Bioness Medical, Inc.
25103 Rye Canyon Loop
Valencia, CA 91355 USA
Telephone: (800) 211-9136
Email: info@bionessmedical.com
Website: BionessMedical.com

Rx Only

612-01233-001 Rev. C
03/2025

L360™

Thigh System

Functional Electrical Stimulation and
Neuromuscular Electrical Stimulation System

USER'S GUIDE

bioness®

Environmental Policy

Service personnel are advised that when changing any part of the L360 Thigh System, care should be taken to dispose of those parts in the correct manner; where applicable, parts should be recycled. For more detailed information regarding these recommended procedures, please contact Bioness. Bioness is committed to continuously seeking and implementing the best possible manufacturing procedures and servicing routines.

List of Symbols

	Caution
	Warning
	Double Insulated (Equivalent to Class II of IEC 536)
	Type BF Applied Part(s)
	Non-Ionizing Radiation
	Date of Manufacture
	Manufacturer
	This Product Must Not Be Disposed of with Other Household Waste
	Refer to Instruction Manual/Booklet
REF	Re-Order Number
LOT	Lot Number
SN	Serial Number
	Single Patient Use - To Prevent Cross Contamination
	Single Patient Use - To Prevent Cross Contamination
MD	Medical Device
	Storage Temperature
	Humidity Limitation
	Atmospheric Pressure Limitation
	Keep Dry
IP22	Degree of Ingress Protection (for Control Unit)
IP42	Degree of Ingress Protection (for EPG)
IP52	Degree of Ingress Protection (for Foot Sensor)
LT	Left
RT	Right

Table of Contents

Introduction

Central nervous system (CNS) and orthopedic injuries often result in problems with gait. Weak thigh muscles can cause considerable difficulties with flexing or extending the knee during ambulation.

The L360 Thigh System, which is designed for Functional Electrical Stimulation (FES) and Neuromuscular Electrical Stimulation (NMES), generates muscular contractions through the application of electrical stimulation to the peripheral nerves. The L360 System delivers stimulation to either the hamstring or quadricep muscles to assist knee flexion or extension, facilitate muscle re-education, prevent/retard disuse atrophy, maintain or increase joint range of motion, and/or increase local blood flow. This system also provides early post-surgical quadricep and hamstring strengthening, improves post-surgical knee stability secondary to quadricep and hamstring strengthening, and relaxes muscle spasms.

The L360 Thigh System consists of a thigh cuff with an External Pulse Generator (EPG), an optional Control Unit, and an optional Foot Sensor. These components communicate wirelessly to electrically stimulate muscles contractions in the affected leg to provide knee flexion or extension.

The L360 Thigh System is designed to be used in a Hospital/Professional Healthcare Facility or Residential/Home Healthcare environment.

Note: The L360 Thigh System uses L300 Go System components with L300 Go labels. In many sections of this guide, statements about the L360 Thigh System are based on testing and evaluation of the L300 Go System components.

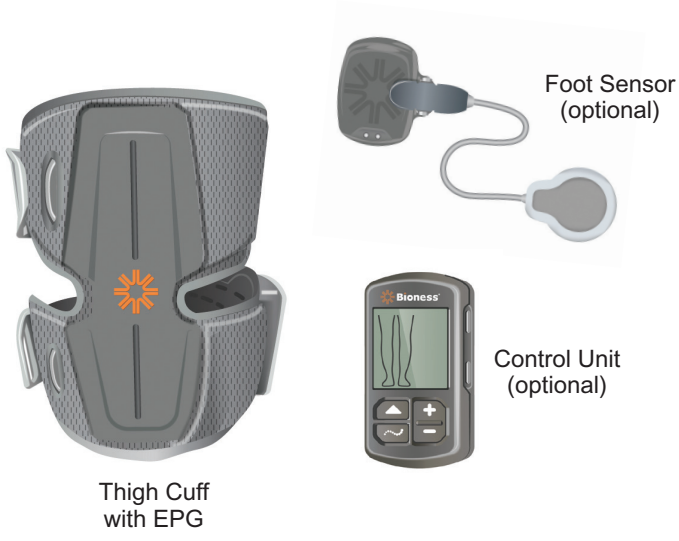


Figure 1-1: L360 Thigh System

This L360 Thigh User's Guide describes:

- Important safety information about the L360 Thigh System.
- The components of the L360 Thigh System.
- How to set up, operate, and maintain your L360 Thigh System.
- Troubleshooting information.

Be sure to review this guide with your clinician before using your L360 Thigh System. If you have any questions contact Customer Service at 800-211-9136 or an authorized distributor. You can also visit the website at: www.BionessMedical.com.

⚠ **Caution:** Do not put on or operate the L360 Thigh System before being properly fitted and trained by a certified clinician.

Safety Information

Indications for Use

The L360 Thigh System is intended to assist knee flexion or extension in adult individuals with muscle weakness related to upper motor neuron disease/injury (e.g., stroke, damage to pathways to the spinal cord). The L360 Thigh System electrically stimulates muscles in the affected leg to provide knee flexion or extension; thus, it also may improve the individual's gait.

The L360 Thigh System may also:

- Facilitate muscle re-education
- Prevent/retard disuse atrophy
- Maintain or increase joint range of motion
- Increase local blood flow
- Provide early post-surgical quadricep and hamstring strengthening
- Improve post-surgical knee stability secondary to quadricep and hamstring strengthening
- Relax muscle spasms

Contraindications

- Users with a demand-type cardiac pacemaker, defibrillator or any electrical implant should not use the L360 Thigh System.

⚠ Warnings

- The L360 Thigh System should not be used on a leg where a metallic implant is directly underneath the electrodes.
- The L360 Thigh System should not be applied over, or in proximity to, cancerous lesions.
- The L360 Thigh System should not be used on a leg with a regional disorder, such as a fracture or dislocation, which could be adversely affected by motion from the stimulation.
- The long-term effects of chronic electrical stimulation are unknown.
- The Thigh Cuff should not be worn over swollen, infected, or inflamed areas or skin eruptions, such as phlebitis, thrombophlebitis, and varicose veins.
- Simultaneous connection of the L360 Thigh System to the user and high-frequency surgical equipment may result in skin burns where the stimulator electrodes touch and damage to the EPG.
- Do not use the L360 Thigh System within three feet of short wave or microwave therapy equipment. Such equipment may produce instability in the EPG output.
- The L360 Thigh System should only be configured by an authorized clinician.
- In case of any inconvenience, turn off stimulation and remove the Thigh Cuff. If the stimulation cannot be turned off, remove the Thigh Cuff to stop stimulation.

Precautions

- Inflammation in the region of the Thigh Cuff may be aggravated by motion, muscle activity, or pressure from the cuff. Stop using the L360 Thigh System until any inflammation is gone.
- Use caution if you have a suspected or diagnosed heart problem.
- Use caution if you have suspected or diagnosed epilepsy.

- Use the Thigh Cuff with caution:
    - If you have a tendency to bleed heavily following acute trauma or fracture.
    - Following recent surgical procedures when muscle contraction may disrupt the healing process.
    - Over areas of the skin that lack normal sensation.
    - If you have suspected or diagnosed epilepsy.
- Some users may experience a skin irritation, an allergic reaction, or hypersensitivity to the electrical stimulation or the electrical conductive medium. Irritation may be avoided by having your clinician change the stimulation parameters or electrode placement.
- Do not use the L360 Thigh System without electrodes.
- After removing the Thigh Cuff, it is normal for the areas under the electrodes to be red and indented. The redness should disappear in approximately one hour. Persistent redness, lesions, or blisters are signs of irritation. Alert your clinician and stop using the L360 Thigh System until any inflammation is gone.
- Stop using the L360 Thigh System and consult your clinician if stimulation does not start at the correct time during gait.
- Turn off the L360 Thigh System when at a refueling place. Do not use the L360 Thigh System near flammable fuel, fumes, or chemicals.
- Only your treating clinician should determine electrode placement and stimulation settings.
- The L360 Thigh System should be kept out of the reach of children.
- Use only the L360 Thigh System electrodes supplied by Bioness.
- Turn off the L360 Thigh System before removing or replacing the electrodes.
- Obtain physician clearance prior to use if you have an alteration in normal arterial or venous flow in the region of the Thigh Cuff because of local insufficiency, occlusion, arteriovenous fistula for hemodialysis, or a primary disorder of the vasculature.

- Obtain physician clearance before stimulating an area with a structural deformity.
- The safe use of the L360 Thigh System during pregnancy has not been established.
- Skin problems, on the leg where the Thigh Cuff is worn, may be aggravated by the L360 Thigh System.
- Adult supervision and assistance should be provided for anyone needing help while using the L360 Thigh System.
- The patient/user is the intended operator of the L360 Thigh System.
- The Control Unit neck strap is meant to be worn around the neck and if not used properly could cause bodily harm.
- Protect all electronic components from contact with water, such as from sinks, bathtubs, shower stalls, rain, snow, etc.
- Do not leave the L360 Thigh System stored where temperatures may exceed the acceptable environmental range: -25°C to 55°C (-13°F to 131°F). Temperature extremes can damage the components.
- Do not attempt to repair your L360 Thigh System. Contact Customer Service if you experience a technical problem not covered in this guide.
- The Thigh Cuff is to be worn only on the leg of the user for whom it is fitted. It should not be worn by anyone else or on any other part of the body.
- Turn off the L360 Thigh System before putting on the Thigh Cuff. Do not turn on the L360 Thigh System until the Thigh Cuff is fastened in place.
- Shut off the L360 Thigh System before operating machinery or performing any activity in which involuntary muscle contractions could injure you (e.g. driving a car, riding a bicycle, etc.).
- Protect the L360 Thigh System electronic components from condensation. When moving the components between hot and cold temperatures, place them in an airtight plastic bag, and let them slowly (for at least two hours) adjust to the temperature change before use.
- Medical electrical equipment needs special precautions for electromagnetic compatibility.

- Remove the L360 Thigh System before undergoing any diagnostic or therapeutic medical procedure such as x-ray examination, ultrasound, MRI, etc.
- Keep away from pets and pests. While not in use, keep away from children. For pediatric use and indications consult the user manual. Care should be taken when removing small parts from the system, which may be accidentally swallowed. If swallowed, consult a doctor immediately.
- Do not modify or alter the system in any way and only use Bioness supplied or approved components and parts.

Adverse Reactions

In the unlikely event that any of the following occurs, stop using your L360 Thigh System immediately and consult your physician:

- Signs of significant irritation or pressure sores where the Thigh Cuff contacts the skin.
- A significant increase in muscle spasticity.
- A feeling of heart-related stress during stimulation.
- Swelling of the leg, knee, ankle, or foot.
- Any other unanticipated reaction.

Skin irritations and burns beneath the electrodes have been reported with the use of powered muscle stimulators.

Skin Care Guidelines

In the absence of proper skin care, extended use of electrical stimulation may cause skin irritation or a skin reaction to the electrodes or the Thigh Cuff. To promote healthy skin with long-term use of the L360 Thigh System, it is important to follow a daily skin-care routine.

- Clean the skin where the electrodes adhere with a wet washcloth. If any oils or lotions are on the skin, then clean with soap and water. Rinse well.

- Always check the skin for redness or a rash when putting on and taking off the Thigh Cuff.
- Replace the electrodes at least every two weeks, even if they appear to be in good condition.
- Wet cloth based electrodes before use and after every 3-4 hours for optimal performance.
- Excess body hair where the electrodes adhere may reduce electrode contact with the skin. If necessary, remove excess body hair with an electric shaver or scissors. Do not use a razor. A razor can irritate the skin.
- When positioning the Thigh Cuff, make sure the electrodes uniformly contact the skin.
- Ventilate the skin by removing the Thigh Cuff for at least 15 minutes every three to four hours.

If skin irritation or a skin reaction occurs, stop using your L360 Thigh System immediately and contact your clinician or dermatologist. You can also contact Customer Service at 800-211-9136 or an authorized distributor. Resume use only when the skin is completely healed, and then follow a skin conditioning protocol per the recommendation of your health-care specialist.

Incident Reporting

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established if within the European Union.

