

The Bio Leg™ & MoPro™ Practitioner's Guide

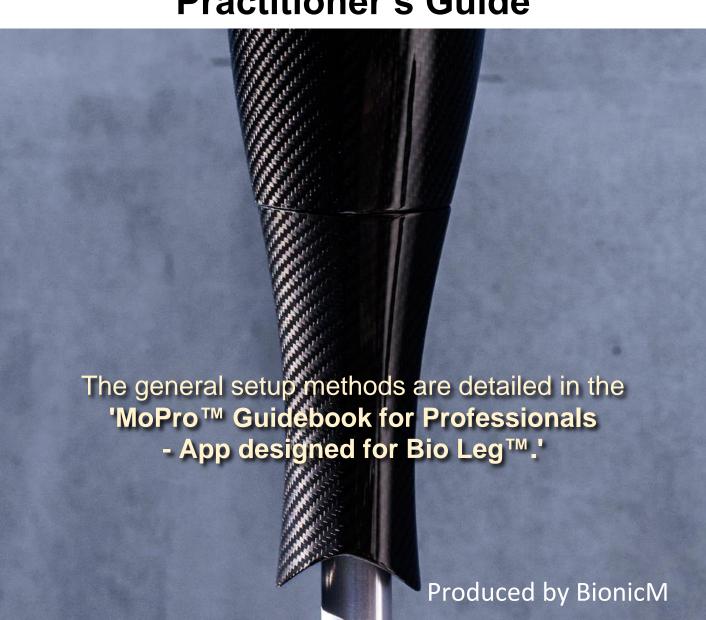


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1. Foreword

- MoPro is an app used for adjusting the parameters of the Bio Leg.
 - If the setup is successfully completed, it is not a daily essential.
- You can download MoPro from the App Store.
 - To download MoPro, an internet broadband connection is required.
 - An internet broadband connection is not required during the setup process.
- To use MoPro, the following devices are required:
 - iOS 14 and later supported devices (available with both iPhone and iPad).
 - Bluetooth version 4.2 or above.
- Setups for several modes available in the Bio Leg[™] come in two levels: Basic and Expert.
 - The general setup methods are detailed in the "MoPro™ Guidebook for Professionals App designed for Bio Leg™."
 - This document primarily focuses on explanations of parameters needed for Expert setups. It partially overlaps with explanations in the "MoPro™ Guidebook for Professionals App designed for Bio Leg™."
- MoPro has CPO mode and User mode.
 - <u>This document provides an explanation of CPO mode.</u>

 Please refer to a separate sheet for information on User mode.
 - After installation, MoPro is in User mode initially.
 To use CPO mode, please switch as instructed by BionicM Inc. at the time of the first setting.

2. Power ON/OFF

- Timing to turn on the power:
 - Always ensure the User wears the prosthetic leg correctly before turning on the power.
 - Attach or detach while the power is ON may lead to unexpected behavior of the Bio Leg™, posing risks of injury or falling.
- When the power is OFF, motor control is not available, similar to a single-axis free-motion knee with no active flexion/extension control.
 - It provides minimal resistance during flexion/extension even the power is OFF.
- While charging, motor control is not available, similar to when the power is OFF.
 - Do not wear the device while the charging cable is connected.
 - Do not move the device while the charging cable is connected to avoid risks of damage due to potential disconnection.

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3. Explanation of each mode & parameter:

This chapter provides tips on mode descriptions, key operation guidance points, the effects of each parameter, parameter adjustment tips, training methods, and screening assessment.

3.1 Yielding

This section explains the Yielding mode in the Bio Leg™, training methods, and parameter adjustments.

3.1.1 What's Yielding?

Yielding refers to the resistance during knee flexion.

Bio Leg adopts a default stance where resistance is always applied, except under specific conditions, providing effectiveness during standing, stance phase of gait, sitting, and stair/slope descent, etc.

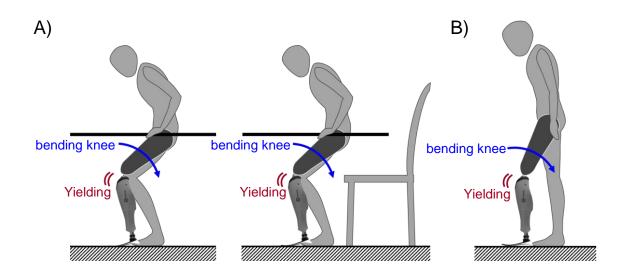
3.1.2 Instruction of Yielding

- The Bio Leg is a "Default stance" knee joint. When the power is ON, Yielding is always active except under specific conditions.
- For users who have never wear a knee joint with Yielding function or have not yet get a feel, help them get accustomed to the resistance of Yielding using one of the following methods.
- A) Within the parallel bars, bend the knee by pulling the buttocks backward.
 Have the user perform this several times to learn the resistance of knee flexion.
 A chair can be placed behind them for sitting as needed.
- B) Step the prosthetic leg forward and bend the knee while applying weight.

 If the knee enters Rest mode (Page. 17) indicated by extension assist from the motor lift the prosthetic leg to exit Rest mode and bend the knee slightly faster.

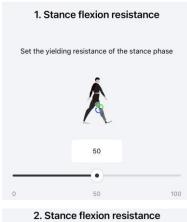
 Alternatively, adjust the settings in MoPro™ → Rest mode → decrease the value of "4. Rest condition(knee velocity)" or increase the value of "3. Rest condition (time[sec])" to make it harder to enter Rest mode.

Have the user perform this several times to learn the resistance of knee flexion.



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3.1.3 Adjust parameters for Yielding



1. Stance flexion resistance / Beginner

This parameter sets the yielding resistance of the stance phase, during sitting motion, and the first 2 steps of prosthetic side during stair descent.

Increasing the value of this parameter = the bending resistance is stronger.

2. Stance flexion resistance (stair descent)

Set the yielding resistance for stair descent



100

2. Stance flexion resistance (stair descent)

/ Beginner

This parameter sets the yielding resistance after the third step on the prosthetic side in stair descent mode.

Increasing the value of this parameter = the bending resistance is stronger.

Please set both parameters to the same value especially for first time users.

There may be times when it feels unstable because the resistance changes after the third step.

If "2. Stance flexion resistance (stair descent)" has a value slightly lower than "1. Stance flexion resistance", it may be beneficial when descending long stairs quickly. However, when the difference in values is extreme, there is a risk of reaching a state close to early knee drop off from the third step onwards, posing a danger of falling. Please exercise caution.



3.2 Gait

This section explains the behavior of the Bio Leg[™] during walking, methods for practicing walking movements, and adjustments to parameters such as knee Assist/Resist.

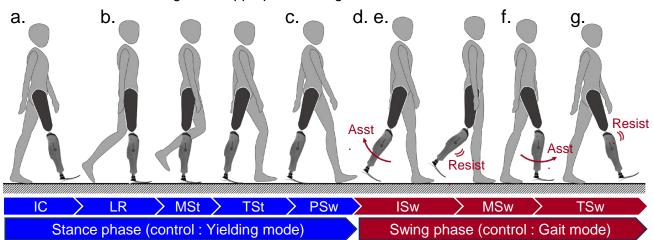
3.2.1 What's Gait mode?

The Gait mode in the Bio Leg refers to the state where the knee joint is controlled during the swing phase of walking mainly.

It setups aspects such as kick height, initiation timing, assistance strength, and terminal impact.

3.2.2 Instruction of Gait mode

 The Bio Leg[™] transitions to Gait mode during the swing phase of walking, and provides assistance and braking at the appropriate timings.



- A) Instruction for the stance phase
 - a. Make contact with the ground using the heel of the prosthetic side.At this time, focus on driving through the hip extensors on the prosthetic side.
 - b. Apply pressure on the prosthetic limb as if pressing into the ground.

