



# USER MANUAL

Biomotum SPARK

This user manual is provided as a comprehensive guide and reference for using the Biomotum SPARK System.

If you need further assistance please contact the Biomotum clinical & technical support team (M-F: 8 am- 4 pm Pacific Time):

support@biomotum.com  
(800) 566-2531

**Caution:** Investigational device. Limited by Federal law to investigational use.



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## CHAPTER 1: INTRODUCTION

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### INDICATIONS FOR USE

The Biomotum SPARK orthotically fits the lower limbs and trunk. The SPARK is intended for use in rehabilitation institutions under the supervision of a trained healthcare professional to assist ambulatory functions, and to temporarily help improve ambulation upon completion of a gait training intervention. The device is intended for adolescents with Cerebral Palsy (ages between 12-21 years old) who are able to walk for 6 minutes with or without a walking aid (e.g., AFO and/or walker), and who do not have a musculoskeletal condition that would prevent the safe use of ankle assistance or resistance .

The Biomotum SPARK is not intended to be used on participants under 12 years old or over 21 years old; it has not been tested in these populations.

The Biomotum SPARK is not intended to be used for running or other sport activity.

The Biomotum SPARK is not intended to be used in individuals with hypertonicity or stiff muscles.

### CONTRAINDICATIONS FOR USE

- Musculoskeletal conditions that would prevent the safe use of ankle assistance or resistance, including:
  - <20 degrees of passive ankle plantarflexion range of motion
  - Knee extension or ankle dorsiflexion contractures >15 degrees
- Orthopedic surgery on foot, ankle, or leg completed in the prior 6-months
- Diagnosis of severe osteoporosis (low bone density)
- Body mass index <5th percentile or >95th percentile
- Cardiovascular disease that prevents mild-moderate physical activity

### DEVICE DESCRIPTION

The Biomotum SPARK consists of the following components:

- *Waist Pack:* The waist pack houses the *motors, battery, and control hardware* (motor drivers, microcontroller, Bluetooth hardware, and measurement hardware) and is worn using a comfortable *belt and harness* with magnetic clasps. The *power button* to turn the device on and off is located on the bottom of the waist pack.



- *Cable Transmission*: The cables transfer torque from the motors to the ankle actuator. The cable transmission system is worn using *thigh straps* to prevent the cables from catching on the environment.
- *Ankle Actuator*: The ankle actuator is a lightweight, single degree-of-freedom rotational joint that interfaces with the wearer's shank and foot to transfer torque from the motors to the wearer's ankle joint. The ankle actuator is held on the shank using a comfortable *shank cuff*. A *footplate* attached to the ankle actuator fits in the wearer's shoe and moves the foot to provide assistance or resistance to the wearer's ankle joint. Shank cuffs and footplates are interchangeable and must be fitted to the wearer so that they are snug yet comfortable. Sensors in the ankle actuator measure the torque transmitted by the device; sensors on the footplate detect whether the wearer's foot is in contact with the ground. Both sensors are integral to the function of the device and must be handled with care.
- *Control Interface*: The control interface is an iOS/Android tablet preloaded with a proprietary application that controls the device wirelessly over Bluetooth. The application stores wearer information and data, starts and stops device sessions and trials, performs device calibration, allows the clinician/researcher to adjust device settings, and uploads collected data to a cloud service. The device cannot be used without the control interface. The control interface must remain within 30 feet (9 meters) of the device at all times to maintain Bluetooth connection. The device will continue to function when disconnected, but the device settings cannot be changed, sessions and trials cannot be ended, and data collected while the control interface is disconnected will not be stored or saved. Normal operations will resume once the device is within range of the control interface.

The Investigational Use SPARK device includes an iOS tablet pre-loaded with the Biomotum application (app).

The SPARK device is also provided with the following tools:

- 2.5mm hex screwdriver, used on the safety bolt for the metal quick-connect bracket on the footplate
- 1.8mm slotted screwdriver, used on the screw for the cuff quick-release mechanism

Materials needed but not provided:

Plastic card, key, or slot-head screwdriver, to check the tension in the actuator cables.



An illustration of the Biomotum SPARK device is included below.

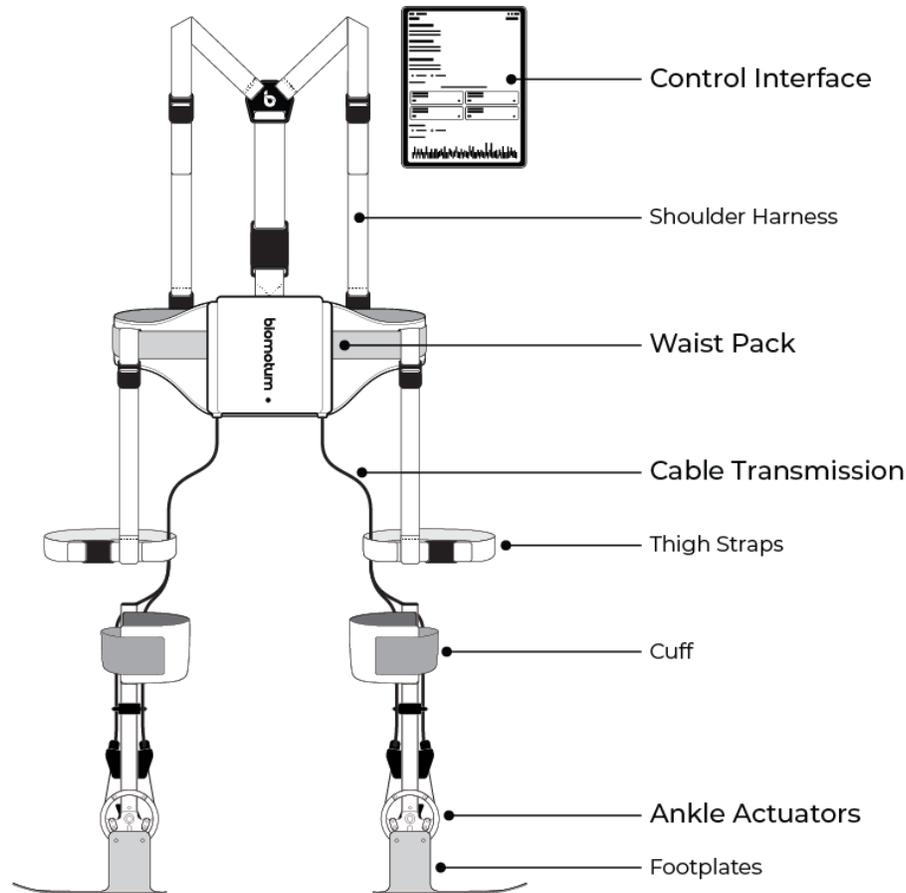


Figure 1. Biomotum Spark System Components

## OPERATING PRINCIPLE

SPARK's hybrid control system adjusts assistance or resistance across variable terrain and walking speeds. Hybrid control uses force sensors embedded into each footplate and provides torque that is proportional to the instantaneous demand placed on the ankle joint (i.e., the net moment generated by muscles and other biological tissues crossing a joint). The peak (maximum) torque that can be applied by the SPARK is set by the user. In simple terms – walking faster or slower results in a greater or smaller registered foot sensor force. The amount of assistance or resistance provided to the user by the SPARK device is automatically adjusted proportional to the change in foot sensor measurement and peak torque setting, in real time.



Hybrid control: **Assist** to make walking easier.  
**Resist** for precision ankle therapy

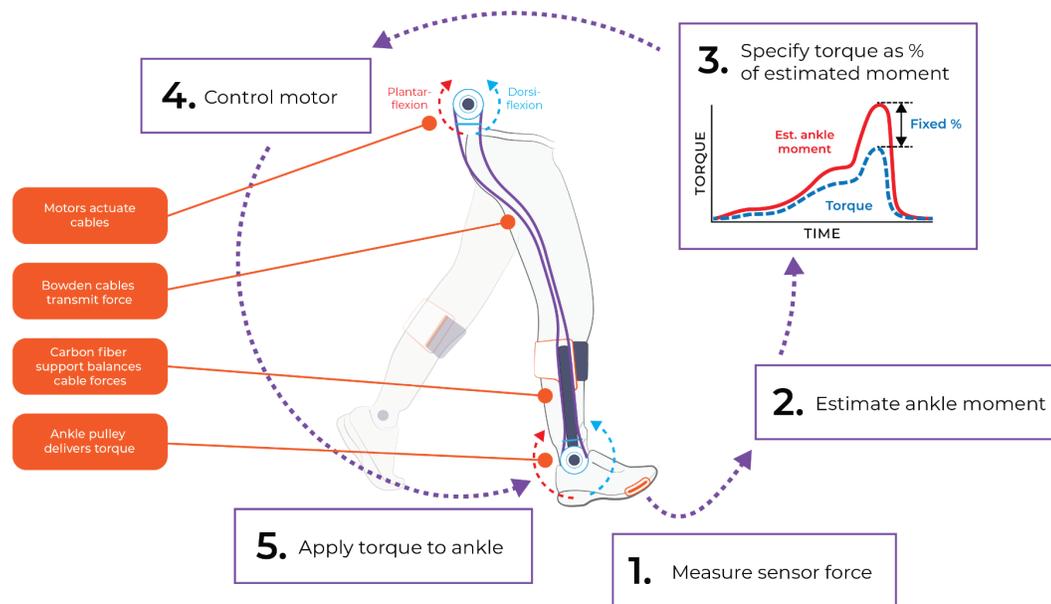


Figure 2. SPARK Control System

The SPARK has two modes of operation (“hybrid control”):

- *Assistance*: Assistance mode provides ankle joint plantarflexion torque during stance and dorsiflexion torque during swing.
- *Resistance*: Resistance mode provides ankle joint dorsiflexion torque during stance.

