SOLEMATE 2

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This project is a continuation of a third-year project started in Michaelmas Term 2023 under the supervision of Manus Henry and Perla Maiolino. It was originally a four-person project, however two of the members suspended studies – Jack Spiller and Alessandra French. Upon their return from suspension in Hillary 2025, Jack and Alessandra decided to continue their work on SoleMate, redesigning sections of the previous year's work where appropriate.

1. Introduction

1.1 Overview - Alessandra

Unilateral lower limb amputees face a wide range of challenges in their daily lives. Across the board, they are outperformed by their able-bodied counterparts on many gait metrics including speed [1], balance [2], [3], and efficiency [4]. These problems can be largely attributed to a lack of awareness of the prosthetic limb's position in space [5].

The human body is complex, with signals running from the brain to the limbs to control movement, and signals from the limbs to the brain to provide feedback. Together these form an efficient and robust sensorimotor loop which is vital for maintaining balance and coordination. But because current prosthetic limbs lack sensory and relay neurons to send the gathered data back to the brain, amputees are not receiving information from the prosthetic limb. As a result, they do not have a good sense of the position of the limb in space and they cannot correct their position if they start to become unbalanced, meaning that they are at greater risk of falling.

The fear of falling can cause amputees to place greater weight on the intact (non-amputated) limb than the prosthetic limb [5], [6]. This underloading of the prosthetic limb and overloading of the intact limb can lead to the development of osteoporosis in the residual (the remaining part of the amputated) limb and osteoarthritis in the intact limb in the long term [6], [7], [8]. Research suggests that interventions aimed at reducing gait asymmetry should be targeted to improve outcomes for lower limb amputees [6].

A promising solution to the problem of missing sensory feedback in lower limb amputees is to use external sensors to collect plantar (sole of the foot) pressure data and relay this information back to the amputee via stimulation of parts of the body other than where the sensors are located (heterotopic stimulation). The efficacy of this class of solutions has been demonstrated in a range of clinical studies [9], [10], [11]. This is significant as it suggests that the brain can learn to interpret signals conveying plantar pressure data that is used to stimulate locations on the body other than

the sole of prosthetic foot as originating from the prosthetic foot. Furthermore, the brain can use this information to develop a better sense of body awareness in the prosthetic limb [12].

In the following report we present our design for a device to improve the gait of unilateral lower limb amputees by providing real-time feedback from the prosthetic limb back to the brain via stimulation of the residual limb. This can restore the broken sensorimotor loop and thus improve the user's balance and gait. We call this system SoleMate.

The system consists of (1) sensor-embedded insoles that collect plantar pressure data, (2) a feedback cuff that transmits information as sensations to the residual limb, (3) a microprocessor to process and store said information, and (4) an integrated mobile application that displays gait analysis for viewing by the device user and selected clinicians.

Currently there is a lack of commercially available devices of this nature. Furthermore, we improve upon devices proposed in the literature: they usually investigate one type of feedback with an aim to convey either a sense of motion (proprioceptive feedback) or a sense of body positioning (tactile feedback). Proprioceptive feedback has shown to be useful for improving walking gait, while tactile feedback is useful for improving standing balance.

SoleMate uses both feedback types. It uses a mode-switching algorithm to identify whether a user is standing or walking and alters the form of feedback based on that – if they are standing, it provides tactile feedback (relays the location of the user's centre of pressure) and if they are walking, it provides proprioceptive feedback (relays key gait events). Moreover, the addition of an integrated mobile health application is novel and allows the user to control the device without the need for a clinician to be present, making it more viable for use in a commercial setting.

1.2 Background: The Need for Sensory Feedback – Jack

Both transtibial amputees (TTA) and transfemoral amputees (TFA), regardless of prosthetic sophistication, experience difficulties attributed to the lack of sensory information from the missing limb. Prevalent among these are increased fear and incidence of falling [13], [14], greater cognitive demand and effort for day-to-day tasks [14], [15] and compromised postural control and gait cycle [16], [17] which can lead to pathologies in the rest of the body. Amputees also experience phantom limb pain [18], [19] and reduced social activity [14], [20].

Research suggests that these problems are strongly influenced by weakened balance/balance-confidence and/or a broken sensorimotor loop [16], [20], [21], as a result of the missing

somatosensory (not from the major sensory organs) feedback. This creates space for an engineering solution – there is good evidence that these weaknesses can be improved by appropriate modes of sensory feedback [21], [22], [23] and a variety of methods exist in the literature to accomplish this. Phantom limb pain has also been shown to diminish in the presence of precisely timed somatosensory feedback [19], [24], with empirical evidence indicating that such feedback could be instrumental in prosthetic embodiment [25]. On this basis, SoleMate targets three areas for improvement: balance, gait dynamics, and embodiment.

1.3 State-of-the-Art Solutions – Jack

A broad variety of approaches to restore somatosensory feedback for upper limb amputees have been successful in medical research [14], [18], [26], [27], and many of these have been applied to lower limb prosthetics, showing improvements in stability, gait biomechanics and embodiment [21], [22], [28], [29], [30]. This includes tactile, haptic and proprioceptive feedback, all of which have proven benefits to lower limb amputees [31], [32], [33]. The tactile and proprioceptive feedback systems are typically distinct from one another, although designs to provide hybrid feedback have shown promise [34]. For rehabilitation purposes, visual or auditory feedback is sometimes supplied in tandem with somatosensory stimulus [35] to assist in learning.

1.3.1 Tactile Feedback Devices

Tactile sensory substitution involves the use of actuators on the skin to relay touch and pressure information to the user, an example being the work of Yang et al. [34] who used the intensity of sensory electrical stimulation to encode grasping force. In lower limb prosthetics the afferent information is usually plantar pressure, from which (for example) parameters affecting stability can be determined and relayed to the user. Bandwidth feedback methods (a form of error correction for the user, where stimulus is provided only when a given criterion is met) have been successful in several studies [36], often chosen in place of continuous feedback.

1.3.2 Proprioceptive Feedback Devices

The limb's principal mechanisms for detecting both exteroceptive (external to the body) and proprioceptive (body motion) changes include mechanoreceptors in the muscles, tendons and skin [27]. Vibrotactile and skin stretch actuation have performed well by encoding information as heteromodal stimulus (combinations beyond the natural mode of the targeted feedback), exploiting the remaining exteroceptors, as opposed to methods that attempt to elicit the missing sensation by direct proprioception such as by kinaesthetic illusion (e.g. tendon-vibration illusion) [27]. The

information relayed may be discrete events [28], [37], biomechanical properties (such as joint position) [35], or a guide for improving gait performance [36].

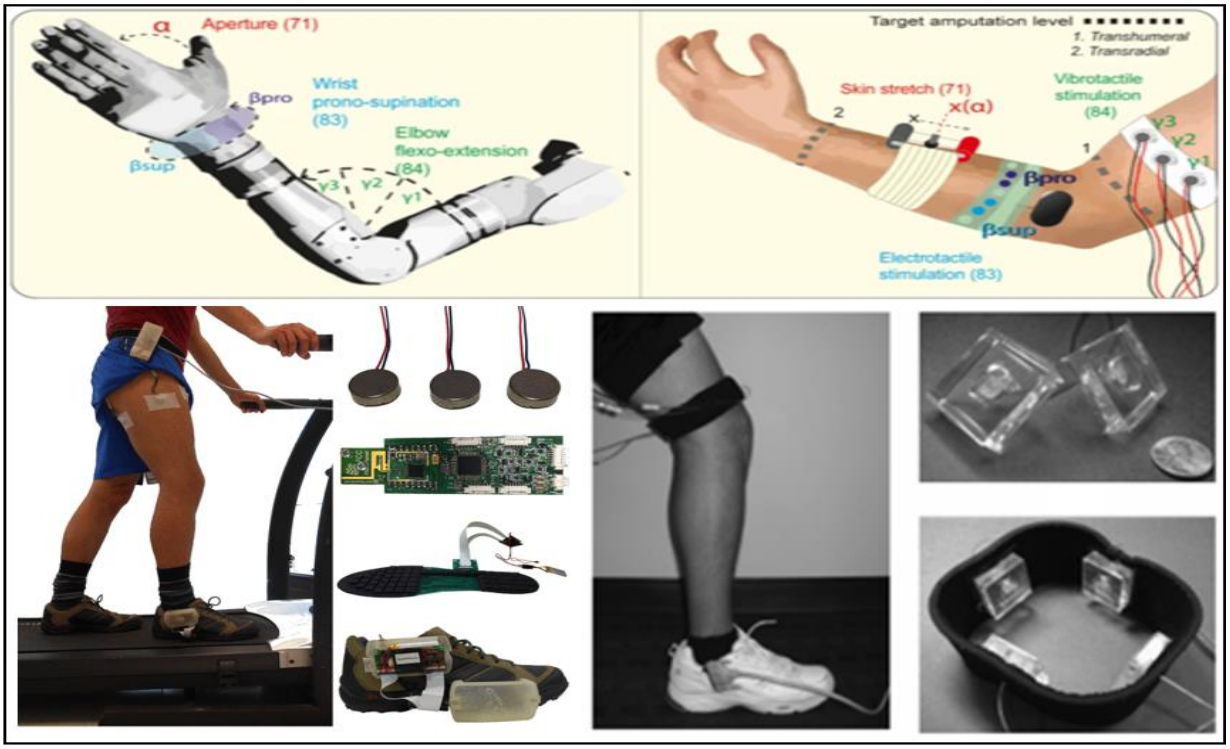


Figure 1.1: Non-invasive devices. *[27] (top) illustrates typical methods for the upper limb. [28] (left) provided proprioceptive feedback by encoding discrete gait cycle events as vibrotactile pulses. [29] (right) provided tactile feedback using pneumatic actuators.*

1.3.3 Surgical Approaches

In addition, invasive methods such as brain-computer-interfaces and subcutaneous neural stimulation have demonstrated potential for substituting somatosensory feedback, with greater potential for homotopic feedback which elicits sensation referred to the missing body part [27], [38]. By nature, a prosthetic module making use of these technologies would likely demand intensive clinical support.

1.3.4 Commercial Products

The presence of sensory feedback modules in the medical devices market is limited. An example plantar pressure monitoring device [39], sold by US digital therapeutics company Orpyx®, collects information that may be clinically relevant to treatment of diabetic peripheral neuropathy (a condition rendering the lower limbs insensate). Orpyx® also possess a patent for a device which

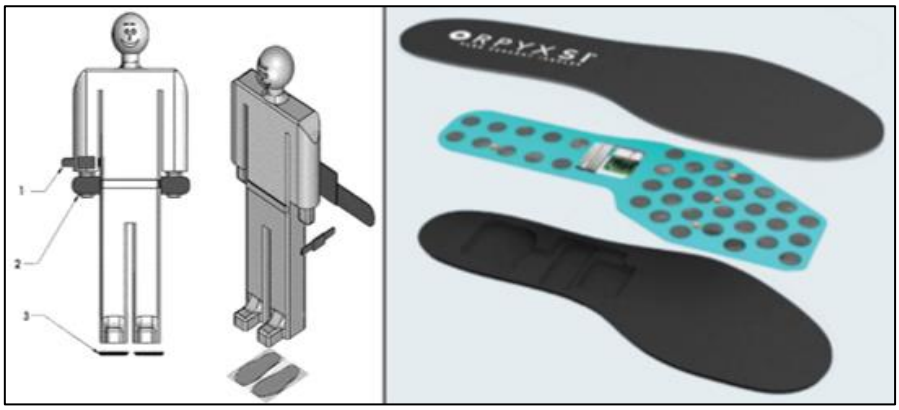


Figure 1.2: *An illustration of the sensory insole offering [39] from Orpyx® (right) and the diagram including the tactile display used in their patent [40] (left).*

delivers the plantar pressure to the user as vibrotactile feedback [40] via a tactile display positioned on the lower back. The background states that this device could be used for lower limb amputees.

2. Overview of SoleMate

2.1 The Full System – Alessandra

Our design features insoles worn in both shoes, each embedded with an array of pressure-sensitive elements. Wired connections relay the information collected by the insoles to the real-time unit of the processor. The processor is housed in a casing that clips onto the user's waistband or belt, and its real-time unit extracts salient gait features from the relayed data and determines whether the user is sitting, standing or walking. If the user is walking, identified gait events trigger the vibration of actuators in a cuff which is worn on the thigh of the residual limb. This provides proprioceptive feedback which aids mobility [28] and creates a sense of embodiment in the prosthetic limb [10], [12]. If the user is standing, the actuators alert them if the centre of pressure the prosthetic foot moves outside a specified region. As mentioned in the previous section, this is a form of tactile feedback and improves balance [33]. Finally, an integrated mobile health (mHealth) application allows the user to adjust device parameters such as actuator signal intensity and displays relevant gait parameters for self-monitoring and to aid clinical gait analysis [41]. The full design is shown in Figure 2.1; red lines indicate wired connections.

The next part of this report will detail the technical design of SoleMate: first we will describe the hardware of the system, including the sensors, controller, actuators, and the wiring between the components. Then we will describe the necessary software, including for data processing, and

actuation signal generation. Finally, we will discuss the higher-level communications and the design of the mHealth app.

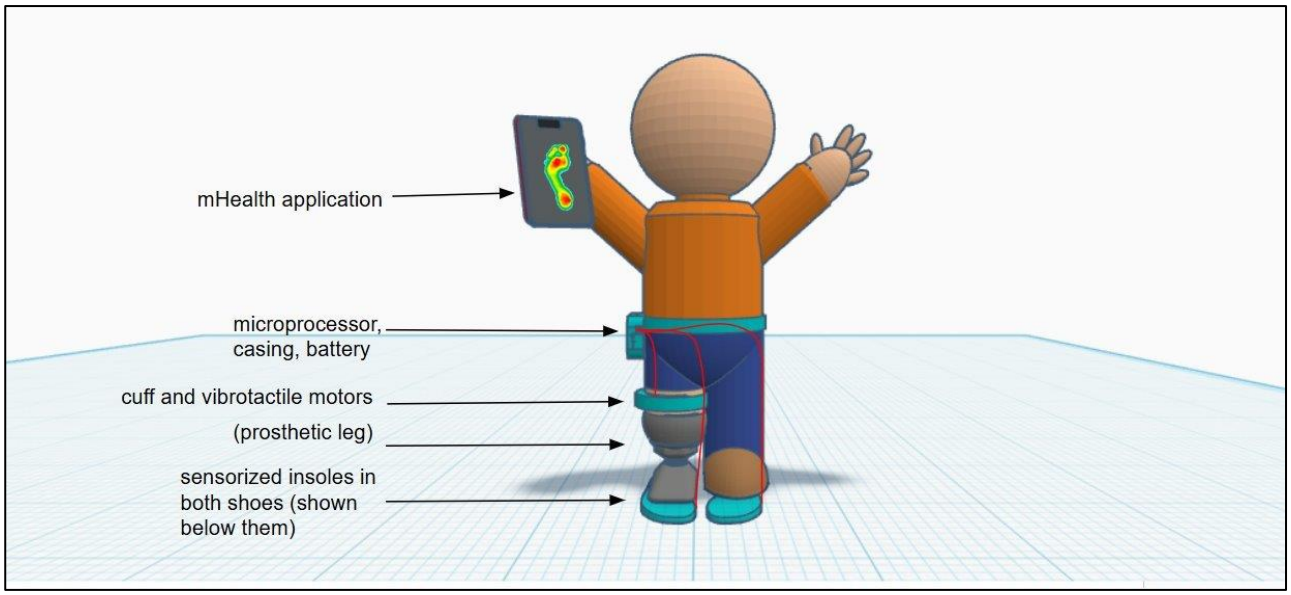


Figure 2.1: Overall system design. *Labelled perspective view of 3D CAD model of SoleMate, created by Alessandra French using Tinkercad software, with selected individual components from Thingiverse (site for sharing CAD models).*

2.2 Design Objectives - Jack

R1 - Must provide improvement to stability, gait characteristics and prosthetic embodiment.