Chapter 3

Environmental Conditions that Affect Use

Radio Frequency (RF) Communication Information

Several components of the L360 Thigh System communicate via radio communication and have been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 (RF Devices) of the FCC (Federal Communications Commission) Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate RF energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Consult the dealer or an experienced radio/TV technician for assistance

The antenna for each transmitter must not be co-located or operating in conjunction with any other antenna or transmitter

Portable and mobile RF communications equipment may affect the L360 Thigh System

Conformity Certification

The L360 Thigh System complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference.

2. This device must accept any interference received, including interference that may cause undesired operation.

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment.

Travel and Airport Security

The system charger with interchangeable charging adapters is compatible with Australian, U.K., European Union, and U.S. voltages: 100-240V, 50/60 Hz.

Turn off your L360 Thigh System before going through airport security. Wear loose clothing so that you can easily show the security person your L360 Thigh System. The L360 Thigh System will likely set off the security alarm. Be prepared to remove the L360 Thigh System so that security can scan it, or ask for the system to be scanned if you do not want to remove it. It is recommended that you carry a copy of your L360 Thigh System prescription.

To request a copy of your prescription, contact Bioness or your physician.

Note: The L360 Thigh System contains radio transmitters. The Federal Aviation Administration rules require that all radio-transmitting devices be turned off during flight. Consult with your airline about use of Bluetooth Low Energy before turning on your L360 Thigh system in flight.

Electromagnetic Emissions

The L360 Thigh System needs special precautions regarding electromagnetic compatibility (EMC). The system needs to be installed and put into service according to the EMC information provided in this manual. See Chapter 12.

The L360 Thigh System was tested and certified to use the following:

- AC Adapter with interchangeable blades, model number LG4-7200, supplied by Bioness.
- Charging Cord, model number LG4-7100, supplied by Bioness.

⚠ Warnings

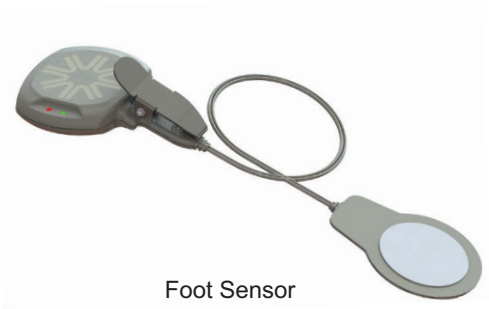
- Do not use the L360 Thigh System within three feet (1 meter) of shortwave or microwave therapy equipment. Such equipment may produce instability in the output of the EPG.
- Remove the L360 Thigh System before undergoing any diagnostic or therapeutic medical procedure such as Xray examination, ultrasound, Magnetic Resonance Imaging (MRI), etc.
- The L360 Thigh System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.
- The use of accessories, transducers, and cables other than those specified (with the exception of transducers and cables sold by the manufacturer of the L360 Thigh System as replacement parts for internal components) may result in increased emissions or decreased immunity of the L360 Thigh System.
- The L360 Thigh System may be interfered with by other equipment, even if that other equipment complies with CISPR (International Special Committee on Radio Interference, International Electrotechnical Commission) emission requirements.
- If the audio alert volume level is lower than the ambient levels, the ambient levels can impede user recognition of the alert conditions.

Chapter 4

L360 Thigh System Kit

Contents

- Box Container
- Thigh Cuff, Right or Left
- Central External Pulse Generator (EPG)
- Foot Sensor (optional, not included)
- Foot Sensor Battery (optional, not included)
- System Charger (with charging adapters)
- Charging Cable
- Thigh Cuff Strap Set with Buckles (Small)
- Thigh Cuff Strap Set with Buckles (Medium)
- Thigh Cuff Strap Set with Buckles (Large)
- Thigh Cloth Electrode Set
- Home Use Cover
- Home Use Strap Holder
- Foot Sensor Pads (optional, not included)
- Control Unit (optional, not included)
- Replacement Battery for use with the Control Unit or Foot Sensor (optional, not included)
- L360 Thigh System User’s Guide

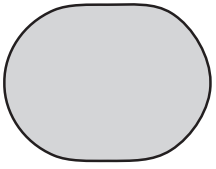


Foot Sensor

Control Unit

Control Unit Neck Strap

Replacement Battery



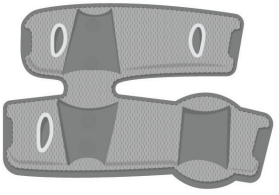
Foot Sensor Pads

System Charger with Charging Cord

Thigh Cuff with EPG

Thigh Cuff Strap with Buckles

Electrode Set



Home Use Thigh Cuff Cover

Home Use Thigh Strap Holder

Device Description

Thigh Cuff

The Thigh Cuff is an orthosis that fits above the knee, centered on the back or front of the thigh. It is designed to assist with knee flexion or extension. See Figure 5-1. The Thigh Cuff is available in right and left configurations.

The Thigh Cuff houses the EPG cradle, the EPG, and integrated electrodes. It also features a locator used to accurately place the Thigh Cuff on the leg and to ensure repeatable electrode contact. The Thigh Cuff has adjustable straps that hold the cuff in place on the thigh.

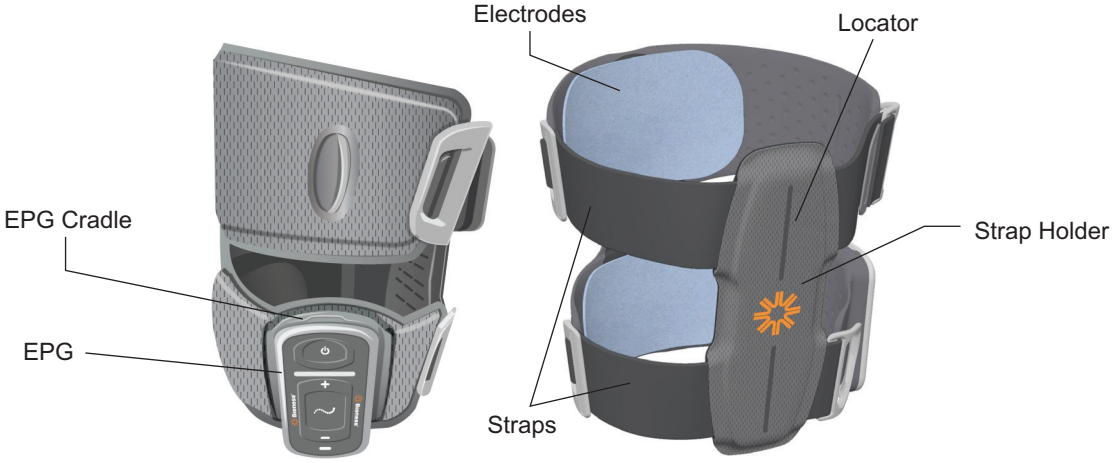


Figure 5-1: Thigh Cuff

External Pulse Generator (EPG)

The EPG features a built-in motion sensor, that detects the position of the leg and it communicates via Bluetooth® Low Energy (BLE) wireless signals with the Control Unit

(optional) and Foot Sensor (optional). The EPG generates the electrical stimulation used to flex or extend the knee.

Electrical stimulation can be adjusted from controls on the EPG or wirelessly with the Control Unit. The EPG snaps into the EPG cradle on the cuff and should only be removed from the cradle for maintenance and when cleaning the cuff.

The EPG has four buttons, two indicator lights, and a rechargeable battery (lithium ion 1000 mAh battery). See Figure 5-2, Table 5-1, and Table 5-2. The battery charging port is located at the bottom of the EPG. The EPG emits an audio and visual alert when wireless communication fails or the component malfunctions.

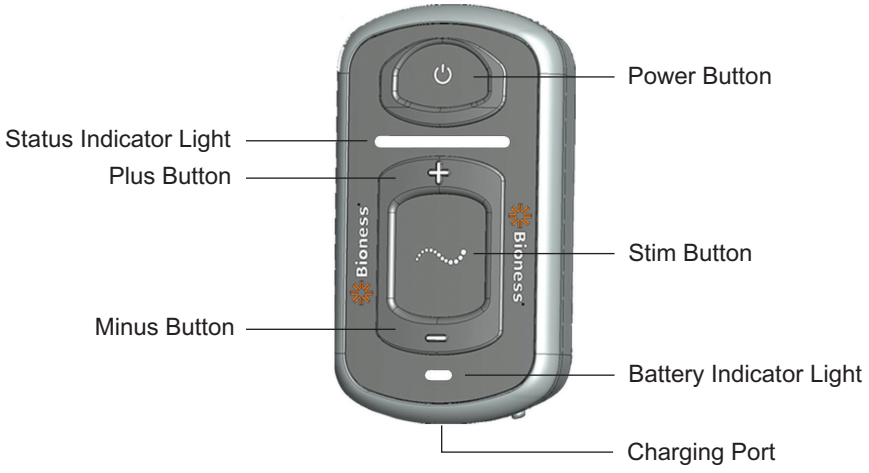


Figure 5-2: EPG

The EPG emits visual (See Table 5-1) and/or audio feedback when:

- An EPG button is pushed
- Stimulation is being delivered (feedback set by the clinician)
- When an error is detected
- When battery level is low

The EPG provides vibration feedback when:

- An EPG button is pushed
- Stimulation is being delivered
- When detecting an error

EPG	Display	Description	Definition
Status Indicator Light	 (Flashing)	Flashing Green Light	EPG is On, No Stimulation
	 (Flashing)	Flashing Yellow Light	EPG is On and Delivering Stimulation
	 (Solid)	Solid Yellow Light	EPG is On and Delivering Manual Stimulation
	 (Alternating)	Alternating Green, Yellow, and Red Light	Pairing Mode
	 (Flashing)	Flashing Red Light	Active Error / EPG Malfunction/ Battery Level-Empty
Battery Indicator Light	 (Flashing)	Flashing Green Light	EPG Battery is Charging
	 (Solid)	Solid Green Light Briefly at Power Up	EPG Charging is Complete
	 (Flashing)	Flashing Yellow Light	EPG Battery Level is Low

Table 5-1: EPG Displays

EPG Button	Description	Function
⏻	Power button	Turns the System On or Off
~	Stim button	Turns Stimulation On or Off in the Current Selected Mode
+	Plus button	Increase Stimulation Intensity
−	Minus button	Decrease Stimulation Intensity

Table 5-2: EPG Button Functions

Control Unit

The Control Unit is an optional handheld controller that wirelessly communicates with the L360 Thigh System. The Control Unit sends and receives wireless communication from the EPG(s) and Foot Sensor. It is used to select an operating mode, turn stimulation on or off, fine-tune stimulation intensity, adjust EPG audio feedback volume, and monitor system performance.

The Control Unit includes six buttons and an LCD display. See Figure 5-3, Table 5-3, and Table 5-4. It is powered by a single button cell lithium battery (CR2032 battery). It displays stimulation intensity level, operating mode, battery charge status, electronic registration status, and error messages. See Table 5-4.