Ranges for optimal peak stance phase plantarflexor assistance and resistance levels (0.25-0.30 Nm/kg for assistance and 0.10-0.15 Nm/kg for resistance) were established during clinical walking testing. The default settings are 0.30 Nm/kg and 0.12 Nm/kg, for assistance and resistance, respectively. For example, peak default assistance torque for a participant with a body mass of 75 lbs (34 kg) would be 8.5Nm. These settings can be customized by the therapist at their discretion after assessing the user’s gait pattern. Nominal, on-off dorsiflexor torque can be provided during the swing phase between 0-5 Nm.

SYSTEM CALIBRATION



The SPARK performs both a static and dynamic calibration each time the SPARK is donned and used.

The static calibration is performed while the user is standing still, after donning the SPARK. Device torque is measured by the torque sensors in each ankle actuator, and is tared during the static calibration to eliminate bias in the measured torque signal that can affect control of the SPARK system.

The dynamic calibration begins after the user starts walking during a trial. Dynamic calibration quantifies the pressure threshold used to determine the stance and swing phases by logging the maximum and minimum pressure sensor signal for each step taken. The dynamic calibration also quantifies the baseline peak pressure (average peak pressure during the initial steps).

The prescribed torque profile is generated by taking the instantaneous pressure sensor signal and normalizing it by the baseline peak pressure value. The resulting normalized signal is bounded by values 0 and 1.5, with the value 1.0 corresponding to the peak torque setting. For example: if a value of 30% or 15 Nm is entered in the app, the controller will specify a peak prescribed torque of 15 Nm when the normalized pressure sensor signal is equal to 1.0.

Assistive/resistive torque is not applied until the dynamic calibration is complete and the pressure sensor baseline is established.

## NOTATIONS USED

Warnings & Cautions used throughout this manual:

**WARNING:** Describes potential safety hazards, limitations in use as a result of the potential safety hazard, and steps that should be taken if a safety hazard occurs.

**Caution:** Information about any special care to be used for the safe and effective use of the device. Not following this information could lead to damage of the device or lead to a poor participant experience.

**Note:** Information that's helpful to use the device correctly.



## SYMBOLS USED



Manufacturer



Date of Manufacture



Serial Number



Catalog number



Batch code



Consult instructions for use



Prescription Device



Caution

## WARNINGS & CAUTIONS:

**WARNING:** The SPARK is not waterproof. Do not use it if there is a risk of the device being exposed to water or other liquids.

**WARNING:** Risk of falling. Falling could be caused by a loss of control of ambulation by the participant or therapist as well as malfunction of the SPARK. The risk of falling can be reduced by having experienced, trained personnel conduct the therapy sessions using manual assistance. If needed, an overhead attachment with a safety harness and/or gait belt can be used during treadmill or over-ground walking. If a participant falls, the device automatically powers off.

**WARNING:** Use of the SPARK may cause discomfort, skin irritation, bruising, pain, or unusual swelling which may lead to skin breakdown or abrasions. This risk can be minimized by proper initial adjustment and regularly checking the skin at points of contact (waist, shoulders, thighs, calves and feet) during each session. Adjustments to the device fit and additional padding can be used to decrease the risk of skin breakdown.



**WARNING:** The SPARK may cause an individual to exceed their ankle joint range of motion, potentially leading to a tendon strain, muscle tear, or avulsion. This risk is reduced by mechanical stops on the SPARK that prevent the device from exceeding the normal ankle joint range of motion in the event of an electrical or software malfunction. Software systems are also in place to further reduce range of motion to improve fit and comfort during walking. The SPARK should only be used on individuals who have sufficient ankle joint range of motion (see Contraindications).

**WARNING:** Use of the SPARK may cause muscle spasms in participants with hypertonicity or tight/stiff muscles. Such individuals should not use the SPARK (see Contraindications).

**WARNING:** Use of the SPARK could result in bone fractures in individuals with severe osteoporosis. Individuals with this condition should not use the SPARK.

**Caution:** Do not use the SPARK on children under 12 years or in adults over 21 years. It has not been tested in these populations.

**Caution:** Do not use the SPARK for running or other sport activities.

**Caution:** Ensure the battery is inserted firmly into the waist pack so that no silver label (other than the pull tab) is showing.

**Caution:** Do not discharge the battery completely (<15%).

**Caution:** Make sure the upright & calf cuff are behind the shank and not off to the side when fitting the device.

**Caution:** Ensure the purple cables are not twisted when fitting the device. Twisted cables can negatively affect device performance.



## CHAPTER 2: PREPARE THE SPARK FOR USE

### SAFETY CHECK PROCEDURES

Prior to using the SPARK, inspect the following:

- Examine all harness parts (including, but not limited to shoulder, waist and thigh straps) for evidence of wear or tearing.
- Inspect the waist pack to ensure the battery is securely seated and the case is intact (i.e., no cracks).
- Ensure the shank cuff is securely fastened to the upright via the quick release. Purple cables must be secured in the guides of the shank cuff.
- Ensure there is appropriate cable tension at the ankle actuator (see *Tensioning the Actuator Cables*), and all bolts are tight with no visible signs of cable wear.
- Ensure the footplate is securely attached to the ankle actuator and there are no visible signs of cracking.

### BATTERY USE

The Biomotum SPARK uses rechargeable lithium ion batteries designed to last up to 45 minutes. Follow the charging and use instructions below to optimize the performance and safety of the system.

- Fully charge the battery prior to use. To confirm if the battery is fully charged, check the battery charge indicator. The charge indicator displays 5 charge levels: if all 5 are illuminated, the battery is fully charged. If only 1 bar is illuminated and blinking, or all bars are absent, the battery must be charged.
- To charge the battery, plug the charger into a wall outlet and plug the battery into the charger. If the LED is solid **green**, the battery is fully charged. If the LED is blinking **green**, the battery is charging. Battery charging takes approximately 90 min.
- Insert the charged battery into the SPARK.



**Caution:** Ensure the battery is inserted firmly into the waist pack so that no silver label (other than the pull tab) is showing. (Figure 3)

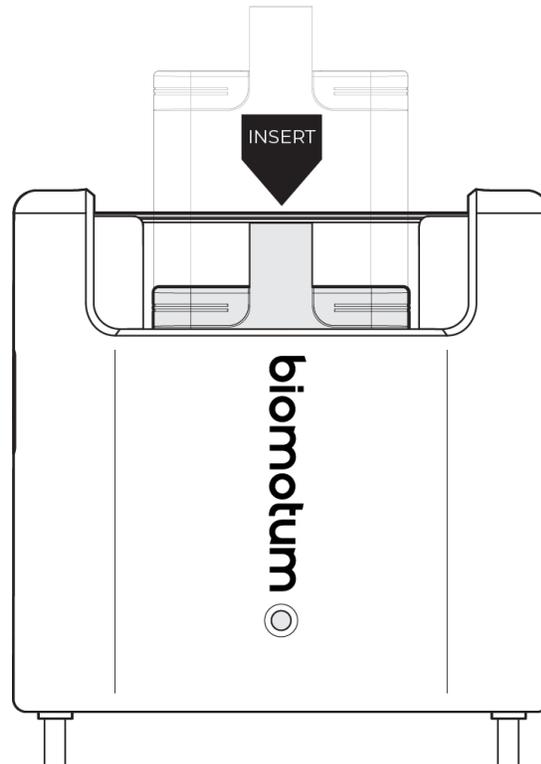


Figure 3. Battery fully inserted into the waist pack

- Avoid discharging the battery completely, as this may damage the battery and cause it to fail prematurely.

**Caution:** Do not discharge the battery completely (<15%).

- Ensure the SPARK is turned off when not in use, as leaving it on will drain the battery.

**NOTE:** To conserve the battery life during a session, turn off the SPARK if an individual will not be using it for more than 5 minutes.



## CHOOSING FOOTPLATE SIZE

The footplate is worn inside the shoe.

- Use the sizing chart in Figure 4 to determine the appropriate size footplate. Use this as a starting point and confirm it is the correct size by having the participant stand on the footplate (Figure 5). The footplate should be about the length of the foot, but it can be slightly smaller than the foot if between sizes.

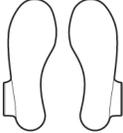
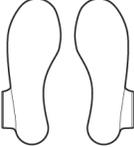
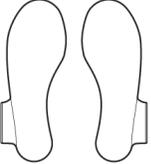
|                          |   |   |   |   |   |
|--------------------------|---|---|---|---|---|
|                          |  |  |  |  |  |
| Biomotum Footplate Sizes | X-SML   | SML   | MED   | LRG   | X-LRG   |
| US Sizes                 | 2.5 - 4   | 4.5 - 6   | 6.5 - 8   | 8.5 - 10  | 10.5 - 12   |
| EU Sizes                 | 34 - 36   | 37 - 38   | 39 - 40   | 41 - 43   | 44 - 46   |

Figure 4. Footplate sizing chart

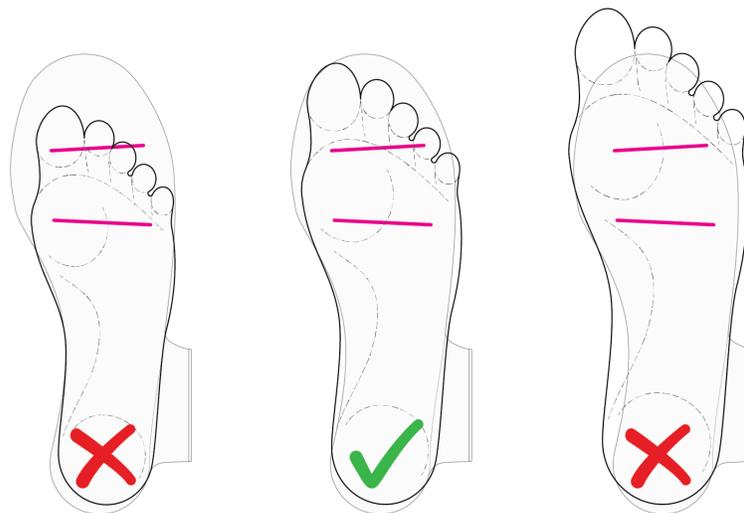


Figure 5. Footplate fitting guide where the pink lines indicate foot sensor placement with respect to the user's foot. The left footplate size is too large for the user. **The middle footplate size fits the user.** The right footplate size is too small for the user.