R2 - Must reliably sense plantar pressure distribution with sufficient fidelity for actuation input.

R3 - Must not injure nor cause the user to be injured by erroneous stimulus. Must not expose user medical data during wireless communication.

R4 - Must not impede user mobility or typical activities. Stimulus obeys comfort limits supported by medical literature. Device conforms to the body.

R5 – Device will operate continuously for a sufficient period as to be useful day-to-day.

R6 – Must be suitable for intended environment (not relevant for prototype).

R7 – Device must relay both clinically useful information, accessible to relevant medical professionals, and informative statistics to the user.

R8 – Device must be simple to set up and operate; requires minimal assistance from a clinician.

R9 – The components must all have a suitable functional lifespan.

R10/11 – Prototype must indicate commercial viability, including expected cost and compliance.

3. Hardware

3.1 Sensors – Alessandra

The sensor-embedded insoles must reliably measure the user's plantar pressure distribution (PPD) with sufficient accuracy to enable the microprocessor to calculate the centre of pressure and gait phase, both of which are necessary to provide tactile and proprioceptive feedback through the cuff. However, the high variability of PPDs of lower limb amputees [42], [43] presents a challenge for standard insoles with a limited number of sensors, including those used in the previous SoleMate project. The following section describes the selection of an insole design which provides accurate measurements while complying with the microprocessor speed, wiring complexity, and cost constraints of SoleMate.

3.1.1 Number of Sensors

SoleMate must require minimal clinical assistance to set up. This will facilitate the accessibility of a commercial product. Many state-of-the-art solutions use a limited number of sensors to collect plantar pressure data [44], [45]. Often the plantar loci of these sensors are uniquely determined for each user to provide maximally useful information, thus requiring a bespoke fitting. However, deducing a user's centre of pressure and key gait events, namely heel strike, flat foot and toe-off, from limited data requires inferring an entire plantar pressure distribution which is difficult with a small number of sensors. PPDs are highly variable for several reasons – a study analysed the standing PPDs of 24 healthy young adults, and found that factors including, age, weight, gender, and surface inclination all influenced the participants' PPDs [46]. Even when instructed to stand still on level ground, individual participants exhibited constantly changing PPDs.

Furthermore, unilateral lower limb amputees have irregular PPDs compared to their able-bodied counterparts [43], [42]. A study conducted by Engsberg et al. [42] recorded the standing PPDs for transtibial amputee and able-bodied children. Each amputee participant used a Solid Ankle Cushioned Heel prosthetic foot, which has a non-articulated ankle and a rigid keel. In the able-bodied group, the children showed similar loading between their heel and forefoot, and similar loading between their left and right feet. In the transtibial amputee group, there were significant differences between the pressure distributions under the prosthetic and non-prosthetic foot. In the prosthetic foot, all of the pressure was applied by the forefoot. In the non-prosthetic foot, pressure

was applied both by the forefoot and the heel, however more of the pressure was applied by the heel. The comparison between the plantar pressure distributions can be seen in Figure 3.1.

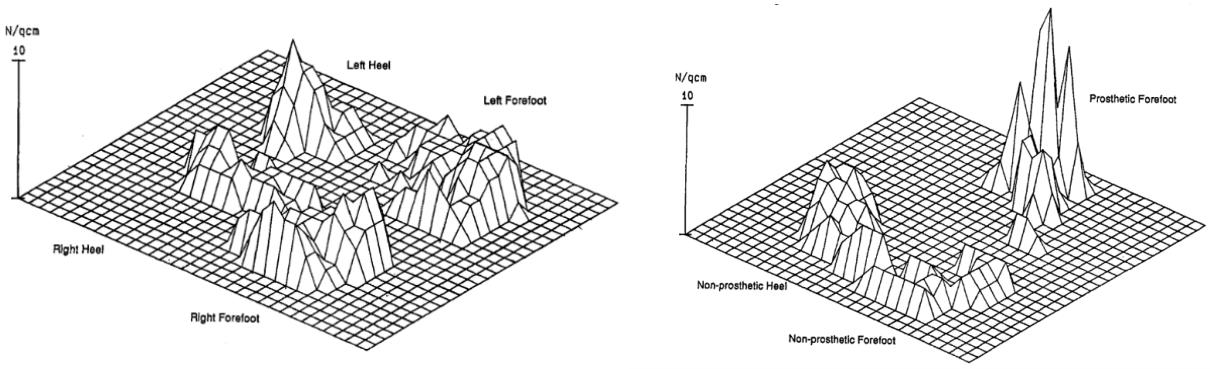


Figure 3.1: *(left) Standing PPD for and able-bodied child, (right) standing PPD for a unilateral lower limb amputee child al. [42].*

Aiordachioae et al. examined the plantar pressure distributions for adult transtibial amputees [43]. In all cases the reason for amputation was peripheral arterial disease with acute limb ischemia. Figure 3.2 shows a difference in the shape of the plantar pressure distribution between the intact and prosthetic limbs, with the PPD of the prosthetic limb exhibiting a sharper distribution, meaning that most of the pressure was concentrated in a small area.

The PPDs of the intact limbs exhibit a similar shape in both studies. However, PPDs of the prosthetic limbs are not only different from their respective intact limbs, but the PPDS of the prosthetic limbs differ between studies.

In the study conducted by Engsberg et al., the participants only applied pressure through the forefoot of the prosthesis. In contrast, in the study conducted by Aiordachioae et al., participants applied pressure both through the forefoot and heel of the prosthesis

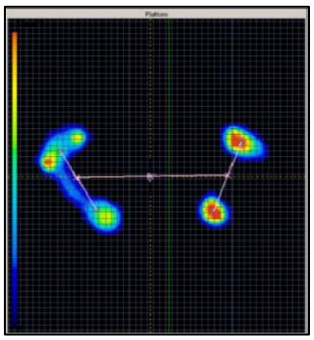


Figure 3.2: *Standing PPD for unilateral lower limb amputee adult [43].*

This provides more evidence to support the claim that the PPDs of unilateral lower limb amputees are highly variable, and may depend on the type of prosthetic, the age of the amputee, or their reason for amputation. This means that if one wishes to reliably determine the user's PPD on both feet with sufficient confidence to accurately determine gait parameters for actuation input (R2), a grid of sensors with high spatial resolution should be used in insoles for both feet. Furthermore, these sensors will improve the accuracy of the gait analysis displayed in the mHealth application (R7).

While this approach will likely increase the cost of the final product, low-cost designs for this type of sensorised insole exist in commercially available products and in academic research designs. This is important for fulfilling our goal of limiting the total cost of SoleMate (R10).

3.1.2 Overall Design

Due to our reduced team size, we have chosen to base our insole on an existing design and modify as needed.

We are primarily interested in accurately measuring centre of pressure (CoP), and vertical ground reaction force (vGRF). These are necessary for the calculation of our desired gait parameters (see section 4). Pataky [47] outlined the requirements for sensors measuring CoP and vGRF, finding that sensor sizes of 30 mm were sufficient to accurately quantify CoP [47]. However, predicting the accuracy of peak pressure and force measurements is more difficult due to the "deep dependency on the measurement context" [47]. The same study found that the minimum sensor width to achieve 90% accuracy for peak pressure measurements ranged from 1.74 mm to 17 mm and concluded that "current results cannot yield specific recommendations regarding spatial resolution" [47]. Given this uncertainty, device accuracy must be demonstrated empirically for each device. Thus, for our selection of a sensorised insole, we used independent evaluations of measurement accuracy where they were available, and the accuracies listed in the source paper or commercial website otherwise.

We have excluded all plantar pressure sensing technologies which use force sensitive plates and pedobarographic technology, due to lack of portability and prohibitively high costs. Instead, we focused on sensorised insoles. The following table analyses four existing insole designs which are either commercially available or proposed in academic research:

1. A Wireless Flexible Sensorized Insole for Gait Analysis (Crea et al.) [48]
2. F-Scan® system (Tekscan® , South Boston, MA, USA) [49]
3. A Wireless Sensory Feedback Device for Real-Time Gait Feedback and Training (Redd et al.) [50]
4. The Pedar® system (Novel® GmbH, Munich, Germany) [51]

Citations will be provided for all properties that do not come from the original source given above.

Criteria	**1.Crea et al.**	**2. F-scan®**	**3. Redd et al.**	**4. Pedar®**
Number of sensors per insole	64	64	2	99
Sampling frequency	100 Hz (oversample at 1.2 kHz, then down sample to 100 Hz)	Up to 500 Hz	1000 Hz	Up to 400 Hz
Cost	Estimated prototype cost of 200-400 USD	Minimum 99 USD / month [52]	Prototype cost of 225 USD	27,000 USD [53]
Sensor drift	Tested for long sessions, no sensor drift found	“Poor durability”, “inaccurate calibration, and poor hysteresis and creep properties” [54]	No data	No data
Comfort	Comfortable when walking for long durations	“Ultra-thin”	No data	“Highly conforming”
CoP and vGRF accuracy	Accurate CoP, vGRF error of up to 160N but “High qualitative correlation of the insole to force-plate vGRF” → capable of gait segmentation	“Overall repeatability was poor” [54]	“Unable to evaluate the centre of pressure”, does not reference vGRF	“Valid and reliable alternative to traditional force plates for assessing vGRF” [55]

The F-scan® n system does not remain accurate during repeated use, the 2-sensor system cannot provide accurate measurements of our gait parameters of interest, and the Pedar® system is prohibitively expensive.

Thus, after conducting a literature review, we have decided to use the flexible sensorised insole proposed by Crea et al. [48]. Their design features a 64-grid array of optoelectronic sensors – this technology is insensitive to changes in temperature meaning that it can be used for long durations without experiencing a drift in sensor measurements (R5, R8). Furthermore, its 64 sensors provide a spatial resolution of 10 mm – this exceeds the minimum resolution required for accurate centre of pressure (CoP) measurement, thus fulfilling R2. It is described as “low cost” [48] which aids in meeting requirement R10. Finally, it was tested by two participants who walked for long periods of time with the insoles and experienced no discomfort [48]. Its main limitation is the absolute accuracy of its vGRF measurements – its maximum error of 160N corresponds to an approximate percentage error of 17% for a person weighing 80kg. This accuracy is high enough to allow accurate gait segmentation (determination of key gait events which we require to provide proprioceptive feedback) but may require developments if used for clinical gait analysis.

3.2 Actuators – Jack

3.2.1 Type and Stimulus Parameters

Design problem: To support the new feedback scheme (see Software section) it was necessary to replace the actuators used in the previous iteration of SoleMate. Research provides a selection of suitable actuation modes for consistently perceptible stimulation of the skin [28], [33], [34], [35], which could provide sufficient information to improve stability, gait characteristics and prosthetic embodiment (as required in R1). The choice is constrained by a required interval of continuous operation (R5), a need to be comfortable and usable (R4), and the requirement of a suitable functional lifespan given the intensive use (R9). Vitally, the actuators must not be a potential hazard; malfunctions in the device software should not cause a risk of causing painful or dangerous levels of stimulation (R3).

The leading non-invasive modalities [27] in research are sensory electrical stimulation (SES), vibrotactile stimulation (VT), pneumatic actuation [29] and skin-stretch actuation.

The properties compared for satisfaction of the functional requirements were:

- **Safety** – Actuator must not injure or cause the user to be injured.

- **Comfort** – Stimulus must not be perceived as unpleasant or painful.
- **Efficiency** – Actuators must minimise power consumption.
- **Form Factor** – The overall cuff must not impede mobility, which requires that 3 actuators are sufficiently light and have the right profile to be aptly accommodated.
- **Functional Lifespan** – SoleMate should not need replacement parts too frequently. As a benchmark, prosthetic legs are typically expected to last 3-5 years [56].
- **Spatial resolution** – User must be able to accurately and immediately perceive stimulus changes at three distinct locations on the residual thigh.
- **Activation delay** – Actuators must be capable of producing perceptible stimulus changes at a temporal resolution matching the sampling rate - which is 40Hz (see Sensors section). This means the maximum acceptable activation delay is 25ms (in fact it should be shorter to accommodate delay in the controller).

Pneumatic and Skin stretch actuation

Pneumatic (balloon) actuation [29] requires a pneumatic control system. The activation delay of 100ms is also prohibitive. These disadvantages prevented further consideration of this actuation method. Skin-stretch actuators have a unique advantage in providing homomodal stimulation which matches the lost afferent pathway in the context of proprioception [27]. This provides no benefit within the chosen feedback scheme and was not considered due to the added complexity, being better suited to joint proprioception.

Somatosensory Electrical Stimulation

SES and FES (Functional Electrical Stimulation) are well represented in the present state-of-the-art. Their small form factor (7mm diameter in commercial devices [26]), high spatial resolution [27], [34] and low power requirement provide unmatched versatility resulting in their use in the more complex actuation schemes [27]. Percutaneous stimulation (i.e. FES) is reported to elicit a more natural sensation, and implanted electrodes can stimulate specific neural sites, evoking sensations in the absent limb [27], [57]. SES and TENS (an equivalent technology used for pain management) tend to exploit the body's exteroceptive capabilities – an approach that has been verified to have no ill effects with long-term use [58], [59]. A current of 0.1mA is perceptible by neural excitation of the afferent nerve fibres [57] – the myelinated nerve fibres that are most responsive, resulting in a highly localised sensation at low current, whereas higher current yields a more generalised sensation. For low currents, the stimulus can be localised to discrete conductive channels less than a millimetre in diameter [57], and in practice an electrode spacing of 20mm gives ample

detection accuracy [34]. The disadvantages of SES stem from safety and longevity considerations; SES is reported to feel unnatural, having an aversive quality for most people, resulting in a very short dynamic range (the difference between the just-noticeable-difference (JND) and pain threshold) varying between 3.5 and 7.4 for non-repetitive signals. For reference this is approximately 100000 for pressure sensation [57]. For design, the fact that small power variation can drive large perceptual changes is efficient, but potentially dangerous in the event of malfunction. A 'borderline hazardous' startle reaction was found to occur when current a factor 3 above JND was applied suddenly to the forearm [57] – substantially lower than the threshold for pain.

Vibrotactile Actuation

Experimental vibrotactile feedback devices have focused on stimulation of the cutaneous tactile receptors and in some instances the deeper proprioceptors such as muscle spindles and Golgi tendon organs [27]. Among the 4 cutaneous sensory corpuscles (rapidly adapting I/II and slowly adapting I/II [60]) it is the Merkel discs, Meissner's corpuscles and Pacinian corpuscles that respond to VT stimulation, and of these, the Pacinian corpuscles (responding to the range 60-400Hz) yield the best detection of vibration [61]. Studies differ on the exact best-detected frequency, placing it somewhere between 220Hz and 300Hz [23], [28], [61]. A major drawback of VT actuators is the poor spatial resolution due to propagation of vibrations to surrounding tissue [27], with research on VT tactor configuration [62] finding that 10mm coin motors required 8cm spacing to facilitate high (90%) recognition accuracy. A peak force of 1N has been proven apt for stimulation of the Pacinian corpuscles [28], although continuous high-powered VT actuation can be cumbersome/uncomfortable for the user. VT devices are safe; long-term vibration can cause neurovascular diseases (e.g. hand-arm vibration syndrome) but only at high intensity [63].