 Be mindful to avoid excessive lateral bending or forward leaning of the torso.
 - c. For establish a late stance phase, ensure adequate weight bearing all the way to the toes. Be mindful to check for any excessive anterior tilting of the lumbar spine.
- B) Instruction for the swing phase
 - d. After the sound limb makes contact, ensure the prosthetic hip joint is sufficiently extended. Coordinate the timing of weight transfer to flex the prosthetic knee through hip flexion, swinging the prosthetic limb forward.
 - Be cautious not to initiate a swing where the prosthetic limb is lifted, as this may hinder proper transition to the Gait mode.
 - e. If the user swings the prosthetic limb correctly, the Bio Leg transitions into Gait mode, activating Swing Assist/Resist.
 - When transitioning correctly from Yielding mode to Gait mode, the Bio Leg™ signals this with a short beep and a single vibration.
 - f. Flex the prosthetic hip joint to swing the prosthetic limb forward.

 Avoid excessive abduction or circumduction during this movement.
 - g. Land on the heel and transition into the stance phase on the prosthetic side.

 When the prosthetic limb makes contact and bears weight, the Bio Leg™ switches from Gait mode to Yielding mode.



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3.2.3 Requirements for successful gait control

[Full gait cycle]

• Throughout the gait cycle, maintaining a stable posture without excessive anterior or posterior tilt of the trunk.

Ensuring there is no excessive anterior tilting of the lumbar spine.

→Practice maintaining posture.

Strengthen muscles around the hip joints and core.

Set an initial flexion angle appropriate for the hip extension angle.

- Smooth weight shift from prosthetic side to sound side, and vice versa, during mid stance and swing phase.
 - →Practice COG shifting.

[Stance phase]

- Ensure sufficient weight bearing on the prosthetic limb during mid stance and avoid excessive reliance on upper limb support.
 - → Practice weight bearing on the prosthetic limb.
- Verify adequate forefoot loading from Pre-Swing to Initial-Swing to ensure proper formation of late stance.
- Ensure the prosthetic hip extension provides sufficient propulsion.
 - →Focus on hip extension for push-off.

Strengthen hip extensor muscles.

Set initial flexion angle appropriate for hip extension angle.

Practice forefoot loading.

[Swing phase]

• Ensure there is no circumduction or abduction gait, and that the prosthetic limb swings straight forward during the swing phase.

Also, ensure that the Bio Leg™ transitions correctly from Yielding mode to Gait mode.

→Foster awareness of loading the forefoot and swinging the hip joint straight forward. Set the prosthetic length to match the length of the sound limb. Set an initial flexion angle appropriate for the hip extension angle.



3.2.4 Adjust parameters for Gait

This section explains how to setup the resistance/assistance strength of knee flexion/extension and etc, during gait.

Generally, adjustments can be made using the parameters within the "Beginner" section located at the bottom of the screen.

As a general adjustment procedure:

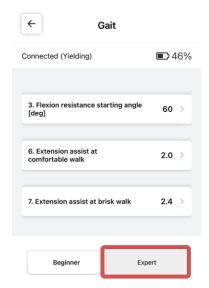
* The document "MoPro™ Guidebook for Professionals - App designed for Bio Leg™" contains the Basic Procedure.

Start by adjusting "3. Flexion resistance starting angle."

Ensure that the knee flexion angle in the early swing phase is not too large and check the symmetry of heel rise on both sides while making adjustments. If feedback from users suggests that the knee swing-out during the swing phase is slow, decrease the value of "3. Flexion resistance starting angle".

Afterward, fine-tune the knee swing-out during the swing phase using "6. Extension assist at comfortable walk" and control the Terminal impact with "9. Extension resistance."

However, in cases where Swing Assist may not function due to reasons such as low height, low weight, or muscle weakness, adjustments may be required using the parameters within the "Expert" section also located at the bottom of the screen.





0.8

Terminal Stance - Initial Swing phase

1. Swing condition Fz (load)

Set the ratio of load to body weight as a condition to transit from the stance to the swing phase



1. Swing condition Fz (load)

Set the ratio load to body weight as a condition to transit from the stance to the swing phase.

In most cases, this parameter does not require setup.

2. Flexion resistance [%]

Set the flexion resistance in the initial swing phase; decrease this value if the maximum flexion angle is too small



2. Flexion resistance [%]

Set the flexion resistance in the initial swing phase; Decrease this value if the maximum flexion angle of swing phase is too small.

3. Flexion resistance starting angle [deg]

Set the knee angle to initiate the flexion resistance in the initial swing phase; increase this value if the maximum flexion angle is too small even after decre...



60

20 55 90

3. Flexion resistance starting angle [deg]

/ Beginner

Set the knee angle to initiate the flexion resistance in the initial swing phase; increase this value if the maximum flexion angle is too small.

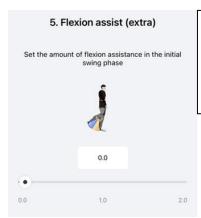
If adjusting this value does not produce sufficient results, increase the value of "2. Flexion resistance [%]".

Initial Swing phase: Flexion assist

4. Flexion assist Set the amount of flexion assistance in the initial swing phase 1.0 2.5 5.0

4. Flexion assist

Set the amount of flexion assistance in the early stage of the initial swing phase; increase this value if the toes make contact with the floor in the swing phase.



5. Flexion assist (extra)

Set the amount of flexion assistance in the mid to late stage of the initial swing phase; increase this value if the toes make contact with the floor in the swing phase.

Adjusting "4. Flexion assist" or "5. Flexion assist (extra)" largely depends on the user's preference, but many users tend to prefer adjusting "4. Flexion assist."

Mid Swing phase: Extension assist

Set the amount of extension assistance in the midswing phase during comfortable walking 5.0

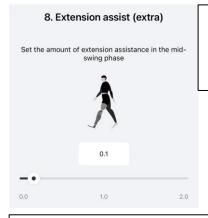
6. Extension assist at comfortable walk/ Beginner

Set the amount of extension assistance in the mid to late stage of the mid-swing phase during comfortable walking; increase this parameter if they feel "the knee extends slowly."

7. Extension assist at brisk walk Set the amount of extension assistance in the midswing phase during brisk walking 5.0

7. Extension assist at brisk walk / Beginner

Set the amount of extension assistance in the mid-swing phase during brisk walking; It is recommended to set this parameter to a value approximately twice that of "6. Extension assist at comfortable walk."



8. Extension assist (extra)

Set the amount of extension assistance in the early stage of the mid-swing phase during comfortable/brisk walking.

Adjusting "6. Extension assist at comfortable walk" or "Extension assist (extra)" largely depends on the user's preference, but many users tend to prefer adjusting "6. Extension assist at comfortable walk"

Terminal Swing phase

9. Extension resistance [%]

Set the amount of extension resistance in the terminal swing phase; increase this value if terminal impact occurs frequently



9. Extension resistance [%] / Beginner

Set the amount of extension resistance in the terminal swing phase; increase this value if terminal impact occurs frequently.

If the knee does not extend completely, decrease this parameter.

Extension resistance starting angle [deg]

Set the knee angle to initiate the extension resistance in the terminal swing phase; increase this value if terminal impact still occurs while increasing the am...



33

0 20 40

10. Extension resistance starting angle[deg]

Set the knee angle to initiate the extension resistance in the terminal swing phase; increase this value if terminal impact still occurs while increasing the amount of the "9. Extension resistance[%]."

11. Extension resistance starting angle (short steps) [deg]

Set the knee angle to initiate the extension resistance in the terminal swing phase for when walking in short strides; increase this value if teminal impact still oc...



0 15 30

11. Extension resistance starting angle (short steps)[deg]

Set the knee angle to initiate the extension resistance in the terminal swing phase for when walking in short strides; increase this value if terminal impact still occurs when walking in short strides.

[Notice]

During Short Step, it beeps twice shortly when transitioning from Yielding mode to Gait mode.







"12. Flexion brake offset at fast walk" and "13. Extension assist adjustment" are provisional parameters. Do not edit them.

