BIONX

Inspired by You.

# Instructions for Use
# BiOM® T2 Ankle

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The BiOM T2 (Ankle) is designed and tested to ISO 10328. Compatibility and compliance with this standard is achieved only when the Ankle is used with other components tested to ISO 10328 that conform to the European Directive for Medical Devices 93/42/EEC or are FDA approved. If unusual movement or product wear in a structural part of the Ankle is detected, immediately stop using the device and contact Customer Service. This device is designed for a single user only.

This product is to be sold by a qualified healthcare professional on the order of a physician. The fitting of the Ankle and its accessories to a user must be performed only by trained healthcare professionals who are authorized by BionX Medical Technologies, Inc.



BionX Medical Technologies, Inc. reserves the right to change its products and services at any time to incorporate the latest technological developments. These Instructions for Use are subject to change without notice.

## CUSTOMER SERVICE


- E-mail: service@bionxmed.com
- Phone: +1 855.889.2466


# INTRODUCTION

The Ankle is a Personal Bionics Device that is intended for medical purposes and is a preassembled external artificial limb for the lower extremity. The Ankle employs a bionic muscle-tendon unit that normalizes self-selected walking speed and metabolism while walking on level-ground across a walking speed range of 0.75 m/sec (1.7 mph) to 1.75 m/sec (3.9 mph)[1] with the potential benefits of reducing comorbidities and long term healthcare costs.

The Ankle provides powered propulsion, stiffness modulation and personal bionics tuning.

The Ankle emulates the muscle-tendon reflex of an intact limb. In early stance, the muscle-tendon applies a spring response that emulates the activation of the dorsiflexors. In late stance, the muscle-tendon applies powered plantarflexion that emulates the activation of the calf muscle and Achilles tendon, propelling the user forward. An embedded wireless interface enables a healthcare professional to customize the reflex responses in accordance with user weight and activity level across various walking speeds.

| | |
|---|---|
|  | Must be disposed of or recycled properly |
| SN | Serial Number |
|  | Consult Instructions for Use |
|  | Caution (Consult the accompanying documents) |
|  | Information Note |
| REF | Reference Part Number |
|  | Manufacturer |
| CE | Declaration of conformity according to the European Directive |
| EC REP | Authorized representative in Europe |

[1] "Bionic ankle-foot prosthesis normalizes walking gait for persons with leg amputation" Published online in Proceedings of the Royal Society B Doi: 10.1098/ rspb.2011.11948

# INTRODUCTION

## INDICATIONS FOR USE

The Ankle is intended to replace a missing foot and ankle. The Ankle is to be used exclusively for fittings of lower extremity amputations as prescribed by a physician.

The Ankle does not work for everyone and individual results may vary. The most common complications are complete battery discharge which may reduce walking distance and speed, improper tuning or improper walking up and down stairs which increases the risk of falls.

AMPUTATION TYPE:

- Unilateral transtibial or transfemoral
- Bilateral transtibial and transfemoral
- Bilateral with one side transfemoral and the other transtibial

FUNCTIONAL LEVEL:

- K3 (ability or potential for ambulation with variable cadence)
- K4 (ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy level)

MAXIMUM WEIGHT: 287 lbs (130 kg)

FOOT SIZES: 25-30cm

MINIMUM CLEARANCE: 8 5/8”

When using the Ankle in combination with a prosthetic knee at maximum flexion, ensure there is no contact between the Battery and the user’s socket. If there is contact, please consult with a BiOM Ankle representative for fitting considerations.

The Ankle is designed to normalize the gait of a user weighing up to 287 lbs (130 kg). If a user’s weight is greater than 287 lbs (130 kg), please consult with a BiOM Ankle representative for fitting considerations.

# SAFETY PRECAUTIONS

A trained healthcare professional must provide each user with training for appropriate use of the Ankle. Carefully review all instructions for proper use of the Ankle and follow safety precautions, as failure to do so can lead to the risk of fall, injury to the user and/or the malfunction of the Ankle.

- Safe use of the Ankle demands proper care and maintenance. Please follow the guidelines in the Maintenance section of the Instructions for Use.
- It is recommended that the Ankle undergo visual inspection by a trained prosthetist at least every 6 months or every 1.5 million steps. Heavier patients should have inspections more frequently.
- Use only the accessories provided with the Ankle for adjustment and operation of the Ankle. Any other adjustments may limit the use of the Ankle.
- If the Ankle exhibits unusual behavior, immediately turn OFF the power using the Power Switch.
- If unusual behavior of the Ankle continues after the Power Switch is turned OFF, immediately remove the Battery from the Battery Holster. DO NOT USE the Ankle after such an event and contact Customer Service for considerations.
- For maximum safety, it is recommended to use a handrail when negotiating ramps or stairs.
- Improper handling or adjustment of the Ankle may cause knee instability which can increase the risk of falls.
- The Ankle is for walking and everyday use. Do not use for sports or high impact activities. Excessive load/forces (i.e. repetitive jumping from heights or ladders and landing on the toe) may cause mechanical failure, risk of fall or injury, and will void the warranty.
- During motor vechile operation, the Ankle should be powered OFF and the foot should be dorsiflexed to avoid unintentional motion.
- The Ankle is water resistant but not waterproof. Limit water exposure to light rain or small puddles. Keep the Ankle dry and protected from water whenever possible. Do not allow water or other liquids to enter the Battery Holster at the top of the Ankle. Water and moisture may cause malfunction and risk of falls.
- Do not use any power source other than the Battery provided with the Ankle as this results in a risk of malfunction.
- Do not reach into the Ankle joint in the front or back, as this results in a risk of pinching.
- Follow local ordinances or regulations for proper disposal of the device, accessories or packaging.
- The Ankle should only be used in the environmental conditions specified in the Ankle specifications. Other conditions result in a risk of malfunction.

# INTRODUCTION

**EVERYDAY CONSIDERATIONS**

- Make user aware of the low level audible sounds that the Ankle makes during power delivery.
- It is recommended that the Ankle is used with the supplied Foot Cover.
- Prior to donning, inspect the visible parts of the Ankle and Battery for wires that are frayed, pinched, loose, bent, cracked, or otherwise damaged. Also, inspect the black covers at the front and back of the joint for cracks or breakage. DO NOT USE THE ANKLE if any damage or irregularity is detected and contact Customer Service for further instruction.
- Ensure that the Power Switch (marked ON/OFF) is in the OFF position prior to and during donning of the prosthetic socket.
- If the Ankle loses power, the system will function as a passive, single-axis, articulated prosthesis and a dynamic response foot. During the initial tuning of the Ankle, dynamic alignment of the Ankle must be established with the power OFF, which functions the same as when power is lost.

**ENVIRONMENTAL SAFETY WARNINGS**

- Battery performance may be affected by very low or very high temperatures which may affect normal operation of the Ankle.
- Avoid exposure of the Ankle and Batteries to dusty, dirty or smoky environments (e.g., wood-working shop) as this results in a risk of malfunction.
- Avoid exposure of the Ankle and Batteries to mechanical vibrations (e.g., heavy machinery environments) as this results in a risk of mechanical failure.
- Avoid the use of the Ankle in environments having high electrical and/ or magnetic energy (e.g., electrical power generators, electrical transformers, high-power radio-frequency transmitters, high-power electromagnetic transmitters, such as TV transmitters or walkie-talkies) as this results in a risk of malfunction.