Final selection

Analysis of the two most suitable actuation types is summarised in the following table:

Engineering Factor	**SES**	**VT**
Min. power for accurate recognition (approximate, contextually dependent)	140mW [26]; widely varies but assume <VT	600mW [28], [62]
Min. spacing for accurate recognition	20mm [34]	80mm [62]

Short/long-term risks	Short dynamic range risks pain/hazardous startle reaction.	Neurovascular disease if high force used (long term).
Temporal resolution	20μs delay [26].	2ms delay [28]
Typical functional lifespan (approximate, based on commercial devices)	10-15 uses (typically an hour per use) [64]	100-600 hours (constant) [65]
Key:		
Unsuitable	**Passable**	**Suitable**

Two VT actuators were shortlisted for SoleMate. These were 10mm eccentric rotating mass (ERM) coin motors by Precision Microdrives®, which operated with different peak accelerations [66], [67] (2g vs 1.65g). Both devices had a small form factor, comparable to those found to be usable in research [28], [33], [62] and both fell within the intensity range shown to be effective and comfortable in the state of the art when operated between 200-240Hz.

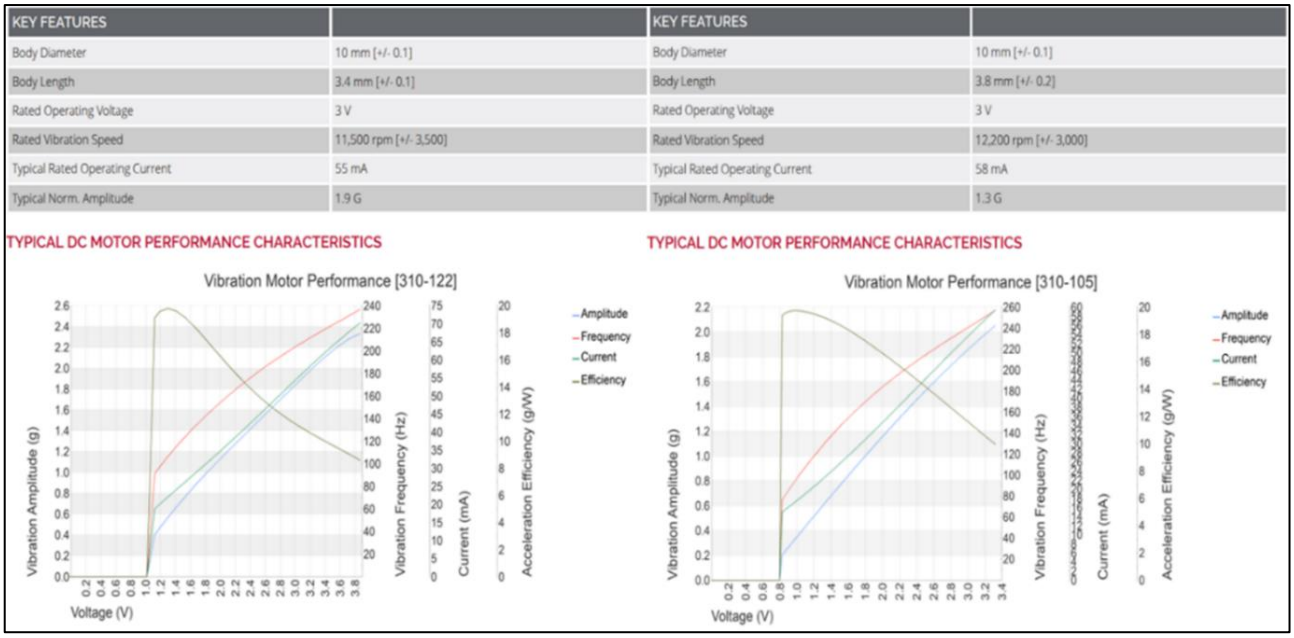


Figure 3.3: *Extracts from the datasheets of the two shortlisted Precision Microdrives® ERM coin vibration motors. The lower amplitude device (right) was selected.*

The lower intensity device was chosen to ensure comfort in static mode; the system cannot guarantee only brief intervals of stimulation so must adopt an intensity that will not become cumbersome or unpleasant [28]. It is also more efficient at 230-250Hz frequency and has a rated operating voltage that puts the frequency near 250Hz, which is another suggested most-

perceivable frequency [68], and leaves room for development if the prototype is found to be lacking perceivability. Similar motors were determined to have an activation delay of 2ms [28], easily within the acceptable limit. The anticipated lifespan (as per the manufacturer) may present an issue; however, this depends on how often the devices are activated during use, which will need to be assessed in the prototype stage. Activations in both static and dynamic mode are intended to have a short duration, so it is provisionally assumed that 600 hours of operation would not accumulate too rapidly for testing.

3.2.2 Placement

Design problem: The stimulus must be applied to a suitable location on the body such that the intended information can be accurately perceived, and it must contribute to an increased embodiment of the prosthetic.

The plurality of studies reviewed, both for the use of sensory feedback in rehabilitation and in designs for prosthetic enhancement, place the actuators either on the residual limb [21], [29] (some suggesting insertion of the actuators into the liner [28], [62]) or on the lower back [30], [35], [69]. The justification for the latter is sensitivity, surface area and consistency of the anatomy of that region among individuals [69], and both options keep the device from impeding the user's mobility [28], [69]. Placement on the residual limb delivers the feedback at a locus that most closely matches its original pathway, intuitively suiting the goal of feedback *restoration*. While this reasoning is somewhat heuristic, there is empirical evidence showing psychometric similarity between the experience of the 'rubber hand illusion (RHI)' in control and amputee participants – an RHI-like kinaesthetic illusion may be a major latent factor in prosthetic embodiment [24], so the sensory feedback should be placed to best exploit this. Additionally, research has shown that reducing intensity of phantom limb pain (PLP) is associated with greater perceived embodiment [24] and a 2023 study [18] on TTAs found that somatosensory feedback via TENS of the peripheral nerves in the residual limb can reduce PLP by up to 100%. Similar results have been produced by other studies [19]. Hence SoleMate positions the cuff on the residual limb to maximise embodiment. Other factors identified by [24] are addressed in the design as summarised below:

Factor in Prosthetic Embodiment [24]	**Influence in SoleMate**
Lower phantom limb pain	Position the cuff on the residual limb. Ensure stimulation delay is within 300ms*.
Lower residual limb pain	Ensure comfortable cuff and stimulus.

Higher mobility	Provides proprioceptive feedback.
Positive valence of residual limb stimulations	Feedback does not exceed discomfort thresholds, uses VT actuation with no perceptible delay.

*According to [70] 300ms is the maximum allowable delay to break the RHI.

Sensation in the stump skin is reduced while walking [71] and placement of motors there may aggravate existing irritation [72]. While some studies have positioned the actuators over targeted muscle groups [33], the onus has been on the user learning to recognise the information spatially encoded [28]. Hence SoleMate positions the cuff on the thigh of the amputated side, but precise positioning is left to the user's preference. A less precisely defined locus also lends itself to fulfilling the requirement of straightforward operation (R8).

Further development: This decision limits the potential users to those with sufficient residual thigh skin surface, i.e. TTAs and TFA with the amputation close to the knee. For accessibility, a lower-back or wrist mounted alternative actuator housing could be developed.

3.3 Controller – Jack

Design problem: Processing the sensor data and implementing the selected actuation scheme impose design requirements on the controller hardware. The final iteration of SoleMate will utilise a bespoke system-on-chip (SoC) which provides precisely the computing resources needed. However, performance assessment of a prototype device is necessary and the prototype iteration of SoleMate needed to allow room for enhancement. Hence an intermediate device had to be chosen, which would include the following:

Real-time processing capability. Necessary to ensure consistent timing of stimulus delivery, as delays can damage both embodiment and perception accuracy [28], [70].

Secure Bluetooth connectivity. Protection of user medical data is important for wearable medical devices. Hardware and software support for Bluetooth LESC are a necessity.

Sufficient non-volatile memory for storing gait data. Given the intended use environment for this wearable device, it is possible that SoleMate may not be able to offload clinical data to a user device for many hours. For this reason, it must have sufficient local storage.

Analogue inputs (ADC) and outputs (PWM) for sensor interfacing and actuator control. The encoding scheme requires 3 PWM outputs. More ADC inputs will aid data acquisition.

Sufficient working memory for running the data processing and actuation algorithms.

Support for machine learning which is anticipated to be necessary to enhance the mode detection and actuation algorithms of the prototype.

The table below compares four popular devices for embedded control, each with excellent development resources. The SoleMate prototype uses the BeagleBone Black (BBB) Rev C.

Function	**Relevant feature**	**BBB Rev C**	**Arduino Uno Rev 3**	**Arduino Mega 2560 Rev 3**	**Raspberry Pi 4**
Real-time processing of sensor inputs/actuator outputs	Software architecture; operating system; clock speed	1GHz AM3358 processor + 2 x 200MHz Programmable Real-time Units	16MHz ATmega328P 8-bit microcontroller (real-time)	16MHz ATmega2560 8-bit microcontroller (real-time)	1.8GHz Broadcom BCM2711 processor running Pi OS
Secure Bluetooth connectivity	Built-in devices; Bluetooth module support	Uses USB Bluetooth adapters. Software supports LESC.	Lacks hardware – other Unos available with this functionality.	Lacks hardware – additional devices required.	Built-in Bluetooth 5.0 secure communication.
Storage of gait data	On-board storage	4GB eMMC + mounting for micro-SD card (supports all SDHC 32GB)	32KB flash memory, possible to add storage (but not easily).	248KB flash memory, 4KB EEPROM, possible to add storage.	Micro-SD card (also used for OS). Can add storage via USB port.

Available PWM pins for output	Header pins	8	6	15	2 + ‘soft’ PWM for all GPIOs
Available ADCs for sampling	Built-in ADC hardware	6, 7th via modification	6	16	0
Sufficient memory for data processing	RAM	512MB DDR3 + 28KB PRU DDR3	2KB SRAM	8KB SRAM	Up to 8GB DDR4
Potential for on-board ML	OS, CPU architecture, RAM, flash storage	Debian Linux supports ML tools. Sufficient hardware.	Lacks hardware. Somewhat possible with Tiny ML kit.	Lacks hardware. Somewhat possible with Tiny ML kit.	Pi OS supports ML tools. Sufficient hardware
KEY:	Unsuitable	Passable	Suitable	Optimal	

3.4 Wiring – Alessandra

This section details the implementation of a wired connection between the sensorised insoles and the BeagleBone Black. As stated in the section 3.1: Sensors, we have chosen to use the insole design of Crea et al. [48]. This design uses a Bluetooth transmitter to send pressure data from the insoles to a remote receiver. The issue is that the Bluetooth connection is not secure, so using it to send medical data would prevent SoleMate from adhering to GDPR. Thus, we must modify their design to use a secure connection.

3.4.1 The Case for a wired connection

A schematic of Crea et al.’s sensorised insole system is shown in Figure 3.4. It comprises of a pressure-sensitive insole for data collection connected to an electronic board via flat cables. The electronic board is used for signal sampling, filtering, and calculation of gait parameters. A Bluetooth transmitter sends these parameters wirelessly to a receiver on a remote device.

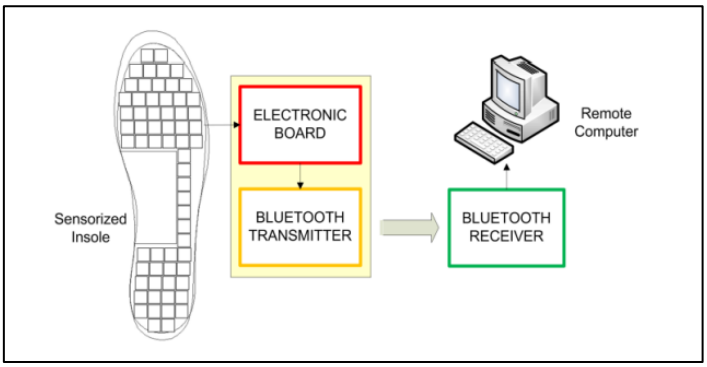


Figure 3.4: *Schematic of Crea et. al.'s sensorised insole system al [48].*

We have chosen to alter the design of Crea et al. and use a direct wired connection for data transmission from the insole to the microprocessor to avoid the following two issues with wireless communications. First, Bluetooth communications are susceptible to latency. They use the 2.4 GHz ISM spectrum band, which is used by other wireless technologies including Wi-Fi and microwaves. Thus, a wide range of other nearby devices can cause interference, leading to signal degradation and latency. This is an issue for safety-critical real-time systems such as SoleMate. Second, a wire is more secure than Bluetooth. Crea et al. do not discuss the security of their Bluetooth transmission, and the simplicity of their electronic board and transmitter means that a Bluetooth connection would not be secure without significant modifications. The wired system satisfies our requirements that the device must not expose the user's medical data, and that it must not risk user injury due to erroneous stimuli (R3) which could be caused by signal delays. (A more thorough analysis of our requirements for device data security and safety are provided in sections 6 and 7 respectively.)

3.4.2 Sampling Rate

The rate at which the microprocessor samples data from the insole must match or exceed the rate at which humans can perceive pressure changes on their skin (temporal resolution) to create an actuation signal which feels natural. This will aid in achieving our goal of maximizing prosthetic embodiment.

Humans have a mean temporal resolution of 68.74ms, and a standard deviation of 36.43ms [73]. From this we gather that approximately 68% of the population have temporal resolution in the range 32.31-105.17ms, corresponding to a required sampling frequency in the range 9.51 Hz-31.0 Hz).

Thus, our minimum requirement for sampling frequency is 30 Hz. Standard practice is to sample at a much higher rate initially, followed by low pass filtering and subsequent down sampling to improve robustness to noise. Crea et al.'s design originally samples at 1.2 kHz, then low pass filters with a cutoff frequency of 40 Hz, then downsamples to 100 Hz. We can reduce the downsampling frequency to 40 Hz while meeting our minimum requirement.

Because most humans have a temporal resolution below 40Hz, we aim for a total actuation delay less than or equal to 25ms.

Our microprocessor's PRU has a clock speed of 200 MHz, and the basic arithmetic and comparison operations we require take 1 to tens of clock cycles, meaning that the maximum computation delay is on the order of microseconds. Finally, the actuation delay is 2ms, so a maximum total delay of 25ms should be possible. We can verify this through prototype testing.

3.4.3 The wired connection

Crea et al. use flat cables to connect the insole to the electronic board. We modify their design by removing the electronic board and extending the flat cables to directly connect each insole to our microprocessor, the BeagleBone Black (BBB). The BBB has six physically accessible analogue input pins, each with a 12-bit analogue-to-digital converter (ADC) [74]. However, we have 64 analogue input channels from each insole, for a total of 128 analogue input channels to connect to the BBB. This means that it is necessary to either use multiplexers or external ADCs to enable the wired data transmission.

3.4.4 Our solution – External ADCs

SoleMate uses external ADCs to transfer data from the 128 analogue channels to the microprocessor. To control this data transfer, we use a serial connection to the microprocessor to minimize the pin count and complexity. In particular, the Serial Programming Interface (SPI) is a serial protocol that allows the BeagleBone Black to communicate with peripherals at a high speed.

The SPI supports 8 bits per word, so SoleMate uses the Texas Instruments ADS7961 8-bit 16 channel ADC. We require 8 such ADCs for the 128 analogue channels. Figure 3.5 shows a configuration that allows the BeagleBone Black SPI to drive multiple peripherals. The peripherals are connected to the same serial clock signal (SCLK) and MOSI and MISO pins, but each peripheral is connected to a different chip-enable line.

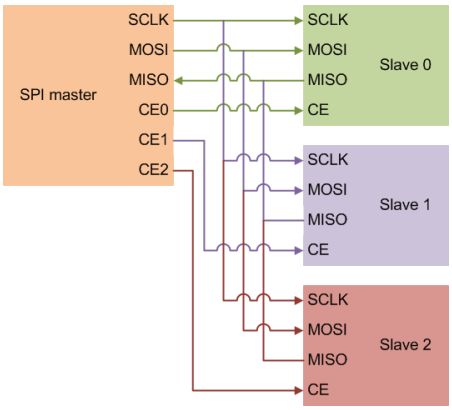


Figure 3.5: *Diagram showing BBB's SPI driving multiple peripherals [98].*

The BeagleBone Black has 2 SPI: SPI0, which is fully supported, and SPI1 – this shares pins with the HDMI interface, so we must disable that to access the second SPI. Each SPI has 2 chip-enable lines. This will allow us to connect 4 ADCs. However, we are using 8 external ADCs, so must use 4 GPIO (general-purpose input/output) pins as extra chip-enables.