3.3 Sit & Stand up

This section explains the details of Sit mode and Stand up mode, practice methods for each movement, and how to adjust parameters.

3.3.1 What's Sit & Stand up mode?

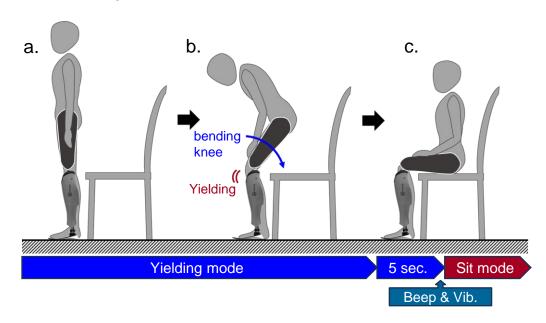
Sit & Stand up mode consists of the following two modes:

- Sit mode: Refers to the state where the knee is flexed and the user is seated, such as in a chair.
- Stand up mode: Refers to the state where the Standing Assist is active. Activating the Standing Assist occurs when weight is applied to the prosthetic limb.

3.3.2 Instruction of Sit & Stand up mode

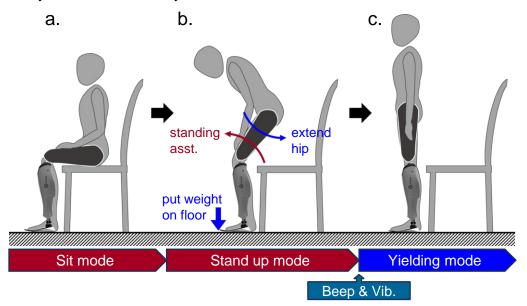
As the basic behavior of Sit & Stand up mode:

- From a standing position to sitting down, control is in Yielding mode.
- After sitting down and waiting for 5 seconds, Bio Leg[™] transitions to Sit mode.
- A) Instruction for the Sitting motion
 - a. Turn your back to the chair.
 - b. While bearing weight equally on both the sound limb and the prosthetic limb, use Yielding mode to slowly bend the knee.
 - c. Sit down. After 5 seconds, Sit mode will activate, and the Bio Leg™ will emit a short beep and one vibration as a signal.
 - * If it transitions to Rest mode (Page.17) during sitting motion, reset it and bend the knee a bit faster.
 - * If it is difficult to sit down while bending the knee, Sit mode will still activate if you bend the knee after sitting in the chair.





- B) Instruction for the Stand up motion
 - a. Sit lightly on the chair. Ensure that the Bio Leg™ is in Sit mode.
 - b. Distribute weight evenly between the sound limb and the prosthetic limb.
 When the weight exceeds a certain threshold, the Standing Assist activates, extending the knee.
 - c. Coordinate by extending the hip joint to push the center of gravity forward and upward. Stand fully until the knee is fully extended.



3.3.3 Tips in Sit & Stand up mode

A) Sit mode

- After transitioning into Sit mode, the Bio Leg[™] applies braking to prevent flexion when weight is applied, keeping it stationary (it is not locked).
 This is to prevent flexion under load.
- If knee movement is detected, such as by rotating the turntable, the Bio Leg's brake is released.

B) Stand up mode

- Even if standing up without sufficient weight on the prosthetic limb and without activating the Standing Assist, knee extension assist activates at the final extension range (both knee and hip are extended, and the hip angle is less than 45 degrees).
- Even if standing up using only the sound limb without placing the prosthetic limb on the ground and with the knee remaining flexed, knee extension assist activates at the final extension range.



3.3.4 Requirements for successful Sit & Stand up control

A) Sit mode

[Trigger movements]

- The Bio Leg[™] is flexed sufficiently.
 - →Use Yielding to practice bending the knee while bearing weight on the prosthetic limb.
 - Use upper limb support as needed.
- It has inadvertently entered Rest mode (absence of motor sound).
 - →Reset it and bend the knee a bit faster.
 - Check whether the trigger movement works or not, especially the knee flexion angle, angle stability, and weight bearing

B) Stand up mode

Transition conditions

- The Bio Leg™ is excessively tilted forward or backward when standing up.
 - →Sit so that the lower leg axis is roughly vertical to the floor.
 - Align the sound limb and prosthetic limb as much as possible.
- The seating depth is appropriate.
 - →Sit lightly.
- Sufficient weight is applied to the prosthetic limb.
 - →Practice weight bearing.
 - Decrease the threshold value for weight bearing in MoPro → Sit & Stand up→
 - "2. Stand up condition (load)."
- The trunk is leaned forward, shifting the center of gravity over the foot.
 - → Practice shifting the center of gravity forward and downward.

[Completion/Release Conditions]

- The Bio Leg™ is fully extended after standing up (whether Stand up mode is complete).
 - →Instruct to fully extend the knee after standing up.



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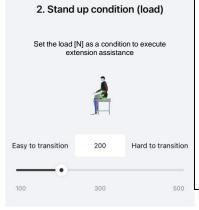
3.3.5 Adjust parameters for Sit & Stand up mode

For adjusting the yielding resistance when sitting, see "2.1 Yielding (Page 3)."



1. Stand up extension assist / Beginner

Set the amount of extension assistance when standing up; increase the value if the start-up assist is insufficient.



2. Stand up condition (load) / Beginner

Set the load [N] as a condition to execute extension assistance.

Ease of entry varies depending on the height of the chair; set according to the height of the chair that the user often

Lowering this value makes it easier to transition to Stand Up mode, but if it's too low, unintended Stand Up assist may occur.

3.4 Rest

This section explains the details of Rest mode, practice methods for each movement, and how to adjust parameters.

3.4.1 What's Rest mode?

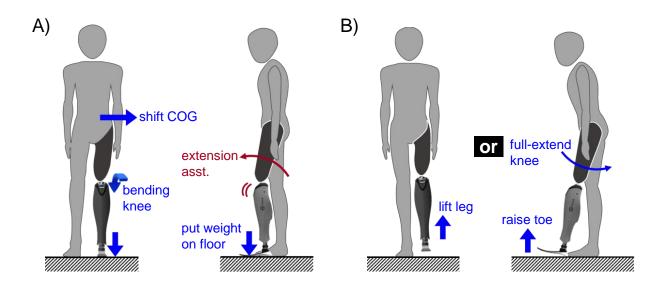
The Rest mode in the Bio Leg refers to the state where the extension assist is activated at a slightly flexed knee position to support body weight.

Unlike the traditional MPK Lock, it allows flexible support, enabling smooth movements like squats.

It's possible to setup the conditions for entering Rest mode and the extension assist conditions.

3.4.2 Instruction of Rest mode

- A) Transition to Rest mode
 - a. Move the prosthetic limb half to one step forward.
 - b. Flex the prosthetic knee approximately 5° to 30° (default value).
 - c. Put weight on floor with prosthetic side. Ensure the knee angle remains stable while bearing weight on the prosthetic limb.
 - d. After maintaining the weight bearing for 1.5 seconds (default value), transition to Rest mode, enabling flexible weight support through extension assist.
- B) Transition from Rest mode
 Lift the prosthetic limb to relieve weight.
 Alternatively, fully extend the knee and raise the toes of the prosthetic limb.



3.4.3 Tips in Rest mode

- Rest mode continues as long as the forefoot remains in contact and weight bearing is maintained, even if the knee fully extends while active.
- You can also use Rest mode while leaning against a wall or another support.
- Rest mode can be deactivated by starting to walk from the state where Rest mode was activated.