- After removing the insole/sock liner from the shoe, insert the footplate in the shoe to confirm that it is the correct length and width (not too long or wide). The footplate is designed to be used without the shoe insole; depending on the volume of the shoe, you may choose to use the insole/sock liner on top of the footplate.

**NOTE:** Avoid using oversized shoes as the foot and footplate will move within the shoe and affect the quality of exoskeleton assistance or resistance.

**NOTE:** The SPARK is designed for use with low-top footwear and will not work with high-top styles that go above the ankle.

### ATTACHING/REMOVING THE FOOTPLATE

The footplate attaches to the ankle actuator via a magnetic quick-connect.

- Use the provided 2.5mm hex screwdriver to unscrew the safety bolt from the metal quick-connect bracket by rotating the screw counter clockwise 1-2 revolutions. (Figure 6)

**NOTE:** Do not remove the screw. It only needs to be loosened to insert the footplate.

- Align the footplate with the studs on the quick-connect bracket, then push the footplate onto the quick-connect bracket - it will “lock” in place using magnets.

**NOTE:** If the footplate does not “lock” into place, check to make sure the footplate is on the correct side of the device. The device will reject the footplate if placed on the wrong side.

- Tighten the safety bolt into the quick-connect bracket by rotating the screw clockwise 1-2 revolutions.

**NOTE:** Do not overtighten the screw. Tighten until the footplate cannot be removed from the device.

- To remove the footplate, loosen the safety bolt and pull the footplate away from the quick-connect bracket.



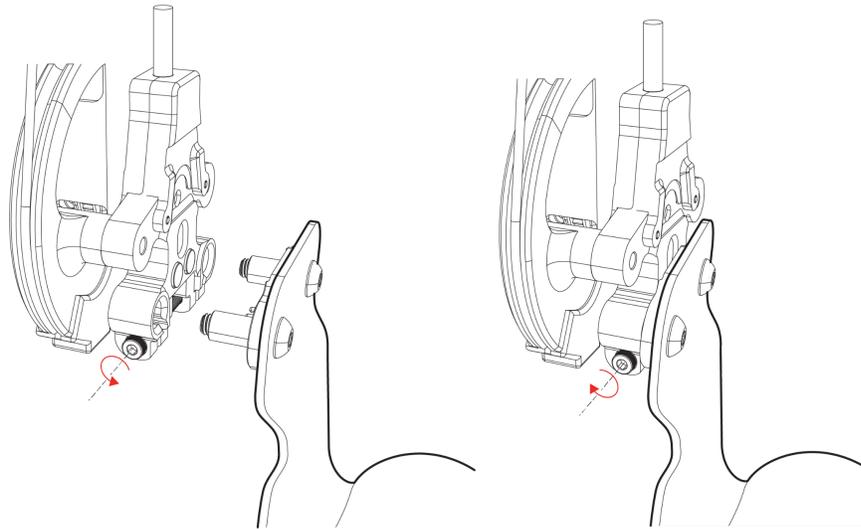


Figure 6. Rotate the safety bolt counter clockwise to loosen (left). Rotate the safety bolt clockwise to tighten (right).

#### ATTACHING AND ADJUSTING THE CALF CUFF

- Select the calf cuff size that fits snugly around the largest part of the calf muscle (the cuff goes around the back of the calf) (Figure 7).

**NOTE:** If the participant is between sizes, use a larger calf cuff and pad the inside of the cuff with foam to create a snug fit.

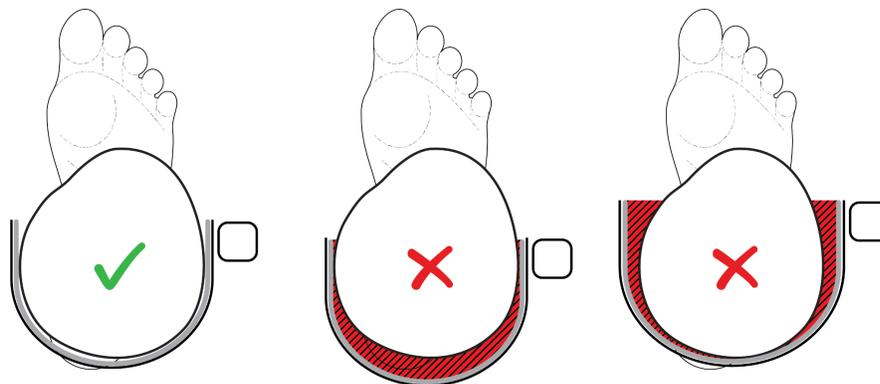


Figure 7. Calf Cuff fitting guide. The left cuff size fits the user. The middle cuff size is too small for the user and has excess space between the user's calf and the cuff. The right cuff size is too large for the user and the user has excess space between the side of the user's leg and the cuff.



- Once the proper size calf cuff has been selected, open the quick-release lever on the calf cuff (Figure 8) and slide the cuff onto the carbon-fiber upright. Be sure that the cuff is facing the same direction as the footplate (i.e., back of the cuff is aligned with the heel of the footplate).
- Adjust the height of the calf cuff so that it aligns with the largest part of the calf musculature. This can be done by having the participant stand on the footplate and sliding the calf cuff up or down to the appropriate height. (Figure 9)
- Tighten the quick-release lever on the calf cuff to secure it in place. Secure the purple cables by snapping them into the clips on both sides of the cuff bracket.
- When the quick-release lever on the cuff is secured, the cuff should not slide up and down. If the cuff moves with the quick-release lever secured, refer to the Troubleshooting Guide.

**NOTE:** Calf cuff height adjustment can also be done when donning the SPARK (after the footplate is in the shoe and the foot is inserted).

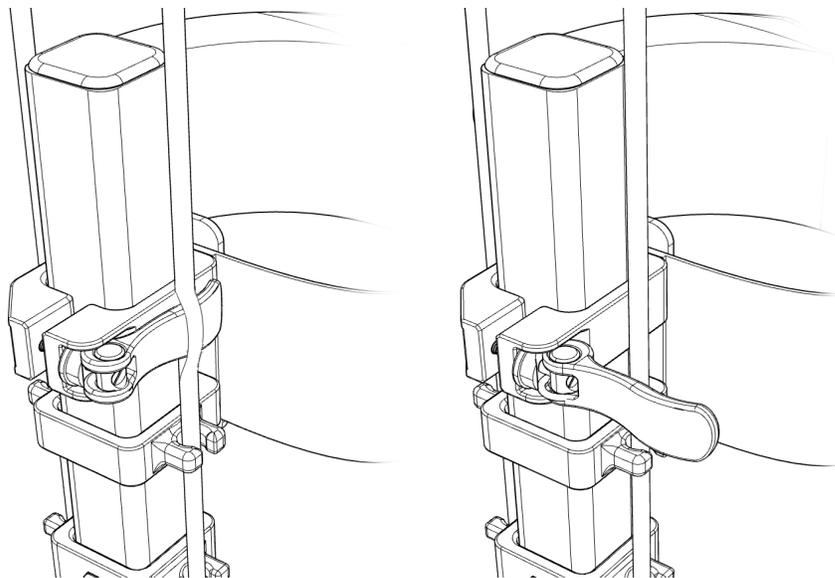


Figure 8. Quick release lever in closed (left) and open (right) positions



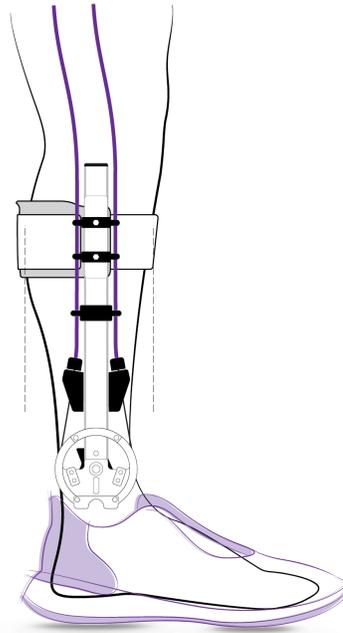


Figure 9. Calf cuff aligned with the largest part of the calf musculature

### CHAPTER 3: DONNING THE SPARK

The SPARK is designed to contact the participant at the foot, lower leg, and around the waist. Avoid direct contact of the device with the skin by using the system with socks and pants. We recommend that the user wear tighter fitting, athletic apparel to avoid excess material and bulky seams which may cause skin irritation.

To don the SPARK:

- Have the participant sit in a chair. The participant must not be wearing shoes.
- Have the participant move forward and sit on the front edge of the chair.
- Put the waist unit behind them on the chair but do not attach it to the waist yet.
- Bring the cables and ankle/foot assemblies around the waist so that they are beside each foot.