Sampling and Filtering

The Nyquist criterion states that if you sample a signal with bandwidth greater than half the sampling rate, the higher frequencies will alias. This is because sampling creates additional frequency-shifted copies of the signal spectrum in the frequency domain. The solution to this is to use an analogue pre-filter before sampling to reduce the bandwidth, thus preventing aliasing.

Our chosen ADC supports sampling at 1 MSPS divided across the channels, so we can sample each of the 16 analogue channels at 1.2 kHz. Sampling at a higher initial rate followed by low pass filtering and subsequent downsampling will give better signal quality and improved robustness to noise. Given a sampling rate of 1.2 kHz, a first-order low pass filter with a 150 Hz cutoff frequency is sufficient to prevent aliasing. We must then use a second (digital) anti-aliasing low pass filter before downsampling to 40 Hz. For this, we have chosen a finite impulse response (FIR) filter to prevent phase distortion, and a cutoff frequency of 18 Hz to prevent aliasing.

3.4.5 Alternative option – Multiplexers

An alternative option is to use multiplexers. Multiplexers (muxes) are electronic devices that select one of multiple input channels to feed to a single output channel. The selection is determined by a control signal. Because of this, we can use muxes to allow the microprocessor to receive signals from all 128 analogue channels through 6 or fewer analogue input pins.

One configuration is to use 4 32-to-1 muxes, with a 5-bit control signal which is common across muxes; an alternative is to create a mux tree by cascading layers of smaller muxes.

In determining whether this is a viable option, the mux settling time is an important factor. It refers to the time taken for its analogue output to fall within a specified error band of the corresponding input signal; in our case the allowable error band is the maximum error for which the true ADC output is identical to the ADC output for the mux input signal, meaning that the error must fall within ± ½ of the least significant bit (LSB) of the ADC. The BBB uses 12-bit ADCs, meaning that it represents the analogue input signal with 2^{12} = 4096 discrete levels. A 'flip' of the LSB corresponds to 0.0244% of the full range, meaning that for the signal to have 'settled' it should be within 0.0122% of its final value. To sample at an initial frequency of 1.2 kHz, each mux would need to have a settling time of less than 1/ (1200×32) seconds, or 26.04μs.

The difficulty is that the settling time for muxes is not published data, as is depends on both the mux's own characteristics, and the impedance of the load it is connected to. It is possible that the settling time of the mux would exceed our maximum allowable time [75].

Creating mux trees would not solve this problem and would likely lead to increased signal degradation. For high-speed applications with many analogue channels such as SoleMate, using external ADCs is generally preferred.

3.5 Power Supply – Jack

Design problem: Amputees may wish to use their device for the entire working day. The battery which ensures this must also be robust enough for day-to-day use and not encumber the user, fitting onto the waistband or belt alongside the controller.

The BBB has a TI TPS65217C Power Management IC (PMIC) which is connected to four battery access pads into which connections to a battery can soldered [74]. Li-ion batteries are employed because their robust construction lends itself more to the durability and safety requirements (R3 and R6). The commercial device will use a bespoke SBC controller, so the power requirement is not readily estimated at this stage; an assessment based on the prototype will suffice to assess feasibility. The power of each component is estimated below:

Sensory Insole – The insole will use, at most, 0.54W [76] although in truth it is likely to be much lower as this figure includes power for a shoe side controller, which is circumvented in SoleMate. The datasheet [77] suggests around 50mA if the board is running as the study describes, hence

the current drawn by the sensors (of 150mA total) is less than 100mA and the power is thus at most 0.35W. Discarding the 'electronics' (Bluetooth transmitter etc) too, the power consumption is approximated here as 0.3W.

Actuators – Assume a 20% up time for the 3 vibration motors described prior. This must be determined through testing and is, for now, a worst-case approximation (consider that at a typical (5km/h) 2Hz cadence [78], each motor will give a 100ms pulse once every 500ms in dynamic mode). Each uses 0.13W when activated, drawing in total 0.078W while in use.

Controller – The BBB will draw variable power depending on the task, and the specification [74] recommends a power supply of 5V at 1.2A, from which it is assumed to run at the maximum of 6W. Note: 10W is recommended if driving high power peripherals – something which, it is assumed, SoleMate's components do constitute.

Hence, assuming an energy density of 260Wh/kg (commercially available, [79]):

$$BatteryWeight = \frac{RunHours \times (BBBPower + 0.3 \times 3 \times motorPower + 2 \times sensorPower)}{Wh\ per\ kg\ battery}$$

The prototype would require a battery weighing just over **200g** providing a total of **8 hours** use. A rotation of two batteries would be recommended if the final device were to be so energy intensive. Given that the BBB draws the largest fraction of the power, and is highly inefficient, the commercial version is expected to need a much smaller battery.

4. Software

4.1 Actuation Signal – Jack

Design problem: The overall actuation scheme of SoleMate had to be redesigned to align better with the available research. Giving the amputee meaningful and sensorimotor loop-integrable information via heterotopic, heteromodal stimulus is not simple and should be based on proven systems.

An assessment of the useful information a person can derive from artificial stimulus is paramount in the successful restoration of somatosensory feedback. SoleMate must supply sufficient information to support the intended performance improvements (requirement R1). As described in the previous section, prosthetic embodiment can be improved by provision of proprioceptive feedback, subject to some timing and location constraints. The other two of the targeted threefold improvements, stability and gait characteristics, must be dealt with by incorporating proven

actuation schemes from prior experiments. Invasive methods do not satisfy the functional requirement for ease of set up (R8) and would require substantial clinical support, so were not considered further for use in SoleMate system. Audio and visual feedback cannot be readily incorporated into the sensorimotor loop, with studies suggesting that they may hinder daily tasks [22] so will not be considered either; they would likely impose an additional cognitive burden associated with operating the prosthetic [34]. Leading designs considered for SoleMate are compared below (note that methods focusing on upper limb and transfemoral amputees were considered with modification for transtibial use in mind).

Comparison of Potential Feedback Schemes

Design and Feedback Type	**Data collected**	**Parameter Conveyed**	**Stimulus Provided**
(1) - Proprioceptive Feedback via Time-Discrete Feedback of Gait Phase Transitions, [28].	Plantar pressure (64 point, FSRs)	Gait phase transitions, based on centre of pressure and ground reaction force changes.	Spatially encoded vibrotactile (3 motors) 230Hz 100ms pulses when a transition occurs.
(2) - Improving Stability using Bandwidth Feedback of the Centre of Pressure (CoP), [33].	Plantar pressure (100 point, FSRs)	CoP excursion beyond 50% foot-span (anterior) or within 20% (posterior).	230Hz vibrotactile, active when CoP excursion exceeds a predefined limit.
(3) - Proprioceptive Feedback relaying Joint Position via a Vibrotactile Array, [35].	Angle of extension of the knee joint (0-90 degrees).	Knee joint position (segmented into four discrete sub-ranges).	Continuous 225-330Hz vibrotactile, each segment mapped to one row of four motors.
(4) - Multimodal Sensations Feedback Scheme for Hybrid	Absolute position of distal interphalangeal joint (potentiometer) and	Grasping force, segmented into 4 sub-ranges. Joint	Biphasic charge-balanced electrical stimulus. 4 central electrodes varied

Tactile-proprioceptive Feedback, [34] .	grasping force (FSR on grasped object).	position, segmented into 4 sub-ranges.	TENS intensity to refer grasping force. Outer 12 electrodes activated in sequences to elicit kinaesthetic sensation of finger movement.

Encoding Scheme Selection

The multimodal sensations feedback method [34] offers a means by which SoleMate can deliver both the stability improvements of plantar pressure tactile feedback and the gait rectification of proprioceptive feedback.

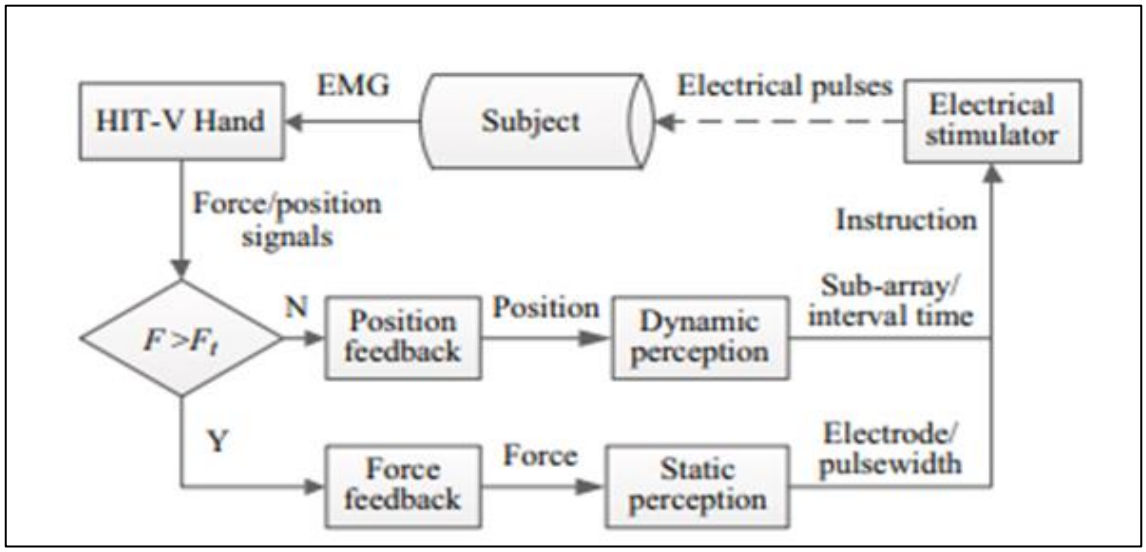


Figure 4.1: *Static-dynamic feedback controller flow diagram ([34]). Dynamic/static perception refers to obtaining joint position and grasping force respectively. The controller determined the required feedback mode by comparison of the grasping force to a predefined threshold value. Both stimulus modalities were identified with a high success rate, and control quality significantly improved on myoelectric prosthesis control tasks.*

Similarly to the design [34] discussed above, SoleMate's controller automatically determines the mode of feedback required for the user's present state – the possible states being ambulation, standing, and lying/sitting. This follows from the fact that perception of stimulus is significantly reduced if applied simultaneously with other stimuli (known as tactile masking) [57], especially if those stimuli are alike and/or applied to the same locus (meaning that if both tactile and

proprioceptive feedback are applied during ambulation (for example), the user will be less able to detect changes as well as reacting more slowly to important real-time information). Research suggests that the CoP provides greater insight into the dynamic function of the foot compared to other plantar pressure-based measures [80], and that the brain can better process time-discrete stimulus in control behaviours, incorporating it into the rhythm rather than having to focus consciously on continued stimulus [37]. Hence, examples (1) and (2) provided the basis for the static and dynamic feedback schemes in SoleMate.

No feedback is supplied while the user is lying, sitting or otherwise not loading the lower limbs, to avoid unnecessary distraction. While in a state of ambulation, a proprioception feedback scheme following the research of Crea et al. is applied. The cartesian coordinates (y-direction aligned with the A-P direction, x-direction with the medial-lateral (M-L)) of the CoP is deduced from the 64 FSR outputs as a force weighted average:

$$x_{cop} = \frac{\sum_{i=1}^{64} F_i x_i}{\sum_{i=1}^{64} F_i} \qquad y_{cop} = \frac{\sum_{i=1}^{64} F_i y_i}{\sum_{i=1}^{64} F_i} \tag{1,2}$$

Where x_i and y_i are the M-L and A-P positions of the i^{th} sensor. The vertical ground reaction force is calculated by summing the measurements:

$$vGRF = \sum_{i=1}^{64} F_i \tag{3}$$

The three gait phase transitions to identify are heel strike, flat foot and toe-off. Owing to variation in plantar pressure distribution of amputees [81], the identification algorithm is made as simple as possible, following example [28]:

Transition	**CoP**	**vGRF**
Heel Strike	N/A	Starts to exceed threshold*.
Flat Foot	Passes the midpoint of the foot in the A-P direction.	Exceeding threshold*.
Toe-Off	N/A	Stops exceeding threshold*.

**The threshold force will be set on a per-user basis and be user configurable. The app will provide the option to measure it during the training routine. The default value, as used in the study, is 20N.*

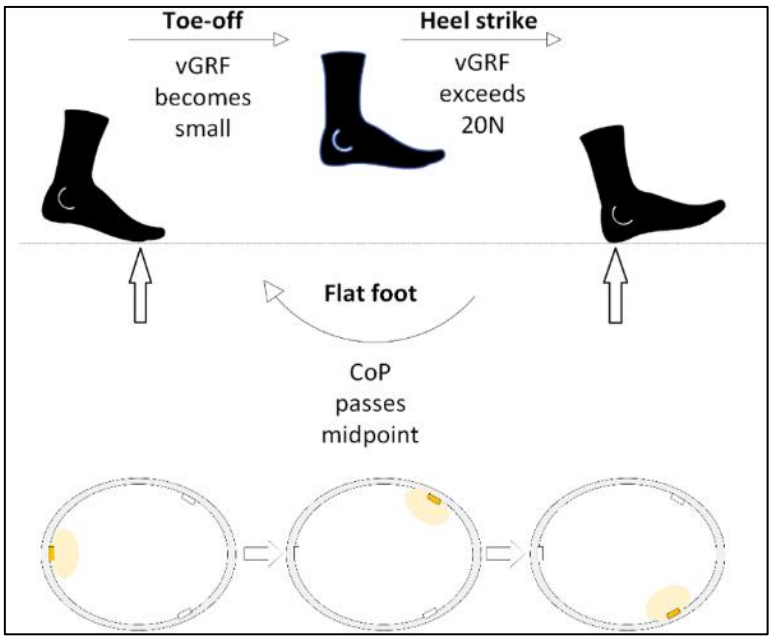


Figure 4.2: *an illustration of the dynamic mode actuation scheme implemented in SoleMate. The user may set the mapping between transitions and actuators to their preference.*

Each transition triggers activation of one of three actuators. The pulse duration is short to minimise the chance of overlapping activations. The discrete nature of the stimulus prevents neural adaptation (the reduced perception of a stimulus as time passes since it was first applied), and 100ms was found to be consistently perceptible – and to be of sufficient brevity to cause no feedback confusion – when tested on healthy participants at a normal walking cadence [28]. The study showed that participants could learn to recognise stimulation patterns with various allocations, so the mapping between transitions and actuators will be left to user preference (set via the companion app). A maximum delay of 200ms is acceptable for this system to deliver gait-phase timing information reliably.

While standing upright and stationary, a CoP bandwidth feedback scheme, based on the work of Vimal et al. (example 3), will be employed to provide tactile feedback. While this feedback may also improve balance confidence when walking, the proven benefits to the LOS apply during static weight shifting, and as stated, only one mode of feedback should be operational at once. As in the study, actuator output will be produced when the excursion of the CoP places it outside of the 'midfoot region' – however the approach was modified to extend the findings of the research to the M-L direction as well as the A-P; while the total movement of the M-L CoP may be viewed as more limited than that of the A-P CoP (based on the gait-cycle CoP path below) [80], modern assessments of balance in high-fall-risk populations [82] (such as the multi-directional reach test

(MDRT)) emphasise testing of stability in both directions and the healthy path of the CoP exhibits clear limitations on the M-L excursion, so a stable region defined in 2D may provide additional benefits. Empirical data for CoP displacement of a non-amputee population [83][33] suggests that the hind/mid/fore foot regions in the A-P direction be segmented as a 20/30/50% division of the total base of stability (BOS) (foot-span, taken from the heel).