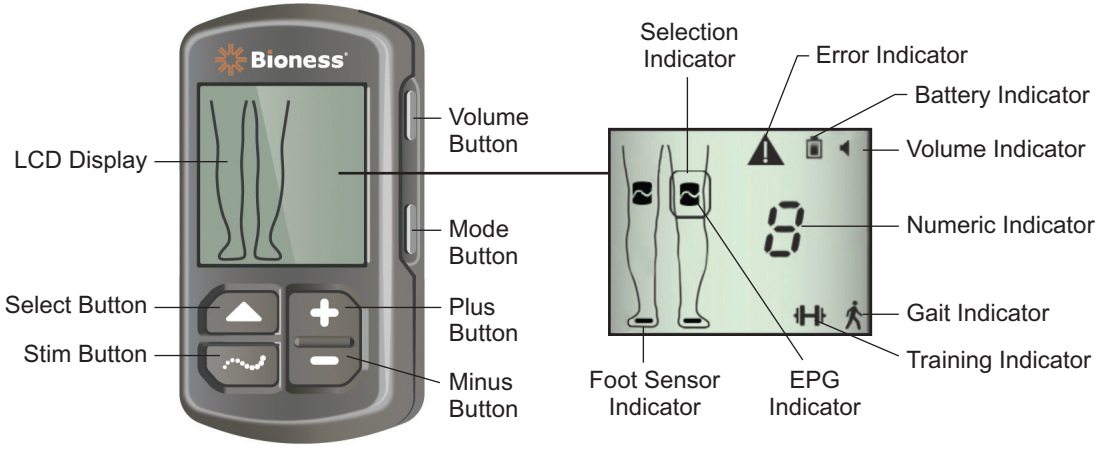


Figure 5-3: Control Unit

Control Unit Button	Description	Function
	Select button	Selects an EPG
	Stim button	Turns Stimulation On or Off in the Current Selected Mode
	Plus button	Increase Stimulation Intensity
	Minus button	Decrease Stimulation Intensity
Not Applicable	Volume button	Turns the EPG Audio Feedback On or Off
Not Applicable	Mode button	Selects Gait or Training mode

Table 5-3: Control Unit Button Functions

LCD Display Icons	Description	Function
	EPG- Ready State icon	System is communicating with EPG, but not delivering stimulation
	EPG- Stim State icon	System is communicating with EPG and EPG is delivering stimulation
 (flashing)	EPG- Error State icon	Error detected with EPG that is flashing
	Selection icon	Indicates selected EPG
	Foot Sensor icon	System is communicating with Foot Sensor
(flashing)	Foot Sensor Error icon	Error detected with Foot Sensor
	Gait Mode icon	System is in Gait mode
	Training Mode icon	System is in Training mode
	Battery Level (Normal) icon	Battery is charged for the selected EPG

LCD Display Icons	Description	Function
 (flashing)	Battery Level (Low) icon	Battery level is low and needs to be recharged for the selected EPG
 (flashing)	Error icon	System has detected an error
	Volume icon	Indicates that audio/tactile feedback is active
	Numeric Indicator-Stimulation Intensity Level	Displays current stimulation intensity level
	Numeric Indicator-Error	Alternates between "E" and the number of the error
	Numeric Indicator-Pairing	"P" appears indicating that the control unit is in pairing mode

Table 5-4: Control Unit LCD Display Icon Descriptions

L360 Thigh System Operating Modes

The L360 Thigh System has three operating modes: Gait mode, Cycle Training mode, and Training mode.

Gait Mode

Gait mode is used when walking. In Gait mode, the motion sensors in the Thigh EPG detect the position of the leg and then send the appropriate signal to that EPG. Stimulation in the EPG(s) responds as programmed by the clinician.

For users with the optional Foot Sensor, the Foot Sensor will detect heel on or heel off events. In Gait mode, the Foot Sensor signals the EPG(s) when your heel or forefoot leaves the ground, turning stimulation on. It also signals when your heel or forefoot contacts the ground, turning stimulation off.

Cycle Training Mode

Cycle Training mode is used to train muscles while the user is using a stationary bicycle. In Cycle Training mode, the stimulation is synchronized with the cycle of the crank position to assist knee extension or flexion. Stimulation during Cycle Training mode is user-initiated and requires the user to engage in the motion of pedaling. For more information and for instructions for operating the L360 Thigh System in Cycle Training mode, please consult the instructions within the myBioness App.

Note: Cycle Training mode is not compatible with the Control Unit.

Training Mode

Training mode is used to train muscles when you are not walking (for example, sitting or lying down). Training mode should not be used when walking. Training mode works independently of the Foot Sensor and the motion sensors in the EPG. Stimulation is delivered in cycles pre-set by your clinician.

For Thigh Cuff users, Training mode is designed to facilitate muscle re-education, prevent or retard disuse atrophy of the thigh muscles, maintain or improve range of motion of the knee joints, and improve local blood circulation.

It may also provide early post-surgical quadricep and hamstring strengthening, improve post-surgical knee stability secondary to quadricep and hamstring strengthening, and relax muscle spasms.

Thigh Cloth Electrodes

The Thigh Cuff uses two cloth electrodes to provide electrical stimulation to the muscles in the upper leg. See Figure 5-4. The electrodes snap to the Thigh Cuff panels. Your clinician will initially attach the electrodes to your Thigh Cuff. Afterward, you will need to replace the electrodes every two weeks.

Your clinician will fit you with the appropriate electrode option and attach them to your Thigh Cuff. Afterward, you will need to replace the electrodes every two weeks. To re-order all electrodes, contact your local representative or visit www.BionessMedical.com.

⚠ **Caution:** Use only the electrodes supplied by Bioness or authorized distributor.

⚠ **Caution:** Do not use the L360 Thigh System without the electrodes attached to the Thigh Cuff.

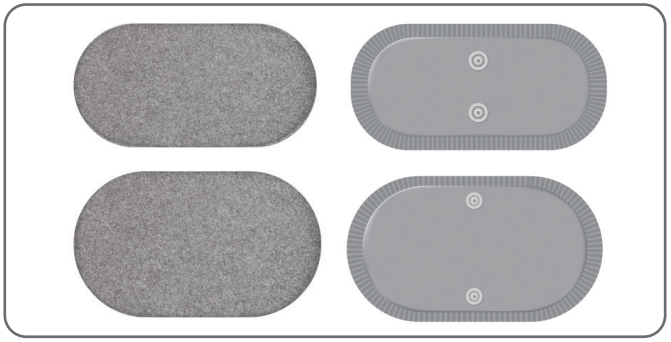


Figure 5-4: Electrodes for the Thigh Cuff

Home Use Cuff Cover

The Home Use Cuff Cover is for users with the Thigh Cuff. The Thigh Cuff inserts into the Home Use Cuff Cover. See Figure 5-5. The Home Use Cuff Cover touches the user's skin and is designed to increase aesthetics and comfort throughout the day.

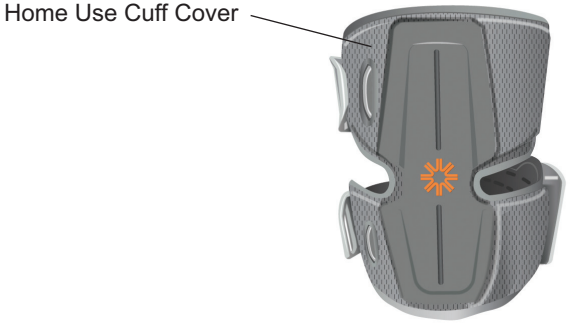


Figure 5-5: Thigh Cuff Home Use Cuff Cover

Home Use Strap Holder

The Home Use Strap Holder is for users with the Thigh Cuff. The Thigh Cuff straps are inserted through the strap holder and it is positioned on the opposite side of the Thigh Cuff. See Figure 5-6. The Home Use Strap Holder is designed to assist with keeping the straps in place while on the user's thigh.

Figure 5-6: Thigh Cuff Home Use Strap Holder

System Charger Set

The system charger set includes a dual USB AC adapter, charging adapters for U.S. and international outlets, and a USB charging cable. The system charger set connects to a main power supply and is used to charge the EPG battery. See Figure 5-7.

Figure 5-7: System Charger Set

⚠ **Caution:** Use only the System Charger Set included in your L360 Thigh System Kit. Use of any other charger will damage the system.

⚠ **Caution:** To completely disconnect the power input, the AC adapter portion of the System Charger Set must be disconnected from the main power supply.

Foot Sensor

The Foot Sensor is an optional component of the L360 Thigh System. Your clinician will determine if you need to use the Foot Sensor with your L360 Thigh System. The Foot Sensor detects when your foot is in the air and on the ground, and communicates to the EPG(s).

Note: The Foot Sensor is not compatible with use of the L360 Thigh system while using Cycle Training mode.

The Foot Sensor features a pressure sensor, transmitter, and a clip. See Figure 5-8. The pressure sensor fits under the insole of your shoe. The transmitter is clipped to the inner rim of your shoe. The Foot Sensor also has two indicator lights and is powered by a single button cell lithium battery (CR2032 battery). See Figure 5-8 and Table 5-5.

The Foot Sensor can be transferred from shoe to shoe, or additional sensors can be purchased for different shoes. You can pair up to five Foot Sensors to a single L360 Thigh System. The Foot Sensor does not need to be detached from the shoe between uses.

An optional Foot Sensor with a longer connection between the transmitter and sensor is also available. To purchase this option, please contact Customer Service at 800-211-9136 or an authorized distributor.

⚠ **Caution:** The Foot Sensor has not been validated for use by individuals weighing more than 300 lbs (136 kg).

⚠ **Caution:** Do not use the Foot Sensor with a rigid insole, such as a custom rigid orthosis or an ankle-foot orthosis.

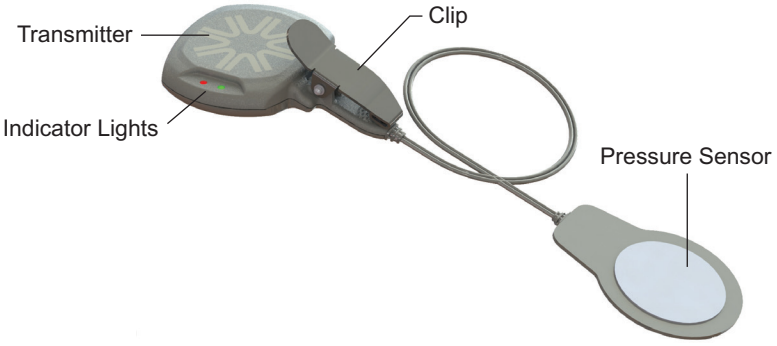


Figure 5-8: Foot Sensor

Foot Sensor	Display	Description	Definition
Indicator Light	(Flashes Twice)	Green Light Flashes Twice	Foot Sensor is Active
	(Flashing)	Slowly Flashing Green Light	Pairing Mode
	(Flashes for 5 Seconds)	Red Light Flashes for 5 Seconds	Low Battery
	(Solid)	Solid Red Light	Error

Table 5-5: Foot Sensor Displays

Foot Sensor Pads

The Foot Sensor Pads are an accessory item that is not included with the L360 Thigh System Kit. See Figure 5-9. A Foot Sensor Pad is placed under the insole of the shoe and the pressure sensor portion of the Foot Sensor attaches to the Foot Sensor Pad to prevent the pressure sensor from moving during activity.

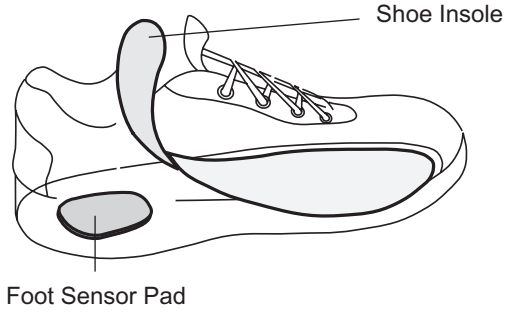


Figure 5-9: Foot Sensor Pad Placement

myBioness™ Mobile Application

The myBioness Mobile Application is an optional application that can be downloaded onto a smart phone. This application can be used to control Cycle Training mode. More information is available in the user instructions provided with the myBioness Mobile Application.

Setup Instructions

Charging the L360 Thigh System

The EPG is the only L360 Thigh System component that can be charged. It is important to charge your EPG(s) daily and for at least four hours before a fitting/programming session. Bioness recommends charging the EPG(s) while attached to the Thigh Cuff(s).

To charge the L360 Thigh System:

1. Remove the System Charger Set from the packaging. The included charging adapters are for use outside of the United States.
2. Insert the USB end on the charging cable into any of the two available USB ports on the AC adapter. For individuals using both the right and left Thigh Cuff, connect an additional USB charging cable to the AC adapter. See Figure 6-1.

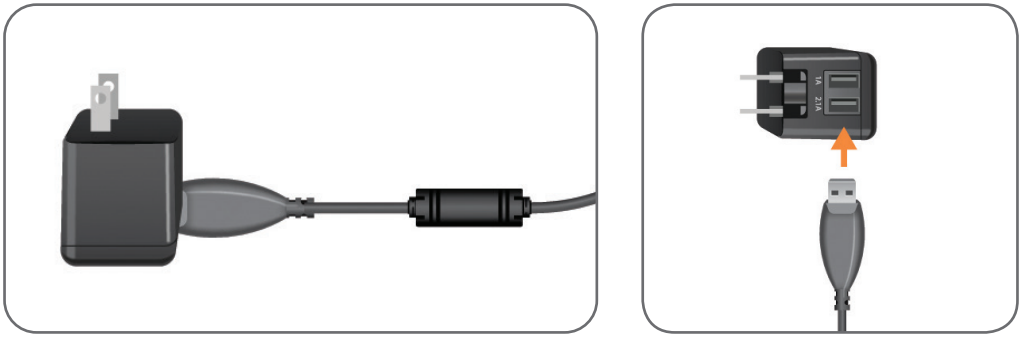


Figure 6-1: Inserting USB Charging Cable into AC Adapter

3. Connect the other end of the charging cable to the charging port on the EPG. The charging port is located at the bottom of the EPG. See Figure 6-2.