3.4.4 Requirements for successful Rest control

[Trigger movement/conditions]

- Is the knee flexion angle within the appropriate range (5-30°)?
 - →If unable to maintain the correct angle after several attempts, adjust the values of MoPro → Rest mode → Expert → "1. Rest condition (knee bent) [deg]" and "2. Rest condition (knee overly bent) [deg]."
- Are there excessive fluctuations in knee angle or weight bearing?
 - →If unable to maintain the appropriate state after several attempts, increase the value of MoPro → Rest mode → "4. Rest condition (knee velocity)."
- Is sufficient weight applied to the prosthetic limb?
 - →Practice weight bearing.
- Is the motor sound of the extension assist running (indicating it is functioning correctly)?
 - →If not audible, check each transition condition.
 If the motor sound is audible but the assistance level is insufficient, increase the value of MoPro → Rest mode → "5. Rest extension assist."

[In Rest mode]

- Ensure it does not result in excessive assistance, causing full knee extension and lifting of the forefoot (deactivation of Rest mode).
 - ightharpoonup Adjust the value of MoPro ightharpoonup Rest mode ightharpoonup "5. Rest extension assist" to ensure appropriate assistance.

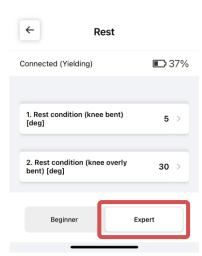
[Completion/Release Conditions]

- Are Rest mode deactivation procedures correct?
 - → Practice the described Rest mode deactivation actions.

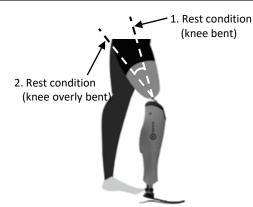
3.4.5 Adjust parameters for Rest mode

Basically, adjustments can be made using the parameters found in the "Beginner" section at the bottom of the screen. Please refer to the separate document (MoPro™ Guidebook for Professionals - App designed for Bio Leg™).

However, if issues arise preventing the transition to rest mode, such as low height, weight, or muscle strength, adjustments may be necessary using the parameters in the "Expert" section at the bottom of the screen.



The transition conditions to rest mode:



In default settings, supporting weight extension assistance is activated when keeping stop the knee angle between 5-30* degrees for 1.5 sec and putting weight on the Bio Leg.

* This angle is defined between "1. Rest condition (knee bent)" and "2. Rest condition (knee overly bent)".

1. Rest condition (knee bent) [deg]

Set the lower threshold of knee flexion angle to initiate the reset mode



1. Rest condition (knee bent) [deg]

Set the lower threshold of knee flexion angle to initiate the rest mode.

2. Rest condition (knee overly bent) [deg]

Set the upper threshold of knee flexion angle to initiate the rest mode; this value should be smaller than the lower threshold value



2. Rest condition (knee overly bent) [deg]

Set the upper threshold of knee flexion angle to initiate the rest mode.

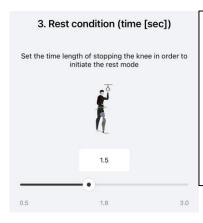
This value should be larger than the "1. Rest condition (knee bent)." Otherwise, rest mode transition will not occur, even if other conditions are met.

To disable the Rest mode:

Set "1. Rest condition (knee bent) [deg]" to exceed the value of "2. Rest condition (knee overly bent) [deg]."

ex.) Set the value of "1. Rest condition (knee bent) [deg]" to 40, and the value of "2. Rest condition (knee overly bent) [deg]" to 30.



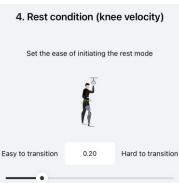


3. Rest condition (time [sec])

Set the time length of stopping the knee in order to initiate the rest mode; setting this value too low may cause malfunction such as unexpected transition to rest mode.

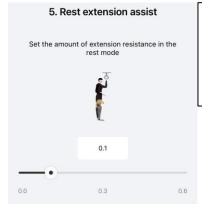
[Notice]

Reducing the value of this parameter excessively increases the risk of unintended transitions to Rest mode, leading to malfunctions and potential falls.



4. Rest condition (knee velocity) / Beginner

Set the ease of initiating the rest mode; if the rest mode is too easily initiated, increase this parameter. Setting it too small may cause malfunctions. This value is typically optimal around 0.2.



5. Rest extension assist / Beginner

Set the amount of flexion resistance in the rest mode; if the feeling of support is poor when applying a load, increase this value.



1.00

6. Rest condition to stance

When this toggle button is turned off, Rest mode cannot be released except by removing the load.

For example, under normal circumstances, extending the knee and lifting the toes releases the Rest mode, but this becomes impossible.

3.5 Stair descent

This section explains the details of Stair descent mode, practice methods for each movement, and how to adjust parameters.

3.5.1 What's Stair descent mode?

The Stair descent mode in the Bio Leg refers to the state where the knee was controlled knee flexion resistance and swing-out during stair and slope descent.

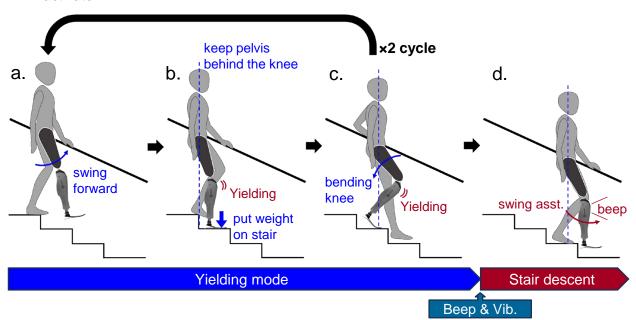
The transition to Stair descent mode occurs when the prosthetic side descends to the second step.

To facilitate the next step's knee flexion, control the knee swing-out so that the lower leg remains slightly bent in a static position. Until accustomed to operation, it's easier to descend by extending the forefoot beyond the step nose.

It is possible to setup the swing-out speed and Terminal Impact.

3.5.2 Instruction of Stair descent mode

- A) Transition to Stair descent mode
 - * Practice exercises to acquire the sensation of knee flexion using Yielding in advance (Refer to: How to instruction Yielding (Page.3)).
 - a. Always use handrails. Initially, start descending stairs from the prosthetic side until you become accustomed.
 - b. Keep your pelvis positioned posterior to your knee, lightly flex the knee, and lower the prosthetic side one step down.
 - Full foot contact is fine, but if you're not used to initiating knee bending, start by placing the forefoot off the step edge.
 - c. Keep your pelvis positioned posterior to the Bio Leg™, use Yielding, and slowly flex the knee while placing the sound side on the next step.
 - d. After two cycles, the Bio Leg™ transitions to Stair descent mode, and Swing assist will activate.

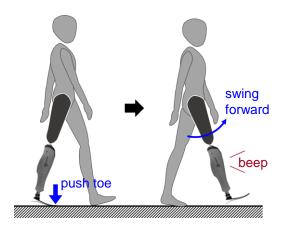




B) Release from Stair descent mode

After descending the stairs, place weight on the forefoot with the prosthetic limb and swing forward to start walking naturally. A beep and strong vibration will be emitted, indicating the deactivation of Stair descent mode.

Alternatively, stand still for 5 seconds. A beep and strong vibration will be emitted, indicating the deactivation of Stair descent mode.

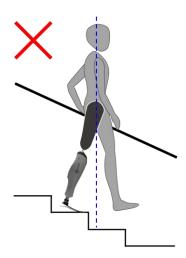


3.5.3 Tips in Stair descent mode

- The Yielding resistance specified in MoPro will activate during Stair descent mode. cf.) Explanation of the parameters for Yielding(Page.3).
- Swing assist functions to stop the Bio Leg in a slightly flexed position.

3.5.4 CAUTION in Stair descent mode

- Always deactivate Stair descent mode following the above procedure after descending stairs.
 Failure to do so may result in unexpected malfunctions of the Bio Leg[™], posing a risk of falling.
- Ensure the pelvis does not move ahead of the knee joint. If the Bio Leg™ misinterprets the situation as walking, the Swing assist of Gait mode might activate, increasing the risk of missing a step and falling.