Similar data was not collected for the M-L direction, so M-L direction segments are approximated based on the typical (non-amputee) CoP variation determined through research [80].

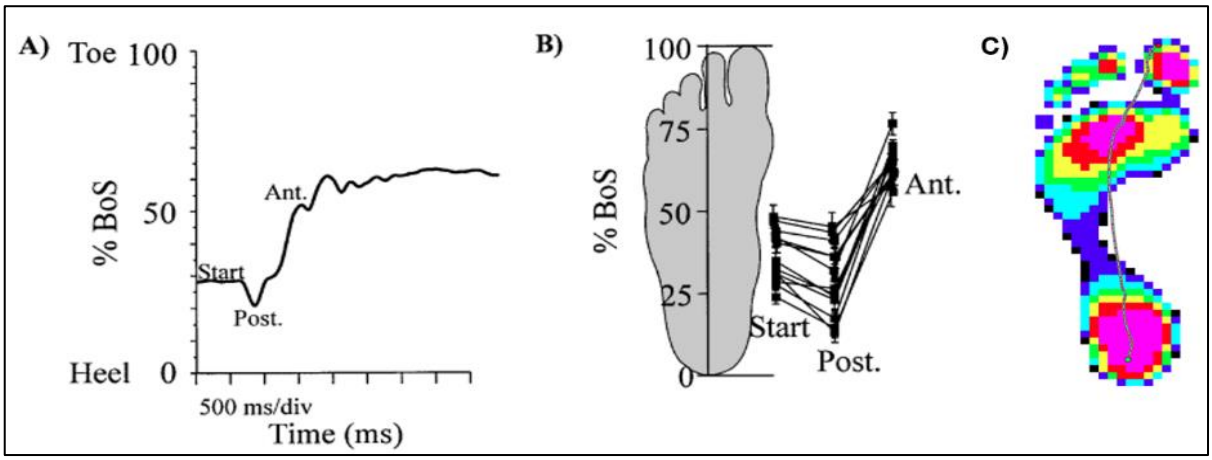


Figure 4.3: *(A) A representative variation of the COP position in the A-P direction during forward weight shifting exercises, [83]. (B) Results for the forward weight shifting exercises among non-amputee participants, [83]. (C) The typical COP path during the healthy gait cycle, [80].*

Note that this approximation (and further development of the midfoot region below) will introduce deviation from proven methods and application of feedback this way is inherently imprecise, hence the need for *user-configurable* CoP excursion detection parameters managed through the SoleMate companion App.

The default outer/mid/inner foot segmentation is 15/70/15% foot width; as confidence is lower in the extent to which this will impact stability and owing to the variability of this range in the population [80], it is only sensitive to extreme CoP positions.

Hence, a 2-D region is defined, which must be mapped from (x, y) or (ML, AP) coordinates to an indication of the position of the CoP excursion (beyond the midfoot region) for the user. The dynamic/proprioceptive feedback mode requires the use of three actuators (for three salient gait phase transitions), therefore a mapping to three actuators is most efficient. Keeping to the minimum number of devices also helps uphold the functional requirements R4, R5, R9 and R10,

for usability, operational time, cost and longevity – although for the prototype version the additional power usage of one or two actuators is of little consequence (see power supply section). The region's corners are rounded, meaning the user will get feedback for the CoP exiting the midfoot region slightly before exceeding the A-P or M-L limit if they are approaching the limit in both axes. This is informed by a study relating functional reach (implying limit of stability) to the total CoP excursion (uses the sum of both axes) [84], and intuitively by the biomechanics of the foot; the hallux hosts the CoP for some of the stride, and there is more deviation towards the medial direction [80]. Thus, the default midfoot region in x-y coordinates is defined piecewise by:

$$0.2L \leq y \leq 0.5L, 0.15W \leq x \leq 0.85W \; if \; \frac{(x+\frac{L}{30}-\frac{W}{2})^2}{a^2}+\frac{(y-0.4L)^2}{b^2} \leq \frac{L}{c} \quad (4)$$

$$\frac{(x+\frac{L}{30}-\frac{W}{2})^2}{a^2}+\frac{(y-0.4L)^2}{b^2} \leq \frac{L}{c}, if \; \frac{(x+\frac{L}{30}-\frac{W}{2})^2}{a^2}+\frac{(y-0.4L)^2}{b^2} > \frac{L}{c} \quad (5)$$

Parameters a, b and c define the curvature of the corners and would need further analysis to be formally optimised. These, along with the foot segmentation, are user configurable (indirectly, to make settings accessible and appropriate for the user's understanding).

To produce the output, this boundary is transformed into polar coordinates and θ, the angle prescribing the position of the excursion, is referred to the user by modulation of the stimulus intensity between the three actuators, which are spread evenly around the circumference of the thigh.

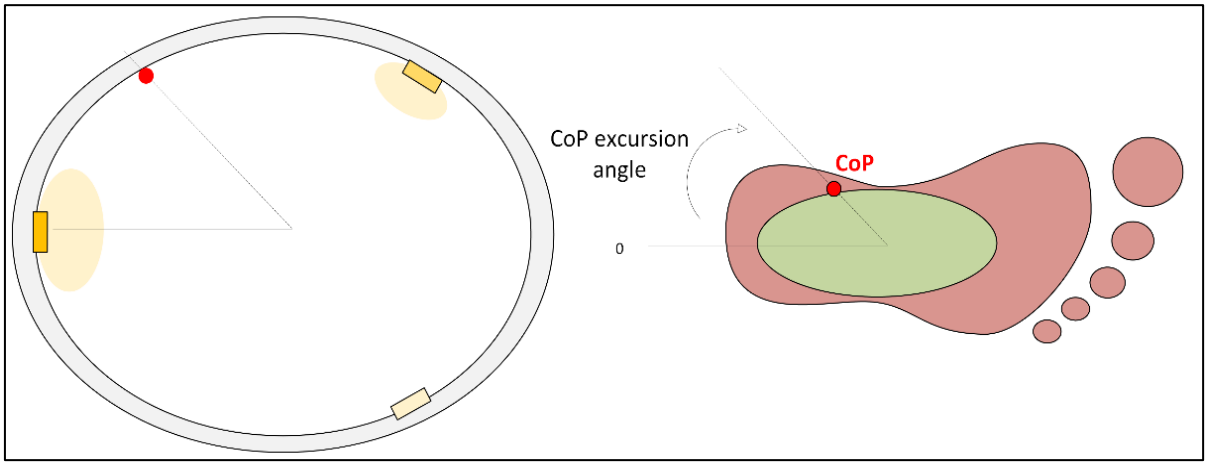


Figure 4.4: *An illustration of the static-mode actuation scheme for SoleMate.*

In the current design, r, the radial coordinate, is not used because there is a lack of evidence for the effective perception of continuous changes in intensity of stimulus [28], [34], although it could

theoretically be used to convey the extent to which the CoP has passed the boundary. Note that this mapping gives a varying traversal rate of the stimulus around the thigh (because the boundary is not circular), and whether this presents an issue must be tested in the prototyping stage.

Let the direction $\theta = 0, 2\pi$ be immediately behind the user. The CP has a greater range of motion in the direction anterior of the midfoot boundary [80] so the position of the first actuator, A1, is aligned with $\theta = 0$ and the positions of the other two actuators, A2 and A3, are $\theta = 2\pi/3$ and $\theta = 4\pi/3$. The actuator output waveform is then given by equation 6 below, where $n \in (0,1,2)$ corresponds to each of the three actuators. In this case, setting $d = 1.6$ gives approximately $V_{peak}/2$ when θ is halfway between adjacent actuators. The intention is that the user will learn to recognise a reduced sensation over two actuators as an indication of the CoP excursion being part-way between them, and increased sensation at one actuator as indicating alignment of the CoP excursion with that actuator's direction. The effectiveness of this method will need to be verified at the prototype stage – an option for adjustment would be optimising d for each user, as perception of stimulus intensity is generally not linear [57] and the individual's minimum intensity perception thresholds will come into effect as intensity decreases.

$$V_{peak} e^{-\frac{(\theta - 2n\frac{\pi}{3})^2}{d}} \quad (6)$$

Vimal et al. [33] showed that this bandwidth feedback approach reduced the learning time for feedback devices, the hardware complexity, and ensured that the feedback was clear and instantaneous – a requirement for subverting the fear of falling while weight shifting.

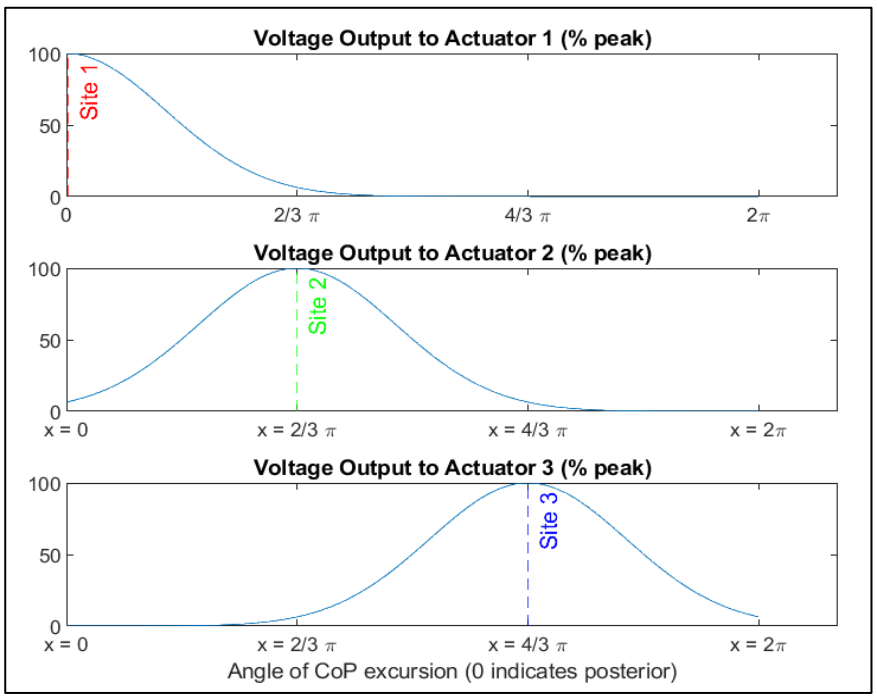


Figure 4.5: *The variation of actuation intensity as the CoP excursion moves around the circumference of the limb. Note that actuation intensity is assumed directly proportional to applied voltage here (in truth this will vary by actuator type).*

The design by Yang et al. alternated between feedback modalities simply by comparing the grasping force to a threshold value. Immediate recognition of the user's intention to walk or stand is not so straightforward – for the SoleMate prototype, the ambulation state is recognised when the timing between gait phase transitions matches that collected during the training routine (for one full cycle of three transitions) and will end when no transitions are detected for a given (user determined) period. The training routine will instruct the user to perform several paces in their natural walking form (number subject to the space available) and record the timings between transitions. The user can set the tolerance (deviation from the recorded mean timings) and will have the option to manually switch modes.

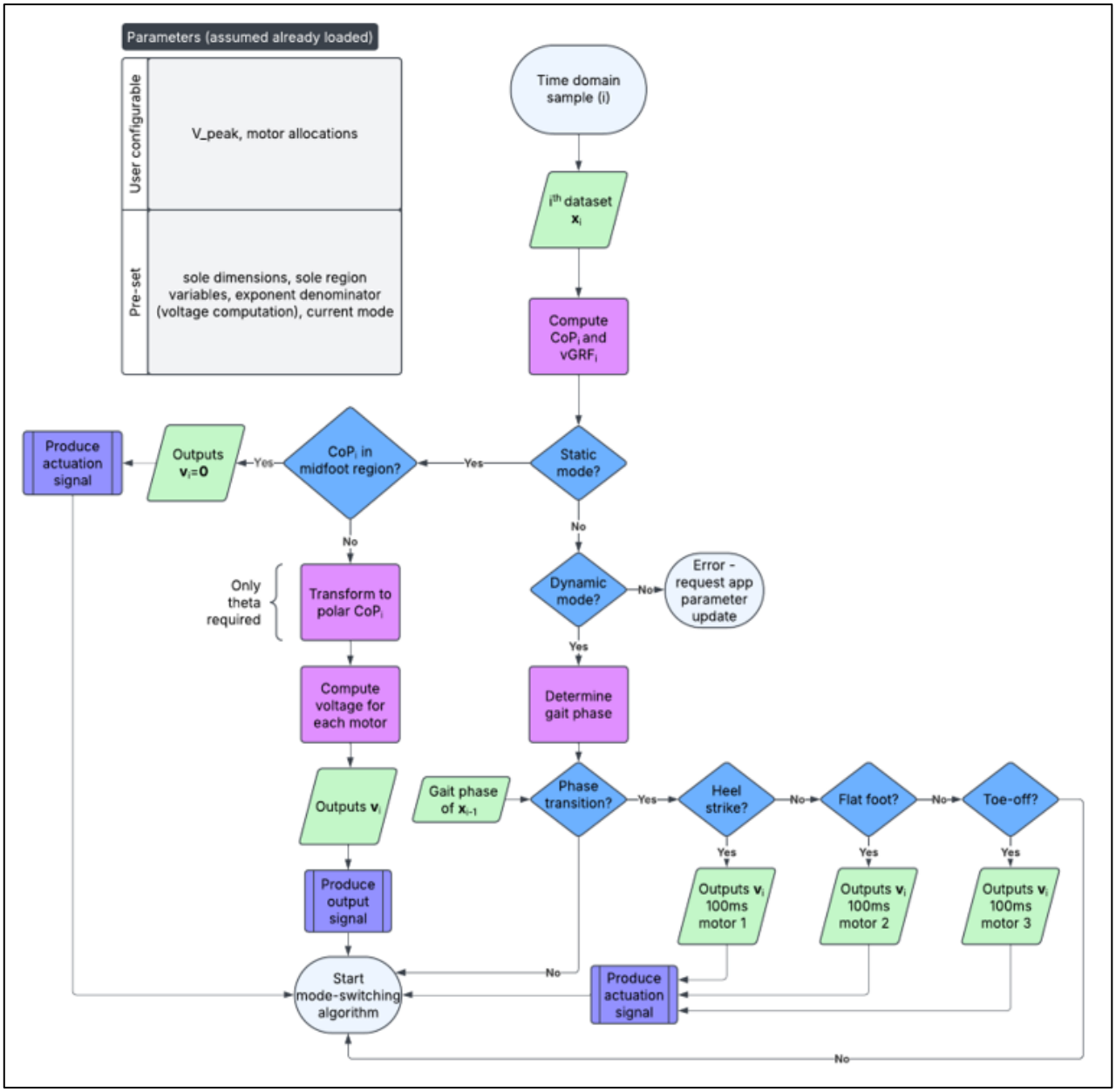


Figure 4.6: *A flow diagram for SoleMate actuation algorithm, for each 64-sample set i.*

Improving the algorithm with Machine Learning

Although the user can modify the parameters, mode switching (and trialling preferred parameters) is likely to be cumbersome and accurate detection is far from guaranteed. Herein lies the principal motivation for the inclusion of a machine-learning-capable controller, so that a future development could exploit the data produced as the user wears the device day-to-day and learn to better classify the feedback state. The use of ML in such circumstances is not unusual; Angelidou et al. [85] successfully developed a pattern recognition and classification strategy to predict the user's intention to walk onto a more compliant surface based on kinematic data (collected at various points on the body) and EMG signals collected from both legs. 534 gait cycles (approx. 12 minutes of walking) was sufficient to train the classifier – not at all an unfeasible requirement for a built-in training routine.

4.2 Controller Software – Jack

4.2.1 Real-time Performance

The BeagleBone Black can be flashed with the latest version of Debian Linux, a distribution for embedded systems. This can be on either the 4GB eMMC or the external SD card [86], setting the location from which Linux will boot.