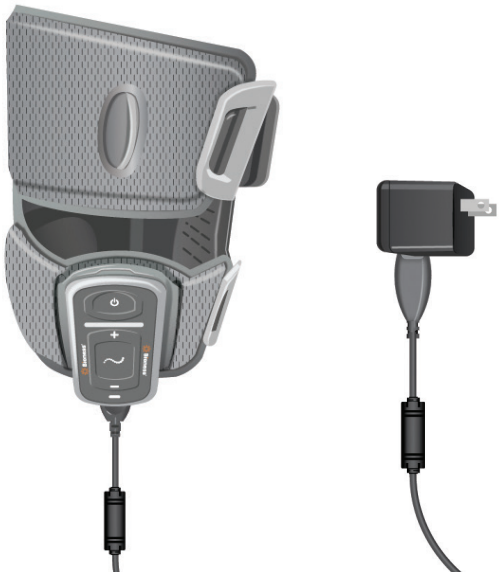


Figure 6-2: L360 Thigh System Charging Setup

4. Plug the AC adapter with connected USB charging cable(s) into a power outlet.
5. The battery indicator light on the EPG(s) will flash green to indicate charging.
6. The battery indicator light on the EPG(s) is a solid green when the system is fully charged.

⚠ **Caution:** Use only the charger included in your L360 Thigh System Kit. Use of any other charger will damage the system.

⚠ **Caution:** Do not use the Thigh Cuff while the EPG is charging.

⚠ **Caution:** To completely disconnect the power input, the AC adapter portion of the System Charger Set must be disconnected from the main power supply.

Preparing the Skin

Before putting on the Thigh Cuff, always check your skin for signs of irritation. If any irritation is present, do not put on the Thigh Cuff and contact your clinician. Wait for complete healing before using the L360 Thigh System. For optimal stimulation, the skin under the Thigh Cuff should be clean and healthy.

To prepare the skin:

1. Clean the skin where the electrodes will touch with a wet washcloth. If any oils or lotions are on the skin, clean the skin with soap and water. Rinse well.
2. If necessary, trim excess body hair from the area using scissors. Do not use a razor. A razor can irritate the skin.

Attaching the Electrodes

⚠ **Caution:** Use only the electrodes supplied by Bioness or authorized distributor.

⚠ **Caution:** Do not use your L360 Thigh System without the electrodes attached.

Thigh Cloth Electrodes

To attach the Thigh Cloth Electrodes to the Thigh Cuff:

1. Make sure the EPG is turned off.
2. If the Thigh Cloth Electrodes are attached to the Thigh Cuff gently remove them.
3. Wet the Thigh Cloth Electrodes with water. See Figure 6-3. Gently squeeze the Thigh Cloth Electrodes together.
4. Remove excess water from the snap side of the Thigh Cloth Electrodes with a cloth. See Figure 6-3.

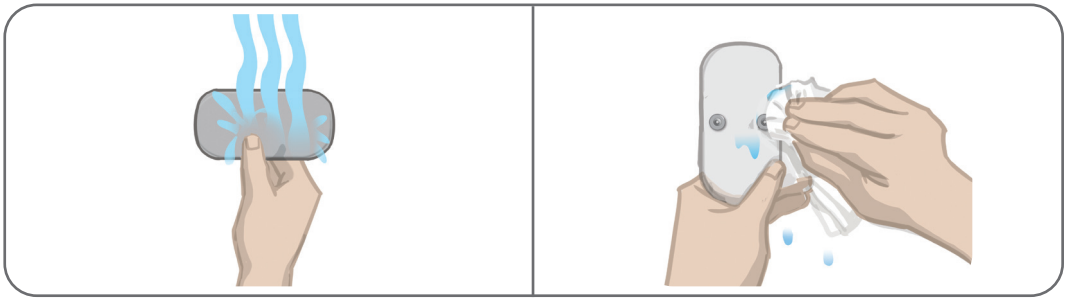


Figure 6-3: Wetting the Electrode and Removing Excess Water

5. Align the snaps on the Thigh Cloth Electrodes to the plug holes on the Thigh Cuff. See Figure 6-4.
6. Press firmly to snap the small Thigh Cloth Electrode to the Thigh Cuff bottom panel. Press firmly to snap the large Thigh Cloth Electrode to the Thigh Cuff top panel. See Figure 6-4.

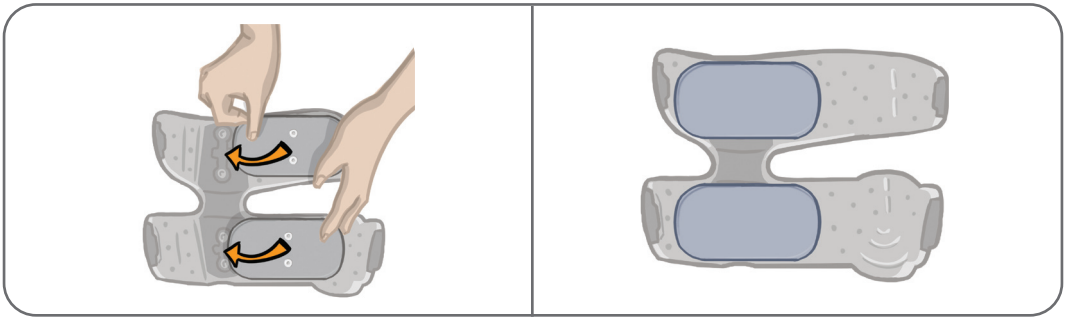


Figure 6-4: Aligning and Attaching the Thigh Cloth Electrodes

Remove and re-wet the Thigh Cloth Electrodes every time you remove the Thigh Cuff from your leg for more than one hour, and after every three to four hours of use. When wetting the Thigh Cloth Electrodes, always remove them from the Thigh Cuff.

Positioning the Thigh Cuff

1. Sit in a stable position on the edge of a chair.
2. Make sure the Thigh Cloth Electrodes are securely attached to the Thigh Cuff panels.
3. Place the Thigh Cuff locator (a tactile finger mark) on the midline of the thigh, approximately three finger widths from the knee. See Figure 6-5. Make sure to place Thigh Cuff in the fitting position determined by your clinician.
4. Center the bridge on the midline of the thigh. See Figure 6-6.
5. Fasten the straps by inserting the strap buckle into the hook attached to the Thigh Cuff panels. See Figure 6-6. If needed, tighten the strap tension by adjusting the strap fasteners.
6. For individuals using the Thigh Cuff in the hamstrings fitting position, insert the straps through the Home Use Strap Holder before fastening the straps. Once fastened place Home Use Strap Holder in the middle of the thigh.

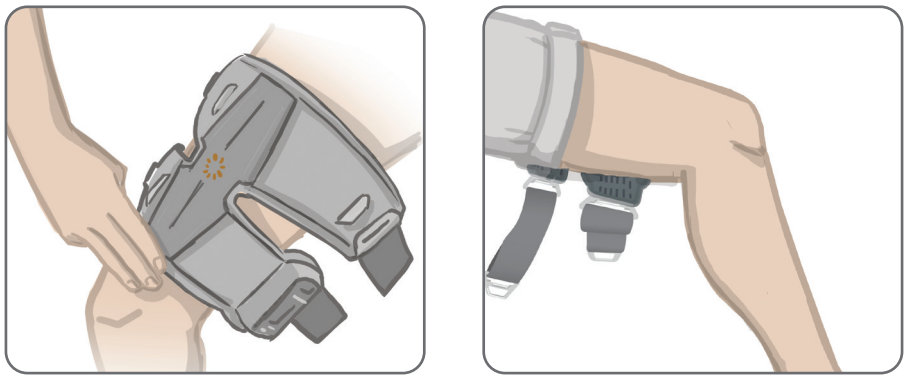


Figure 6-5: Correct Position of the Thigh Cuff Locator
(Left) Quadriceps Position Shown, (Right) Hamstrings Position Shown

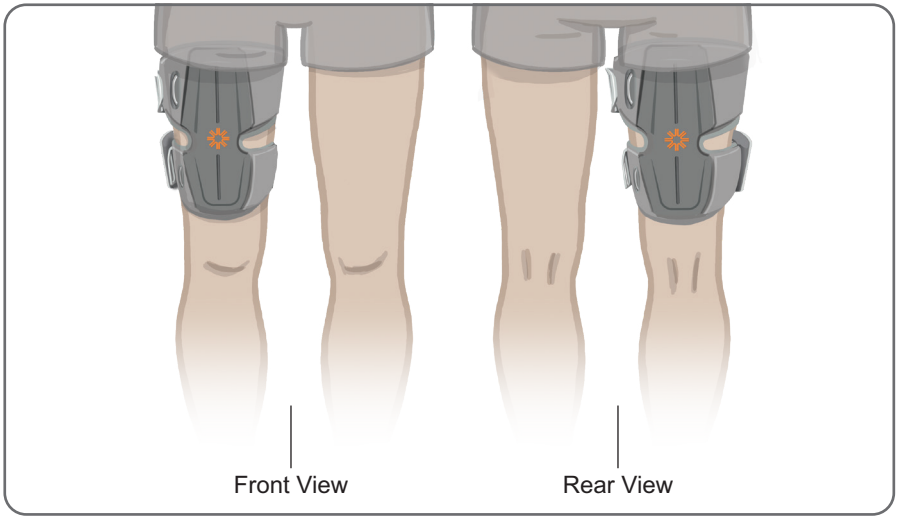


Figure 6-6: Correct Position of the Thigh Cuff
(Left) Quadriceps Fitting Position on Right Leg,
(Right) Hamstring Fitting Position on Right Leg

Testing the Position of the Thigh Cuff

1. Press the Power button on the EPG. The EPG will give vibration and audio feedback when turned on.
2. Press and hold the Stim button on the EPG for at least ten seconds. The EPG will deliver stimulation until the Stim button is released.

Removing the Thigh Cuff

To remove the Thigh Cuff:

1. Turn off the EPG.
2. Unhook both sets of straps.
3. Slowly lift the Thigh Cuff away from your skin.

Note: Remove the Thigh Cuff (for at least 15 minutes) after every three to four hours of use, to allow the skin to breathe.

Positioning the Foot Sensor

The optional Foot Sensor pressure sensor is placed under the insole of your shoe. If your shoe does not have a detachable insole, place the sensor on top of the insole. Then, place a generic soft, thin (one layer versus two) insole over it. Generic insoles can be purchased over the counter.

To position the Foot Sensor:

1. Lift the shoe insole.
2. Attach a Foot Sensor Pad under the insole, in the position that was defined by your clinician. See Figure 6-7.
3. For heel position placement, point the wire of the Foot Sensor toward the toe of the shoe. For forefoot position placement, point the wire of the Foot Sensor toward the heel of the shoe. Attach the pressure sensor to the Foot Sensor Pad. See Figure 6-8. Refer to the foot image on the pressure sensor for positioning.

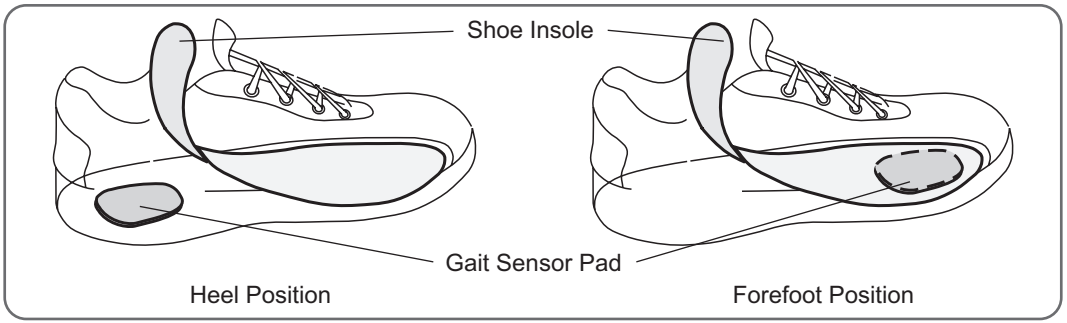


Figure 6-7: Placement of the Foot Sensor Pad

Note: The image of the foot on the Foot Sensor pressure sensor will be reverse when in the forefoot position.