3.5.5 Requirements for successful Stair Descent control

[In Stair descent mode]

- The trunk remains upright without leaning forward or backward, maintaining good posture.
 - →Practice maintaining posture.
 - Set an appropriate initial flexion angle.
 - Strengthen the hip and trunk muscles.
- The pelvis remains behind the knee.
 - → Practice descending using the last step repeatedly.
 - This issue often occurs in cases not accustomed to Yielding, so practice flexing the knee in response to Yielding resistance.
- The prosthetic limb is placed on the step with the knee slightly flexed, or it transitions smoothly into knee flexion using Yielding immediately after contact.
 - →Practice descending using the last step repeatedly.
 - This issue often occurs in cases not accustomed to Yielding, so practice flexing the knee in response to Yielding resistance.

[Completion/Release Conditions]

- Ensure Stair descent mode is correctly deactivated, and the deactivation signals (Beep and Vibration) are confirmed.
 - → Practice the release movements repeatedly.

 Set the appropriate initial flexion angle to allow weight-bearing on the forefoot.

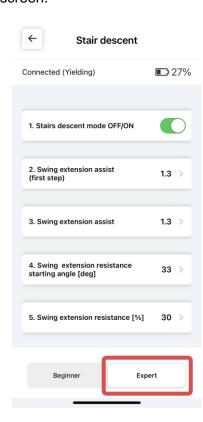


3.5.6 Adjust parameters for Stair descent mode

This section explains the adjustment of the Bio Leg's behavior during Stair Descent mode.

Generally, adjustments are only needed for the Yielding parameter (Page 3).

However, in cases where Stair Descent mode is not suitable for the user due to reasons such as low activity, extremely high activity, or special prosthetic alignment, adjustments may be necessary in the parameters located in "Basic" or the "Expert" section at the bottom of the screen.



1. Stairs descent mode OFF/ON

1. Stair descent mode ON/OFF

When not using Stair descent mode, such as when descending stairs using a two-foot-one-step approach or when preferring to control the descent themselves, set this toggle button to OFF.

If this toggle button is set to OFF, the Stair Descent mode will not activate, thus maintaining the Yielding mode during stair descent. This means that the Swing assist, which holds a slight bent position after swing-out, and the Yielding's "2. Stance flexion resistance (stair descent)" defined by Yielding resistance values will not engage.

2. Swing extension assist (first step) Set the amount of swing extension assistance when descending the first step 1.3

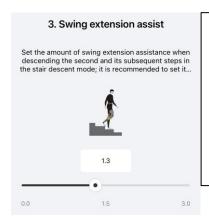
2. Swing extension assist (first step)

/ Beginner

Set the amount of swing extension assistance when descending the first step.

[Notice]

Set "2. Swing extension assist (first step)" and "3. Swing extension assist" to the same value unless there is a specific reason not to do so.



3. Swing extension assist / Beginner

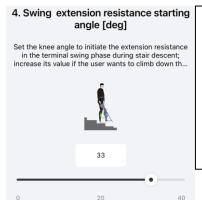
It will be effective from the second step onward on the prosthetic side during stair descent.

If the user wants the knee to extend faster, increase the value.

[Notice]

Set "2. Swing extension assist (first step)" and "3. Swing extension assist" to the same value unless there is a specific reason not to do so.

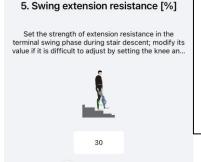




4. Swing extension resistance starting angle [deg]

Set the knee angle to initiate the extension resistance in the terminal swing phase during stair descent; increase this value if users find it easier to descend stairs when their knees are in a more flexed position.

In most cases, this parameter does not require setup.



5. Swing extension resistance [%]

Set the strength of extension resistance in the terminal swing phase during stair descent; modify its value if it is difficult to adjust by setting "4. Swing extension resistance starting angle."

In most cases, this parameter does not require setup.

3.6 Stair ascent

This section explains the details of Stair ascent mode, practice methods for each movement, and how to adjust parameters.

3.6.1 What's Stair ascent mode?

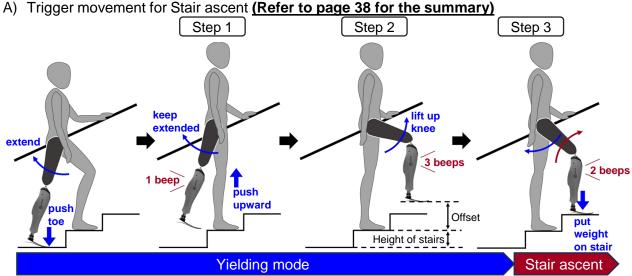
The Stair ascent mode in the Bio Leg™ refers to the state where knee swing-out and extension assist are activated during stair ascent.

It transitions to Stair ascent mode upon achieving the Trigger movement as shown below. It is possible to setup conditions to transition to Stair ascent mode and adjust the strength of the extension assist.

Stair ascent mode requires sufficient range of motion, muscle strength, and practice.

Due to factors such as physical abilities and others, there is a possibility that it may not reach a practical level.

3.6.2 Instruction of Stair ascent mode



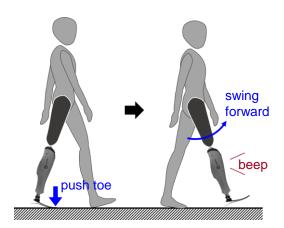
- Step 0: Always use the handrail. Place the sound leg on the first step. The prosthetic leg should be in a state where the hip is extended and the forefoot is loaded.
- Step 1: Straighten the knee of the sound leg as if reaching up. Keep the hip of the prosthetic leg extended. Once the Bio Leg emits a short beep and a vibration, Step 1 is complete.
- Step 2: Within 1.5 seconds after completing Step 1, quickly flex the hip to lift the prosthetic knee. At this point, the Bio Leg will flex with the force of the user's hip flexion, stopping so that the lower leg is at a 90° angle to the step. Once the Bio Leg is lifted to the specified height, it will emit three short beeps and vibrations, completing Step 2.
 - * If the prosthetic leg swings forward, the toe may catch on the riser or step edge. Even if it catches, Step 2 can still be completed if the Bio Leg is lifted to the specified height, but be cautious of losing balance and the risk of falling.
- Step 3: Place the prosthetic leg straight on the step and apply weight directly onto it. When the Bio Leg emits two long beeps and vibrations, Step 3 is complete. The Stair ascent mode is activated, and the knee extension assist will engage. Match the timing by extending the hip to ascend the step.



B) Release from Stair ascent mode

After ascending the stairs, place weight on the forefoot and swing the prosthetic limb forward to start walking naturally. A beep and strong vibration will be emitted, indicating the deactivation of Stair ascent mode.

Alternatively, stand still for 5 seconds. A beep and strong vibration will be emitted, indicating the deactivation of Stair ascent mode.



3.6.3 Tips in Stair ascent mode

- During contact with the step, the extension assist in Stair ascent mode activetes as specified in MoPro.
- In response to the hip flexion of the prosthetic leg, the knee flexion assist activates to avoid contact between the stair and the forefoot.
- The Swing assist ensures the knee is in a slightly flexed position to facilitate knee flexion for the next step.

3.6.4 Notes of Stair ascent mode

- After ascending the stairs, always follow the above steps to deactivate Stair ascent mode. Unexpected malfunctions of the Bio Leg can increase the risk of falling.
- For safety reasons, do not use Stair ascent mode in strong winds.
- Mastering Stair ascent mode requires considerable muscle strength, joint range of motion, balance ability, and practice.
 - It should also be explained to the user in advance that even if the above conditions are met, it may not reach a practical level depending on the individual case.
- When walking on stair landings, deactivate Stair ascent mode according to the above steps. Unexpected malfunctions of the Bio Leg can increase the risk of falling.
 - * It is possible to move short distances on landings without deactivating Stair ascent mode if the late stance phase is avoided and the knee is fully extended. However, the risk of falling remains due to the continuation of swing phase flexion assist. This is not recommended for non-experts. Additionally, if the knee is not fully extended during the stance phase, the knee brake will engage fully, almost locking the knee, which should be avoided.