Design problem: An SBC running an operating system (as opposed to a microcontroller) is advantageous for the flexibility and software tools it provides, expanding the development options for the prototype. However, use of an operating system (OS) can be a barrier to real-time processing, with the OS able to prioritise kernel operations over real-time tasks. Significant delays in responding to events were considered unacceptable for SoleMate, as both embodiment [70] [24](suppression of phantom limb pain) and accurate communication of gait events [28] are contingent on timely feedback, and some degree of real-time processing is required to ensure delays are not introduced by the controller. In the study by Crea et al. for a system feeding back discrete gait events [28], delays over 200ms had a significant impact on the percent total true positive responses among participants testing the system, and delays of 500ms caused indication of transition when the participant was mid-phase.

Broadly, Linux is for general purpose computing, although it includes soft real-time scheduling policies – 'soft' implying that the kernel attempts to meet timing deadlines but cannot guarantee it. An unmodified Linux kernel can cause a latency for user applications reaching hundreds of milliseconds [87], by a combination of elements such as the real time bandwidth limiter (a function

that prevents real-time tasks monopolising the processor) which delays them by up to 50ms every second; Linux soft real-time policies may not grant the reliability required for SoleMate.

Fortunately, there exist two workarounds for real-time processing in Linux on the BeagleBone Black:

(a) Modify the Linux kernel for soft real-time processing with high probability of meeting deadlines [87]**:** For effective real-time performance in Linux, the following modifications must be made:

Requirement for real-time OS (RTOS)	**Modifications to Linux to behave as RTOS**
Allows the application to lock data into RAM during initialisation.	Application should use ***mlockall***.
Allows CPU isolation for real-time applications.	Combined use of ***isolcpus*** boot parameter and a ***cpuset***.
Prioritises real-time application access to processor, while also running asynchronous applications.	Use **preemptible kernel**. Disable ***real-time bandwidth limits***.
Allows developer to establish application precedence via scheduler.	Use **preemptible kernel**. Developer must manually balance priority of real-time tasks and kernel tasks including interrupt requests, and appropriately configure IRQ load balancing.
Prevent page faults and delayed paging.	Disable ***overcommit memory***.
Limits OS interference with applications.	Use **preemptible kernel**.

The preemptible kernel is a mechanism by which the Linux mainline kernel can be configured to allow real-time tasks to pre-empt kernel operations. When configured to the fully preemptible mode, modern ARM (advanced RISC machine) processors show a worst-case latency of $100\mu s$ [87].

(b) Utilise the integrated Programmable Real-time Units [74], [86]**:**

A key feature of the AM335x processors (the BBB is built around the AM3358) is the Programmable Real-Time Unit Subsystem and Industrial Communication Subsystem (PRU-ICSS), which includes two hard real-time slave processors connected directly to the main AM3358 processor. These PRUs are provided their own RAM (8KB each) and can be controlled by the host

processor using the built-in Remote Processor Framework (remoteproc) and Remote Processor Messaging Framework (rpmsg), included with the latest Debian images, which has been flashed to the on-board eMMC in the prototype SoleMate system. They also share 12KB of RAM with the host processor.

The SoleMate prototype will use the PRU-ICSS rather than modifying the kernel. The advantage offered by the PRUs over the Raspberry Pi and similar single-board-computers was a key factor in selecting the BBB, giving it the capacity to fully meet the technical requirements, possessing both a full OS and real-time capability, and this hardware advantage should be exploited rather than adding software complexity.

4.2.2 Overall Operation

The host processor operation is summarised as follows:

1) BBB power button is pressed. Systemd acts as the init function, starting the required background processes (services).
2) A Systemd service configures the header pins for PRU use and mounts the SD card, as well as initialising a shared ring buffer in host memory (RAM).
3) A Python script is started as another Systemd service. This is the main script for the controller.
4) The main software uses remoteproc to update the PRU firmware with currently stored actuation parameters and starts PRU 0.
5) The script listens for Bluetooth inputs from the App and stores the useful information sent back by the PRU. The requests from the app may include starting the training routine, modifying actuation parameters, retrieving clinically significant features (of the plantar pressure data), retrieving user information (remaining charge, step count), and stop/start.

Clearly, step 5 brings significant challenges: the host must be able to both send new instructions to and frequently receive data from the PRU. This is an issue because messaging between the ARM processor and PRU via RPMsg is known to be quite slow – certainly not real-time, and not fast enough for rapid transmission of large amounts of data. The solutions used in SoleMate follow:

Host giving instructions to PRU: The PRUs run firmware which cannot be directly modified by the host at runtime, but it can routinely read values from any shared memory location. New actuation parameter values, and an indicator for starting the training sequence, are compact and

not frequently changed, so this can easily be done using RPMsg and a small allocation in the 12KB shared system memory.

PRU supplying host with salient plantar pressure data features: As mentioned in step 2, a Systemd service can be used to set up a ring buffer in host DDR and make it accessible to the PRUs. The PRU can write to this location unimpeded, as it is not done via RPMsg, meaning a large amount of data can be delivered to the host software. This is important because the limited size of the PRU RAM dictates how many datasets (meaning each sample of 64 single-precision floats representing force values) can be worked on at once, so 'intermediate features' are sent through to the host processor from which the clinically significant features can be computed. For example, the App requires the temporal average of the peak vertical ground reaction force during the gait cycle. A 16KB ring buffer* is available for the PRU, which is enough for 64 datasets (i.e. 1.6s of pressure data at the 40Hz sampling frequency), but the peak vGRF in this window is not necessarily the peak for one cycle; a well accustomed unilateral TFA's walking cadence is around 2 steps per second at 5km/h meaning more than 4 cycles could be recorded [78]. For this reason, the PRU in the prototype will send these averages over 64 datasets to the shared buffer along with the timing of capture (accurately provided by the clock cycle counter register) as intermediate features. The identified gait-phase transitions are also sent through, which allows the host software (python script) to deduce the peak vGRF for subsequent cycles and update the temporal average. The host will use a sliding window to read the most recent values from the shared buffer because it does not operate in real-time so cannot be perfectly synchronised with the PRU outputs, computing the features and storing them in the SD card. At this point, the Python script is ready to read the currently stored gait features and transmit them to the app upon request. Additional information, such as the current actuation parameters, are also retrieved and stored in the SD card as these need to be reported to the App.

**It is presently unknown how much RAM the firmware will use during operation, so a provisional 16 KB of the available 28 [74] was allocated to the buffer in PRU RAM. A rate of 0.46875Hz (sampling frequency over 64) is achievable by the ARM processor.*

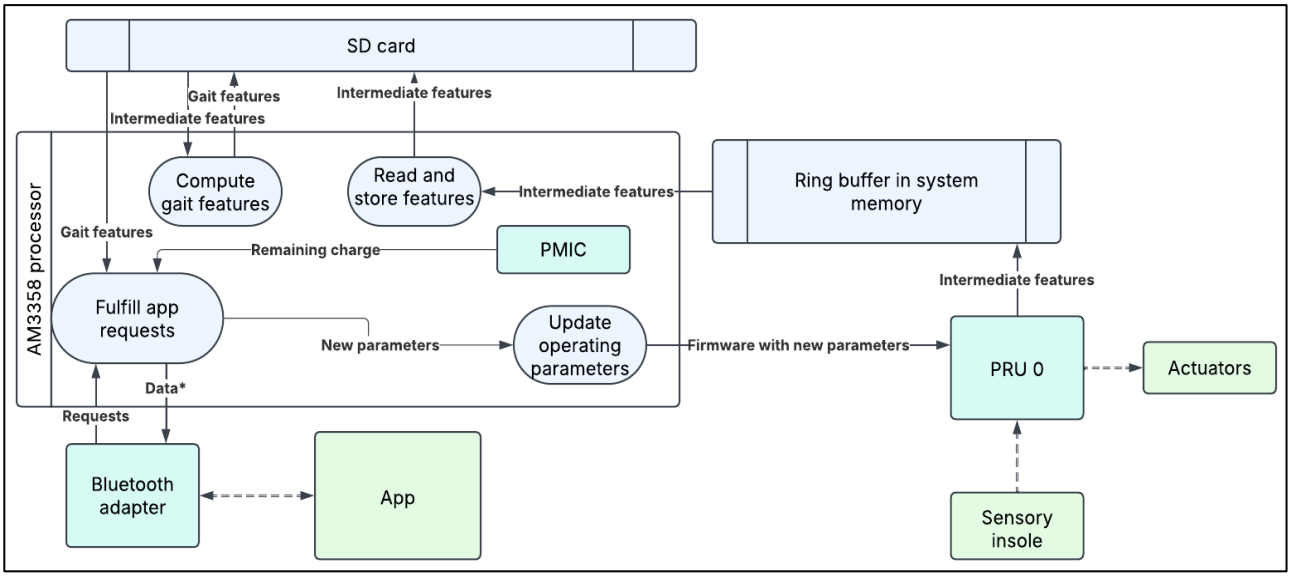


Figure 4.7: *A simplified data flow diagram representing the operation of the host processor (AM3358) on the BBB ('Data*' includes the clinical gait parameters, current actuation parameter settings and the extraneous information to be displayed to the user, such as step count and remaining charge).*

5. Higher Level Communications and the App

5.1 The App – Alessandra

The following section outlines the design of the integrated mobile health (mHealth) application that allows SoleMate users to independently control their device and self-monitor their gait.

5.1.1 Primary functional requirements

The app must allow a user to control their device without requiring assistance from a clinician. Furthermore, NHS England has highlighted the potential of the "convergence of medical devices with mobile health", stating that it can enable patients to be more informed about their conditions, and allow clinicians to monitor their patients remotely [88]. Therefore, we require the app to enable users to give (restricted) access to selected clinicians, who will be able to view daily gait analysis. Thus, our primary functional objectives include:

1. Allow user to control operation of their device easily without clinician assistance (R8)
    a. Allow user to adjust actuation parameters
    b. Show user important device information e.g. battery level, repair information
    c. Initialise 'training routine' for calibration of mode-switching algorithm

2. Display useful gait analysis, with the primary focus of allowing user to consciously change their gait for better short and long-term clinical outcomes (R7)
3. Allow clinician to remotely access gait analysis for monitoring of user's condition (R7)

5.1.2 Design Philosophy – User-centred design

User-centred design (UCD) for mHealth applications plays an important role in creating user engagement, thus improving the effectiveness of any intervention proposed by the app [89].

A study conducted by Schnall et al. [90] concluded that the Information Systems Framework (ISR) framework may be useful in designing a mobile application capable of integrating end-user and expert feedback into a final product. The ISR framework prioritises iterative builds, incorporating end-user feedback, evaluation by experts, and literature reviews in the design of a final product. This can be seen in Figure 5.1.

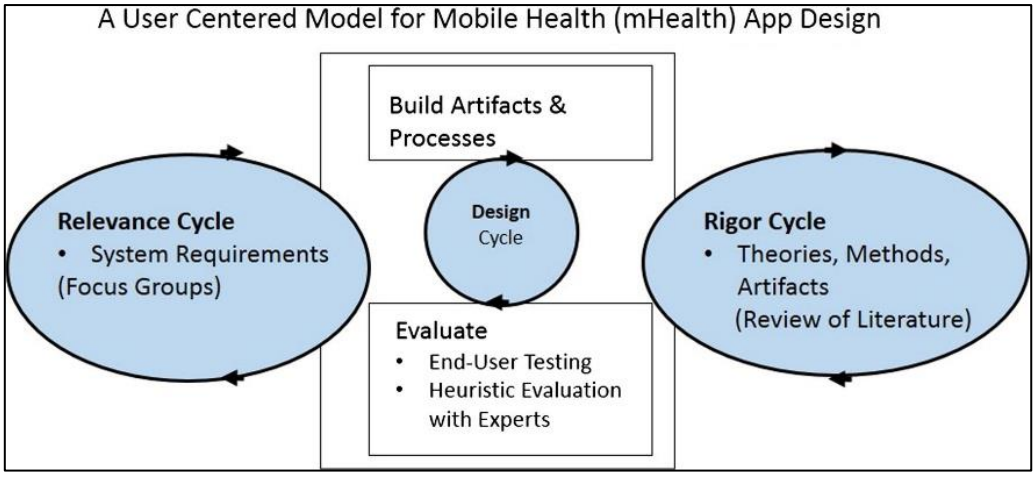
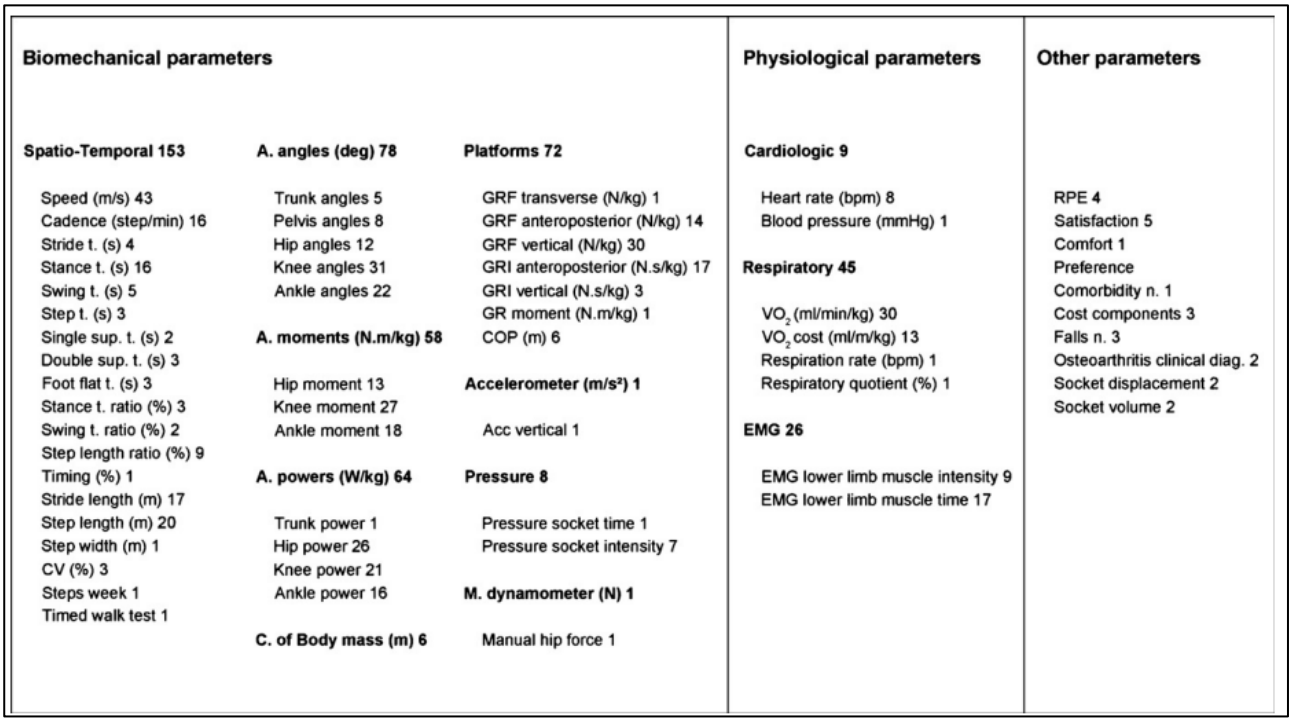


Figure 5.1: *The Information Systems Framework for designing mHealth Applications [90]*

While we have not been able to entirely follow this structure, we have been able to incorporate many of its elements to form our final design. These include literature reviews to determine clinically salient gait parameters, incorporation of direct user feedback, and creating multiple designs. Despite attempts to consult experts by meeting with doctors or other clinicians, this was not possible but would be valuable in an extension of this project. As an alternative, we have used suggestions from NHS England articles on effective use of digital tools in healthcare to inform our design.