# PRODUCT OVERVIEW

## SAFETY STANDARDS AND CLASSIFICATIONS

The Ankle is internally powered with classification IP24. The Ankle is tested and compliant with the IEC/EN60601-1, standard of electrical safety for medical devices and IEC/EN60601-1-2, electromagnetic compatibility for medical electrical devices and ISO 10328. The Ankle carries the CE mark accordingly.

## AUTHORIZED REPRESENTATIVE

EC REP

EMERGO EUROPE
Molenstraat 15
2513 BH, The Hague
The Netherlands

## SYSTEM COMPONENTS AND ACCESSORIES DESCRIPTION

| | |
|---|---|
| Black Edition Ankle | (11-03B) |
| Silver Edition Ankle | (11-03S) |
| Heel Wedges and Loctite® Kit | (2000290) |
| Battery | (2001596) |
| Charger | (2001793) |
| Instructions for Use | (2003142) |
| Personal Bionic Tuning Device + Application | (2001219) |
| Hardstop Cover | (2001406) |

For a new Foot Module or Foot Cover, please contact Customer Service.

# INTRODUCTION

**ANKLE SPECIFICATIONS**
WEIGHT of the Ankle with Battery, Foot Module and Foot Cover: 5.1 lbs (2.3 kg)
MINIMUM CLEARANCE: 8 5/8”
PLANTARFLEXION RANGE OF MOTION: 24° degrees
DORSIFLEXION RANGE OF MOTION: 0°-10° Foot Module flexion

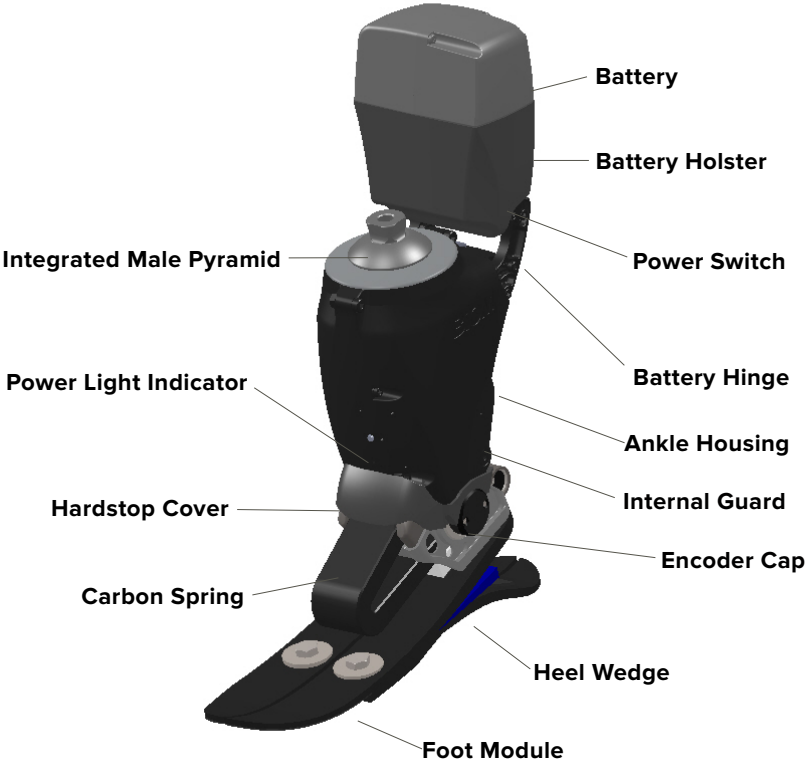
**BATTERY SPECIFICATIONS**
BATTERY TYPE: Rechargable Lithium-Ion Battery
BATTERY VOLTAGE: 22.2 Vdc (nominal)
CHARGING TIME: 45 minutes after normal usage depletion

**CHARGER SPECIFICATIONS**
CHARGER INPUT: 13-30 VDC, 5A MAX
AC POWER ADAPTER INPUT: 100-240 VAC, 50/60Hz
OUTPUT: Charging current of 2.0 amperes

**ENVIRONMENTAL SPECIFICATIONS FOR ANKLE AND BATTERY**
OPERATING: 32°F (0°C) to 113°F (45°C), 20-90% relative humidity, non-condensing.
SHIPPING & STORAGE: A fully charged Battery and Ankle can withstand storage conditions from -22°F (-30°C) to 140°F (60°C), 20-90% humidity, non-condensing.

**ENVIRONMENTAL SPECIFICATIONS FOR BATTERY ONLY**
OPERATING DURING CHARGING: 41°F (5°C) to 113°F (45°C), 20-90% relative humidity, non-condensing.
SHIPPING & STORAGE: -22°F (-30°C) to 140°F (60°C), 20-90% relative humidity, non-condensing.

**ENVIRONMENTAL SPECIFICATIONS FOR CHARGER ONLY**
OPERATING: 14°F (-10°C) to 113°F (45°C), 20-90% relative humidity, non-condensing.
SHIPPING & STORAGE: -22°F (-30°C) to 140°F (60°C), 20-90% relative humidity, non-condensing.




**INDICATORS**

VISUAL

- The Power Light Indicator is a light on the front of the Ankle that blinks green when the Ankle is ON.
- When the Ankle is OFF, the light is OFF.

TACTILE

- When Battery power is low the Ankle will vibrate once for 3 seconds.
- When Battery power is very low the Ankle will vibrate twice for 3 seconds each.

# POWERING ON/OFF

Press the Power Switch on the Battery Holster to the ON position to activate the Ankle. The Power Light Indicator, on the front of the Ankle should be illuminated.

With the Hardstop Cover near but not in contact with the Ankle Housing, listen for a single, high pitched beep to confirm ankle calibration.

If a series of low beeps is heard, have the user plantarflex the foot until the single, high pitched beep confirms calibration is complete.

To power the Ankle OFF, press the Power Switch to the OFF position.

If the visual indicator fails to blink green when power is ON and a properly charged Battery is installed, contact Customer Service.

# SETUP

## ALIGNMENT

**INITIAL ALIGNMENT - TRANSTIBIAL**

1. ESTABLISH NEUTRAL POSITION
   - Ensure Ankle Housing is in contact with the Hardstop Cover.
   - If the heel height of the shoe is greater than 3/8” (9.5mm), extend the pylon to achieve a neutral position.

2. ADJUST BATTERY HOLSTER TO AVOID INTERFERENCE WITH SOCKET AND CONNECTORS
   - Loosen Battery Hinge screws with a 2.5mm hex key until the Battery Hinge can move freely.

3. ATTACH SOCKET TO THE ANKLE
   - Attach socket to the Integrated Male Pyramid on the Ankle.
   - Do not exceed 5° of external rotation of the ankle assembly.
   - Reference line should bisect the socket, and fall at the junction of the posterior and middle one third of the foot.

4. POSITION BATTERY HOLSTER AS CLOSE TO THE SOCKET AS POSSIBLE
   - Loosen upper Battery Hinge screws to further customize the Battery position.
   - Hand-tighten all 8 Battery Hinge screws when Battery Holster is in desired position.
   - For the lower screws, be sure to tighten screws within the scallop design.
   - Check that the Battery will easily clear the socket when removing from the Battery Holster.

# SETUP

**INITIAL ALIGNMENT - TRANSFEMORAL**

1. For transfemoral applications, please reference the knee manufacturer's recommended alignment.
2. Follow relevant instructions from INITIAL ALIGNMENT - TRANSTIBIAL.