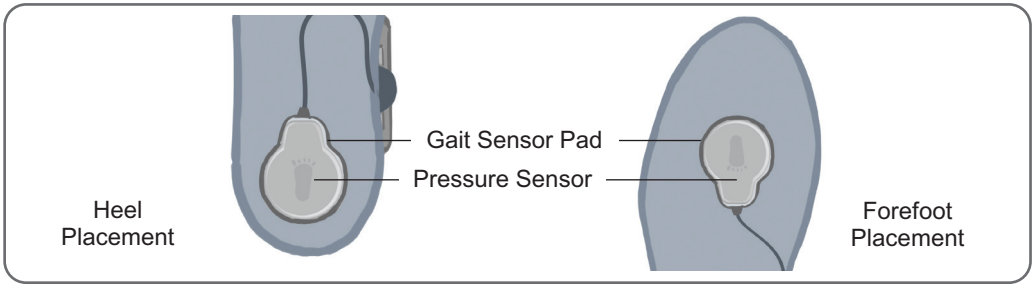


Figure 6-8: Positioning the Foot Sensor in the Shoe

4. Clamp the Foot Sensor transmitter on to the inner rim of the shoe. Face the starburst logo on the transmitter away from the ankle. See Figure 6-9.
5. Cover the pressure sensor with the insole. Tuck any excess wire under the insole. See Figure 6-9.

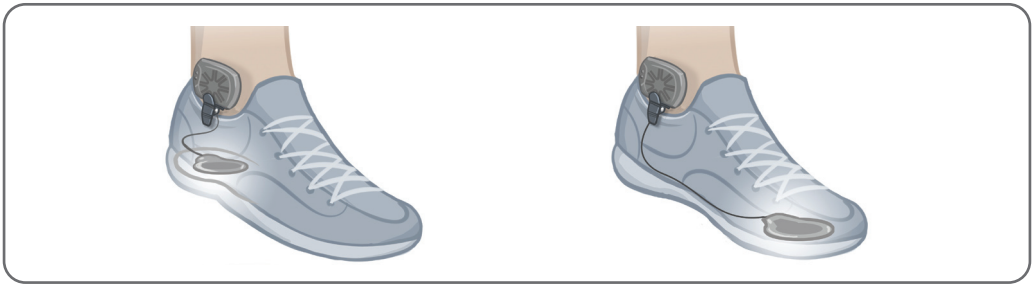


Figure 6-9: Final Position of the Foot Sensor Attached to the Shoe

Switching Shoes/Foot Sensors

When switching the Foot Sensor to a different shoe, make sure to place a Foot Sensor Pad in the other shoe first.

1. Make sure the EPG, and the Control Unit is turned off.
2. Remove the Foot Sensor from the shoe.
3. Follow the steps outlined in this chapter for placement in the other shoe.

If you have more than one Foot Sensor, you can place each one in a different shoe, and then switch shoes.

1. Make sure the EPG and the Control Unit is turned off.
2. Switch shoes.
3. Register the new Foot Sensor to the EPG. Refer to the "Pairing Replacement Part Components" section in this guide for more information.

Chapter 7

Operating the L360 Thigh System

Turning the L360 Thigh System On/Off

To turn on the L360 Thigh System, press the Power button once on the EPG. The system will be in a ready state. All indicator lights will light up for a few seconds while the system performs a self-test. The Status Indicator Light on the EPG(s) will flash green to indicate the system is on.

To turn off the L360 Thigh System, press and hold the Power button, for three seconds, on the EPG. The EPG will provide vibration feedback when turning off.

Selecting an Operating Mode Using the Control Unit

There are two different operating modes (Gait mode and Training mode) that can be selected using the Control Unit.

To select an operating mode using the Control Unit:

1. Turn on the EPG by pressing the Power button on the EPG(s).
2. Turn on the Control Unit by pressing any button.
3. The paired EPG(s) will appear in the digital display on the Control Unit with the Selection Indicator icon around the EPG Indicator icon(s). See Figure 7-1. Refer to the "Pairing a New Control Unit to the EPG" section of this guide for pairing instructions.
4. For users with both right and left Thigh Cuffs, the Select button on the Control Unit can be used to toggle between the right and left EPG or to select both EPGs. See Figure 7-1.
5. To select Gait mode, press the Mode button on the Control Unit until the Gait Indicator icon appears in the lower right corner of the digital display. See Figure 7-1.
6. To select Training mode, press the Mode button on the Control Unit until the

Training Indicator icon appears in the lower right corner of the digital display. See Figure 7-1.

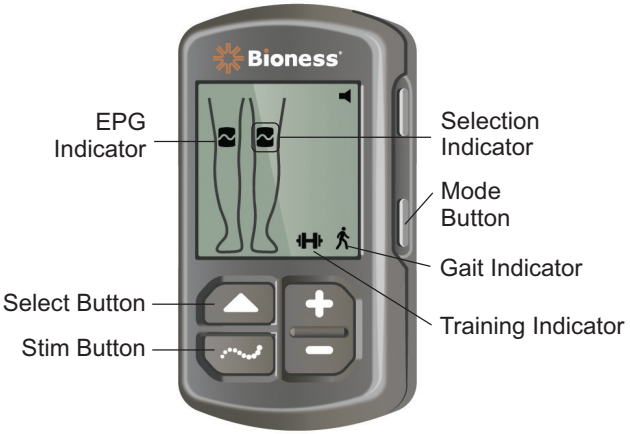


Figure 7-1: Selecting a Operating Mode on the Control Unit

7. To activate Gait mode or Training mode, press the Stim button on the Control Unit.
8. The Status Indicator Light on the EPG(s) will change to a flashing yellow light.
9. To unpair the Control Unit from an EPG, ensure the Control Unit is in sleep state and simultaneously press mode and Stim button for five seconds. Selection Indicators will appear without EPG icons confirming unpairing was successful.

To turn on an operating mode using the EPG:

1. Turn on the EPG(s) by pressing the Power button on the EPG(s).
2. Press the Stim button on the EPG(s) to activate Gait mode.
3. Press and hold the Stim button on the EPG(s) for three seconds to activate Training mode. Press Stim button for an additional three seconds to return to Gait mode.

When the EPG is first turned on and the Stim button is pressed it will always activate Gait mode, unless it was previously in Training mode and was not powered off. The Control Unit can also be used to switch to Training mode. Once Training mode has been selected on the Control Unit, the Stim button on the EPG can be used to activate the selected operating mode.

Adjusting Stimulation Intensity

When Gait or Training mode is first activated the stimulation intensity level will always be "5". This level is set by your clinician. Normally, you will not need to adjust stimulation intensity other than when walking on different surfaces or in different shoes.

Note: An intensity level of “0” equals no stimulation.

To adjust stimulation intensity (for users with one Thigh Cuff):

1. Press the Plus or Minus button on the Control Unit or on the EPG to increase or decrease the stimulation intensity. See Figure 7-2.
2. The new level number will appear in the digital display on the Control Unit.

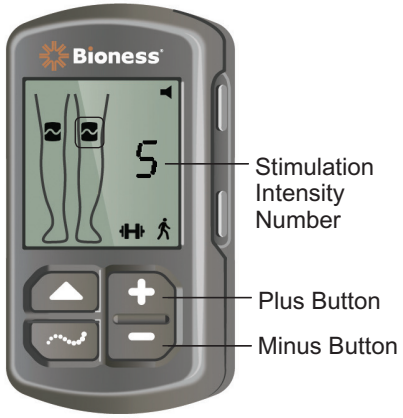


Figure 7-2: Adjusting Stimulation Intensity

To adjust stimulation intensity (for users with both right and left Thigh Cuffs):

1. The stimulation intensity will need to be adjusted separately for each connected EPG. Press the Select button on the Control Unit to select desired EPG. See Figure 7-1.
2. Press the Plus or Minus button on the Control Unit to increase or decrease the stimulation intensity. See Figure 7-2.
3. The new level number will appear in the digital display on the Control Unit.
4. Repeat steps one through three for the other connected EPG.

Note: The stimulation intensity can also be adjusted without using the Control Unit, by pressing the Plus or Minus buttons on each of the EPGs.

Changing Audio and Vibration Feedback Using the Control Unit

The EPG has the capability to provide audio and vibration feedback when stimulation is being delivered. Audio feedback during stimulation can be turned off using the Control Unit. Vibration feedback can not be turned off with the Control Unit. The only way to turn off vibration feedback is to have your clinician disable the feature during the programming session for your L360 Thigh System.

To turn off audio feedback during stimulation:

1. Press the Volume button on the Control Unit. See Figure 7-3. The Volume Indicator icon in the upper right corner of the digital display will disappear.

To turn on audio feedback during stimulation:

1. Press the Volume button on the Control Unit. See Figure 7-3. The Volume Indicator icon in the upper right corner of the digital display will appear.

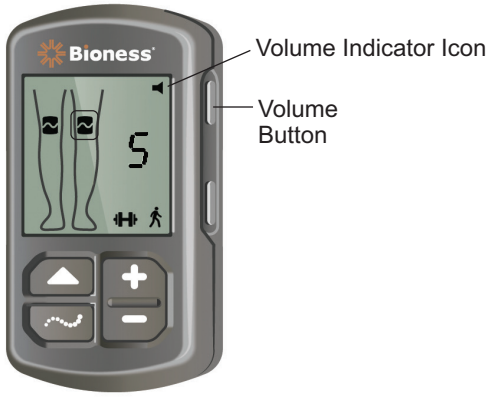


Figure 7-3: Volume Button on Control Unit

Turning Stimulation Off Using the Control Unit and EPG

To turn stimulation off using the Control Unit:

1. Turn on the Control Unit by pressing any button.
2. The stimulating EPG(s) will appear in the digital display on the Control Unit as an EPG- Stim State icon.
3. Press the Stim button on the Control Unit to stop stimulation. See Figure 7-1.

To turn stimulation off using the EPG:

1. Press the Stim button on the EPG(s) to stop stimulation.
2. The Status Indicator Light on the EPG(s) will change to a flashing green light.

Note: Once the Stim button is pressed, the EPG(s) will be in a ready state in the last selected operating mode. If the Stimulation button is pressed again, the EPG will activate stimulation in the last operating mode that was selected before stimulation was turned off.

Chapter 8

Maintenance and Cleaning

Daily Maintenance and Storage

1. Detach the Thigh Cloth Electrodes from the Thigh Cuff panels when not in use. Store the Thigh Cloth Electrodes where they can air dry, to prevent mold growth.
2. Allow the Thigh Cuff to air dry, when not in use.
3. Fully charge the EPG batteries daily.
4. Check each component for wear or damage. Replace any components that appear old, worn, or damaged.

Charging

The EPG batteries should be charged daily. Charging instructions can be found in the "Charging the L360 Thigh System" section of this guide.

Note: The batteries must be charged before initial use, daily, and after extended storage.

EPG Battery Maintenance

The EPG has a rechargeable battery that is not removable. Do not attempt to replace the EPG battery. Maintain a routine of daily charging if using the system regularly, and at minimum, once monthly if your system is in storage. Avoid leaving your EPG uncharged indefinitely to minimize the risk of decreased battery longevity. Refer to the technical specifications section in this manual for appropriate operating and storage conditions. An EPG battery can be expected to last several years when maintained accordingly. For support with your device, contact Customer Service at 800-211-9136 or an authorized distributor.

Replacing the Thigh Cloth Electrodes

You will need to replace the Thigh Cloth Electrodes at least every two weeks or sooner if they become damaged.

⚠ **Caution:** Use only the electrodes supplied by Bioness.

⚠ **Caution:** Do not use your L360 Thigh System without the electrodes attached.

To replace the Thigh Cloth Electrodes: (See Figure 8-1)

1. Make sure the EPG and Control Unit are turned off.
2. Gently remove the Thigh Cloth Electrodes from the Thigh Cuff.
3. Wet the Thigh Cloth Electrodes with water. Gently squeeze Thigh Cloth Electrodes together.
4. Remove excess water from the snap side of the Thigh Cloth Electrodes with a cloth.
5. Align the snaps on the Thigh Cloth Electrodes to the plug holes on the Thigh Cuff.
6. Press firmly to snap the small Thigh Cloth Electrode to the Thigh Cuff bottom panel. Press firmly to snap the large Thigh Cloth Electrode to the Thigh Cuff top panel.