5.1.3 Literature review – Selection of Gait Parameters to Display

In deciding the most important gait data for our app to show, we used the results of a systematic review [41] which investigated the most relevant parameters for conducting clinical gait analysis in lower limb amputees (LLA), divided between the categories of biomechanical parameters, physiological parameters, and other parameters. The most frequently used parameters they identified are shown in Figure 5.2.



Biomechanical parameters

Spatio-Temporal 153

- Speed (m/s) 43
- Cadence (step/min) 16
- Stride t. (s) 4
- Stance t. (s) 16
- Swing t. (s) 5
- Step t. (s) 3
- Single sup. t. (s) 2
- Double sup. t. (s) 3
- Foot flat t. (s) 3
- Stance t. ratio (%) 3
- Swing t. ratio (%) 2
- Step length ratio (%) 9
- Timing (%) 1
- Stride length (m) 17
- Step length (m) 20
- Step width (m) 1
- CV (%) 3
- Steps week 1
- Timed walk test 1

A. angles (deg) 78

- Trunk angles 5
- Pelvis angles 8
- Hip angles 12
- Knee angles 31
- Ankle angles 22

A. moments (N.m/kg) 58

- Hip moment 13
- Knee moment 27
- Ankle moment 18

A. powers (W/kg) 64

- Trunk power 1
- Hip power 26
- Knee power 21
- Ankle power 16

C. of Body mass (m) 6

Platforms 72

- GRF transverse (N/kg) 1
- GRF anteroposterior (N/kg) 14
- GRF vertical (N/kg) 30
- GRI anteroposterior (N.s/kg) 17
- GRI vertical (N.s/kg) 3
- GR moment (N.m/kg) 1
- COP (m) 6

Accelerometer (m/s²) 1

- Acc vertical 1

Pressure 8

- Pressure socket time 1
- Pressure socket intensity 7

M. dynamometer (N) 1

- Manual hip force 1

Physiological parameters

Cardiologic 9

- Heart rate (bpm) 8
- Blood pressure (mmHg) 1

Respiratory 45

- VO_2 (ml/min/kg) 30
- VO_2 cost (ml/m/kg) 13
- Respiration rate (bpm) 1
- Respiratory quotient (%) 1

EMG 26

- EMG lower limb muscle intensity 9
- EMG lower limb muscle time 17

Other parameters

- RPE 4
- Satisfaction 5
- Comfort 1
- Preference
- Comorbidity n. 1
- Cost components 3
- Falls n. 3
- Osteoarthritis clinical diag. 2
- Socket displacement 2
- Socket volume 2

Figure 5.2: *The most frequent parameters used in clinical gait analysis [41].*

We are unable to extract any physiological parameters (e.g. heart rate, VO_2, respiration rate) from the data provided by our sensorised insole, however integration of SoleMate with other fitness wearables which track these would be an interesting extension of this project.

Within the biomechanical parameters, we also cannot calculate joint angles, moments, powers, or anything related to the socket. We have selected biomechanical parameters to display on the app based on prevalence in clinical studies in the systematic review and our ability to accurately calculate them using measurements from the insole. The spatio-temporal parameters we have selected include cadence (step/min), stride time (s), stance time (s), swing time (s), step time (s), single support time (s), double support time (s), foot flat time (s), stance time ratio (%), swing time ratio (%), and total steps per day. Other biomechanical parameters the app displays include average peak vertical ground reaction force and average centre of pressure while standing.

The app can also allow users to track a selection of the “Other parameters” from the systematic review, including rate of perceived exertion (RPE) while walking and any falls they experience, through a “Journal” feature. This allows them to record their daily average pain level and any phantom limb pain.

Furthermore, in clinical studies, there is ample evidence to suggest that interventions aimed at reducing LLA gait asymmetry should be investigated, as proportional decreased loading on the residual limb and increased loading on the sound limb are likely responsible for the increased prevalence of osteoporosis in the residual limb, and osteoarthritis in the sound limb observed in LLA [6]. Because of this, SoleMate displays a daily gait symmetry score, and allows clinicians to suggest “Tips” on how the user can strive to walk more symmetrically.

5.1.4 Expert opinions

In lieu of directly meeting with clinicians, we have consulted NHS articles on best practices for using digital tools in healthcare. As mentioned previously, they have stated that mobile health applications can help patients monitor their own conditions and allow clinicians to monitor their patients’ conditions remotely [88]. Our selection of biomechanical parameters to show, outlined in the previous section, helps SoleMate to achieve these goals. The NHS have also highlighted “messaging, video calls, and multimedia such as images” as particularly effective digital tools for promoting communication between patients and clinicians, thus improving access to care [88]. We have incorporated this into our app design by creating a “chat” feature, where clinicians and patients can easily discuss the gait analysis shown in the app. Furthermore, clinicians will be able to set “goals” for individual gait parameters.

5.1.5 End-user feedback

During the development of SoleMate, we presented a design proposal to a current prosthesis user (Adam) to incorporate end-user feedback into our design. We have implemented much of his feedback in our final design.

Adam stressed the importance of clearly showing device manufacture data, model number and serial number to facilitate any necessary repairs of SoleMate. We have incorporated this into an “About Device” section in the “Settings” tab. He added that designing the app in the style of popular wearable fitness tracker apps could significantly improve user experience – because of this, our final design has a home screen showing a “Daily review” where users are shown four gait summary statistics in colourful circles. He also suggested the use of video instruction for the

training routine – the popularity of this has been confirmed by a study [91] which found that 85% of users preferred auto-generated video versions of instruction manuals over the original text-based manuals. Video-based instruction is not only preferred by users – it is effective, as demonstrated by a study investigating the relative efficacy of video versus text instruction for teaching inhaler use [92]; they concluded that while written instruction proved inadequate in teaching safe inhaler use to users, video instruction led to users learning adequate technique. Because of this, the 'training routine' section of the app uses video instruction to accompany standard text-based instruction.

5.1.6 Final Design

Figure 5.3 shows four images displaying the user interface of the app.

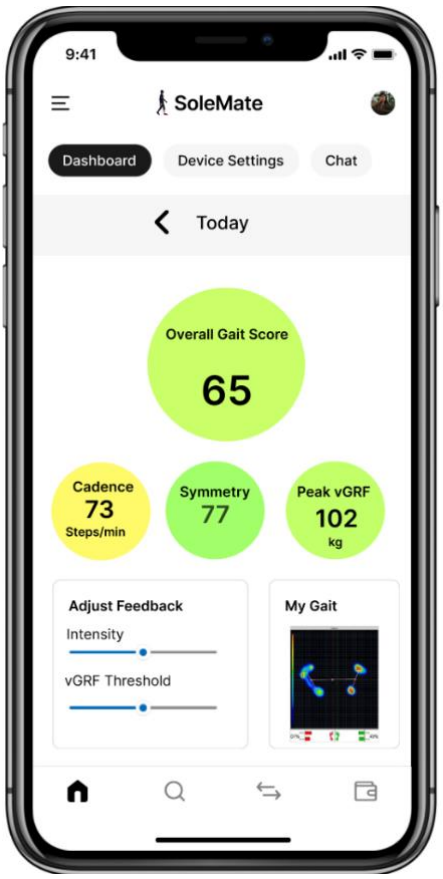
The final app operates as follows: on first use, the user is prompted to give consent for the collection and processing of their data – this is required for SoleMate to comply with GDPR regulations. They are then be instructed to follow the "training routine" to calibrate their device. This involves instructing the user to find a flat, open space, then press a 'start' button and walk 20 paces, then press a 'stop' button. The device then calculates their average cadence and uses that to calibrate the mode-switching algorithm. The home screen of the app, shown in Figure 5.3 (A), displays a daily overview of the user's gait, quantified by four statistics – an "Overall gait score", the user's average step cadence, a "Symmetry score", and their average peak vertical ground reaction force over a gait cycle.

Upon clicking any of the "Daily review" statistics, the user is shown a graph tracking the changes of the selected parameter over time. This is shown in Figure 5.3 (B). Underneath this graph is a 'goals' section where the user is able to set themself goals or choose to accept targets suggested by their clinician. Under this is a "Tips" section where again, the user is able to input their own "cues" for actively improving the gait metric in question or accept a tip from their clinician.

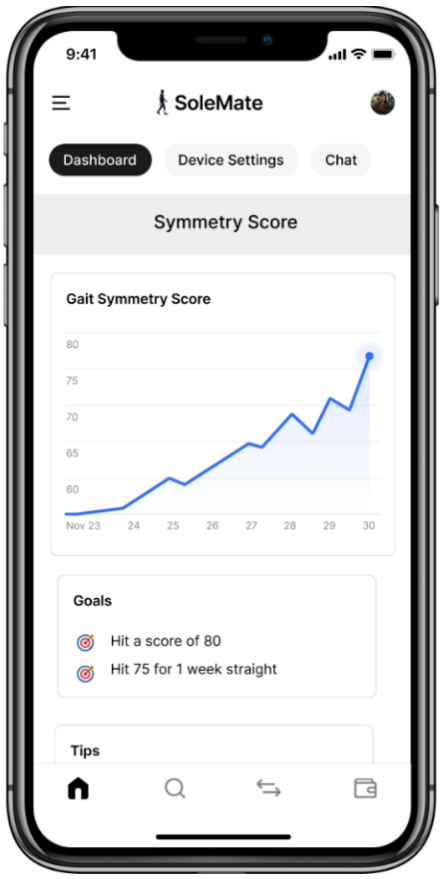
The user is able to view in-depth gait analysis by clicking on the "My Gait" button on the home screen. This takes them to Figure 5.3 (C), which shows the gait parameters discussed in the literature review above.

Finally, the app allows a device user to discuss their condition and review gait analysis using the "Chat" feature. This is shown in Figure 5.3 (D).

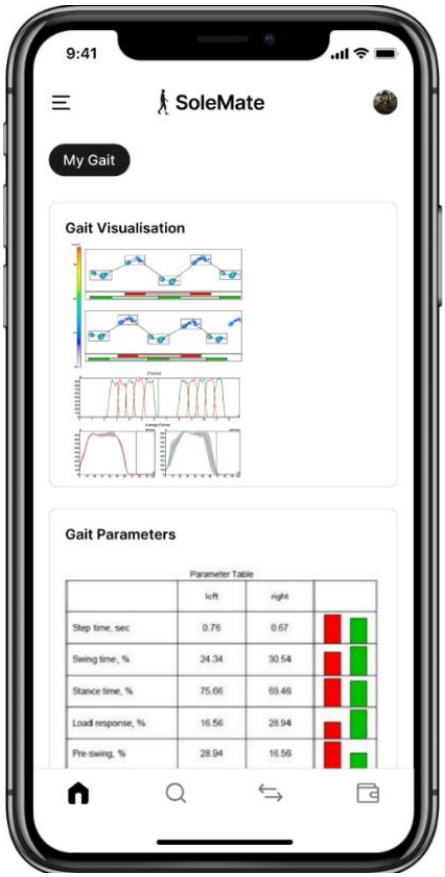
(A)



(B)



(C)



(D)

Figure 5.3: *Images of the user interface of the mHealth application, created by Alessandra French using Figma software.*

5.2 Connecting the Microprocessor and the App – Alessandra

We require a connection between the BeagleBone Black (our microprocessor) and the mobile application. This is necessary to allow the app to access gait data from the microprocessor and send actuation parameter updates back to it. GDPR mandates that this connection has a high level of security because SoleMate uses it to transfer personal health information.

5.2.1 The Choice of Bluetooth

We have chosen to use a secure Bluetooth connection for communication between the BeagleBone Black (BBB) and the application on the user's mobile phone. More specifically, we use Bluetooth Low Energy Secure Connections (LESC). This pairing method was introduced in Bluetooth version 4.2 and offers more secure communication than legacy pairing. Data transfer using Bluetooth Low Energy has a lower power consumption than Wi-Fi, and LESC encrypts all transmitted data, which is critical for SoleMate to adhere to GDPR requirements. Furthermore, features where Wi-Fi excels compared to Bluetooth communication such as faster data transfer speeds and longer-range data transmission are not required for our system.

5.2.2 Hardware

We have selected the BleuIO Pro Bluetooth dongle to add Bluetooth functionality to the BBB. It is compatible with Linux OS and the BBB. Furthermore, the BleuIO dongle uses a Bluetooth 5.2 chip, so supports LESC. (This is also explicitly stated in the BleuIO documentation.) The cost is 35 USD, so will not make SoleMate prohibitively expensive. However, we must enforce LESC in the BeagleBone software to prevent fallback to communication using weaker security levels. The BBB runs a Linux Operating System so BlueZ is the software it uses to handle the dongle and the Bluetooth functionality it enables. It is therefore necessary to configure it appropriately to enforce LESC.

5.2.3 Introduction to Association Models

LE Secure communications' algorithm supports four different pairing methods (called association models) based on the input/output capabilities of the peer devices: Just Works, Passkey Entry, Numeric Comparison, and Out of Band (OOB). We will not consider OOB pairing as it does not use traditional Bluetooth frequencies and is not mentioned anywhere in the official BleuIO documentation, so is likely not supported. The selection of association model used for Bluetooth connection, given the I/O capabilities of the peer devices is outlined in the Bluetooth Core Specification. Part of the table mapping peer device I/O capabilities to key generation methods is

shown in Figure 5.1. Note that either the initiator or the responder device must **set** the man-in-the-middle (MITM) option, otherwise the I/O capabilities of the devices will be ignored, and the pairing

<table>
<tr><th></th><th colspan="5">Initiator</th></tr>
<tr><th>Responder</th><th>DisplayOnly</th><th>Display YesNo</th><th>Keyboard Only</th><th>NoInput NoOutput</th><th>Keyboard Display</th></tr>
<tr><td>Display Only</td><td>Just Works
Unauthenti-cated</td><td>Just Works
Unauthenti-cated</td><td>Passkey Entry: responder displays, ini-tiator inputs
Authenti-cated</td><td>Just Works
Unauthenti-cated</td><td>Passkey Entry: responder displays, ini-tiator inputs
Authenti-cated</td></tr>
<tr><td rowspan="2">Display YesNo</td><td rowspan="2">Just Works
Unauthenti-cated</td><td>Just Works (For LE Legacy Pairing)
Unauthenti-cated</td><td rowspan="2">Passkey Entry: responder displays, ini-tiator inputs
Authenti-cated</td><td rowspan="2">Just Works
Unauthenti-cated</td><td>Passkey Entry (For LE Legacy Pairing): responder displays, ini-tiator inputs
Authenti-cated</td></tr>
<tr><td>Numeric Comparison (For LE Secure Con-nections)
Authenti-cated</td><td>Numeric Comparison (For LE Secure Con-nections)
Authenti-cated</td></tr>
</table>

Figure 2.1: *Table mapping I/O capabilities of peer devices to key generation method [99].*

method will default to Just Works.

5.2.4 Just Works

Just Works pairing is more secure when using LE Secure Connections than when using legacy pairing. Despite this, it is still an unauthenticated pairing method, meaning that it is vulnerable to man-in-the-middle attacks. An MITM attack is a type of cyberattack in which an unauthorized party eavesdrops on wireless communications to steal sensitive information. They may also relay information between the peer devices, altering data along the way [93]. This would constitute a security breach in SoleMate system and must be avoided. Thus, Just Works pairing is not acceptable.

5.2.5 Numeric Comparison and Passkey Entry

Numeric Comparison and Passkey Entry are both authenticated connection methods, meaning that they protect against MITM attacks. Furthermore, they both use encryption to protect against

passive eavesdropping. Therefore, we can conclude that both key generation methods use an appropriate level of security for our purposes. The BleuIO Bluetooth dongle supports pairing via either of these key generation methods [94]. However, Numeric Comparison requires both devices, including the BBB, to have DisplayYesNo capabilities, whereas Passkey Entry only requires the BBB to have DisplayOnly. Therefore, we choose to enforce Passkey Entry as the key generation method.