When using the Ankle in combination with a prosthetic knee at maximum flexion, ensure there is no contact between the Battery and the user's socket. If there is contact, please consult with a BiOM Ankle representative for fitting considerations.

**STATIC ALIGNMENT**

1. With the prosthesis donned, verify the height of the prosthesis is correct by establishing a level pelvis.
2. Verify that the foot is flat on the floor.
3. Establish that the pylon is vertical in both the sagittal and the coronal planes.

**DYNAMIC ALIGNMENT**

1. Keep the Ankle turned OFF.
2. Walk user to ensure the Ankle provides damped motion when turned OFF.
3. Walk user to determine if the Ankle needs heel wedges between the keel and heel module to stiffen the heel.
4. Adjust adduction/abduction, flexion/extension and toe rotation as necessary.

To maximize the function of the Ankle, it is important to walk with gait characteristics of normal human locomotion. Do not use compensatory motions, especially on stair ascent and decent. A full length step will allow the user to obtain maximum performance from the Ankle.

# ATTACH FOOT MODULE

(If necessary)

Before installing the Foot Module, determine if a foot shim is necessary by turning the ankle over and looking at the bottom of the foot structure. If “NO SHIM” is printed proceed to Step 2 “INSTALL FOOT MODULE”. If there is no inscription on the foot structure follow instructions in Step 1 “INSTALL FOOT SHIM”.

1. INSTALL FOOT SHIM
   - Install onto threaded bosses of foot structure with the flat side of foot shim facing away from foot structure.

2. INSTALL FOOT MODULE
   - Install the Foot Module by aligning the two holes with the bosses located on the bottom side of the foot structure. Ensure the toe end faces forward.
   - Secure the Foot Module with two bolts and a .05” washer on each bolt (provided with system kit).
   - Using a wrench with a 1/2” hex head, torque the bolts to 110 ± 5 in-lbs

3. INSTALL FOOT COVER
   - Pull the spectra sock over the Foot Module.
   - Slide toe end of the Foot Module into the Foot Cover. Next (using a shoe horn if necessary), fit the heel into the Foot Cover and push down until it pops into place. Confirm the Foot Module heel is captured below the interior ridge at the base of the Foot Cover.

# SETUP

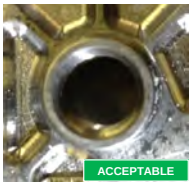
## REMOVE FOOT MODULE
(If necessary)

1. REMOVE FOOT COVER
   - Pull the heel on the Foot Cover out and down to release. Remove it from the interior ridge at the base of the Foot Cover and remove it from the Foot Module.
   - Remove the spectra sock from the Foot Module.

2. REMOVE SCREWS
   - Remove and discard screws and accompanying washers that attach the Foot Module to the foot structure.

3. REMOVE FOOT MODULE
   - Remove the Foot Module and the foot shim (if present) from the Ankle.

4. CLEAN FOOT STRUCTURE
   - Clean the internal threads of the foot structure using a spiral brush.
   - Inspect the internal threads of the foot structure using a flashlight to ensure that the bosses are clean.


⚠ If the internal threads of the foot structure are damaged, please contact Customer Service.

# HARDSTOP COVER

(If necessary)

The Hardstop Cover prevents socks or pants from inadvertently being caught in the hardstop. This ensures that the Ankle function is not compromised.

| ATTACHING THE HARDSTOP COVER | |
|---|---|
| 1. Snap the hook of the Hardstop Cover over the top edge of the Encoder Cap. |  |
| 2. With the hook still in place, pull the plug side over and around the hardstop until it is centered in the hole of the Ankle axis. |  |
| 3. Press firmly to click into place. |  |

# TUNING

## CONNECT TO THE ANKLE

1. Start the Personal Bionics Tuning Application by selecting the blue-colored BiOM icon on the desktop screen.


2. Reset the password at your preference. To continue without changing the password, enter the default password ‘1234’ and select ‘Go’.


3. Select the Ankle from the list with the serial number of the Ankle you are about to tune.


If the Ankle asks to pair, enter in System Default PIN ‘0000’ and click ‘OK’.

# TROUBLESHOOT CONNECTION

If the Personal Bionics Tuning Application cannot communicate with the Ankle:

1. Make sure the Ankle is powered ON.
2. Make sure Bluetooth is enabled on the Personal Bionics Tuning Application.
3. Make sure Ankle is paired with the Personal Bionics Tuning Device, see PAIRING THE ANKLE WITH PERSONAL BIONICS TUNING APP.
4. If still unable to connect, unpair and re-pair the Ankle with the Personal Bionics Tuning Device, see PAIRING ANKLE WITH THE PERSONAL BIONICS TUNING APP.
5. If still unable to connect, calibrate the Ankle, see POWERING ON/OFF section.

**PAIRING THE ANKLE WITH THE PERSONAL BIONICS TUNING APP**

1. Select the Settings icon.

2. Select ‘Bluetooth’ and make sure that Bluetooth is turned on (a green checkmark or box should be visible).

# TUNING

## TUNE THE ANKLE

### BASIC TUNING SETTINGS

| PARAMETER | DESCRIPTION | DEFAULT |
|---|---|---|
| Resistance at Heelstrike | Use to adjust resistance of plantarflexion at heel strike. | 0% |
| Self-Selected Power | Use to adjust power at self-selected speed, before fine-tuning power for fast and slow speed. Adjusts both power bars together. | 0% |
| Fast Power | Use to adjust power between self-selected and fast walking speeds and for stairs and ramps. Use the Net Work Graph as guidance for tuning power on level ground. | 0% |
| Slow Power | Use to adjust power between slow to self-selected walking speeds. Use the Net Work Graph to guide tuning power on level ground only. | 0% |

### ADVANCED SETTINGS

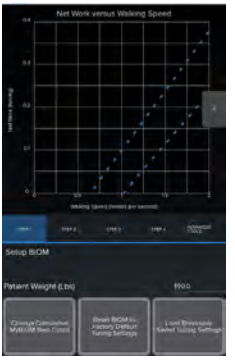
| PARAMETER | DESCRIPTION | DEFAULT |
|---|---|---|
| Power Sensitivity | Affects power based on patient's body weight. Most commonly used (increased) when there is a zero power response when tuning power settings at Step 2. | 0% |
| Fast Power Timing | Affects the timing of the powered push off phase at faster walking speeds. Increase if powered push off is more up than forward between self-selected and fast walking speeds. | 44 |
| Slow Power Timing | Affects the timing of the powered push off at slow walking speed. Increase if powered push off is more up than forward between slow and self-selected speeds. Decrease if patient reports "inconsistent power response" when walking slowly. | 16 |
| Cadence Range | The Cadence Range affects the slope of the power progression based off of the current settings for Slow Power and Fast Power. Increase if powered push off is flat towards fast speed in order to trigger maximum powered push off at a higher speed. May also need to increase Fast Power. Increase to balance power at level ground after increasing Fast Power or virtual plantarflexion when ascending stairs. | Weight Dependent |
| Virtual Dorsi/Plantarflexion | This adjustment will have the same effect as plantar or dorsiflexing the foot. Positive changes represent virtual plantarflexion. negative changes represent increased virtual dorsiflexion. Adjustments will affect both power and timing equally. This parameter is most commonly used in troubleshooting insufficient power on stair ascent, as well as inconsistent power at all walking speeds on flat surfaces. | 0 |

When using the application for the first time, you will be asked to choose between English and Metric Units. Select which you prefer.

