy and adaptiveness after deployment, which, for explicit or implicit objectives, infers from the input it receives how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments.<sup>72</sup>

Hence, robotic prostheses must also comply with the AI Act. These prostheses will be categorized as high-risk AI systems because machine learning and human-in-the-loop algorithms are embedded within the devices. Several legal challenges arise from the interaction between the hardware and software components of a prosthesis, which are worth examining. These are covered next; however, data protection issues are not included in the analysis despite a growing awareness of privacy and data security matters among medical device manufacturers and AI developers. Notably, the GDPR has been in force for 6 years, and EU Member States (MS) have been applying its regulations consistently. However, the same cannot be said for the MDR, which still requires implementation in certain areas despite coming into effect in 2021. Similarly, the AI Act, which took effect on August 1, 2024, is still in the early stages of application. This raises several critical compliance challenges, especially for the designers and developers of robotic prostheses.

### ***5.1 Hardware: How the MDR Applies to Regular and Custom-Made Medical Devices***

For passive prostheses, applying the rules of the MDR is relatively straightforward. The same clarity extends to robotic prostheses, particularly in terms of their hardware components. In fact, both robotic and passive lower limb prostheses fall under the category of medical devices (MD). And, as mentioned in the previous chapter, the MDR is, in essence, an EU safety law specifically focused on medical devices. According to Article 1 of the MDR, the regulation’s primary goal is to ensure that only safe and compliant medical devices are placed on the EU market and put into service.

Three key conditions must be met for the MDR to apply. First, the device must be listed within the general and extensive categories schedule outlined in Article 2(1) (including software). Second, it must serve at least one of the functions listed in that same article. For prostheses, this is reflected in the second paragraph, which

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<sup>70</sup>Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and Repealing Directive 95/46/EC (General Data Protection Regulation).

<sup>71</sup>See Sect. 2.

<sup>72</sup>See Article 3(1) of the AI Act.

defines a medical purpose as the “diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability”.<sup>73</sup> The third condition is that the manufacturer’s intended purpose must be to create a medical device as specified in implementing rule 3 of Annex VIII. This condition is particularly relevant to the software components of the device, which will be discussed in the next few sections.

Notably, the MDR is a risk-based regulation, meaning the higher the risk to human health and safety, the more stringent the compliance requirements. Medical devices are classified into four risk categories—I, IIa, IIb, and III—all of which must undergo a clinical evaluation<sup>74</sup> before being marketed and all of which must receive a conformity marking<sup>75</sup> certifying sales for the EU market. This certification is granted by a third party known as a Notified Body.<sup>76</sup> To determine the appropriate classification for a device, manufacturers must follow the rules in Article 51 and Annex VIII of the MDR, which consider factors such as whether the device is implantable. Once classified, the manufacturer must then identify the correct conformity assessment procedure by applying the general rules outlined in Article 52 in conjunction with the procedures detailed in Annexes IX, X, and XI. In general, the hardware aspects of robotic prostheses are typically classified as medium-risk (i.e., IIa) as they are considered to be therapeutic devices. This, however, means they are subject to stringent and lengthy conformity procedures.

## ***5.2 The AI Act and Prostheses Control Algorithms: A Short Overview***

The AI Act pertains to the software associated with robotic prostheses. Starting with the simplest scenario, if the control function of a robotic prosthesis is viewed solely as a means of ensuring patient safety, the algorithms embedded in a prosthetic would be regarded as safety components within a larger medical device. In such cases, the software would only need to comply with the AI Act, which specifically governs algorithms and AI systems in this context.

The main purpose of the AI Act is to ensure the safety of AI systems from both a risk management and human rights perspective.<sup>77</sup> Like the MDR, the AI Act classifies AI systems based on their risk levels. This includes prohibited practices,<sup>78</sup> high-risk systems,<sup>79</sup> and systems that fall outside these categories. In terms of the latter, a mixed regulatory regime applies, combining general principles such as AI literacy

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<sup>73</sup> Article 2(1) MDR.

<sup>74</sup> See Article 61–82 in combination with Annex XIV and XV MDR.

<sup>75</sup> See Article 20 MDR.

<sup>76</sup> See Chapter IV and Annex VII. Only class I devices do not require a NB to certify them.

<sup>77</sup> See Article 1(1) AI Act.

<sup>78</sup> See Article 5 AI Act.