**Caution:** Ensure the purple cables are not twisted. Twisted cables can negatively affect device performance.



## PUTTING ON THE ANKLE/FOOT ASSEMBLY

- Fully plantarflex the device (so that the upright is out of the way of the lower leg).

**Caution:** Make sure the upright & calf cuff are behind the shank and not off to the side.

- Remove the insole/sock liner from the shoes and insert the footplate into the footwear. (Figure 10)

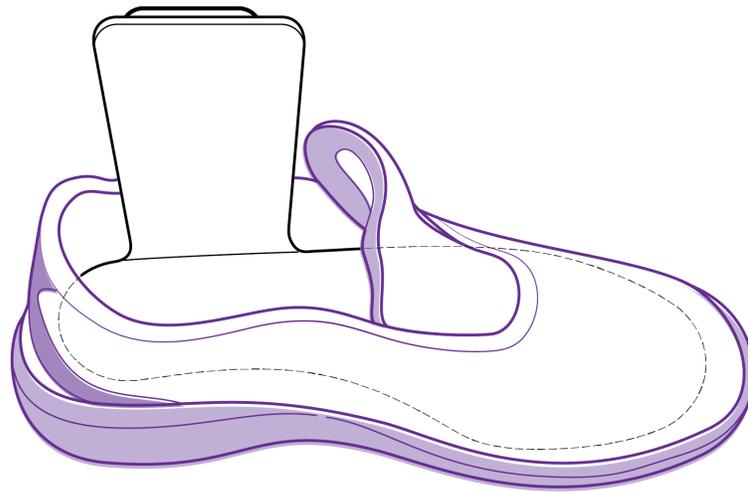


Figure 10. Footplate correctly inserted into shoe

- Have the participant slide their foot into the shoe while you pull back on the ankle assembly - this will make it easier to insert the foot without the footplate sliding forward.
- Tie the shoes (if applicable) so that the foot is secure. If the foot moves in the shoe after tying, untie and tighten the laces and tie again. Tighten the shoelaces as much as comfortably possible.

**NOTE:** The sock liner can be placed over the footplate if there is enough room in the shoe to accommodate it. It's better to have the shoe be snug than loose.

- Move the calf cuff forward until it touches the back of the calf. Adjust the height, if needed. Pull the velcro strap across the front of the shin and secure it to the other side of the calf cuff. The calf cuff should be snug.
- Confirm that the ankle/foot assembly is comfortable and the participant can plantarflex and dorsiflex the ankle.
- Repeat with the other foot.



## DONNING THE WAIST PACK

- While the participant is seated, wrap the waist belt around the participant and latch the belt. The magnetic buckle used on the waist assembly snaps closed when the ends are brought close to each other. Release the buckle by sliding the front part of the buckle upwards and the rear part down, in the opposite direction. (Figure 11)

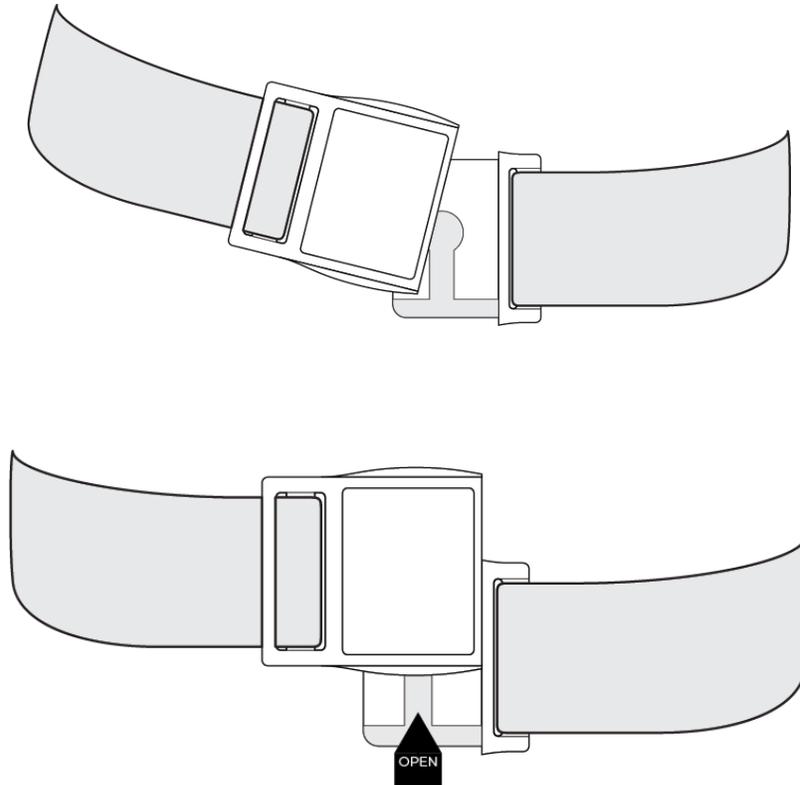


Figure 11. Operation of waist buckle

- Have the participant stand and tighten the waist strap so that the waist pack is snug.

**NOTE:** Raise or lower the waist pack so that the purple cables have just enough slack to allow the participant to move without the cables becoming fully extended and pulling on the waist pack. Use the shoulder harness straps if necessary; see page 22 for instructions.

## TENSIONING THE ACTUATOR CABLES

- While the participant is standing, check the tension in the actuator cables by inserting a rigid object (e.g., key, plastic card, small flathead screwdriver or similar) in the slot near the top of the pulley covers.



- Press the rigid object inward and observe the cable movement. Cable tension is appropriate if the cable aligns with the engraved line on the pulley cover. If the rigid object contacts the inner wall of the slot, the cables must be tightened. If the cable can not be pushed to the engraved line, the cables must be loosened.

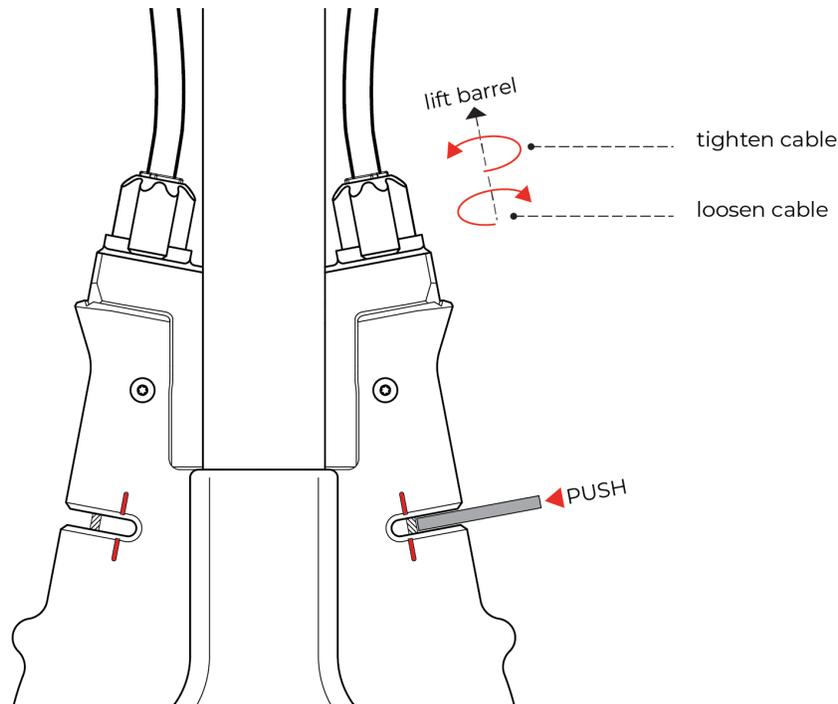


Figure 12. Checking and adjusting cable tension

- To tighten the cables, lift the barrel adjusters then turn counter-clockwise, adjusters are located at the top of the pulley covers. (Figure 12)

**NOTE:** To rotate, pull up on the barrel adjusters so the extruded gear features clear the surface. When you are done tensioning the system, make sure the extruded gear features are properly meshed with the surface so the barrel adjusters cannot loosen.

- To loosen the cables, lift and tighten the barrel adjusters, turning clockwise.

#### SECURING THE THIGH STRAPS

- Connect the thigh straps to the purple cables by opening up the Velcro on each thigh strap (left image) and enclosing the cables securely (right image), repeat for both legs. (Figure 13)



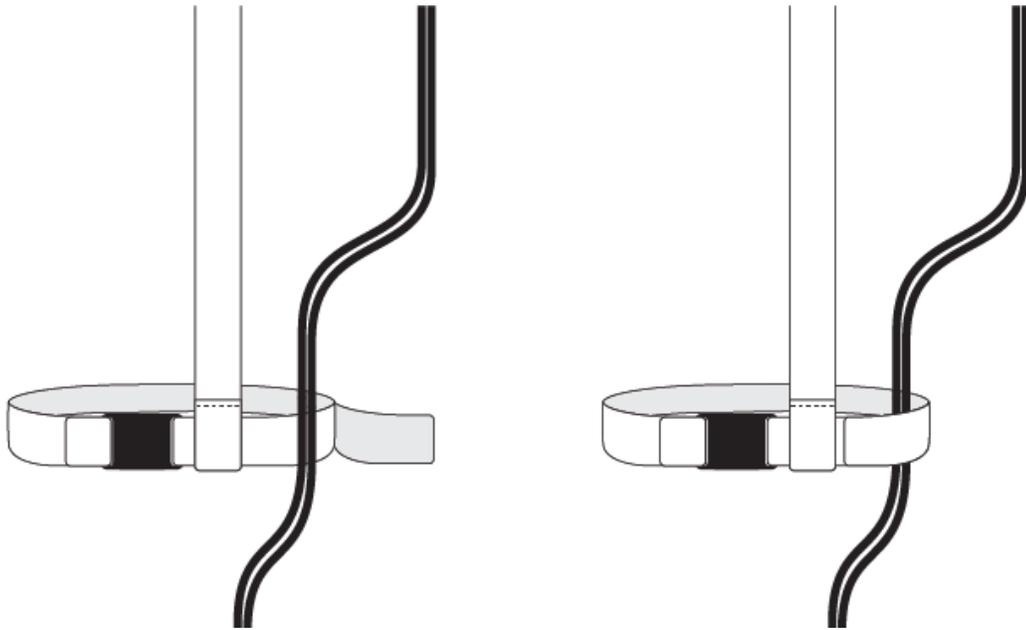


Figure 13. Securing the purple cables with the thigh straps

- The thigh straps are held around users thighs using magnetic latches. The latches snap together when you bring both sides close to each other. To release, push both sides of the buckle toward each other using a sliding motion. (Figure 14)