Remove and re-wet the Thigh Cloth Electrodes every time you remove the Thigh Cuff from your leg for more than one hour, and after every three to four hours of use. When wetting the Thigh Cloth Electrodes, always remove them from the Thigh Cuff.

If the Thigh Cloth Electrodes dry out, your response to the stimulation may change. If you need to adjust stimulation intensity more often than usual, try re-wetting the electrodes. When not in use, store the Thigh Cloth Electrodes where they can air dry.

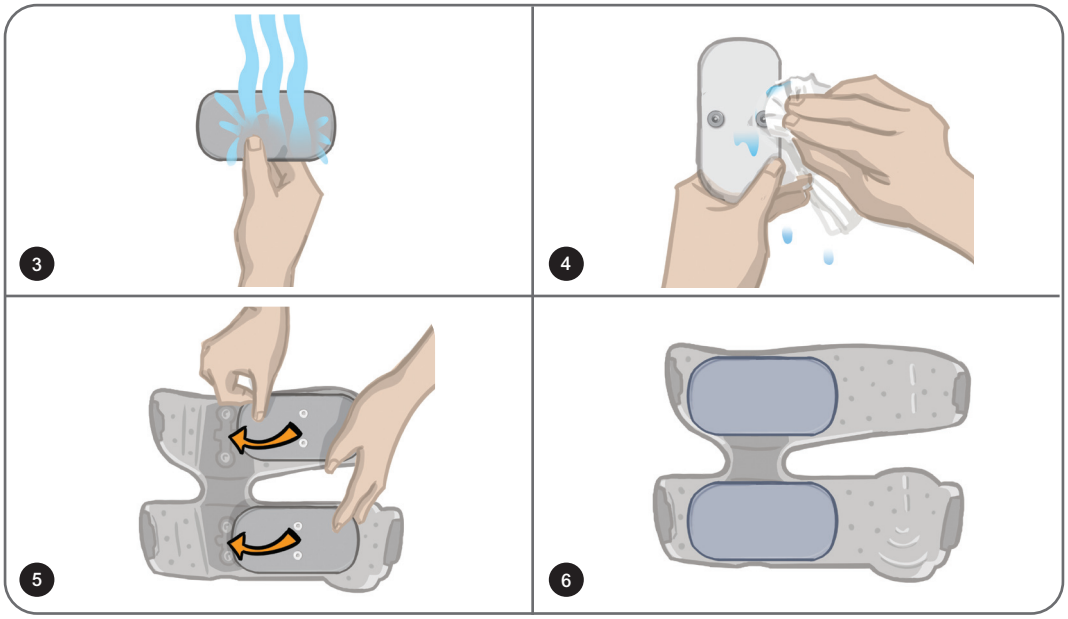


Figure 8-1: Replacing the Thigh Cloth Electrodes

Replacing the Control Unit Battery

The battery in the Control Unit is not rechargeable and, depending on use, will need to be replaced approximately every six months. The Control Unit is powered by a single button cell lithium battery (CR2032 battery).

The Battery Indicator icon on the Control Unit will flash for five seconds at startup when the Control Unit battery is low.

⚠ **Warning:** For battery replacement only use a lithium coin battery, CR2032. Use of an incorrect battery may result in damage to the L360 Thigh System.

Figure 8-2: Replacing the Control Unit Battery

To replace the Control Unit battery:

1. Use the recessed area on the back of the Control Unit to pop out the battery lid cover. If you find it difficult to remove the cover a coin (quarter) may be used to open the cover. See Figure 8-2.
2. Remove the old battery by pushing the battery toward the metal tabs (as shown by the arrow on Figure 8-2), and carefully lifting the battery up. Metal tools, such as a screwdriver, should not be used.
3. Insert the new battery by inserting the battery toward the back first and then carefully pressing down on the battery. The “+” should face up.
4. Reattach the battery lid cover to the back of the Control Unit by pressing firmly to snap the cover back on.

Remove the old battery, and properly dispose of it according to your local environmental regulations.

Replacing the Foot Sensor Battery

The battery in the Foot Sensor is not rechargeable and should be replaced approximately every six months. The Foot Sensor is powered by a single button cell lithium battery (CR2032 battery).

The red indicator light on the Foot Sensor will flash for five seconds when a low battery is detected. The Foot Sensor Indicator icon on the Control Unit will also be flashing.

⚠ **Warning:** For battery replacement, only use a lithium coin battery, CR2032. Use of an incorrect battery may result in damage to the L360 Thigh System.

To replace the Foot Sensor battery:

1. Use the recessed area on the back of the Foot Sensor to pop out the battery lid cover. See Figure 8-3.

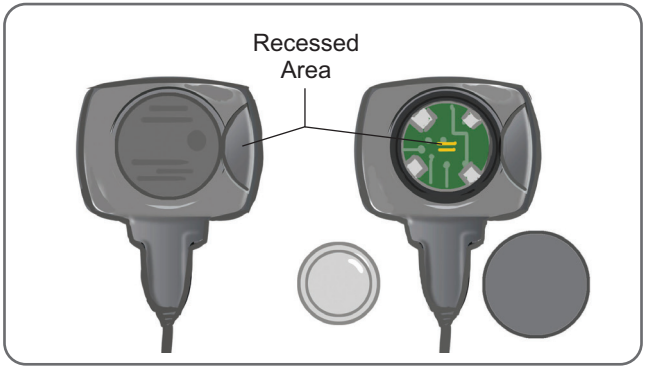


Figure 8-3: Replacing the Foot Sensor Battery

2. Note the “+” orientation of the old battery.
3. Remove the old battery.
4. Wait for at least 120 seconds (two minutes) and then insert the new battery. The “+” should face up.
5. Reattach the battery lid cover to the back of the Foot Sensor by pressing firmly to snap the cover back on.
6. Press the Foot Sensor pressure sensor to activate the sensor.
7. If this does not power on the foot sensor, short the battery connector by placing a coin or the battery itself between the positive and the negative terminal of the foot sensor. Repeat steps five through six.

Remove the old battery, and properly dispose of it according to your local environmental regulations.

Removing the EPG

The EPG should only be removed for maintenance and to clean the Thigh Cuff.

To remove the EPG:

1. Make sure the EPG and Control Unit are turned off.
2. Pull the top of the EPG away from the cradle. See Figure 8-4.
3. Remove the bottom of the EPG from the cradle.

To re-insert the EPG:

1. Insert the bottom of the EPG into the cradle. Then, gently push the top of the EPG until it snaps into the cradle.

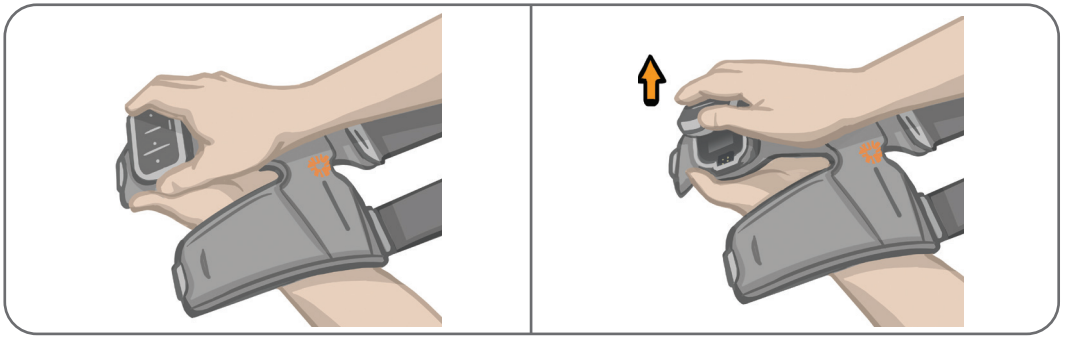


Figure 8-4: Removing the EPG

Removing the Thigh Cuff Straps

The thigh straps can be removed from the Thigh Cuff for cleaning or for strap replacement.

To remove the thigh straps:

1. Push the attached thigh strap buckle toward the Thigh Cuff while making a twisting motion. See Figure 8-5.
2. Slide the thigh strap out away from the Thigh Cuff to detach.

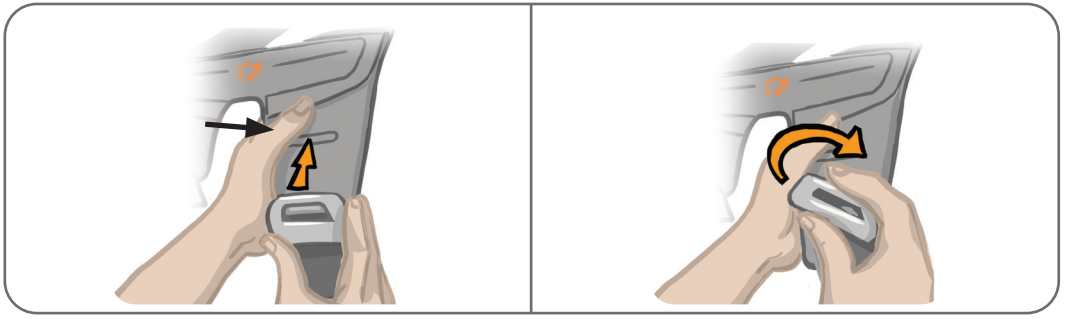


Figure 8-5: Removing the Thigh Straps

To reattach the thigh straps:

1. Align the strap buckle to the hook attached to the Thigh Cuff panels.
2. Push the strap buckle with your thumbs toward the strap (direction away from the Thigh Cuff). See Figure 8-6.
3. The strap buckle will snap into the Thigh Cuff panel hook.

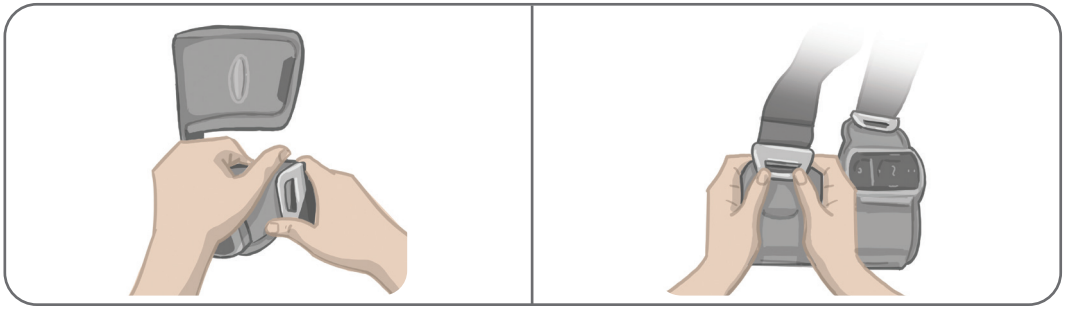


Figure 8-6: Reattaching the Thigh Straps

Note: For individuals using the Thigh Cuff in the Hamstrings fitting position, insert the straps through the Home Use Strap Holder.

Removing the Home Use Thigh Cuff Cover

The Home Use Thigh Cuff Cover can be removed from the Thigh Cuff for cleaning.

To remove the Home Use Thigh Cuff Cover:

1. Remove the thigh straps from the Thigh Cuff.
2. Detach the Velcro pocket located on the bottom Thigh Cuff panel near the back of the EPG cradle.
3. Remove the Home Use Thigh Cuff Cover from the bottom Thigh Cuff panel first and then remove the cover from the top panel.

To reattach the Home Use Thigh Cuff Cover:

1. Insert the upper Thigh Cuff panel into the cover first and then attach the Velcro pocket around the bottom panel. See Figure 8-7.