<sup>79</sup> See Article 6 AI Act.

with the General Product Safety Regulation (GPSR), as inferred from Recital 166 and Article 4 of the Act. Additionally, the AI Act also addresses Large Language Models (LLMs), which are termed general purpose AI (GPAI) models.<sup>80</sup> These systems can pose systemic risks, defined as:

risks specific to the high-impact capabilities of general-purpose AI models, with significant potential to affect the Union market or to have negative impacts on public health, safety, security, fundamental rights, or society as a whole, propagated at scale across the value chain.<sup>81</sup>

The key distinction between GPAI models that pose a systemic risk and those that do not lies in whether or not the system requires scrutiny by the newly created AI Office or any other surveillance systems put in place by the EU's MS, whose regulatory regimes generally align with the risk categories mentioned earlier. More detailed information on systemic and non-systemic GPAI is available in Articles 51-56 of the AI Act.

Regarding the control algorithms, the AI Act considers this software to be high-risk for the simple fact that it is embedded in a certified medical device.<sup>82</sup> Moreover, the field of application sits within a closed list of EU-regulated disciplines specified in Annex I of the AI Act. Markedly, Point 11 directly mentions the MDR, which means that the algorithms installed in robotic prostheses need to adhere to the general principles of AI literacy outlined in Article 4. AI literacy involves ensuring that those people who need to work with an AI system are aware of its potential risks, intended purposes, and proper implementation.<sup>83</sup> Key obligations include making transparent, well-documented choices regarding data governance,<sup>84</sup> ensuring human oversight,<sup>85</sup> and creating robust AI systems with strong cybersecurity measures.<sup>86</sup>

Thus, the AI Act not only protects fundamental rights but is also a product safety regulation based on risk assessment. It requires AI providers to create a quality management system, fulfill record-keeping obligations<sup>87</sup> and draft technical documentation,<sup>88</sup> which needs to be shared both with competent EU and State authorities and with those implementing or using the AI system. Moreover, as stated in the MDR, Notified Bodies must be consulted before marketing high-risk AI systems.<sup>89</sup>

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<sup>80</sup> Article 4(63) AI Act; (Bommasani et al., 2022).

<sup>81</sup> Article 3(65) AI Act.

<sup>82</sup> Article 6(1) AI Act.

<sup>83</sup> See Article 4 and Article 3(56) AI Act. The complete list of fundamental principles to follow for high-risk AI systems is outlined in Sect. 2, Chapter III of the AI Act, while a more complete list of high-risk AI provider duties can be found in Sect. 3 of the same chapter.

<sup>84</sup> See Article 10 AI Act.

<sup>85</sup> See Article 14 AI Act.

<sup>86</sup> See Article 15 AI Act.

<sup>87</sup> See Article 12 AI Act.

<sup>88</sup> See Article 11 AI Act.

<sup>89</sup> See Chapter III Section IV AI Act.

### 5.3 *Open Questions: Will Prostheses Equipped with AI Be Considered Medical Devices?*

In Sects. 2–4 the control algorithms were considered as primarily serving a safety role without directly fulfilling a medical purpose.

However, if these algorithms have a medical purpose, they are likely to be classified as Software as a Medical Device (SaMD). When dealing with SaMD, the MDR applies the same rules to software as it does to medical devices, especially Article 2.1 MDR.<sup>90</sup> Additionally, Annex VIII of the MDR provides guidelines for attributing a risk class to the software. Hence, if the software is part of the device, or the software drives or influences the device’s behavior, it will share the same risk class as the hardware.<sup>91</sup> Alternatively, if the software works independently, it will have its own class of risk.<sup>92</sup> Rule 11 further specifies the corresponding risk class based on the software’s function, and all risk classes can apply to any SaMD. Determining whether some piece of software qualifies as an SaMD is extremely challenging. Therefore, in 2019, the Medical Devices Coordination Group (MDCG) issued a guidance to help manufacturers and regulators make this distinction.<sup>93</sup> This group is a cohort of experts formed under Article 103 of the MDR that acts under the supervision of the EU Commission.<sup>94</sup>

Since the medical purpose of robotic prostheses is the “alleviation of, or compensation for, an injury or disability” and since the software drives the device, the embedded software is likely to take on its own class of risk. Simultaneously, the AI Act would apply, as any AI system used in an MD must comply with these regulations. However, to streamline the regulation process, Article 8 of the AI Act introduces the principle of complementarity. It states that when an AI system operates within an EU-regulated field, compliance should first be based on the existing regulations, and only the AI-specific requirements should be applied. In this case, in addition to MDR compliance, AI-specific rules, such as the principle of AI literacy, must be integrated. However, the application of the complementarity principle for SaMD presents complexities. For example, one key challenge lies in aligning the MDR’s requirement for a quality management system (Annex IX) with the AI Act’s quality management obligations. Additionally, while Article 29 of the AI Act suggests that MDR Notified Bodies may also manage AI certification, clear guidance from the MDCG and the AI Office is essential. Also, manufacturers of SaMDs face significant legal uncertainty, making it crucial to establish precise instructions to ensure compliance with both frameworks.