5.2.6 Enforcing Passkey Entry

The BeagleBone Black is *headless* in normal use, meaning that it has no user facing input/output capabilities. Thus, an LE Secure connection will normally default to using Just Works as the key generation method. However, as stated above, this is unacceptable. Thus, we will connect an external display to the BeagleBone black to enable Passkey Entry pairing. Once pairing is complete, the user will be able to disconnect the external display because the BeagleBone and user's mobile phone will share a Long-Term Key (LTK) and not need to pair again unless information is lost.

An HDMI monitor can be used as the external display, connected to the BeagleBone via a microHDMI to HDMI cable; instructions of how to set this up are given in the BeagleBone guide [74]. During pairing, the user's mobile phone will act as the initiator, and the BeagleBone Black as the responder. We will display the 6-digit passkey on the monitor using a small Python program. Then the user will type the passkey on their mobile app. If successful, the devices would be 'bonded' and share an LTK. Because of this, they would be able to reconnect securely without requiring the monitor.

Note: to ensure that LE Secure Connection is possible, the BBB's Linux kernel and BlueZ software must be up to date.

Finally, we have chosen to transfer relevant data from the BBB to the App once per hour. This allows users to view up-to-date data and device status, while reducing the risk of the data being intercepted. Data will only be sent from the app to the BBB when the user updates a device parameter within the app.

6. GDPR and Security – Alessandra

We have designed SoleMate to comply with current data protection legislation in the United Kingdom, which is outlined in the UK General Data Protection Regulation (UK GDPR) and the Data

Protection Act 2018 [95]. The relevant pieces of legislation referenced in the following section are up to data as of 20 May 2025, however long-term maintenance of SoleMate system would require continuous assessment to ensure that our security measures continue to meet the requirements.

Users of SoleMate can exercise their basic data privacy rights, including accessing their personal data, receiving transparent communication about how their data is being used, and requesting the deletion of their data at any time [95].

We must also note there are stronger protections for more sensitive information, including health information. As our device handles medical data, guidance for processing it is given in the UK GDPR, Article 9: Processing of special categories of personal data.

> *"Processing of personal data revealing" … "data concerning health" … "shall be prohibited" unless "the data subject has given explicit consent to the processing of those personal data for one or more specified purposes."*

In accordance with this, it is essential that any SoleMate user is prompted to give explicit consent for our device to process their personal data before any data is collected.

However, these pieces of legislation also detail the level of security systems required by parties responsible for handling of personal data. UK GDPR, Article 5: Principles of processing personal data, states that

> *"Personal data shall be processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures ('integrity and confidentiality')."*

In this section, we will focus on the *technical* rather than *organisational* measures used by SoleMate system to prevent unauthorised processing. Detailed guidance on appropriate security levels required by data processing systems is given in UK GDPR, Article 32: Security of processing, which states that

> *"The processor shall implement appropriate technical and organisational measures to ensure a level of security appropriate to the risk", including "the pseudonymisation and encryption of personal data". Moreover, "in assessing the appropriate level of security account shall be taken in particular of the risks that are presented by processing, in*

particular from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to personal data transmitted, stored or otherwise processed."

This informs our choices when considering methods of data transmission between individual components within SoleMate. During data transmission, we must encrypt and anonymise all personal data. Furthermore, a risk assessment is required to determine the appropriate level of security when processing and transmitting data. The following table presents a security risk assessment, detailing the potential harms associated with processing user data within SoleMate system, and appropriate security measures to mitigate these risks. The security of stored data on the BeagleBone Black is not discussed in this project, but merits further consideration.

Risk	**Data transmitted between insole and BeagleBone Black**	**Data transmitted between BeagleBone Black and the App**	**Data stored on the App server**
Destruction/Loss of data	Loss of signals to user when they are expecting feedback and receive none; could result in falls – high risk	BBB → App: User loses some gait data – low risk. App → BBB: BBB is not updated with new device parameters, user will resend – low risk.	Potentially large amounts of gait data lost; not ideal but not a significant data breach – low risk. Device parameters not saved – low risk
Alteration of Data	Erroneous signals relayed to user, giving them false information about their gait and balance; could result in falls – high risk.	BBB → App: Gait data is altered. User is given incorrect information regarding their gait and how to improve it – medium risk. App → BBB: BBB is updated with incorrect device parameters. If done maliciously, this could include setting the actuation intensity level at a higher level than desired. However, maximum	Device settings altered. If done maliciously, this could include setting the actuation intensity level at a higher level than desired. Same reasoning as App → BBB section, has potential to cause a fall – high risk.

		actuator output is constrained (by physical limits) to remain below discomfort threshold. Despite this, unexpected jumps in actuation intensity could be confusing and have potential to cause a fall – high risk.	
Unauthorised access to personal data	Unauthorised parties gain access to gait data of user; this could be used to infer a medical condition – medium risk.	BBB → App: Unauthorised parties gain access to gait data of user; this could be used to infer a medical condition – medium risk. App → BBB: Unauthorised parties gain access to device settings of user. No personal information revealed – low risk.	Unauthorised parties gain access to gait data of user; this could be used to infer a medical condition – medium risk.
Overall security risk	High – data breaches could result in a fall.	High – altered actuation intensities could result in a fall.	High – altered actuation intensities could result in a fall.
Mitigation of risk: Appropriate security measures	Wired connection between insole and BeagleBone Black to avoid risks associated with wireless data transmission.	Wireless Bluetooth connection for data transmission. Use Bluetooth 5.2 dongle and enforce data transmission using Low Energy Secure Communications, Passkey Entry association model.	Access controls – multi-factor authentication, platform-specific secure storage APIs, secure communication protocols (HTTPS), all data stored in encrypted database (cloud storage)

The UK GDPR also details requirements for data access controls, regularity of security testing, and data breach response plans, as well as organisational measures to ensure adequate security levels, however specific plans for adherence to these requirements goes beyond the scope of this project.

7. Health and Safety

7.1 Risk register – Jack

The Medical Device Regulations 2002 (and similar international legislation) place requirements on the design of general medical devices. Council Directive 93/42/EEC Annex 1 requires that risks to the user's safety must be reduced as far as possible, with protective measures and risk information for the user provided in cases where risk cannot be eliminated. SoleMate's safety risks include:

Risk	Impact	Mitigation
Battery becomes damaged.	Fire hazard, electrical hazard, user exposed to harmful chemicals.	Use Li-Ion battery in protective casing. Ensure water-resistance in final product.
Stimulus causes startle reaction.	User reacts involuntarily, leading to injury.	Low power VT actuators.
Actuators receive too much power.	Discomfort.	Commercial version will have protective circuitry.
Actuation data interfered with.	Incorrect actuation patterns.	Wired communication used in real-time system. SD card hardware encrypted. Bluetooth LESC used.
The controller is damaged by excess current, as the BBB is limited to 50mA over the P8/9 headers.	Device stops functioning. Erroneous actuation signals. Electric shock hazard.	External power circuitry used for actuators and sensors.

7.2 Medical device classification – Alessandra

Regulation and classification of medical devices in the UK is carried out by the Medicines and Healthcare products Regulatory Agency (MHRA) [96]. If SoleMate is classed as a medical device, it must comply with the appropriate regulations.

Is SoleMate a medical device?

As per the latest version of The Medical Devices Regulations 2002, a "medical device" is defined as

> *"any instrument, apparatus"… "or other article"… "which is intended by the manufacturer to be used for human beings for the purpose of"… "treatment, alleviation of or compensation for an injury or handicap,"… "replacement or modification of"… "a physiological process"… "and"… "does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means".* (MDR Article 2(1))

By this definition, SoleMate is clearly a medical device—it is an apparatus intended for the treatment of gait pathologies associated with amputation and could also be considered to replace the physiological process of somatosensory feedback from the missing limb.

The UK Johnson Conservative government (2019-2022) have published guidelines on the appropriate classification of general medical devices (Consultation on the future regulation of medical devices in the United Kingdom, Chapter 2: Classification, Section 5 - Classification of general medical devices). They are classified into four groups of increasing levels of risk posed by their use. Classification is required so that manufacturers can undertake the correct conformity assessment to demonstrate that their device meets the appropriate requirements. This is shown in Figure 7.1. Higher risk devices require more rigorous testing by an Approved Body than lower risk devices. Classification can be determined using regulations 7(2) or 52(2) of the MDR.

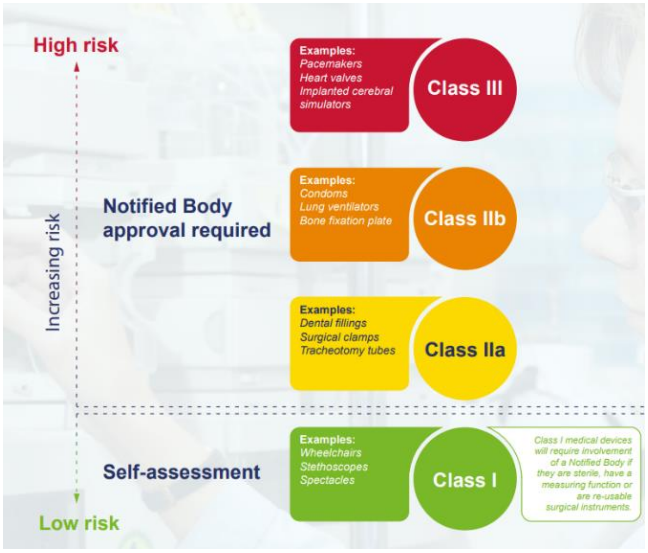


Figure 7.1: *Classification of medical devices [88].*

For the classification of general medical devices in England, Scotland and Wales, regulations are laid out in Annex IX of Directive 93/42 – this is what we will use to classify SoleMate; note that the following analysis does not apply to Northern Ireland.

Our device meets the criteria to be classed as an "active therapeutical device", which is defined as *"any active medical device" … "used" … "to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap"*, where an **active** medical device *"depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy".[97]*

SoleMate uses an external energy source to power the vibration of actuators. This is used to restore the biological function of somatosensory feedback to alleviate the handicap of lower limb amputation.

The MDR states that

> *"All active therapeutic devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in Class IIb."* [97]

SoleMate exchanges energy to the human body, but not in a potentially hazardous way. The cuff features low power vibrational actuators which are not capable of harming the user. This is largely because the cuff is placed on the residual thigh, which is not an especially vulnerable or sensitive

part of the body. SoleMate is not currently suitable for persons with a sensitive or painful residual thigh. (Future developments of SoleMate would include alternative cuff designs which could be worn on other parts of the body if the residual thigh were an unsuitable location – the efficacy of alternative locations has been demonstrated in the literature, but design of cuffs fit for alternative locations falls outside the scope of this project.) Because of this, SoleMate should be a Class IIa device.

Due to this classification, if we were to make SoleMate commercially available, we would need a UKCA (conformity assessment) via a Notified Body. The conformity assessment is extensive, but above all else manufacturers are instructed to “eliminate or reduce risks as far as possible (inherently safe design and construction)”, which we have considered in the design of every part of SoleMate.

8. Potential Commercialisation Route – Alessandra

If we were to develop a business centred around selling SoleMate as a commercial product, we would utilise the lean-startup framework, as developed by American entrepreneur Eric Ries, to inform our business strategy. It has the advantage of allowing a faster time to market and more efficient use of resources than traditional business models. Within this framework, our current design constitutes a ‘minimum viable product’ – it has implemented the core features thus allowing maximum validated learning from user feedback in a short time frame. After testing the market and learning more about consumer needs, we would persevere if our product succeeded in delivering the value we hypothesised to consumers, and pivot otherwise. If consumers found value in one feature in particular, we would “zoom-in pivot” and focus on developing that feature, or “zoom-out pivot” and use that feature as the basis of a different product.

9. Conclusion – Alessandra

This report describes the design of a novel device to return somatosensory feedback to lower limb amputees that will improve their quality of life. The device provides real-time proprioceptive and tactile feedback to users. The insole collects plantar pressure data at a high spatial resolution to extract useful gait features without requiring individual calibration for each user. Comfort-testing suggests the insole does not impede mobility even when worn for long periods of time. Furthermore, the collected data remains accurate when the insole is worn all day. Our selected feedback scheme uses proven strategies – the placement of the cuff on the residual thigh

maximises prosthetic embodiment, and the use of vibrotactile actuators provides safe and effective feedback. The real-time system operates quickly enough to ensure the feedback feels natural. Moreover, the mHealth application was designed to be user-friendly while providing useful clinical insights. It allows the user to operate SoleMate without the need for regular assistance from a clinician. The device provides secure data transfer between the individual components of SoleMate. A focus on user experience is central to the design of our system. SoleMate has enough battery life to be worn for a full day with one battery change. Furthermore, the full system, including the power supply, is light enough to be worn comfortably and not detract from our goal of reducing the cardiovascular demand of walking for the user. To the best of our knowledge, SoleMate would be safe for use in the short and long term. We have implemented extensive security measures to keep the user's medical data private and prevent unauthorised persons from controlling the device. This also ensures that our device adheres to GDPR.

We acknowledge the limitations of our system; the battery is large and requires a change-over during the day. Furthermore, the mode-switching algorithm requires user testing because the current system has switching delays which may feel unnatural. In places, the design of our system is high-level and requires more work to create a usable product. Moreover, for our current device to work, the user requires a mobile phone and the ability to download and navigate our mHealth application.

A future version of our project would allow operation of SoleMate through a website or solely using physical buttons on the device, making SoleMate usable for persons with limited technological access or skills. Another extension would include integrating the mHealth application with existing health and fitness applications – this would allow the user to view a more holistic gait picture by combining the biomechanical data from SoleMate with physiological data from wearable fitness trackers. Furthermore, rather than allowing a clinician restricted access to the user's mobile application, an extension of this system would have a separate website for clinicians to view which would feature more technical language and detail and store the gait parameters in a way that integrates well with existing NHS systems. It would also provide more information about the accuracy of the data collected by SoleMate. Additionally, we could create a range of cuffs tailored to different demographics. Currently our use of eccentric rotating mass motors means that the cuff can only operate at a small range of actuation amplitudes while remaining in the optimal frequency range – it is unlikely that this range would be suitable for both small children and large adults. Furthermore, the cuff is currently designed to be worn on the amputee's residual thigh. This means

that SoleMate is unsuitable for amputees with a sensitive or painful residual thigh. In the future, SoleMate could offer an alternative model that uses the lower back as the actuation site, as this has shown to be an effective alternative in clinical studies. Moreover, the current system is a prototype; it could be made significantly lighter in a commercial version by using a bespoke single-board computer to reduce power consumption.

In conclusion, this report describes the design of a commercially viable product capable of restoring somatosensory feedback to lower limb amputees. It advances state-of-the-art research by using an algorithm to determine whether tactile or proprioceptive feedback is better given the user's current activity and providing said feedback. Furthermore, its use of insoles which do not require bespoke fitting to determine sensor placement, combined with a mobile application which enables users to operate their device independently, greatly improves large-scale usability.

10. References

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3YP - Engineering in Society Supporting Statement

Please complete this supporting statement as a group/team and include one copy with your report submission at the end of your report. (This statement does not count towards your page count). This statement is not assessed, but ensures that your group have considered these important topics

Project Title:	(Please Select)
Student Name:	**Date:**
Alessandra French	21/05/2025
Jack Spiller	21/05/2025

Please indicate exactly where in your project submissions (Report and/or Logbook) the following topics have been considered.

Technology Strategy – Societal, User, Business and Customer Needs:
Section 8, pp.52

Project Financing:
Low cost prioritised throughout for commercial viability - e.g. section 2.2 pp.7, section 3.1.1 pp.10, section 5.2.2 pp.43

Sustainability and the Environment:
Longevity of device components considered throughout - e.g. section 3.2.1 pp. 15

Diversity and Inclusion:
Section 9 pp. 53/54.

Considerations of Health and Safety:
Used throughout; a vital part of this project. e.g. section 7 pp. 49

Refer to page numbers, section numbers, etc. Please refer to the example Supporting Statement.