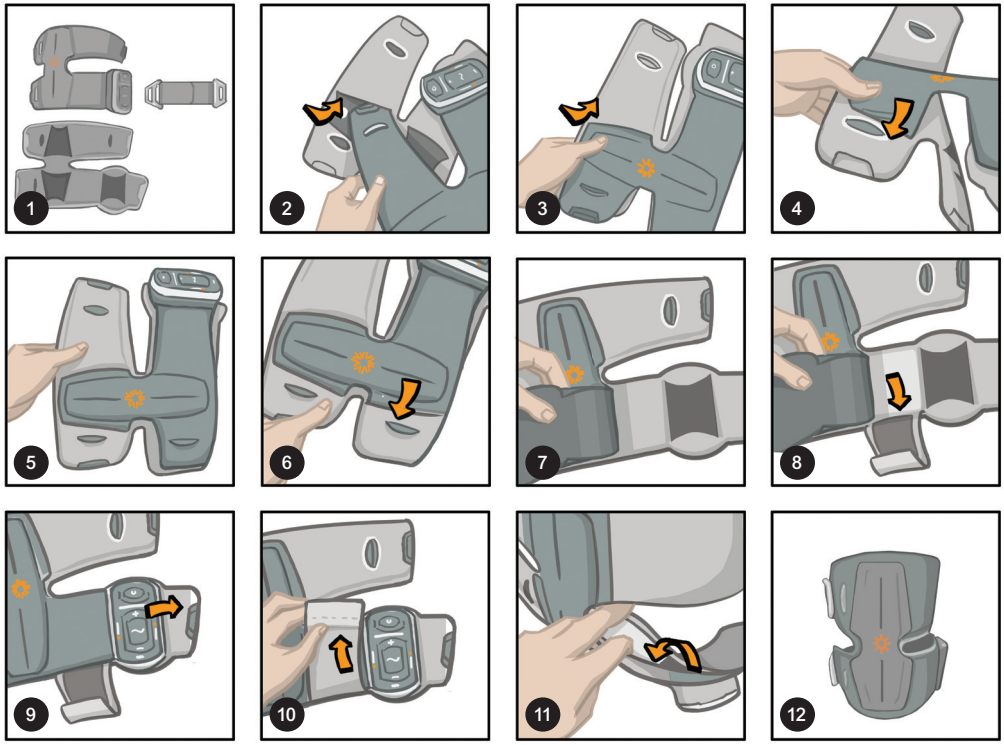


Figure 8-7: Attaching the Home Use Thigh Cuff Cover

Cleaning Your L360 Thigh System Components

All L360 Thigh System components may be cleaned by carefully by wiping them with a damp cloth. The electrical components are not waterproof. **Do not immerse them in water.**

Cleaning the Thigh Straps, Home Use Cuff Cover, and Home Use Strap Holder

1. Make sure the thigh straps and Home Use Cuff Cover are removed from the Thigh Cuff.
2. Immerse the thigh straps, Home Use Cuff Cover, and Home Use Strap Holder for 30 minutes in lukewarm water and mild detergent. Do not use a washing machine.
3. Rinse the straps, cuff cover, and strap holder thoroughly under running water.
4. Immerse the straps, cuff cover, and strap holder for an additional 15 minutes in clean, lukewarm water.
5. Rinse the items again under running water.
6. Lay the straps, cuff cover, and strap holder flat in the shade to dry. If desired, place the items in front of a circulating cold-air fan. Do not use a hot-air dryer or other heat source to dry.

Cleaning the Control Unit Neck Strap

The Control Unit neck strap is made of polyester and may be machine washed on a delicate cycle in cold water.

Disinfecting Your L360 Thigh System Components

Disinfecting the Thigh Cuff

The plastic parts of the Thigh Cuff (the cuff without the Home Use Thigh Cuff Cover) may be disinfected using a combination of CaviWipes™, per the manufacturer's instructions, and 70% ethanol wipes.

To disinfect the Thigh Cuff:

1. Make sure the Home Use Thigh Cuff Cover is removed from the Thigh Cuff.
2. Remove the EPG from the EPG cradle.

3. Wipe the plastic surface of the Thigh Cuff (the side that faces the skin) with a wet CaviWipes disinfection wipes. Make sure to use a new CaviWipes for each of the Thigh Cuff panels.

Note: Read the manufacturer's instructions for use, and follow standard precautions for personal protection as appropriate.

4. Using one or more new CaviWipes, wipe the entire surface again for one minute. The surface should be visibly wet. Repeat this process again three times, using a new wipe each time.
5. Place a wipe saturated with 70% ethanol over each of the Thigh Cuff panels (on the side that faces the skin). Cover the entire surface and leave the saturated wipes on the Thigh Cuff for at least five minutes.
6. After five minutes, wipe the Thigh Cuff panels with the 70% ethanol wipes and remove them to allow the plastic surface to dry.

Disinfecting the EPG and Control Unit

The EPG and Control Unit may be cleaned and low-level disinfected using wipes or cloths saturated (but not dripping) with 70% isopropyl alcohol (IPA) per the instructions below:

1. Use one saturated disinfectant wipe or cloth to thoroughly wet the component surface.
2. Use a second saturated disinfectant wipe or cloth to remove any surface contaminants. If not removed, soil will impede the disinfectant's effectiveness.
3. As needed, use additional saturated disinfectant wipes or cloths to keep the components surface wet for three minutes.

Note: Follow the instructions for the specified contact time to ensure an effective bacteria kill.

Do not use other cleaning/disinfecting agents such as a diluted bleach mixture, or other disinfecting wipes. Bioness has not tested these products' effectiveness on the L360 Thigh System components.

Chapter 9

Pairing Replacement Part Components

The L360 Thigh System components must be paired to each other to communicate wirelessly. The EPG and Control Unit in your System Kit are already paired. Your clinician will pair the Foot Sensor (if applicable) to the other components during your fitting session. When a Control Unit, EPG, or Foot Sensor is replaced, the new replacement component must be paired to the existing components.

Note: When pairing make sure the components are within a few inches of each other.

Pairing Setup

1. If the replacement component is an EPG, make sure the new EPG is fully charged. See the "Setup Instructions" section in this guide for more information.
2. Make sure the EPG is attached to the EPG Cradle on the Thigh Cuff.
3. Turn on the EPG by pressing the Power button on the EPG.

Pairing a New Control Unit to the EPG

1. Make sure the EPG is turned on.
2. Place the Thigh Cuff, with EPG attached, and the Control Unit within a few inches of each other.
3. Turn on the Control Unit by pressing any button. A flashing "P" will appear in the display screen, if not, press the Plus and Minus buttons simultaneously until a flashing "P" appears.
4. Simultaneously press the Plus and Minus buttons on the EPG. The EPG will go into pairing mode and the EPG State Indicator Light will display an alternating green, yellow, and red light.

5. Once paired the EPG State Indicator Light on the EPG will flash green. The connected EPG/s will appear on the display screen on the Control Unit.

Pairing a New Foot Sensor to the EPG

1. Make sure the EPG is turned on.
2. Place the Thigh Cuff, with EPG attached, and the Foot Sensor within a few inches of each other.
3. Remove the battery from the Foot Sensor, wait 120 seconds (two minutes), and then insert the battery back into the Foot Sensor. Make sure to press firmly on the battery cover to snap back into place.
4. Press the Foot Sensor pressure sensor to activate the sensor.
5. Simultaneously press the Plus and Minus buttons on the EPG. The EPG will go into pairing mode and the EPG State Indicator Light will display an alternating green, yellow, and red light.
6. Once paired the EPG State Indicator Light on the EPG will flash green and the indicator light on the Foot Sensor will flash green.
7. If this does not power on the foot sensor, short the battery connector by placing a coin or the battery itself between the positive and the negative terminal of the foot sensor and then insert the battery back into the Foot Sensor. Make sure to press firmly on the battery cover to snap back into place. Repeat steps 4 and 5.

Note: Once the new Foot Sensor has been paired to the existing EPG, the Control Unit will automatically recognize the paired Foot Sensor.

Troubleshooting

If you have any questions or concerns, please contact the Customer Service at 800-211-9136 or an authorized distributor.

Error Code Descriptions

When an error occurs with the L360 Thigh System the EPG will emit an audio alert and the Status Indicator Light on the EPG will display a flashing red light. The Control Unit LCD display will show a flashing Error Indicator icon and a flashing Numeric Indicator communicating the error code. Refer to Table 10-1 for the error code descriptions and solutions.

Error Code	Description of Error	Solution
E1	Overstimulation Fault	Stimulation is being delivered at a higher intensity than expected. This is a possible hardware issue. Stop using the L360 Thigh System and contact Customer Service.
E2	Overstimulation Fault	Stimulation is being delivered at a higher frequency than expected. This is a possible hardware issue. Stop using the L360 Thigh System and contact Customer Service.
E3	Understimulation Fault	Stimulation is being delivered at a lower intensity than expected. This is a possible hardware issue. Stop using the L360 Thigh System and contact Customer Service.

Error Code	Description of Error	Solution
E4	Understimulation Fault	Stimulation is being delivered at a lower frequency than expected. This is a possible hardware issue. Stop using the L360 Thigh System and contact Customer Service.
E5	Charge Imbalance	This is a possible hardware issue. Stop using the L360 Thigh System and contact Customer Service.
E6	Communication Fault	The Foot Sensor and EPG are not communicating. Press the Foot Sensor pressure sensor to activate the Foot Sensor.
E7, E8, E9	Software Fault	Reset the EPG. If error persists, stop using the L360 Thigh System and contact Customer Service.
E10	Parameter Corrupted	The L360 Thigh System needs to be reprogrammed. Stop using the L360 Thigh System and contact Customer Service.
E11, E22	Incorrect Cuff Fault	Make sure EPG is correctly inserted into the EPG cradle on the Thigh Cuff.
E12	Shorted Electrode Fault	Electrodes are shorted, cuff has an electrical short, or the hardware is not functioning correctly. Stop using the L360 Thigh System and contact Customer Service.
E13	Bad Electrode Fault	Electrodes are worn or damaged. Replace any worn or damaged electrodes or electrode bases. Refer to the "Maintenance and Cleaning" chapter of this guide for instructions.

Error Code	Description of Error	Solution
E14	Open Electrode Fault	Turn the EPG off by pressing the Power button on the EPG. Make sure the electrodes and/or electrode bases are snapped into the plug holes of the Thigh Cuff.
E15	EPG Battery Empty	Charge the EPG. Refer to the "Charging the L360 Thigh System" section in this guide.
E17	EPG Battery Temperature Fault	Battery temperature is too high. Disconnect the charger from the EPG. Place the EPG in a room within the operating conditions temperature range (5°C to 40°C/41°F to 104°F) for 30 minutes. After 30 minutes reconnect the EPG to the charger to continue charging.

Table 10-1: Error codes, descriptions, and solutions

Testing the Functionality of the Alert Indicator

Do not test the functionality of the alert indicator while wearing the Thigh Cuff. Remove the Thigh Cuff before starting the test.

To test the functionality of the alert indicator:

1. Remove the electrodes from the Thigh Cuff.
2. Press the Power button on the EPG.
3. Press and hold the Stim button on the EPG for at least ten seconds.
4. The EPG will detect an "Open Electrode Fault". The EPG will emit an audio alert and the Status Indicator Light on the EPG will display a flashing red light.
5. To turn off the alert indicator press the Power button on the EPG.

Note: If the EPG does not emit an audio alert and display a flashing red light, contact Customer Service at 800-211-9136, Option 3 or an authorized distributor.

Frequently Asked Questions

When charging the EPG, how will I know when the batteries are fully charged?

The Battery Indicator Light on the EPG will display a solid green light, briefly at power up, when the EPG battery is fully charged. Charging takes approximately three hours. If the EPG is completely discharged it can take up to six hours for the EPG battery to charge.

If I charge the EPG every day, will I harm the batteries?

No, daily charging will not affect the lifespan or functionality of the EPG battery. Daily charging of the EPG is recommended.

How will I know when the EPG battery charge level is low?

The Battery Indicator Light on the EPG will display a solid yellow light.

How will I know when the Foot Sensor battery charge level is low?

A Foot Sensor battery will last for approximately six months, and then it will need to be replaced. When the Foot Sensor battery charge level is low, the red Indicator Light on the Foot Sensor will flash for five seconds.

What should I do if the electrodes or electrode bases are frayed, peeling, damaged, or falling off the Thigh Cuff?

- Replace any worn or damaged electrodes or electrode bases. Refer to the "Maintenance and Cleaning" chapter in this guide.

How come my knee is not moving satisfactorily, and the L360 Thigh System is not indicating any errors?

- Make sure the EPG(s) and Control Unit are turned off.