3.6.5 Requirements for successful Stair Ascent control

[Trigger movement]

- Ensure all three steps are completed correctly, and the Beep and Vibration signaling the transition to Stair descent mode are confirmed.
 - →Check if Stair descent mode is enabled in MoPro and verify that the Beep and Vibration are not turned off.
 - cf.) Explanation of the parameters for Stair ascent mode(Page.31) and Other settings(Page.36)

If transitioning to Stair ascent mode remains difficult after several practice attempts, use Training mode (Page.38) to identify the cause.

[Behavior in Stair ascent mode]

- The trunk remains upright without leaning forward or backward, maintaining good posture.
 - →Practice maintaining posture. Set an appropriate initial flexion angle. Strengthen the hip and trunk muscles.
- Ensure that the extension assist level in Stair ascent mode is appropriate and acts as the driving force for upward movement of the center of gravity synchronized with the extension of the prosthetic hip joint.
 - \rightarrow Adjust the value of "10. Stance extension assist" in MoPro \rightarrow Stair ascent.
 - Practice the movements of Stair ascent repeatedly.
 - Strengthen hip and core muscles.
 - To streamline the transition to Stair ascent mode during practice, use Motion training in Training mode (Page.41).

[Completion/Release Conditions]

- Ensure Stair ascent mode is correctly deactivated, and the deactivation signals (Beep and Vibration) are confirmed.
 - → Practice the deactivation movements repeatedly. Set the appropriate initial flexion angle to allow weight-bearing on the forefoot.

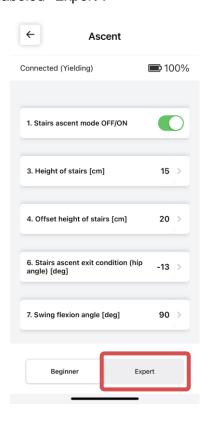


3.6.6 Adjust parameters for Stair ascent mode

This section explains the transition conditions to stair ascent mode and adjustments to the behavior of the Bio Leg during Stair Ascent mode.

Primarily, adjustments beyond those in "Basic" are unnecessary.

In cases where stair ascent mode is unsuitable for the user due to reasons such as low activity, muscle weakness, joint range of motion limitations, or unique staircase environments, adjustments may be required using parameters in "Basic" or in the lower section of the screen labeled "Expert".





1. Stair ascent mode ON/OFF / Beginner

When not using stair ascent mode, such as when ascending stairs using a two-foot-one-step approach, set this toggle button to OFF.

Stair ascent mode transition/cancellation conditions (1/2)

2. Ascent trasition condition (tibia angle) [deg]

Set the lower leg angle (the vertical direction) as a condition to initiate the stair ascent mode; increasing its value makes it easier to start the stair ascent mo...

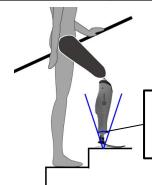


•——

2. Ascent transition condition (tibia angle) [deg]

Set the lower leg angle (the vertical direction) as a condition when loading weight in "Step 3" to initiate the stair ascent mode; increasing its value makes it easier to start the stair ascent mode and vice versa.

In most cases, this parameter does not require setup.



The value of "2. Ascent transition condition (tibia angle)[deg]" multiplied by 2

3. Height of stairs [cm]

Set the height of steps to identify the stair ascent motion; note that it is likely to misidentify a step that is not a stair when this value is set to a smaller value.



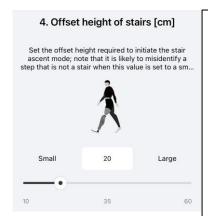
Low steps

High steps

3. Height of stairs [cm] / Beginner

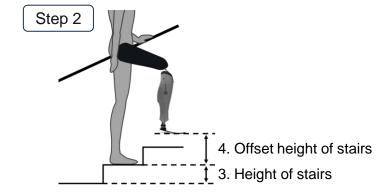
Set the height of steps to identify the stair ascent motion in "Step 2"; note that it is likely to misidentify a step that is not a stair when this value is set to a smaller value.

Stair ascent mode transition/cancellation conditions (2/2)



4. Offset height of stairs [cm] / Beginner

Set the offset height required to initiate the stair ascent mode in "Step 2"; note that it is likely to misidentify a step that is not a stair when this value is set to a smaller value.



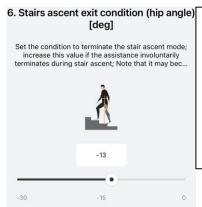
Set the ease of switching to the stair ascent mode Hard to transition 150 Easy to transition

5. Stairs ascent condition (knee velocity)

Set the threshold of the filter to distinguish between the "Step 1" movement for transitioning into Stair Ascent Mode and continuing to walk, based on the speed of the knee movement.

Adjustments may be required for users who have mastered the movement and can transition smoothly from walking to stair ascent.

In most cases, this parameter does not require setup.



6. Stairs ascent exit condition (hip angle) [deg] / Beginner

Establish the criteria to end the stair ascent mode based on the estimated toe load from the hip joint extension angle. Increase this value if assistance terminates involuntarily during stair ascent. Be mindful that it might be challenging to end the stair ascent mode if this value is too high.

Behavior of Bio Leg during Stair ascent mode (1/2)

7. Swing flexion angle [deg] Set the knee flexion angle in the swing phase during stair ascent

7. Swing flexion angle [deg] / Beginner

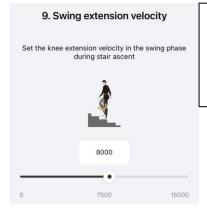
Set the knee flexion angle in the swing phase during stair ascent; increase this value if there is insufficient clearance, such as when the toes touch the stairs during the swing phase.

8. Swing flexion velocity Set the knee flexion velocity in swing phase during stair ascent; increase this value when increasing the knee flexion angle

8. Swing flexion velocity

Set the knee flexion velocity in swing phase during stair ascent; please also increase this value when increasing "7. Swing flexion angle."

Otherwise, if this value is not increased, the timing of Bio Leg extension during the swing phase will be delayed.



9. Swing extension velocity

Set the knee extension velocity in the swing phase during stair ascent; increase this value if the user feels that the Bio Leg swing is slow.

10. Stance extension assist Set the amount of extension assistance in the stance phase during stair ascent; the amount of knee torque raising the user's body will increase if this value is i... Set the amount of extension during stair ascent; increase amount of knee extension