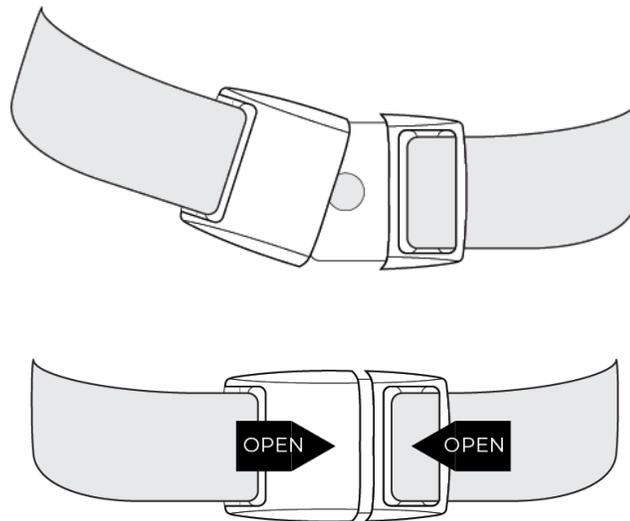


Figure 14. Operation of the thigh strap latches



### USING THE SHOULDER HARNESS (OPTIONAL)

The shoulder harness supports the waist pack. Use the shoulder harness in smaller individuals where the waist pack may have to be located higher on the torso.

- Connect the waist harness to the back of the waist pack using the magnetic latch.
- Bring the shoulder straps over the shoulders and attach to the front of the waist strap using the magnetic latches.
- Raise or lower the harness by tightening or loosening the shoulder straps.

### USING THE FOOTPLATE STRAPS (OPTIONAL)

Use footplate straps during walking trials where the participant's foot needs to be secured to the footplate, such as in resistance mode. To use footplate straps, follow the steps outlined below.

- Attach the adhesive hook fastener dots (provided with the device) to the bottom side of the footplate as seen in Figures 15 and 16.

**NOTE:** There are only enough adhesive hook fasteners in the box to outfit all footplates once.

- Place the participant's foot on the footplate and attach the elastic loop fastener to the hook fasteners on the bottom of the footplate.

**NOTE:** Useful wrapping techniques are shown in Figures 15 and 16.



- Slide the footplate (with the participant's foot secured on the footplate) into the shoe, then proceed with the rest of the device set up

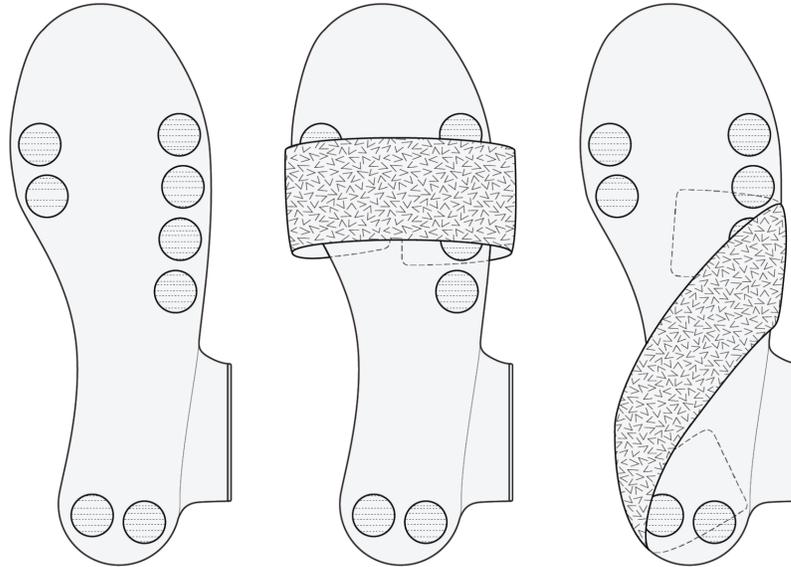


Figure 15. Positioning for Velcro hook tabs and 2" footplate straps (LARGE)

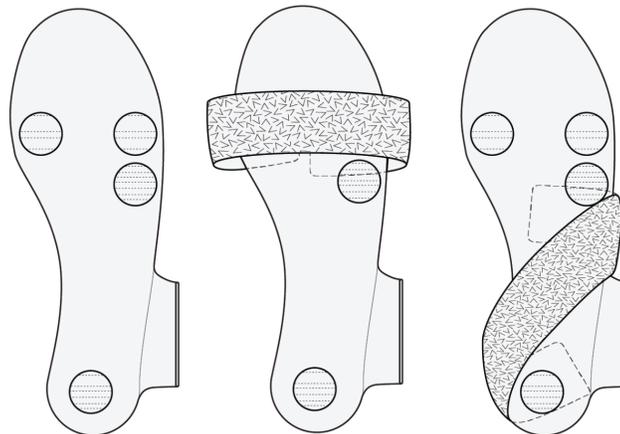


Figure 16. Positioning for Velcro hook tabs and 1" footplate straps (SMALL)

### SYSTEM CHECK

Now that the SPARK is on the participant, have them move around and take a few steps to confirm that it is comfortable and does not interfere with movement.



## CHAPTER 4: SETTINGS, CALIBRATIONS AND USE

### TURNING ON AND PAIRING THE SPARK

- The power button for the SPARK is located on the bottom of the waist pack (Figure 17). Turn on the SPARK by toggling the switch to the ON position. The LED light on the face of the waist unit will illuminate (green).



Figure 17. Power button and LED Indicator

- Using the tablet provided with the SPARK, ensure Bluetooth is on and open the Biomotum app. The app will automatically pair with the SPARK and the LED on the waist unit will turn purple. A Bluetooth icon in the upper right corner of the app will appear.



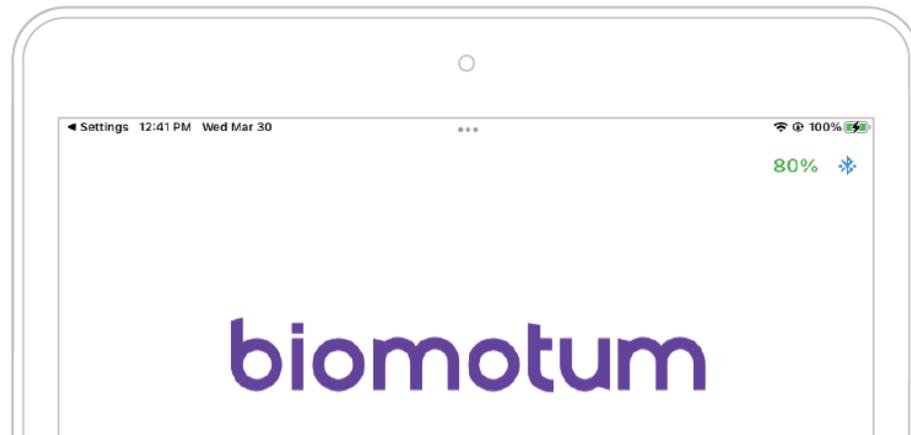


Figure 18. Battery charge level and Bluetooth connection indicators

- The battery charge level (%) is indicated at top right of the home screen in the app. (Figure 18)
- Keep the tablet within 30 ft. of the user at all times to maintain a Bluetooth connection.
- If the Bluetooth connection is lost, a trial can be ended by powering off the device.

**NOTE:** If the system fails to pair, close the app, turn the SPARK off, turn the SPARK on again, and re-open the app (in the correct sequence of actions). BT pairing is done automatically, there is nothing for the user to do to start BT pairing.

**NOTE:** Ensure Bluetooth is enabled on the tablet being used to control the SPARK.

**NOTE:** If the battery charge level is <50%, charge the battery prior to use.

## INPUT USER SETTINGS

All user information and walking settings are entered using the Biomotum app. Sessions are participant visits (i.e., intervention sessions) and trials are the individual walking trials completed during a visit/session. As such, a session can include multiple trials.