If you later want to change to different units, select the tool icon in the top right corner and then select ‘Weight and Temperature Display’.

### STEP 1 - SETUP THE ANKLE

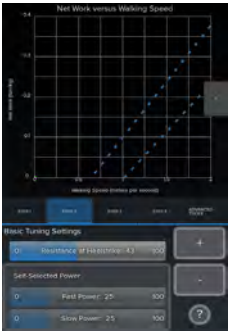
Enter the patient’s weight by selecting the value on the screen and typing in the weight.




To lower the keyboard, select the down/back button on the bottom of the screen.

To transfer a step count from a previous Ankle to this one, select ‘Change Cumulative MyBiOM Step Count’.

### STEP 2 - BASIC TUNING SETTINGS




To adjust a parameter, highlight the bar and use the + and – buttons to increase and decrease the value.

For helpful parameter tips, highlight the bar and select the help button (?).

Use the Net Work Graph to help you find the optimal power settings. At optimal tuning, the dots will plot near the dashed lines and form a parallel slope.

1. With the power parameters set at 0%, adjust the ‘Resistance at Heelstrike’ while at self-selected speed. This will control the rate of plantarflexion (rate to achieve foot flat) at heel strike.
2. Select ‘Self-Selected Power’ and use the + button to increase both power parameters together and establish an acceptable amount of powered push off at ‘Self-Selected Power’.
3. Select ‘Fast Power’ to fine tune powered push off at ‘Fast Power’.

# TUNING

4. Select ‘Slow Power’ to fine-tune the powered push off at ‘Slow Power’.
5. To adjust powered push off on stairs and ramps, select ‘Fast Power’ and adjust as needed. In stair ascent, instruct the user to lead with their non-affected side on the first step. When stepping onto the Ankle, the user should land directly on the toe with approximately 15° of flexion in the knee. The user should completely transfer his/her weight to the affected side, using minimum assistance from rails, in order to generate the required torque to invoke a reflex from the Ankle.

For optimal performance, power settings should be tuned to the lowest acceptable level for the user.

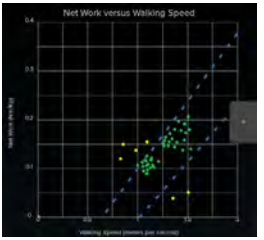
NOTE FOR BILATERAL USERS
- Tune power on the non-dominant side before the dominant side.
- Ensure the patient feels stable while standing.

- All users must be trained to ascend and descend stairs. Failure to do so may result in users being surprised by an unexpected powered reflex. Such a surprise may lead to a fall causing serious injury or death.
- For stair descent, it is important to teach the user to place the foot in a manner such that the forefoot does not make contact with the steps. This will ensure the Ankle will not respond with a reflex while descending stairs.
- User may receive Toe Strike Power while walking backward on level ground.

If power settings are not optimized for all speeds, ramps and stairs, move to the Advanced Tools tab.

THE NET WORK GRAPH - The graph shows the BiOM Net Work normalized by the patient weight as a function of walking speed. It also shows the range of Net Work for the anatomical ankle.

- Each dot represents one step with the Ankle.
- Dots distributed horizontally in the graph demonstrate the patient's cadence range.
- Dots between the dashed lines are within normal limits for the anatomical ankle.




ATTENTION MESSAGE - "Motor is overheating!"
This message will appear if the motor is overheating. Please follow the instructions and lower the power settings if this message appears when the patient is walking on level ground. If not addressed, the Battery may drain unusually fast.

ATTENTION MESSAGE - "Net Work is too high!"
This message will appear if the Net Work is excessively high for the patient's weight. The dots on the Net Work Graph will also be red. Please follow the instructions and lower the power settings if this message appears when patient is walking on level ground.

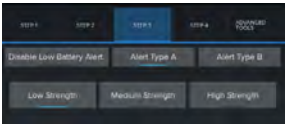
ATTENTION MESSAGE - "Motor is overextending!"
This message will appear if the Ankle is moving into full motor extension at a speed that is too high, and therefore straining the mechanical components on the inside of the Ankle.

Please add motor protection or lower the power settings if this message appears. If not addressed, the mechanical components can fail. By adding motor protection, the patient may feel a slight reduction in powered push off.

# TUNING

**STEP 3 - BATTERY ALERT SETTING**

1. Select an Alert Type or Disable Low Battery Alert.
2. Select the Alert Strength.
3. Select “Preview ‘Low Battery’ Alert” to demonstrate the Battery Warning to the user.



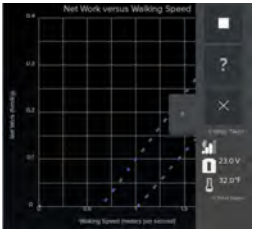

- Inform user that the Low Battery Alert will occur once with approximately 400 steps remaining and twice with 150 steps remaining.
- Vibration Strength and Alert Type will be the same for both Low and Very Low Battery Alert. Duration will be longer for Very Low Battery Alert.
- A reminder alert will also occur each time the Ankle is turned on with a low battery.
- These alerts are only issued when the Ankle is static, not during walking.

**STEP 4 - SAVE SETTINGS**

Select ‘Save BiOM Settings to Tablet’ to save the settings to the Ankle.


Select ‘Read BiOM Configuration’ to view the detailed BiOM Configurations.

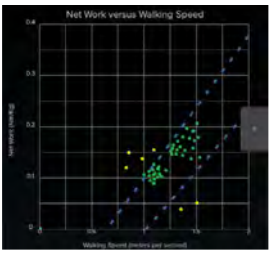
## GENERATE AN ANKLE TUNING RECORD




1. Touch the arrow to the left of the Net Work Graph to open a drawer that contains:
    - A record button (• REC)
    - A button for more information about the Net Work Graph (?)
    - A button to clear the dots on the graph (X)
    - Bluetooth connection strength
    - Battery charge level
    - Ankle temperature
    - Ankle step count

2. Select the ‘Record’ button to start recording. The graph will automatically be cleared to start the recording.

3. Have the user walk on level ground at 3 speeds: Slow, Self-Selected and Fast Power for a minimum of 20 steps each.




The graph to the right is an example of a Net Work Graph when tuning has been optimized. Note the green dots are plotted between the dashed lines and form a slope parallel to the dashed lines. A few yellow dots outside the dashed lines is normal, as long as the user is satisfied.

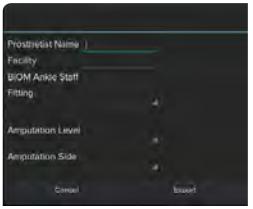
Do not collect data for the Net Work Graph when the user is walking on uneven terrain or stairs.

4. Select ‘stop recording’ (same button as the record button).

5. Respond to the Confidentiality and Patient Privacy notice.

# TUNING

6. Complete the information for the Tuning Record by selecting the relevant field line and either selecting from a list of options or typing the information.




7. A pdf file named H2_XXXXXXXX_YYYYMMDD HHMMSS_tuning (where XXXXXXXXX is the ankle serial number, YYYYMMDD is the year, month and day and HHMMSS is the hour, minute and second) will be saved to the tablet. To access the tuning record, select the white BiOM file folder icon on the desktop.