- Reposition the Thigh Cuff.
- Make sure the straps are snug.
- Turn on the EPG by pressing the Power button on the EPG.
- Test the placement of the Thigh Cuff by pressing and holding the Stim button on the EPG for at least five seconds. The EPG will deliver stimulation until the Stim button is released.

Why is the stimulation inconsistent when I am walking, but the L360 Thigh System is not indicating any errors?

Stop walking and shift your weight from side to side.

For users with the Foot Sensor:

- Check for proper placement of the pressure sensor, reposition the pressure sensor slightly forward in your shoe, or loosen your shoelace.
- Check the Foot Sensor wire for wear or fraying, and check the transmitter and pressure sensor for damage.
- If damaged, contact Customer Service for a replacement part.

What should I do if my skin is irritated or has a skin reaction where the electrodes or Thigh Cuff adheres?

- Stop using the L360 Thigh System immediately.
- Contact your clinician or dermatologist, and Customer Service at 800-211-9136, Option 3 or an authorized distributor.
- Resume use only when the skin is completely healed.
- Ask your clinician or dermatologist for a skin conditioning protocol.

I received a replacement component and was told I need to “pair” it. Why is pairing important and how do I pair a component?

The L360 Thigh System components must be paired to each other to communicate wirelessly. When a Control Unit, EPG, or Foot Sensor is replaced, the new replacement component must be paired to the existing components. Refer to the "Pairing Replacement Part Components" chapter in this guide for more information.

Technical Specifications

Control Unit Specifications	
Classification	Internally powered, continuous operation with type BF applied part(s)
Operation Modes	Gait, Training, and Clinician
Battery Type	Button cell lithium battery, CR2032, 3V, 240 mAh
Controls	• Select button- to select an EPG • Mode button- to select an operating mode • Stim button- to turn stimulation on/off • Minus and Plus buttons- to decrease or increase stimulation intensity level • Volume button- turns the EPG audio feedback on/off
Indications	• EPG icon (Ready, Stim, and Error State), Foot Sensor icon, Operating Mode icon, Battery Level icon, Error icon, and Volume (mute) icon • Numerical display for stimulation intensity and error code display
Carrying Options	In pocket or neck strap
Dimensions	• Length: 75 mm (3 in.) • Width: 40 mm (1.6 in.) • Height: 17 mm (0.7 in.)
Weight	60 grams

Control Unit Specifications	
Environmental Ranges	Transport and Storage Conditions: • Temperature: -25°C to +55°C • Relative humidity: 5% to 90% • Pressure: 20 kPa to 106 kPa Operating Conditions: • Temperature: 5°C to 40°C • Relative humidity: 5% to 75% • Operating pressure: 80 kPa to 106 kPa
Ingress Protection Rating	IP22 Protection Against: • Object Sized >12.5mm • Dripping Water When Tilted up to 15° Effective Against: • Fingers or Similar Objects • Vertical dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position.
FCC ID Number	RYYEYSGJN

EPG Specifications	
Classification	Internally powered, continuous operation with type BF applied part(s)
Battery Type	Rechargeable lithium ion battery, 3.7V, 1000 mAh
Controls	• Power button - turns system on/off • Stim button- to turn stimulation on/off • Minus and Plus buttons- to decrease or increase stimulation intensity level

EPG Specifications	
Indications	• Status Indicator Light and Battery Indicator Light • Audio and vibration feedback • “Beeps” for audio alerts
Dimensions	• Length: 82 mm (3.2 in.) • Width: 47 mm (1.9 in.) • Height: 15 mm (0.6 in.)
Weight	60 grams
Environmental Ranges	Transport and Storage Conditions: • Temperature: -25°C to +55°C • Relative humidity: 5% to 90% • Pressure: 20 kPa to 106 kPa Operating Conditions: • Temperature: 5°C to 40°C • Relative humidity: 5% to 75% • Operating pressure: 80 kPa to 106 kPa
Ingress Protection Rating	IP42 Protection Against: • >1mm Solids Ingress • Dripping Water When Tilted up to 15° Effective Against: • Most wires, screws, etc. • Vertical dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position.
Product Lifetime (Given Intended Use)	2 Years

EPG Specifications	
Rechargeable Battery Lifetime	3 Years
FCC ID Number	RYYEYSGJN

Pulse Parameters	
Pulse	Balanced Biphasic
Waveform	Symmetric or Asymmetric
Intensity (Peak)	0–100 mA, 1-mA resolution (positive phase)
Maximum Intensity (rms)	16.5 mA (rms)
Max Voltage	130 V

	Symmetric				
Positive Pulse Duration (µsec)	100	150	200	250	300
Negative Pulse Duration (µsec)	100	150	200	250	300
Interphase Interval (µsec)	50, 100, 200				
Total Pulse Duration for Interphase Interval of 50 µsec	250	350	450	550	650
	Asymmetric				
Positive Pulse Duration (µsec)	100	150	200	250	300
Negative Pulse Duration (µsec)	300	450	600	750	900

Interphase Interval (µsec)	20, 50, 100, 200				
Total Pulse Duration for Interphase Interval of 50 µsec	450	650	850	1050	1250
Max Load	80000 ohm (Subject to max voltage limitation)				
Min Load	100 ohm				
Pulse Repetition Rate	10–45 Hz, 5 Hz resolution				
Gait Parameters					
Swing Control Delay (%)	0–100% of phase* time, 5% resolution				
Swing Control End (%)	0–100% of phase* time, 5% resolution				
Stance Control Delay (%)	0–100% of phase* time, 5% resolution				
Stance Control End (%)	0–100% of phase* time, 5% resolution				
Ramp Up	0–0.5 seconds, 0.1-second resolution				
Ramp Down	0–0.5 seconds, 0.1-second resolution				
Extend (%)	0–100% of stance time, 5% resolution				
Max. Duration of Stimulation	1–10 seconds, 1-second resolution				
* Stimulation burst can start either on swing or stance phase.					

Cycle Training Parameters	
Ramp Up	Not adjustable. Preset to 0 seconds.
Ramp Down	Not adjustable. Preset to 0 seconds.
Max. Duration of Stimulation	Not adjustable. Preset to 2 seconds.

EPG Alert Onset Time	
Incorrect Stimulation	Delay to Alert < 5 sec
Communication Failure	Delay to Alert < 1 sec
Corrupted Memory	Delay to Alert < 100 ms
EPG is in the Incorrect Cuff	Delay to Alert (after stimulation is enabled) < 100 ms
Electrode Condition Alert (short / bad contact /open)	Delay to Alert < 2.5 sec
Battery Empty	Delay to Alert < 1 sec

Note: The alert signal range is from 39-51 dBA.

Foot Sensor Specifications	
Classification	Internally powered, continuous operation with type BF applied part(s)
Battery Type	Button cell lithium battery, CR2032, 3V, 240 mAh
Dimensions of the Transmitter	•Length: 65 mm (2.6 in.) •Width: 50 mm (2 in.) •Height: 10 mm (0.4 in.)
Weight	25 grams

Environmental Ranges	Transport and Storage Conditions: • Temperature: -25°C to +55°C • Relative humidity: 5% to 90% • Pressure: 20 kPa to 106 kPa Operating Conditions: • Temperature: 5°C to 40°C • Relative humidity: 5% to 75% • Operating pressure: 80 kPa to 106 kPa
Ingress Protection Rating	IP52 Protection Against: • Dust • Dripping water when tilted up to 15° Effective Against: • Ingress of dust is not entirely prevented, but it must not enter in sufficient quantity to interfere with satisfactory operation of the equipment. • Vertical dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position.
FCC ID Number	RYYEYSGJN

Thigh Cuff Specifications	
Material	Fabric-Polymer
Fits Limb Circumference	•Upper thigh circumference: 53 cm–85 cm •Lower Thigh circumference: 33 cm–50 cm •Thigh length: 24 cm–35 cm
Dimensions	Length: 200 mm Circumference (minimal): •Proximal panel: 270 mm •Distal panel, regular: 310 mm •Distal panel, large: 510 mm
Weight	Approximately 300 grams

System Charger Specifications	
Use the medical Class II safety approved power supply provided/approved by Bioness with the following ratings:	
Input	
Voltage	100–240 V
Current	0.5 A
Frequency	50–60 Hz
Output	
Voltage	5.0 V
Current	3.0 A

Note: Do not use the L360 Thigh System while charging. Do not wear the Thigh Cuff while charging.

Thigh Cuff Cloth Electrode Specifications	
Material	Non-woven cloth **Note:** Use only electrodes provided by Bioness.
Dimensions	Proximal Oval: 130 mm x 75 mm Distal Oval: 120 mm x 63 mm

Chapter 12

Wireless Information

System Characteristics

The L360 Thigh System communicates wirelessly between components.

Description	Industry-standard Bluetooth® Low Energy (BLE) 4.1 communication protocol
Operating Frequency Band	2.4 Ghz, ISM band (2402-2480 MHz)
Type of Modulation	FSK
Type of Modulating Signal	Binary data message
Data Rate [=Frequency of Modulating Signal]	250 Kbps
Effective Isotropic Radiated Power	4 dBm
Receiver Bandwidth	812 kHz around a selected frequency
EMC Testing	Complies with FCC 15.2473 (for U.S.) regulations Complies with IEC 60601-1-2 Complies with IEC 60601-2-10

- **Quality of Service (QOS):** The L360 Thigh System was designed and tested to have a response rate of 10-100ms latency depending on system configuration after the detection of a heel event.
- **Wireless Interference:** The L360 Thigh System was designed and tested to not have interference from other RF devices (including other L360 Thigh Systems, WiFi networks, Cellular Devices, Microwaves and other Bluetooth® devices).

L360 Thigh System is not susceptible to the wide range of expected EMI emitters, such as Electronic Article Surveillance Systems (EAS), Radio Frequency Identification Systems (RFID), Tag Deactivators, and Metal Detectors. However, there is no guarantee that interference will not occur in a particular situation.

⚠ **Caution:** If performance of the L360 Thigh System is affected by other equipment, the user should turn the L360 Thigh System off, and move away from the interfering equipment.

Electromagnetic compatibility (EMC) Information

Guidance and Manufacturer's Declaration—Electromagnetic Emissions		
The L360 Thigh System is intended for use in the electromagnetic environment specified below. The customer or the user of the L360 Thigh System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment — Guidance**
RF emissions CISPR 11	Group 1	The L360 Thigh System 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 CISPR 11	Class B	The L360 Thigh System 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 IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration— Electromagnetic Immunity for All Equipment and Systems			
The L360 Thigh System is intended for use in the electromagnetic environment specified below. The customer or the user of the L360 Thigh System 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	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 kV 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 +/- 1 kV for Input/ output lines	+/- 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/-1 kV line to line +/-2 kV line to earth	+/-1 kV line to line +/-2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the L360 Thigh System requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
The L360 Thigh System is intended for use in the electromagnetic environment specified below. The customer or the user of the L360 Thigh System 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 L360 Thigh System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM and Amateur Radio Bands	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM and Amateur Radio Bands	**Recommended separation distance:** d = 1.2√P
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz Proximity Fields per 60601-1-2 4th edition	[E1] = 10 V/m in 26 MHz to 2.7 GHz Proximity Fields per 60601-1-2 4th edition	**Recommended separation distance:** d = 0.4√P, 80–800 MHz range d = 0.7√P, 800-2700 MHz range

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.

NOTE 3: *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).
NOTE 4: 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]
NOTE 5: Interference may occur in the vicinity of equipment marked with the following symbol: 

[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 L360 Thigh System is used exceeds the applicable RF compliance level above, the L360 Thigh System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the L360 Thigh System.

[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 L360 Thigh System			
The L360 Thigh System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the L360 Thigh System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the L360 Thigh System 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**		
	150 kHz to 80 MHz Outside ISM Bands d = 1.2√P	**80 MHz to 800 MHz d = 0.4√P**	**800 MHz to 2700 MHz d = 0.7√P**
0.01	0.12 m	0.04 m	0.07 m
0.1	0.38 m	0.13 m	0.22 m
1	1.2 m	0.4 m	0.7 m
10	3.8 m	1.3 m	2.2 m
100	12 m	4 m	7 m

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.

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined 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: All calculations were made according to tables 204 and 206 of IEC 60601-1-2 for not life-supporting equipment using factors of 3.5 in 0.15–800 MHz and 7 in 800–2500 MHz. There are no requirements for ISM bands in these tables.