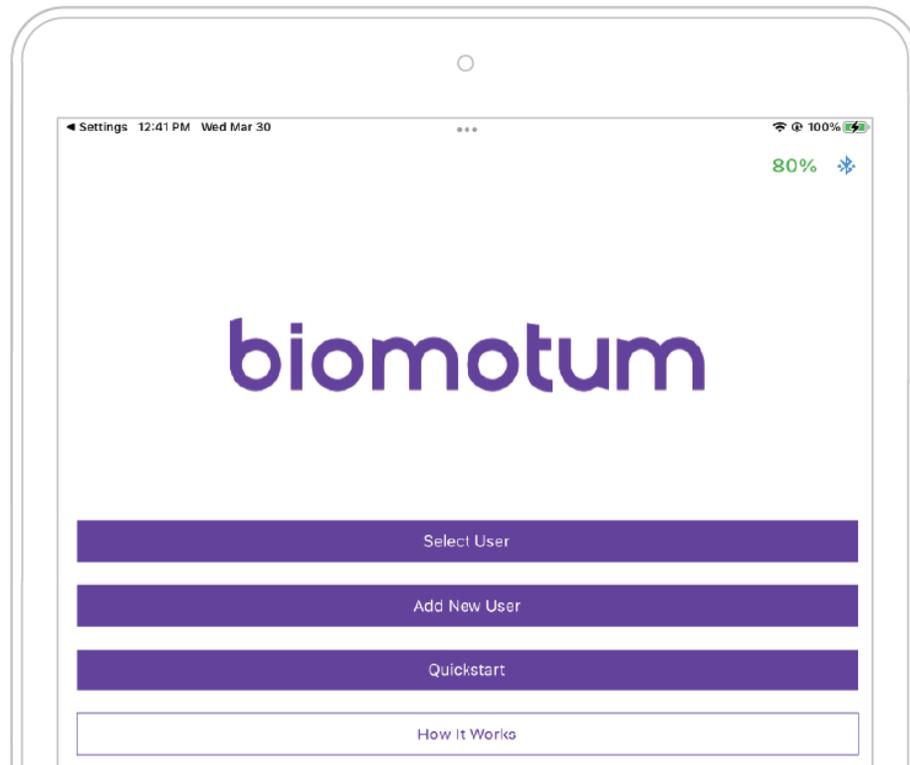


Figure 19. Startup input choices

There are 3 input choices (Figure 19) when opening the app:

1. **Select User:** Used for a participant who is already in the database.
  - a. Select participant from the list (or select add new user if not in list).
  - b. Select View Session History, View Last Session, or Start New Session.
    - i. View Session History: Select session to view. You can select Torque or State chart mode to view the session data. Zoom in to view chart data by selecting the chart and using two fingers to zoom in or out. Press done when finished.
    - ii. View Last Session: Displays last session. Press done when finished.
    - iii. Start New Session: Starts a new session, checks Bluetooth connection. See Input Walking Settings (below) for next steps
    - iv. Edit the participant data displayed by selecting the pencil icon in the upper right corner of the screen.
2. **Add New User:** Used to input participant information for new participants.
  - a. Enter the Study/Clinic Name, the Participant's ID#, and weight (lbs). These fields are required.
  - b. Once user data is saved, press "Start New Session". See Input Walking Settings (below) for next steps.



3. **Quickstart:** Used when testing the device (i.e., not during a trial).
  - a. App checks Bluetooth connection. Press Continue once connection is verified.
  - b. Enter body weight in pounds.
  - c. See Input Walking Settings (below) for next steps.

## INPUT WALKING SETTINGS

The SPARK settings for a walking session are entered from the New Session screen on the app. This screen lets you select the peak torque settings (Prior, Default, Custom, or Advanced), mode (Assistance or Resistance), and values (as percentage of body mass or N-m).

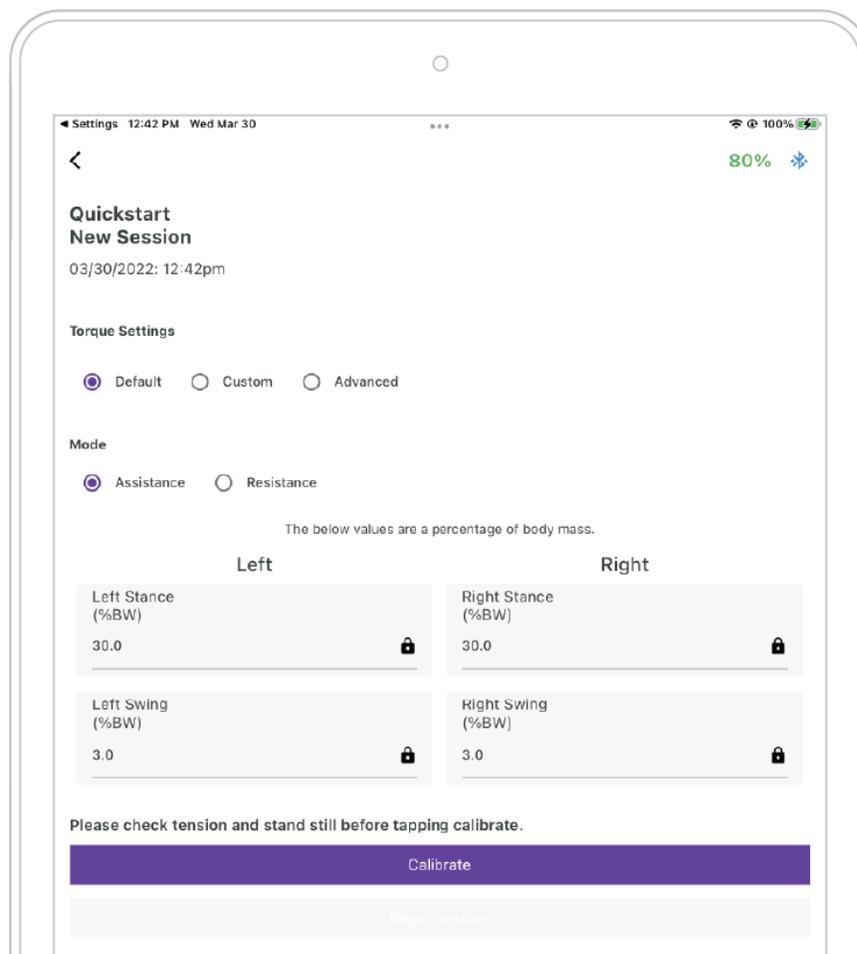


Figure 20. Input user settings

- Peak Torque Settings (the maximum torque that will be delivered to the participant)



- Default: Uses default torque settings
  - Assistance: Stance 30% body weight (kg), swing 3% body weight (kg)
  - Resistance: Stance 12% body weight (kg), swing 3% body weight (kg).
- Custom: User inputs stance and swing values for left and right legs as percentage of body weight. This button is selected when you want to use torque settings that are different from the last session and from the default settings.
- Advanced: User inputs stance and swing values for left and right legs as N-m. This button is selected when you have specific peak torque values you want the system to use.

**Note:** Settings can be different for each leg.

The below values are a percentage of body mass.

| Left              |      | Right              |      |
|-------------------|------|--------------------|------|
| Left Stance (%BW) | 30.0 | Right Stance (%BW) | 30.0 |
| Left Swing (%BW)  | 3.0  | Right Swing (%BW)  | 3.0  |

Please check tension and stand still before tapping calibrate.

Calibrate

Logout Session

Figure 21. Device peak torque input

- Peak Torque Inputs (Left and Right). These values are the peak torque that will be applied by the SPARK. Torque inputs can only be entered if you select Custom or Advanced buttons above.
  - Custom Peak Torque (Percentage of Body Weight)
    - Enter appropriate left and right peak stance torques (30% is assistance default, 12% is resistance default). Enter a value between 0-35% for assistance and 0-25% for resistance.
    - Enter appropriate left and right peak swing torques (3% is assistance default, 3% is resistance default). Enter a value between 0-15%.
  - Advanced Peak Torque (Nm)



- Enter appropriate left and right peak stance torques. Enter a value between 0-21 Nm for assistance or resistance.
- Enter appropriate left and right peak swing torques. Enter a value between 0-15 Nm.

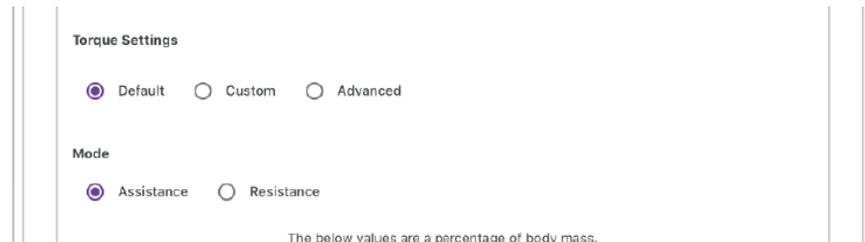


Figure 22. Mode inputs

- Mode
  - Assistance: This provides an assistive torque during walking. The torque is proportional to the pressure applied to the footplate. It is plantarflexion during stance and dorsiflexion during swing.
  - Resistance: This provides resistance torque during walking. The torque is proportional to the pressure applied to the footplate. The torque is directed in dorsiflexion during stance (brings shank towards the foot). In swing phase, either dorsiflexion assistance (to assist drop foot) or no torque can be applied during Resistance mode.

Once Settings are selected, start the trial by having the participant stand perfectly still and then press the calibration button (while they remain standing still).

## CALIBRATING THE SYSTEM

Static Calibration: Once the device is on the participant and the device settings have been entered, have the participant stand still. Select the calibration button at the bottom of the New Session screen. The SPARK will conduct a quick (<1 second) static calibration.

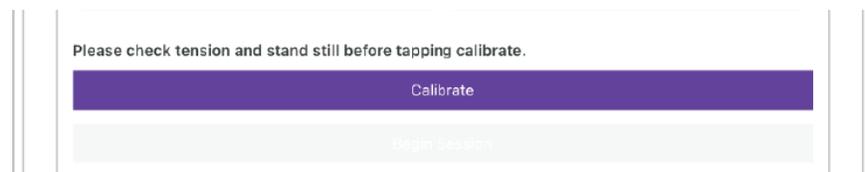


Figure 23. Calibration button



Select Begin Session to start a trial.

Dynamic Calibration: Once a participant begins walking, it takes about 7 steps before the SPARK produces torque. During those initial steps, the system performs the dynamic calibration.

**NOTE:** If a trial is paused (the pause symbol is shown in the upper left corner of the image below), the motors stop producing torque immediately. Torque is applied once the Play button is pressed and the trial is resumed.