## TROUBLESHOOT TUNING

VERIFY THE FOLLOWING:

- Make sure sock or pants are not caught in the Hardstop Cover.
- Make sure the Ankle calibrates when powered ON. Have user unload foot, place light pressure on heel, power ankle ON and listen for the high pitched beep for calibration confirmation.
- Before adjusting the tuning parameters, verify the alignment. The table below lists how alignment changes can affect the Ankle response.

**ALIGNMENT CHANGE EFFECT ON THE ANKLE RESPONSE**

| | |
|---|---|
| **PLANTARFLEX FOOT (EXTEND SOCKET)** | • Increase in powered push off at toe off<br>• Powered push off occurs earlier in late stance |
| **DORSIFLEX FOOT (FLEX SOCKET)** | • Decrease in powered push off at toe off<br>• Powered push off occurs later in late stance |
| **SLIDE FOOT FORWARD** | • Increase in powered push off at toe off<br>• Powered push off occurs earlier in late stance |
| **SLIDE FOOT BACK** | • Decrease in powered push off at toe off<br>• Powered push off occurs later in late stance |

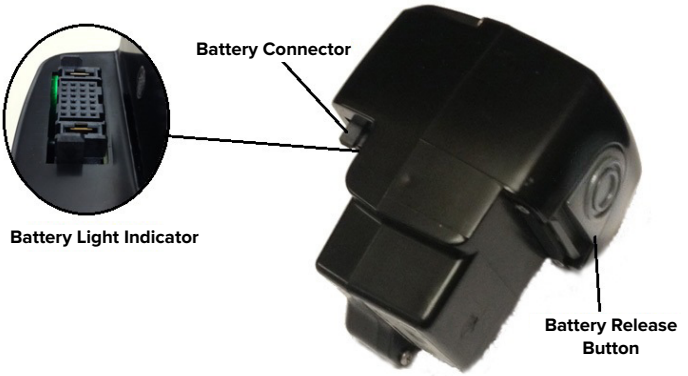
To maximize the function of the Ankle, it is important to walk with gait characteristics of normal human locomotion. Do not use compensatory motions, especially on stair ascent and descent. A full length step will allow the user to obtain maximum performance from the Ankle. The table below lists how gait deviations can affect the Ankle response.

| TUNING ISSUE | SOLUTION/ADJUSTMENT |
|---|---|
| Zero powered push off at self-selected speed during initial tuning<br><br>(Fast Power is 100% with no power response) | • Input correct weight.<br>• Set slow and fast speed to 30% on 'Step 2'. Increase Power Sensitivity in Advanced Tools until some power registers on Net Work Graph. Tune normally from 'Step 2'. |
| Powered push off is overly sensitive during initial tuning | • Input correct weight.<br>• Decrease Power Sensitivity in Advanced Tools.<br>• Decrease Virtual Dorsi/Plantarflexion setting in Advanced Tools. |
| Inconsistent powered push off at slow speed | • Decrease Slow Power Timing in the Advanced Tools on the Tuning Application. |
| Inconsistent power across all walking speeds | • Instruct user to take consistent steps.<br>• Increase Virtual Dorsi/Plantarflexion setting in Advanced Tools until power is consistent. You may need to reduce Fast Power in 'Step 2' after making this adjustment. Verify normalized power on Net Work Graph. |
| Zero or inconsistent powered push off on stairs and ramps | • Instruct user to land on toe of the Ankle by placing toe closer to edge of step. User should maintain slight knee flexion and transfer full body weight to the Ankle.<br>• Increase Virtual Dorsi/Plantarflexion setting in Advanced Tools to 50. Increase Fast Power in 'Step 2' by 10%. Have the user walk at normal walking speed on a flat surface while increasing Cadence Range in Advanced Tools until power is normalized on Net Work Graph. Have the user attempt stairs using proper technique. |

| TUNING ISSUE | SOLUTION/ADJUSTMENT |
|---|---|
| Not enough power during stair ascent | • Increase Fast Power and/or Increase Virtual Dorsi/Plantarflexion setting (+30% to +50%). Have user walk on a flat surface and increase Cadence Range until power is normalized on Net Work Graph. |
| User feels unstable during hill/ ramp descent | • Decrease Resistance at Heelstrike setting in 'Step 2'. Verify this setting is still appropriate during level ground walking. |
| Too much powered push off at slow speed | • Decrease Slow Power in 'Step 2'. |
| Powered push off felt too late at slow/fast speed | • Decrease Slow/Fast Power Timing in Advanced Tools. |
| Power pushes wearer up rather than forward at slow/fast speed | • Increase Slow/Fast Power Timing in Advanced Tools. |
| User reports loss of power | • Review calibration procedure.<br>• Inspect Hardstop Cover and clear any obstructions.<br>• Verify battery is fully charged.<br>• Verify battery is seated in holster properly. |
| User reports loss of power and ankle is overheating | • Decrease Virtual Dorsi/Plantarflexion setting (-30% to -50%). Increase at Slow and Fast Power Timing by 10%. Dorsiflex the foot. |

# BATTERY AND CHARGER

Before using the Battery and Charger, read all instructions and cautionary markings in the Instructions for Use and on the Charger and Battery.




Before using the Ankle in a cold weather environment where the temperatures are below 32°F (0°C), ensure that the Battery is initially kept in an environment where the temperature is between 32°F (0°C) and 113°F (45°C).

**BATTERY SPECIFICATIONS:**

BATTERY TYPE: Rechargeable Lithium-Ion Battery

BATTERY CAPACITY: 30 W-Hr which results in 1500-2000 strides per battery depending on user activity and weight.

BATTERY OUTPUT VOLTAGE: 22.2 Vdc (nominal)

CHARGING TIME: 45 minutes after normal usage depletion

OPERATING TEMPERATURE (CHARGING): 41°F (5°C) to 113°F (45°C)

OPERATING HUMIDITY: 20-90% relative humidity, non-condensing.

SHIPPING & STORAGE TEMPERATURE: -22°F (-30°C) to 140°F (60°C)

SHIPPING & STORAGE HUMIDITY: 20-90% relative humidity, non-condensing.

BATTERY LIFE EXPECTANCY: 12-18 months depending on use

INDICATOR: A blinking green light visible through the Battery Connector right after removing it from the Charger or Ankle. The duration of illumination indicates the level of charge. Solid light means fully charged and fast blinking means almost empty.

Do not operate the Ankle at temperatures below -4°F (-20°C) or above 113° F (45°C).

# BATTERY AND CHARGER


**CHARGER SPECIFICATIONS:**

CHARGER INPUT: 13-30 VDC, 5A MAX

AC POWER ADAPTER INPUT: 100-240 VAC, 50/60Hz

OUTPUT: Charging current of 2.0 amperes

CHARGING TEMPERATURE: 14°F (-10°C) to 113°F (45°C)

CHARGING HUMIDITY:20-90% relative humidity, non-condensing.

SHIPPING & STORAGE TEMPERATURE: -22°F (-30°C) to 140°F (60°C)

SHIPPING & STORAGE HUMIDITY: 20-90% relative humidity, non-condensing.

⚠ Do not attempt to operate the Charger at temperatures below 14°F (-10°C) or above 113°F (45°C).

# CHARGE THE BATTERY

1. Connect the Power Supply's cord to the charger unit. Connect the Power Cord directly to an outlet.

A blue LED will illuminate in the charger when it is receiving power.