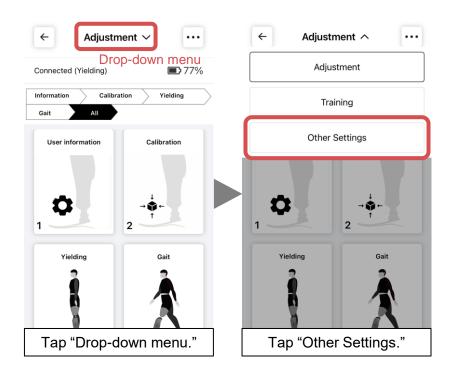
10. Stance extension assist / Beginner

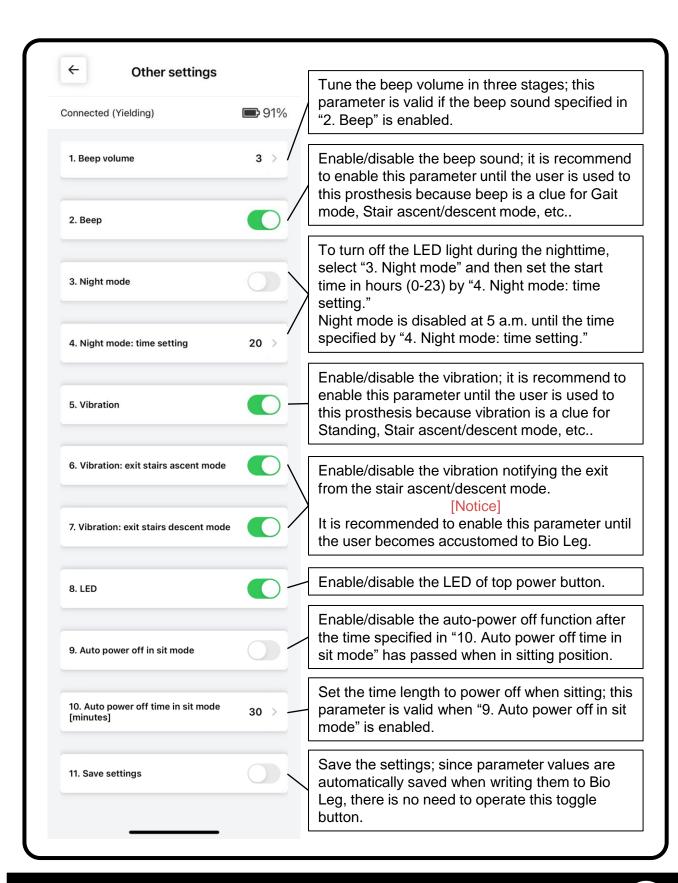
Set the amount of extension assistance in the stance phase during stair ascent; increase this value to increase the amount of knee extension assist during Stair ascent mode.

3.7 Other settings

This section explains adjustments for features like Beep sound and auto-power-off function.

Some parameters serve as cues for each mode, such as Gait mode or Stair ascent/descent mode, so adjust them according to the user's proficiency.





4. Training mode

What's Training mode?:

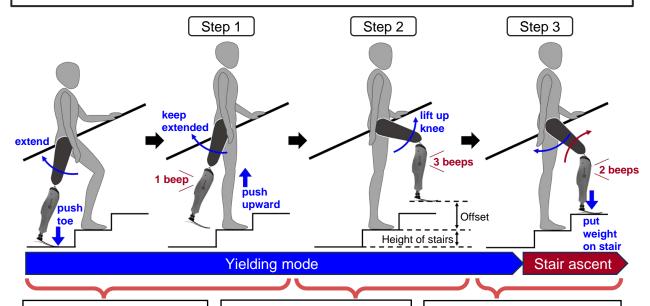
This function is designed for practicing the transition and operation of the stair ascent mode. The Training mode is divided into two parts: Transition Training and Motion Training.

<u>Transition Training</u>: This is used to practice trigger movement described below.

By activating this mode and performing the Trigger movement, MoPro reflects on its screen which movements are not being executed correctly and provides feedback.

<u>Motion Training</u>: This is used to practice getting accustomed to the behavior of the Bio Leg after the initiation of the stair ascent mode. The Bio Leg is automatically into Stair ascent mode and coordinating the timing of the extension assist with your own prosthetic side hip extension.

- * Stair ascent mode requires sufficient range of motion, muscle strength, and practice.
- * Due to the potential risk of falling depending on the situation, perform this activity in an environment with a nearby assistant, following the precautions.
- * Due to factors such as physical abilities and others, there is a possibility that it may not reach a practical level.

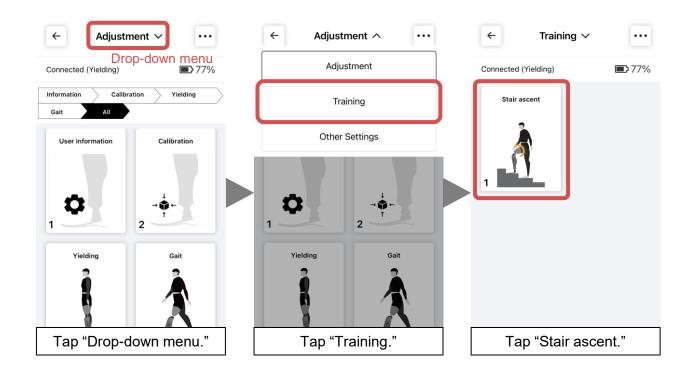


Place the sound leg on the first step. Load weight onto the toe of the prosthetic side extending the hip. Extend the sound knee to lift the prosthetic leg. When Bio Leg emits one short beep, Step 1 is completed.

Flex the hip joint to lift the knee (within 1.5 seconds). Bio Leg emits three short beeps when Step 2 is completed.

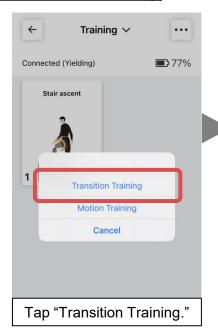
After Step 2, quickly load the weight on the stair tread vertically (within 1.5 seconds). Bio Leg emits two long beeps when all three steps for the ascent mode is completed.

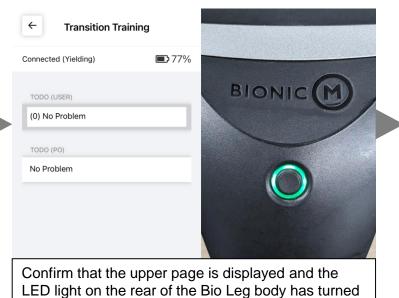






4.1 Transition Training:





green as shown in the above picture.



(Refer to page 23.)

back **Transition Training 74**% Connected (Yielding) TODO (USER) Flex the hip joint and move a prosthetic foot forward to the body quickly after lifting the prosthetic leg. Lift the foot higher by flexing the hip joint quickly after lifting a prosthetic leg. Confirm that a healthy foot goes up stairs first. Test with the condition that the prosthetic leg is visible (i.e., uncovered by clothes). Confirm that the height of the step is at least 15 cm. TODO (PO) Reconfirm the value of parameter (0x400) with the user. Test by changing the value of parameter (0x84E) to 10. If the transition still fails, test by changing the value of parameter (0x850) to 10. If the transition is successful, increase the value of parameter (0x84E, if changed, both 0x850 and 0x84E) by 5 to an appropriate value. 0x84E

When an issue is detected by the Bio Leg during Trigger movement, the LED light on the back of the device temporarily goes out. The device side will display information similar to the left screen. The instructions for the user and parameters to be adjusted in MoPro will be displayed as "TODO." Take appropriate action, practice until smoothly transitioning to Stair ascent mode is achieved consistently.

When exiting Transition
Training mode, please tap
the "back" button in the
upper-left corner of the
screen.

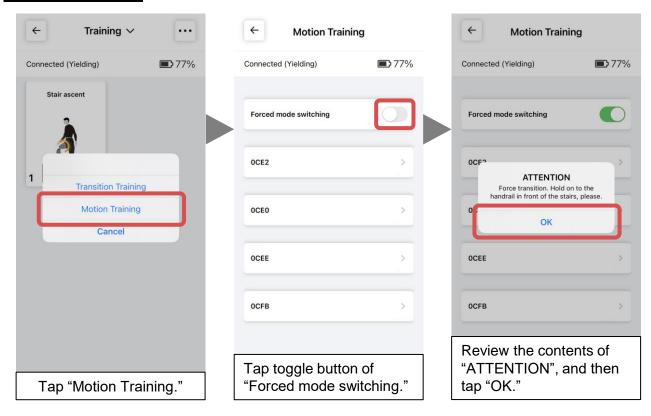
[notice]

No history of detected issues is retained. Please adjust as needed each time.

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4.2 Motion Training:





Confirm that the LED light on the rear of the Bio Leg body has turned green as shown in the left diagram. When the LED light illuminates successfully, the Bio Leg

transitions to Stair ascent mode.

In Stair ascent mode, lifting the prosthetic leg upward causes the knee to swing, placing the foot on the stepping surface. Subsequently, when loading the prosthetic leg, the extension assist is activated, lifting the body upward. If for any reason the Trigger movement cannot be completed but the user wishes to experience Stair ascent mode or practice it, please use this mode.

Be sure to turn the toggle button to the OFF position to end Motion Training.