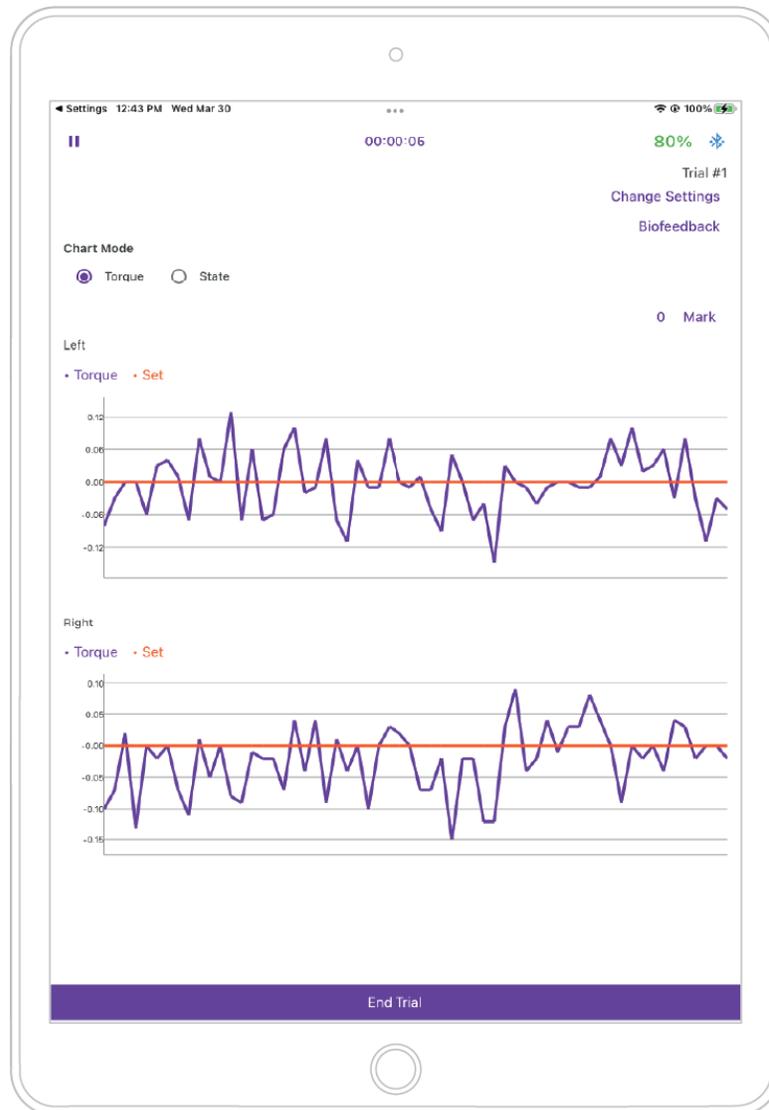


Figure 24. In-Trial screen



## USING IN-TRIAL FEATURES

Once calibration is complete and a trial has started, there are several features that are available. These include: Pause, Mark, Chart Mode, Biofeedback, and Change trial settings.

- **Pause:** Pushing the Pause button (upper left corner of screen) turns the motors off, stopping torque production. Torque can be resumed by pressing the Play button.
- **Mark:** Pressing the mark button creates a marker in the session data. This feature is helpful to denote events that occur during a trial (e.g., changing speed, terrain). You can press the mark button as many times as needed during a trial.
- **Chart Mode:** These buttons toggle the display from Torque Mode to State Mode. Torque Mode displays the torque being produced. State Mode displays whether the leg is in stance or swing.
- **Biofeedback:** Selecting biofeedback will open a new window where you can set a biofeedback threshold (e.g., . percentage of body weight) that the clinician wants the participant to achieve. This can be set individually for the right and left leg. This can be helpful to encourage push-off during late stance. Once a threshold has been set (e.g., 5%), each time the actual torque exceeds that threshold, the app will sound (ding) and the screen will change color briefly. In the biofeedback window there is also a retake baseline button. If it seems difficult for the participant to exceed the threshold, you can press retake baseline to ensure the baseline values are appropriate. If it's still difficult for the participant to exceed the threshold, reducing the threshold value may be necessary.



- **Change Settings:** Selecting the Change Settings text will open up the INPUT WALKING SETTINGS page. See above for how to adjust the peak torque settings. Keep in mind it will take several steps for the new settings to be achieved.

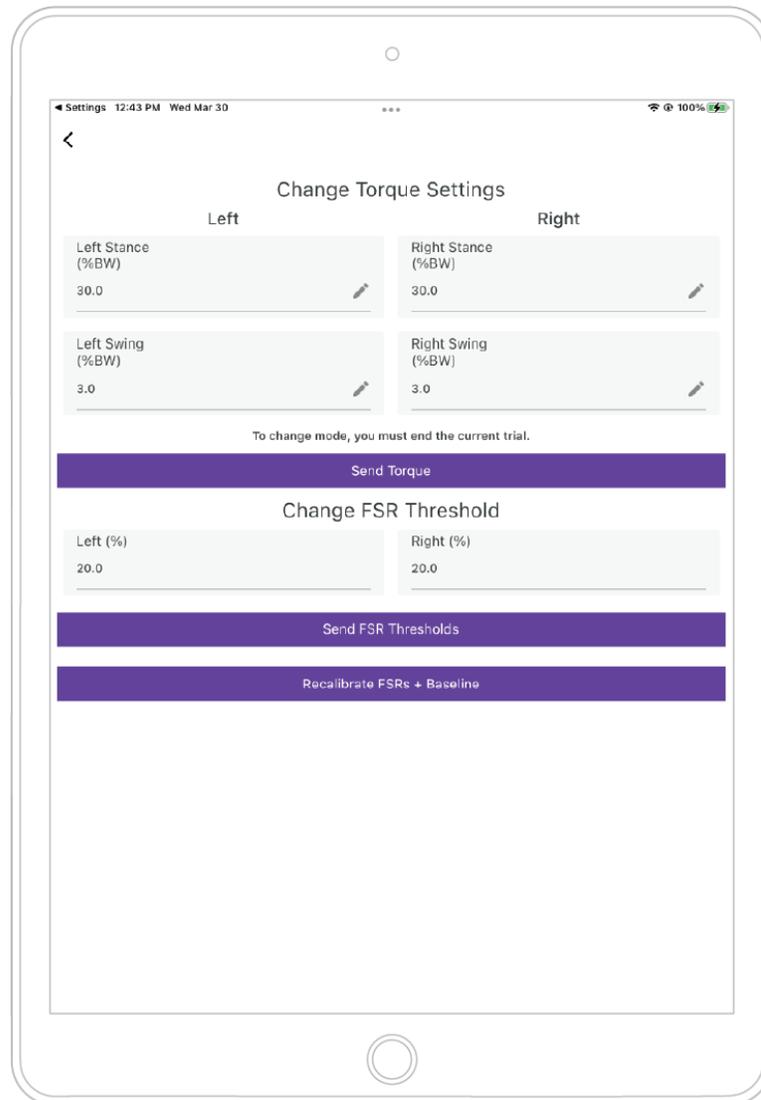


Figure 25. Change settings

- **Recalibrate FSRS + Baseline:** Pushing the Recalibrate FSRs + Baseline button will reset the dynamic calibration of the fore-foot sensors. The fore-foot sensor uses Force Sensitive Resistors (FSRs) to transition between gait phases and control stance phase torque output. Keep in mind it will take several steps for the new dynamic calibration to be complete. Torque



will continue to be applied using the previous dynamic calibration until the new dynamic calibration is complete.

Select End Trial to end the trial and open the session summary page.

## SESSION SUMMARY OVERVIEW

As noted above, this page opens when End Trial is selected. This page contains a summary of the session including the duration and number of steps. It also includes trial summary information. If there was more than one trial in a session, you can select which trial to review from the trial dropdown menu. Trial data displayed includes duration, number of steps, mode (i.e., assistance or resistance), torque settings, and charts displaying either the torque or state data (depending on the selection). Moving two fingers away from each other will zoom in on the charts. This page can be closed by selecting New Trial or End Session.

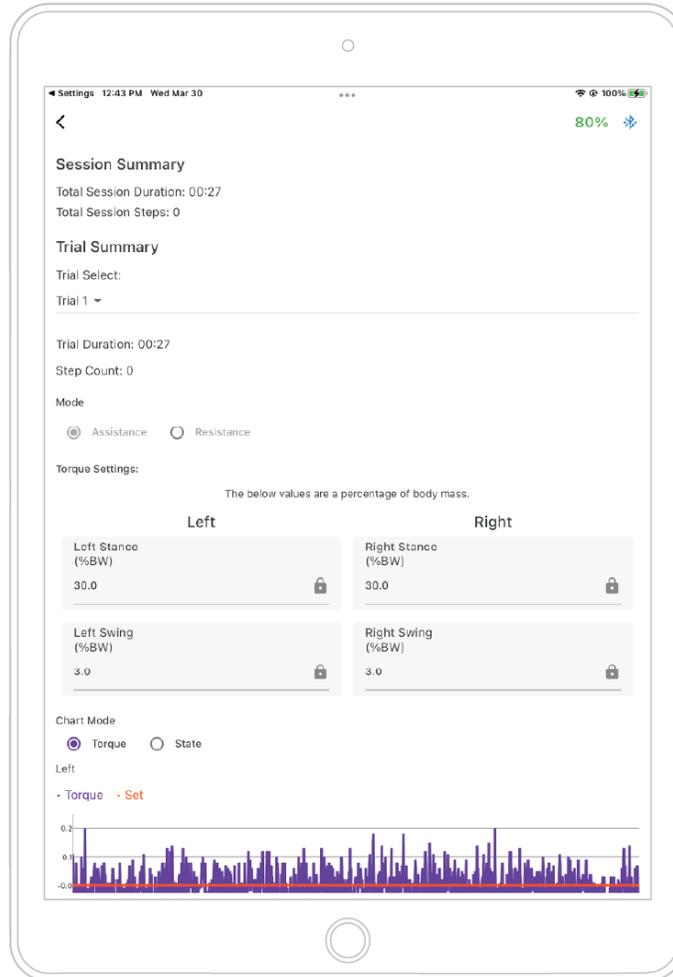


Figure 26. Session summary overview



## CHAPTER 5: ERROR MESSAGES, TROUBLESHOOTING

This chapter describes issues that occur while using the SPARK app and actions to take to resolve the issue.