Only operate the Charger with the supplied power supply.

2. Remove the Battery from the Ankle by first turning the Ankle OFF and then pressing the Battery Release Button and lift the Battery out.

3. Align the Battery Connector with the Charger Holster and press the Battery firmly into place.


Battery will begin charging immediately and charger light indicator will flash slowly with a green light. Charging should only take about 45 minutes.

If there is a red fast blinking light indicator on the charger, remove the battery from the charger and see troubleshooting battery and charger.

**CLEANING BATTERY AND CHARGER**

1. Before any cleaning, unplug the Charger from the Power Supply.
2. Wipe the Charger and Battery clean with isopropyl alcohol.
3. After cleaning, let the Battery and Charger dry thoroughly before using.

Do not use solvents stronger than isopropyl alcohol to clean.

Do not use compressed air to clean.

# BATTERY AND CHARGER

## BATTERY MANAGEMENT

The Ankle is powered by a state-of-the-art Lithium-Ion Battery. The Batteries have been tested to last 1 million steps and still maintain 80% of their original capacity. Users typically get 3 to 6 hours of battery life a day depending on their usage.

To ensure the Battery provides the longest life possible, try the following:

- When possible, charge the Battery before it becomes fully depleted. It may extend battery life.
- Always charge the Battery after use. Storing an empty Battery can make it unusable in as little as 30 days.
- Do not store the Battery in the Ankle when not in use. This can deplete its life.
- Before charging the Battery, allow it to warm or cool to room temperature.
- After inserting the Battery in the Charger, watch the status light on the Charger for 10 seconds to confirm the Battery is actually charging.
- Store and charge the Batteries in a climate-controlled, dry location out of direct sunlight. Avoid leaving the Batteries in a car where temperature extremes can permanently damage the Batteries.

**EXTENDING SHELF LIFE**

The most common problem people experience with their Batteries is the result of incorrectly storing them, because a Battery continues to slowly discharge during storage. A fully charged Battery can be stored as long as 3 years. Storing a discharged battery may cause it to become permanently disabled in as little as one month.

A Battery left in the Ankle will also drain relatively quickly (3% per day) even if the Ankle is powered OFF. To extend Battery life, fully charge and store it separately from the Ankle or the Charger.

**UNDERSTANDING SLEEP MODE**

If a Battery suddenly loses power, it may have automatically shut down as a precaution for safety reasons or to protect the Battery. You will know if this happens as the Ankle will lose all power the same as when the ON/OFF switch has been turned OFF. The Ankle will continue to function, but it will not offer powered propulsion and it will feel heavy.

This power ‘lock out’ happens automatically if the Battery operating limits are exceeded. In this state, the Battery will not charge or discharge. Causes for the ‘lock out’ include:

- Too high of a temperature (110˚F while charging, 150°F while walking).
- Too low of a temperature (40°F while charging, but no limit while walking).
- The Battery has reached its discharge limit.

If a Battery has been “locked out”, simply unplug the Battery and then plug it back in to correct it.

- If the temperature was too high, allow the Battery to cool to below 110˚ F.
- If the Battery reached its discharge limit, simply recharge the battery.

Some conditions cause the Battery to lock out permanently because charging or discharging could present a safety hazard. If a Battery goes into permanent lock mode, it is time to replace the Battery.

**ANKLE WILL NOT POWER ON**

Unplug the Battery and examine the status LED inside the male side of the Battery. If the light is blinking very short pulses, charge the Battery or try another.

Low Battery Alerts will not be given in the midst of normal walking, so as to not surprise the user.

When the Ankle loses power, it will revert to non-powered operation. If the Ankle loses power, turn the power OFF and install a fully charged battery to insure proper operation of the Ankle.

To conserve battery power, when not using the Ankle, turn it OFF with the power switch. Battery operation, and therefore the Ankle operation, may be affected by very low or very high temperatures.

# BATTERY AND CHARGER

## BATTERY AND CHARGER SAFETY PRECAUTIONS

- WARNING: Do not use any other Power Supply and Cord with the Charger other than the one supplied with the Charger.
- WARNING: Do not block the cooling vents on the Charger, as this can result in overheating and risk of Charger malfunction.
- WARNING: Do not expose the Battery to prolonged periods of direct sunlight, as this can result in a risk of malfunction.
- WARNING: Avoid exposure of the Battery to dusty, smoky, dirty environments, as this can cause malfunction.
- WARNING: Avoid exposure of the Battery to mechanical vibrations or impact, as this can cause malfunction.
- Never carry the Charger by its cord or yank to disconnect from receptacle, as this can cause malfunction.
- WARNING: DO NOT DISCARD IN TRASH OR BURN THE BATTERY. They should never be incinerated due to a risk of explosion.
- WARNING: Do not use the Charger to charge anything other than Batteries.
- WARNING: Only use the Charger provided with the Ankleto charge the Batteries.
- WARNING: Do not expose the Batteries or Charger to liquids. Protect against water, rain, snow, etc. as this can cause malfunction.
- If the Battery or Charger is exposed to liquid, allow it to dry out and contact Customer Service before resuming use.
- WARNING: Do not drop metal objects or other debris (e.g., paper clips, coins, etc) into the Charger itself or the connectors on the Charger, as this will result in a risk of malfunction. Always examine the Charger and its connector prior to use and clear away any foreign objects before inserting a Battery.
- WARNING: Avoid exposure of the Battery to high electrical and/or magnetic energy (e.g. electrical power generators, electrical transformers, high-power radio-frequency transmitters, and high-power electromagnetic transmitters like TV transmitters or walkie-talkies), as this will result in a risk of malfunction.
- ELECTRIC SHOCK HAZARD. Avoid touching the metal terminals on the Battery and Charger connectors and do not allow the metal terminals to come in contact with metal objects.
- ELECTRIC SHOCK HAZARD. Do not crush, disassemble, puncture, or incinerate the Battery or Charger.
- Do not drop or otherwise mishandle the Battery or Charger. If the Battery or Charger is dropped, inspect for damaged and loose parts. DO NOT USE the Battery if damage is observed or suspected.
- WARNING: Do not operate the Ankle at temperatures below -4°F (-20°C) or above 113° F (45°C), as this will result in a risk of malfunction.
- WARNING: Do not attempt to operate the charger at temperatures below 14°F (-10°C) or above 113°F (45°C), as this will result in a risk of malfunction.
- To turn the Charger off, unplug from the wall.