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<sup>90</sup> See *supra* the subsection Hardware: How the MDR applies to regular and custom-made medical devices.

<sup>91</sup> See Rule 3.3, Annex VIII MDR.

<sup>92</sup> See Rule 3.3, Annex VIII MDR, second part.

<sup>93</sup> Medical Device Coordination Group Document (2019).

<sup>94</sup> [https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/medical-device-coordination-group-working-groups\\_en](https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/medical-device-coordination-group-working-groups_en).

Several factors can influence whether an AI provider or manufacturer classifies robotic prostheses control algorithms as a safety component or as SaMD. In two landmark rulings, *Brain Products v. Biosemi VOF and Others* (2012)<sup>95</sup> and *Snitem v. Philips France* (2017),<sup>96</sup> the Court of Justice of the EU (CJEU) clarified that, while an object may have a medical function, its classification as a MD depends on the intended purpose set by its manufacturer. Currently, there are no criteria to certify algorithms as medical devices, leaving the decision up to the manufacturers or AI providers to make. This ultimately means that their decisions tend to be based on R&D strategies and how they want to position the prosthetic in the market. Opting not to create a medical product can reduce initial investments, as clinical investigations or trials are not required, allowing faster market entry. Conversely, certifying a MD is a longer process but can offer greater market protection for the manufacturer.

In conclusion, achieving legal compliance for algorithms controlling robotic prostheses presents significant challenges, particularly in coordinating the MDR and AI Act. The specific approach taken by the manufacturer regarding how the control algorithm functions will lead to two different outcomes in terms of how the legislation applies. The first option involves applying the MDR solely to the hardware and the AI Act to the software, interpreting the term “control” as limited to ensuring patient safety. The second, more holistic but complex approach, requires applying both the MDR and the AI Act to the software, following the principle of complementarity. In this scenario, the software would be classified as SaMD, as the AI algorithms not only ensure patient safety but also compensate for injuries. This is the path fraught with the most uncertainty due to the lack of specific guidance available for manufacturers. Fortunately, some scholars are beginning to outline a framework for complementary compliance, which should help the manufacturers and developers navigate the coming days.<sup>97</sup>

## 6 Conclusions

There are numerous open technical challenges to developing lower limb prostheses. However, perhaps the most pressing is to design controllers that make interacting with the prosthetic natural and intuitive while maintaining overall safety and reliability. This step is a fundamental part of translating research achievements into solutions that can be applied in a clinical setting. As outlined, methods based on machine learning have the potential to improve rehabilitation outcomes by learning directly from the user. In this way, the prosthesis can effectively understand the

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<sup>95</sup> *Brain Products GmbH v. BioSemi VOF and Others*. (2012).

<sup>96</sup> *Snitem v. Philips France v. Premier Ministre and Ministre Des Affaires Sociales et de La Santé* (2017).

<sup>97</sup> Gennari (2024), pp. 451–453.

specific habits of the user, adapt their control strategy in real-time, and provide a personalized experience, ultimately increasing the adoption of robotic devices in clinical practice. These methods have been key enablers of human-in-the-loop optimization strategies, which have shown promising results in tailoring the functioning of a prosthetic device to the user.

From a legal perspective, marketing robotic prostheses seems challenging because of the current uncertainty about how to apply the MDR and AI Act rules together. If the prosthesis manufacturer is also the AI provider, they face the critical decision of determining whether the control algorithms embedded in a robotic prosthesis have a medical function. In fact, the Court of Justice of the EU has ruled that the manufacturer's intended purpose is the primary criterion for deciding whether a treatment qualifies as a medical device. This applies to both SaMD and AI-based SaMD, like the control algorithms of robotic prostheses.

If the manufacturer decides that the control function is limited to patient and device safety, compliance is relatively straightforward: the hardware must comply with the MDR, while the software would follow the AI Act. However, if they determine that the algorithms serve a medical function, the software will be considered AI-based SaMD. In this case, both the MDR and relevant AI Act provisions would apply,<sup>98</sup> making compliance more complex. Given these challenges, it is essential that the newly created AI Office and the Medical Device Coordination Group engage with stakeholders to provide clearer guidance and ensure greater legal certainty in this area.

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<sup>98</sup> See Article 8 AI Act.

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