### DEVICE SETUP

| BEHAVIOR  | POSSIBLE REASONS                         | SOLUTION  |
|---|--|---|
| Footplate does not lock into place                                      | Footplate is on the wrong side.          | Check footplate and device side compatibility.  |
| Cuff does not slide onto upright  | Cuff is on the wrong side.               | Check that the cuff is on the correct side of the device. Cuffs are directional and have different sized sliders.   |
|   | Cuff slider may be too tight.            | If cuffs are on the correct side of the device in the correct orientation, rotate the quick release handle counterclockwise 1-2 rotations. Try attaching the cuff to the upright again. |
| Cuff slides freely on upright even though the quick release is engaged. | Cuff may be on the wrong side.           | Check that the cuff is on the correct side of the device. Cuffs are directional and have different sized sliders.   |
|   | Cuff slider may be too loose.            | If cuffs are on the correct side of the device in the correct orientation, rotate the quick release handle clockwise 1-2 rotations. Try attaching the cuff to the upright again.        |
| Cuff quick release won't engage or disengage.                           | Quick release screw may have backed out. | Using the 1.8mm slotted screwdriver, insert the screw so that it does not come in contact with the handle.  |
| Battery will not seat fully into the device.                            | Incorrect battery orientation.           | Check that the battery is inserted so that the silver pull tab is facing up and away from the body. The battery can only be inserted in one orientation.                                |



|                          |   |  |
|--------------------------|---|--|
|                          | Obstructions.                                 | Check that there are no obstructions in the battery housing.             |
| Device will not turn on. | Battery not inserted or battery is discharged | Check that you have a charged battery properly inserted into the device. |

## WALKING

| BEHAVIOR   | POSSIBLE REASON   | SOLUTION  |
|--|---|---|
| Gait phase transitions (changing between stance and swing phase) are inconsistent  | The fore-foot FSR sensor thresholds may need adjustment.                            | If the device transitions to stance phase too quickly, enter a higher (e.g., 30%) FSR threshold % for the affected leg and click "Send FSR Thresholds" under the Change Settings page. If the device does not transition to stance phase quickly enough, enter a lower (e.g., 20%) FSR threshold % for the affected leg and click "Send FSR Thresholds" under the Change Settings page. |
| Device torque does not reach peak torque.  | Desired torque is above the upper limit.  | Recalibrate FSRs + Baseline.  |
| Plantarflexion/dorsiflexion bias in zero torque control.<br><br>OR<br><br>User feels like torque is applied when no torque was prescribed. | Static calibration was captured when the participant was moving their ankle joints. | End and restart trial. Ensure the patient is not moving during torque calibration.  |
|  | An issue (e.g., mis-step) occurred during the walking calibration.                  | Recalibrate baseline. Did it improve? If not, see below.  |



|                                  |                                      |  |
|----------------------------------|--------------------------------------|--|
| Torque application inconsistent. | Footplate sensor malfunction.        | Check the states graph. If you see inconsistent state changes and fore-foot sensor readings, end trial and replace the footplate.<br><br>If replacing the footplate solved the problem, contact Biomotum Technical Support for a replacement footplate. If replacing the footplate did not solve the problem, see below. |
|                                  | Torque sensor malfunction.           | If replacing the footplate did not solve the problem, stop using the device immediately and contact Biomotum Technical Support for next steps.   |
| Torque application is lagging.   | Purple cables twisted.               | Ensure the cables are not twisted around each other. If cables are not twisted, see below.   |
|                                  | Cables are not adequately tensioned. | Check the cable tension, and tension as required.  |

## SOFTWARE

| BEHAVIOR                  | POSSIBLE REASONS      | SOLUTION  |
|---------------------------|-----------------------|---|
| Application slowing down. | Out of date software. | Update application through the app store.   |
| Device not connecting.    | Bluetooth error.      | Close the app, power off the SPARK device. Then power the SPARK on and open the app.. Try connecting to the device again. Make sure you fully quit the application by double clicking the iPad home button and swiping up on the application. |



|                            |   |  |
|----------------------------|---|--|
|                            | Device is connected to another application. | If you have multiple software devices to control the SPARK, ensure all applications are closed. If the SPARK LED light is purple, it is already connected to another device. |
|                            | Application has crashed.                    | Force quit the application. To do this on an iOS device, double tap the home button and swipe up on the app.   |
| Internet Connection Alert. | Not connected to WiFi.                      | Connect the device running the app to a WiFi network. Make sure the WiFi network is connected to the internet.   |
| Graph not plotting.        | Poor Connection                             | End the current session. Turn off the SPARK device. Close the mobile application. Turn on the device. Re-open the application.   |
|                            | Application has crashed.                    | Turn off the SPARK device. Turn on the device. Re-open the application.  |



## CHAPTER 6: CLEANING & MAINTENANCE

### CLEANING

Wipe the waist belt, buckles, harness, calf pads, and foot pads of the device with all purpose/multi surface disinfectant wipes and allow to air dry between uses (e.g., Lysol or Clorox wipes).

Wash the calf and foot pads by hand or machine (cold water, gentle cycle) when visibly soiled. Use household laundry detergent.

Do not spray cleaner on the motor assembly, ankle assembly, or battery cavity directly. Do not allow liquid to enter the motor assembly, ankle assembly, or battery cavity.

### MAINTENANCE

Complete the following maintenance/service checks at the indicated times. Consult the User Manual for detailed instructions. Contact Biomotum if clarification is needed. Biomotum will alert each customer by phone or email when each step-count milestone has been reached.

| <b>Milestone/Frequency</b>                                     | <b>Maintenance Description</b>  |
|--|---|
| At the start of each use                                       | <ul style="list-style-type: none"><li>· Check cable tension</li><li>· Visually check system for signs of excessive wear</li></ul>   |
| 25,000 steps or after first 25 sessions, whichever comes first | <ul style="list-style-type: none"><li>· Check cable tension</li><li>· Check ankle bolts for loosening</li><li>· Balance battery per provided battery manufacturing instructions</li><li>· Visually check system for signs of excessive wear</li></ul>   |
| 50,000 steps or after first 50 sessions, whichever comes first | <ul style="list-style-type: none"><li>· Conduct video chat with Biomotum engineering team; schedule via website Contact Us link</li><li>· Check cable tension</li><li>· Check ankle bolts for loosening</li><li>· Balance battery per provided battery manufacturing instructions</li><li>· Gently clean ankle quick connect terminal pads with an alcohol swab</li><li>· Visually check system for signs of excessive wear</li></ul> |



|  |   |
|--|---|
| 75,000 steps or after first 75 sessions, whichever comes first   | <ul style="list-style-type: none"> <li>· Check cable tension</li> <li>· Check ankle bolts for loosening</li> <li>· Visually check system for signs of excessive wear</li> </ul>   |
| 100,000 steps or after first 100 sessions, whichever comes first | <ul style="list-style-type: none"> <li>· Conduct video chat with Biomotum engineering team; schedule via website Contact Us link</li> <li>· Check cable tension</li> <li>· Check ankle bolts for loosening</li> <li>· Balance battery per provided battery manufacturing instructions</li> <li>· Gently clean ankle quick connect terminal pads with an alcohol swab</li> <li>· Visually check system for signs of excessive wear</li> <li>· Check footplate bolts</li> </ul> |
| 125,000 steps or after first 125 sessions, whichever comes first | <ul style="list-style-type: none"> <li>· Check cable tension</li> <li>· Check ankle bolts for loosening</li> <li>· Visually check system for signs of excessive wear</li> </ul>   |
| 150,000 steps or after first 150 sessions, whichever comes first | <ul style="list-style-type: none"> <li>· Conduct video chat with Biomotum engineering team; schedule via website Contact Us link</li> <li>· Check cable tension</li> <li>· Check ankle bolts for loosening</li> <li>· Balance battery per provided battery manufacturing instructions</li> <li>· Gently clean ankle quick connect terminal pads with an alcohol swab</li> <li>· Visually check system for signs of excessive wear</li> </ul>                                  |
| 175,000 steps or after first 175 sessions, whichever comes first | <ul style="list-style-type: none"> <li>· Check cable tension</li> <li>· Check ankle bolts for loosening</li> <li>· Gently clean ankle quick connect terminal pads with an alcohol swab</li> <li>· Visually check system for signs of excessive wear</li> </ul>  |
| 200,000 steps or after first 200 sessions, whichever comes first | <ul style="list-style-type: none"> <li>· Conduct video chat with Biomotum engineering team; schedule via website Contact Us link</li> <li>· Check cable tension</li> <li>· Check ankle bolts for loosening</li> <li>· Balance battery per provided battery manufacturing instructions</li> <li>· Gently clean ankle quick connect terminal pads with an alcohol swab</li> <li>· Visually check system for signs of excessive wear</li> <li>· Check footplate bolts</li> </ul> |