If you are unsure about any problem or about proper use of the charger and batteries, call Customer Service

# TROUBLESHOOT BATTERY AND CHARGER

| ISSUE | SOLUTION |
|---|---|
| Battery does not fit properly inside the Charger | • With the Charger unplugged, remove any debris in the Charger Holster, or the connector.<br>• Examine connectors in the Charger Holster and on the Battery for damage.<br>⚠ DO NOT USE the damaged Charger. Call Customer Service. |
| Charger rattles when shaken, indicating a possible loose part inside the device | ⚠ DO NOT USE the damaged Charger. Call Customer Service. |
| Battery rattles when shaken, indicating a possible loose part inside the device | ⚠ DO NOT USE the damaged Battery. Call Customer Service. |
| Fast blinking red light on Charger | • Remove Battery, unplug Charger, replug Charger and insert Battery. If fast blinking red light persists, contact Customer Service. |
| Red light blinking 3 times on 5 sec interval on Charger | • Indication of a Battery error. Remove Battery from Charger and do not use. Call Customer Service. |
| Red light blinking 5 times on 5 sec interval on Charger | • Indication of out-of-temperature condition. Ensure Charger vents are not blocked and Charger is in a cool environment. Unplug Charger and allow to cool before use. |
| No blue LED illuminated in Charger | • Ensure Power Supply is securely plugged into the Charger and Power Cord is plugged into an outlet.<br>• Try a different outlet. |

| ISSUE | SOLUTION |
| --- | --- |
| Battery does not charge | • Ensure Battery Connector is firmly placed in the Charger.<br>• Verify blue LED is illuminated. Follow troubleshooting for no blue LED illuminated on charger.<br>• Be sure to use the correct Battery in the Charger. Only batteries with a gray Battery Release Button are compatible with the dual bay Charger.<br>• Try the alternate bay of the dual bay Charger. Contact Customer Service for Charger replacement and/or Battery replacement.<br>• If Battery is below operating temperature allow battery to warm. See Battery Specifications in this manual for details. |

# MAINTENANCE

**SERVICE**

To ensure proper function, it is recommended that the Ankle is inspected every six months to check for signs of unusual wear. Refer to the image on page 12 of this manual and visually inspect:

- The Hardstop Cover in the front of the ankle and the Internal Guard at the back of the ankle joint for wear.
- The condition of the fasteners on the Battery Hinge and Battery Holster. Ensure that they are firmly in place.
- The Carbon Spring for cracking or delamination.
- The Foot Module for signs of excessive wear and loose bolts.
- The Battery area that mates with the Battery for bent pins.

**CLEANING**

Utilize a small dry brush to clean any debris or dirt from the Ankle. Clean the Ankle with a damp cloth and mild soap or isopropyl alcohol. Remove the Foot Cover and clean any debris on the inside. Use a soft cloth to clean any dirt or debris from the Foot Module and the heel wedge area.

⚠ • DO NOT use solvents stronger than isopropyl alcohol.
• DO NOT use compressed air to clean the system, as it can cause the Ankle to malfunction and deteriorate prematurely.

**RETUNING**

To ensure proper performance of the Ankle, the Ankle should be retuned by a trained healthcare professional after 2 weeks of initial use and again after 6 weeks of use.

**REPAIRS**

- If you have exhausted all troubleshooting methods and are still unable to get the Ankle to work, please contact Customer Service.
- The Ankle, Battery and accessories shall be sent to Customer Service for repairs or maintenance.
- No other company or individual is allowed to repair the Ankle, Battery or accessories in any way.

⚠ DO NOT disassemble the Ankle, Battery or accessories and do not attempt repairs as this may create a hazard.

**TRANSPORT**

- Always use the packaging supplied with the Ankle for transporting the Ankle, when not attached to the socket.
- When traveling via air with Batteries not in use, individually package and transport them in carry-on luggage. The Batteries should not be put in checked luggage. Before traveling, please check the latest FAA regulations and any airline carrier regulations.
- For damaged or defective Batteries, please contact Customer Service for appropriate shipping considerations. Damaged or defective Batteries can only be shipped via ground transportation.

**DISPOSAL**

- Lithium-Ion Batteries should never be disposed of in residential or commerical garbage. They should never be incinerated due to a risk of explosion.

# WARRANTY

BionX Medical Technologies, Inc. (“Company”) provides the following warranty only to the initial purchaser (“Purchaser”) of each new Device (as defined below).

**1. WHAT DOES THIS LIMITED WARRANTY COVER?**
This limited warranty covers any material defects in the following new devices purchased by Purchaser: Ankle with Foot Module (not including Foot Cover), Batteries, Charger (each, a “Device”).

**2. WHAT IS NOT COVERED BY THIS WARRANTY?**
This limited warranty does not cover any problem with, or damage to, a Device that is caused by use outside of the Company’s Instructions for Use as set forth in the Instructions for Use, accident, abuse, misuse, negligence, modification, or improper maintenance or installation including, without limitation, any problem or damage caused by factors external to the Device such as, without limitation, failure of or faulty electrical power.

**3. HOW LONG DOES THE COVERAGE LAST?**
The Ankle with Foot Module is covered with a 36 month limited warranty, the Charger is covered with a 36 month limited warranty and the Batteries are covered with a 12 month limited warranty. This limited warranty begins on the date the Device was originally shipped from the Company (“Warranty Period”). With respect to any Device (“Replacement Device”) which is shipped by the Company in replacement of a returned Device (“Original Device”), the Replacement Device will be warranted for the remainder of the original Warranty Period applicable to the Original Device or thirty (30) calendar days, whichever is longer. Forthwith upon the receipt of a Replacement Device, the Original Device must be returned to the Company to avoid charges for the Replacement Device.

**4. WHAT WILL THE COMPANY DO IF THERE IS A MATERIAL DEFECT?**
If the Company, in its reasonable discretion, determines that a Device is covered by this limited warranty, then the Company will replace the Device at the Company’s cost. Any Replacement Device may, in the Company’s sole discretion, be a refurbished Device or may contain refurbished parts. The Company’s replacement of any Device with a Replacement Device is Purchaser’s sole and exclusive remedy for breach of this Limited Warranty. Title and ownership of any Device which is returned and replaced by the Company shall vest in the Company. The Purchaser shall have title to the Original Device or, if such Original Device is replaced, the Replacement Device except to the extent further replaced.

**5. WARRANTY DISCLAIMERS.**

To the maximum extent permitted by law, the company expressly disclaims any implied warranty of merchantability and any implied warranty of fitness for a particular purpose. The device is for walking and everyday use only. Do not use the device for sports or high impact activities. The company makes no warranty that the device will (a) meet the particular or special needs of the user which are not contemplated by, or are beyond the activities described in, the company's instructions for use; (b) operate in combination or conjunction with any non-company approved accessories or other equipment or materials not provided by the Company; or (c) provide uninterrupted or error free service, or that any error can be corrected at all or be corrected within any particular time period. The device is to be used only in accordance with the instructions for use including, without limitation, the instructions with respect to walking speed, negotiating ramps and stairs, cleaning, maintenance, tuning, charging, and use with company-approved accessories. The company specifically disclaims any express or implied warranty of fitness for use outside of the instructions for use.

**6. CAP AND OTHER LIMITS ON LIABILITY.**

To the maximum extent permitted by law, in no event will the total liability of company arising out of or in connection with the device exceed the cost of replacing the device. In no event will company be liable for any special, indirect, incidental, exemplary, punitive or consequential damages, including, without limitation, personal injury, lost profits, damage to property, loss or damage to data or impairment of other assets, whether or not foreseeable. And whether or not purchaser has been advised of the possibility of such damages or losses, or the company could foresee such damages or losses.

**7. AUTHORIZED PROSTHETISTS**

This warranty is conditioned upon Purchaser dealing with a Company-approved prosthetist for fitting, tuning, maintenance, and replacement. Using anyone other than a Company-approved prosthetist shall void this warranty.

**8. RETURN POLICY**

We value our customer's satisfaction. We make every effort to provide a personal demonstration prior to a purchase decision. Therefore, BionX Medical Technologies, Inc. does not accept returns of the Ankle or it's accessories including, Charger, Batteries and Foot Cover.