[notice]

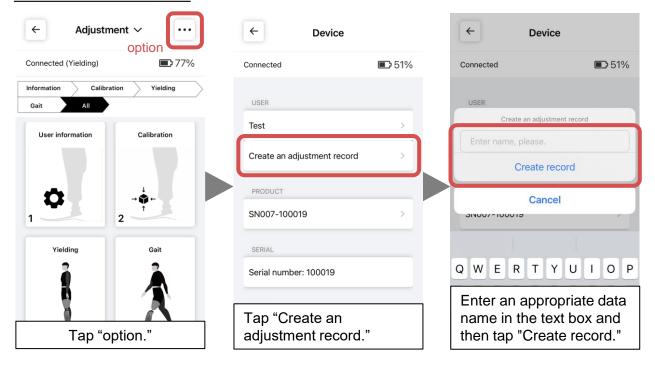
If the user starts walking without doing this, there is a risk of falling due to unexpected movements of the Bio Leg.

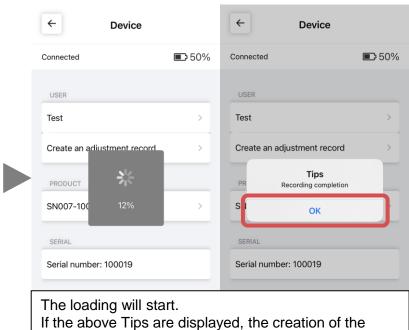


5. Create/Recover an adjustment record

For the backup in case of device replacement or the preservation of the journey history, it is recommended to create a record.

5.1 How to create a record:





Record has been completed successfully.

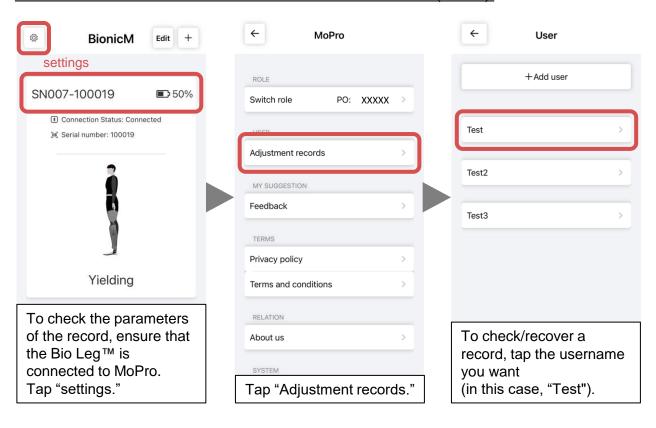
Tap "OK" to finish.

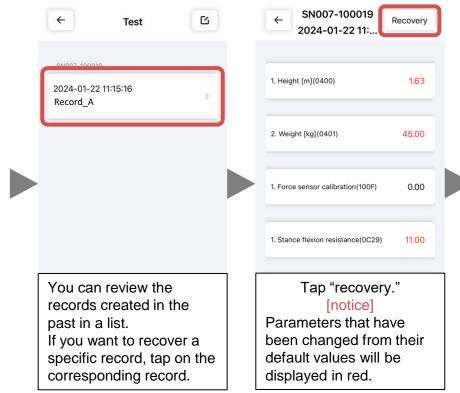
BIONIC

Create/Recover

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5.2 Methods how to check the created record and how to recover(rewrite):











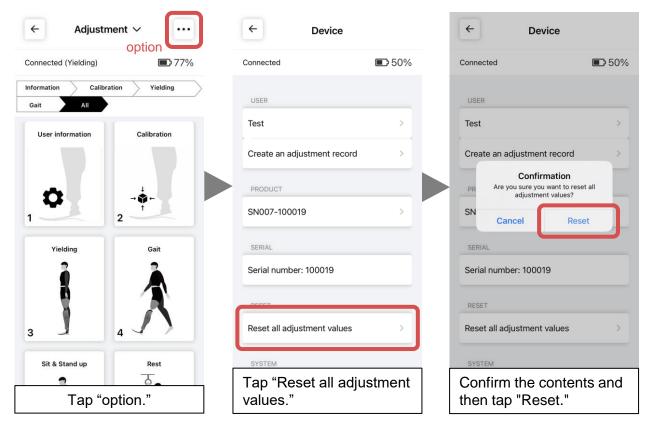
Tap "OK" to finish.

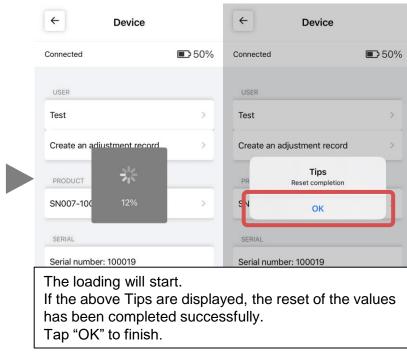


6. Reset all adjustment values

Reset all adjusted parameter values to their default settings.

- Reset the Bio Leg if it will be worn by another user or under different circumstances.







7. Example of advanced adjustments

Depending on the user's physical abilities and preferences, basic adjustments may not provide sufficient benefits.

Below are some adjustment examples for reference.

* The solution involves both adjustments in MoPro settings and modifications to the prosthetic leg.

Unable / difficult to transition to the swing phase during gait:

Please address one or more of the following, listed in order of likelihood of relevance:

- 1. If the foot component's category is too rigid for body weight, consider switching to one with the appropriate firmness.
- 2. Encourage weight-bearing on the toes during the terminal stance phase.
- 3. If there is a tendency for circumduction, vaulting, or attempting to lift the prosthetic limb during the pre-swing phase, make corrections.
- 4. Set the foot component to a slightly plantarflexed or dorsiflexed position (adjust as needed based on gait).
- 5. Increase the initial flexion angle and slide the structure below the socket backward.
- 6. Decrease the value of "Weight" in MoPro's "User Information" by around 10 lbs.

Increasing the extension assist still delays the swing-out timing during gait:

Please address the following actions:

- 1. Increase the value of "2. Flexion resistance [%]" by 2-3% in MoPro's "Gait" settings.
- 2. Decrease the value of "3. Flexion resistance starting angle [deg]" in the "Gait" settings.
- 3. Increase the values of "9. Extension resistance [%]" in the "Gait" settings.
- 4. Decrease the value of "10. Extension resistance starting angle[deg]" in the "Gait" settings.

<u>Inadvertently entering Rest mode:</u>

Please address one or more of the following, listed in order of likelihood of relevance:

- 1. Increase the initial flexion angle and slide it slightly backward from directly under the
- 2. Increase the value of "1. Rest condition (knee bent) [deg]" under "Rest" in MoPro.

To disable the Rest mode:

Set "1. Rest condition (knee bent) [deg]" to exceed the value of "2. Rest condition (knee overly bent) [deg]."

ex.) Set the value of "1. Rest condition (knee bent) [deg]" to 40, and the value of "2. Rest condition (knee overly bent) [deg]" to 30.



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Not accustomed to bearing weight on the prosthetic leg when standing-up or stairs-ascent:

Please address one or more of the following, listed in order of likelihood of relevance:

- 1. For stand-up, it's acceptable to temporarily lower the threshold until a weight-bearing sensation is achieved.
 - Decrease the value of "2. Stand up condition (load)" in MoPro's "Sit & Stand up" settings.
 - During seated posture, be cautious as there is a higher likelihood of extension assist inadvertently activating. (Lifting the prosthetic limb will deactivate it.)
- 1. Using your hands on the knees, push to stand up (be careful not to catch fingers or other objects in moving parts).

Stair ascent mode is deactivated during stair ascent:

Please address one or more of the following, listed in order of likelihood of relevance:

- 1. Increase the value of "6. Stairs ascent exit condition (hip angle) [deg]" in MoPro's "Stair ascent" settings.
 - Be mindful that it might be challenging to end the stair ascent mode if this value is too high.
 - After ascending stairs, it's necessary to extend the hip joint further.
- 1. When stationary for 5 seconds during stair ascent, the Stair ascent mode deactivates automatically.



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