# EMC PRECAUTIONS - ANKLE

| Guidance and Manufacturer's Declaration – Electromagnetic Emissions | | |
|---|---|---|
| The Ankle is intended for use in the electromagnetic environment specified below. The customer or the user of the Ankle should assure that it is used in such an environment. | | |
| **Emissions Test** | **Compliance** | **Electromagnetic Environment - Guidance** |
| RF Emissions CISPR 11 | Group 2 | The Ankle emits electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected |
| RF Emissions CISPR 11 | Class B | The Ankle is suitable for use in all establishments, including domestic establishments |
| Harmonic Emissions IEC 61000-3-2 | Not Applicable | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Not Applicable | |

# EMC PRECAUTIONS - ANKLE

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity | | | |
|---|---|---|---|
| The Ankle is intended for use in the electromagnetic environment specified below. The customer or the user of the Ankle should assure that it is used in such an environment. | | | |
| **Immunity Test** | **IEC 60601 Test Level** | **Compliance Level** | **Electromagnetic Environment - Guidance** |
| Electrostatic Discharge (ESD) IEC 61000-4-2 | ± 6kV contact<br>± 8kV air | ± 6kV contact<br>± 8kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst IEC 61000-4-4 | ± 2 kV for power supply lines<br>± 1kV for input/ output lines | Not applicable | Not applicable. The Ankle is battery powered. |
| Surge IEC 61000-4-5 | ± 1 kV line to line<br>± 2 kV line to earth | Not applicable | Not applicable. The Ankle is battery powered. |
| Voltage dips, short interrupts and voltage variations on power supply input lines | <5 % $U_T$ (>95 % dip in $U_T$) for 0,5 cycle<br>40 % $U_T$ (60 % dip in $U_T$) for 5 cycles<br>70 % $U_T$ (30 % dip in $U_T$) for 25 cycles<br><5 % $U_T$ (>95 % dip in $U_T$) for 5 s | Not applicable | Not applicable. The Ankle is battery powered. |
| Power frequency (50/60Hz) magnetic field IEC 61000-4-11 | 3A/m | 3A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE: $U_T$ is the a.c. mains voltage prior to application of the test level. | | | |

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity | | | |
|---|---|---|---|
| The Ankle is intended for use in the electromagnetic environment specified below. The customer or the user of the Ankle should assure that it is used in such an environment. | | | |
| **Immunity Test** | **IEC 60601 Test Level** | **Compliance Level** | **Electromagnetic Environment - Guidance** |
| Conducted RF<br>IEC 61000-4-6<br><br>Radiated RF<br>IEC 61000-4-3 | Not Applicable<br><br>3 V/m<br>80MHz to 2.5GHz | Not Applicable<br><br>3V/m | Portable and mobile RF communications equipment should be used no closer to any part of the Battery Charger, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>**Recommended separation distance:**<br>Not applicable. The Ankle is battery powered.<br><br>$d=1.2\sqrt{P}$ 80 MHz to 800 MHz<br>$d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz<br><br>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Ankle is used exceeds the applicable RF compliance level above, the Ankle should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Ankle.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Ankle**

The Ankle is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Ankle can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Ankle as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter m | | |
|---|---|---|---|
| | 150 kHz to 80 MHz d=1.2√P | 80 MHz to 800 MHz d=1.2√P | 800 MHz to 2.5 GHz d=2.3√P |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The Ankle utilizes a Bluetooth® radio for wireless tuning. The tuning radio may be interfered with by other equipment, including equipment that complies with CISPR emission requirements. If poor tuning range or responsiveness is experienced, it may be necessary to tune the Ankle in a location further from sources of RF energy. The Bluetooth® radio receives and transmits the following RF electromagnetic energy:

- Frequency Band: 2402 - 2480MHz
- Modulation: FHSS/GFSK
- Effective Radiated Power: 12dBm

| Guidance and Manufacturer's Declaration – Electromagnetic Emissions | | |
|---|---|---|
| The Battery Charger is intended for use in the electromagnetic environment specified below. The customer or the user of the Battery Charger should assure that it is used in such an environment. | | |
| **Emissions Test** | **Compliance** | **Electromagnetic Environment - Guidance** |
| RF Emissions<br>CISPR 11 | Group 1 | The Battery Charger uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF Emissions<br>CISPR 11 | Class B | The Battery Charger is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic Emissions<br>IEC 61000-3-2 | Class B | |
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3 | Complies | |

# EMC PRECAUTIONS - CHARGER

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity | | | |
|---|---|---|---|
| The Battery Charger is intended for use in the electromagnetic environment specified below. The customer or the user of the Battery Charger should assure that it is used in such an environment. | | | |
| **Immunity Test** | **IEC 60601 Test Level** | **Compliance Level** | **Electromagnetic Environment - Guidance** |
| Electrostatic Discharge (ESD) IEC 61000-4-2 | ± 6kV contact<br>± 8kV air | ± 6kV contact<br>± 8kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst IEC 61000-4-4 | ± 2 kV for power supply lines<br>± 1kV for input/output lines | ± 2 kV for power supply lines<br>± 1kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV line to line<br>± 2 kV line to earth | ± 1 kV line to line<br>± 2 kV line to earth | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interrupts and voltage variations on power supply input lines IEC 61000-4-11 | <5 % $U_T$<br>(>95 % dip in $U_T$)<br>for 0,5 cycle<br>40 % $U_T$<br>(60 % dip in $U_T$)<br>for 5 cycles<br>70 % $U_T$<br>(30 % dip in $U_T$)<br>for 25 cycles<br><5 % $U_T$<br>(>95 % dip in $U_T$)<br>for 5 s | <5 % $U_T$<br>(>95 % dip in $U_T$)<br>for 0,5 cycle<br>40 % $U_T$<br>(60 % dip in $U_T$)<br>for 5 cycles<br>70 % $U_T$<br>(30 % dip in $U_T$)<br>for 25 cycles<br><5 % $U_T$<br>(>95 % dip in $U_T$)<br>for 5 s | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Battery Charger requires continued operation during power mains interruptions, it is recommended that the Battery Charger be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60Hz) magnetic field | 3A/m | 3A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment |
| NOTE: $U_T$ is the a.c. mains voltage prior to application of the test level. | | | |

**Guidance and Manufacturer's Declaration – Electromagnetic Immunity**

The Battery Charger is intended for use in the electromagnetic environment specified below. The customer or the user of the Battery Charger should assure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment - Guidance |
|---|---|---|---|
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the Battery Charger, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>**Recommended separation distance:**<br>$d=1.2\sqrt{P}$<br>$d=1.2\sqrt{P}$ 80 MHz to 800 MHz<br>$d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz |
| Conducted RF<br>IEC 61000-4-6 | 3Vrms<br>150kHz to 80MHz | 3V | Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80MHz to 2.5GHz | 3V/m | Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b].<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Battery Charger is used exceeds the applicable RF compliance level above, the Battery Charger should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Battery Charger.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Battery Charger**

The Battery Charger is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Battery Charger can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Battery Charger as recommended below, according to the maximum output power of the communications equipment.

| **Rated Maximum Output Power of Transmitter** W | **Separation Distance According to Frequency of Transmitter** m | | |
|---|---|---|---|
| | **150 kHz to 80 MHz d=1.2√P** | **80 MHz to 800 MHz d=1.2√P** | **800 MHz to 2.5 GHz d=2.3√P** |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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This product, and the use thereof, may be covered by one or more of the following US patents: 5,650,704 and 7,313,463 with additional patents pending.

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