



Functional Electrical Stimulation System

USER'S GUIDE

L300 Go User's Guide Copyright

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Environmental Policy



Service personnel are advised that when changing any part of the L300 Go 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 Inc. Bioness Inc. is committed to continuously seeking and implementing the best possible manufacturing procedures and servicing routines.



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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
	Re-Order Number
	Lot Number
	Serial Number
	Single Patient Use - To Prevent Cross Contamination
	Single Patient Multiple Use
	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)
	Left
	Right
	Underwriters Laboratories (UL) is an independent, globally recognized agency that certifies, validates, tests, inspects and audits corporations and products.
	European Authorized Representative

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Introduction

Central nervous system (CNS) injuries often cause a gait disorder called foot drop. People who have foot drop are unable to raise their foot while walking. They often drag their foot, resulting in instability and increased effort during gait. Many people with CNS injuries/diseases and other disabilities also suffer from thigh muscle weakness that is concurrent with or independent of foot drop. Weak thigh muscles can cause considerable difficulties with flexing or extending the knee during ambulation.

The L300 Go System is designed to improve gait in people suffering from foot drop and/or with thigh muscle weakness. The L300 Go System also can deliver stimulation to either or both the muscles in the upper and lower leg to facilitate muscle re-education, prevent/retard disuse atrophy, maintain or increase joint range of motion, and/or increase local blood flow. The L300 Go System consists of a Lower Leg Cuff (available in regular and small sizes) with an External Pulse Generator (EPG), a Thigh aCuff with an EPG, an optional Control Unit, and an optional Foot Sensor. These components communicate wirelessly to electrically stimulate muscles in the affected leg to raise the foot and/or to provide knee flexion or extension. The Lower Leg Cuff and Thigh Cuff can be used either independently or together.

The L300 Go System is designed to be used in a Hospital/Professional Healthcare Facility or Residential/Home Healthcare environment.



Figure 1-1: L300 Go System

This L300 Go User's Guide describes:

- Important safety information about the L300 Go System.
- The components of the L300 Go System.
- How to set up, operate, and maintain your L300 Go System.
- Troubleshooting information.

Be sure to review this guide with your clinician before using your L300 Go System. If you have any questions contact Bioness Technical Support at 800.211.9136, Option 3 (USA & Canada) or your local distributor. You can also visit the Bioness website at: www.bioness.com.

Caution: Do not put on or operate the L300 Go System before being properly fitted and trained by a certified clinician.

Safety Information

Indications for Use

The L300 Go System is intended to provide ankle dorsiflexion in adult and pediatric individuals with foot drop and/or 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 L300 Go System electrically stimulates muscles in the affected leg to provide ankle dorsiflexion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait.

The L300 Go System may also:

- Facilitate muscle re-education
- Prevent/retard disuse atrophy
- Maintain or increase joint range of motion
- Increase local blood flow

Contraindications

- Users with a demand-type cardiac pacemaker, defibrillator or any electrical implant should not use the L300 Go System.

Warnings

- The L300 Go System should not be used on a leg where a metallic implant is directly underneath the electrodes.
- The L300 Go System should not be used on a leg where a cancerous lesion is present or suspected.
- The L300 Go 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 beyond 12 months have not been established.
- The Lower Leg Cuff and 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 L300 Go 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 L300 Go System within three feet of short wave or microwave therapy equipment. Such equipment may produce instability in the EPG output.
- The L300 Go System should only be configured by an authorized clinician.
- In case of any inconvenience, turn off stimulation and remove the Lower Leg Cuff and/or Thigh Cuff. If the stimulation cannot be turned off, remove the cuff to stop stimulation.

Precautions

- Inflammation in the region of the Lower Leg Cuff and Thigh Cuff may be aggravated by motion, muscle activity, or pressure from the cuff. Stop using the L300 Go 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 Lower Leg Cuff and 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, type of electrodes, or electrode placement.
- Do not use the L300 Go System without electrodes.
- After removing the Lower Leg Cuff and/or 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 L300 Go System until any inflammation is gone.
- Stop using the L300 Go System and consult your clinician if stimulation does not start at the correct time during gait.
- Turn off the L300 Go System when at a refueling place. Do not use the L300 Go System near flammable fuel, fumes, or chemicals.
- Only your treating clinician should determine electrode placement and stimulation settings.
- Use only the L300 Go System electrodes supplied by Bioness Inc.
- Turn off the L300 Go 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 cuff because of arterial or venous thrombosis, 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 L300 Go System during pregnancy has not been established.
- Skin problems, on the leg where the Lower Leg Cuff and/or Thigh Cuff is worn, may be aggravated by the L300 Go System.
- Adult supervision and assistance should be provided for anyone needing help while using the L300 Go System.

- The patient/user is the intended operator of the L300 Go 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 L300 Go 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 L300 Go System. Contact Bioness if you experience a technical problem not covered in this guide.
- The Lower Leg Cuff and 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 L300 Go System before putting on the Lower Leg Cuff and/or Thigh Cuff. Do not turn on the L300 Go System until the Lower Leg Cuff and/or Thigh Cuff is fastened in place.
- Shut off the L300 Go 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 L300 Go 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 L300 Go 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.
- While the L300 Go (Small Lower Leg Cuff) is designed to fit and be worn by both pediatric users and small individuals, the system is intended to be managed and maintained only by adult users, adult caregivers and/or healthcare professionals.

Adverse Reactions

In the unlikely event that any of the following occurs, stop using your L300 Go System immediately and consult your physician:

- Signs of significant irritation or pressure sores where the 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 Lower Leg Cuff and Thigh Cuff. To promote healthy skin with long-term use of the L300 Go 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 Lower Leg Cuff and/or 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 3-4 hours for optimal performance.
- After taking off the Lower Leg Cuff and/or Thigh Cuff, always re-cover hydrogel electrodes with the protective plastic covers, where applicable.
- 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 Lower Leg Cuff and/or Thigh Cuff, make sure the electrodes uniformly contact the skin.
- Ventilate the skin by removing the Lower Leg Cuff and Thigh Cuff for at least 15 minutes every three to four hours.

If skin irritation or a skin reaction occurs, stop using your L300 Go System immediately and contact your clinician or dermatologist. You can also contact Bioness Technical Support at 800.211.9136, Option 3 (USA & Canada) or your local 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.

Environmental Conditions that Affect Use

Radio Frequency (RF) Communication Information

Several components of the L300 Go 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 L300 Go System.

Conformity Certification

The L300 Go 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 L300 Go 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 L300 Go System before going through airport security. Wear loose clothing so that you can easily show the security person your L300 Go System. The L300 Go System will likely set off the security alarm. Be prepared to remove the L300 Go 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 L300 Go System prescription.

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

Note: The L300 Go 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 L300 Go system in flight.

Electromagnetic Emissions

The L300 Go 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 L300 Go System was tested and certified to use the following:

- AC Adapter with interchangeable blades, model number LG4-7200, supplied by Bioness Inc.

- Magnetic Charging Cord, model number LG4-7100, supplied by Bioness Inc.

Warnings

- Do not use the L300 Go 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 L300 Go System before undergoing any diagnostic or therapeutic medical procedure such as Xray examination, ultrasound, Magnetic Resonance Imaging (MRI), etc.
- The L300 Go 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 L300 Go System as replacement parts for internal components) may result in increased emissions or decreased immunity of the L300 Go System.
- The L300 Go 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.

L300 Go System Kits

Contents

L300 Go System, Small Lower Leg

- Box Container
- Small Lower Leg Cuff, Right or Left, with (XS) Strap 
- Central External Pulse Generator (EPG) 
- System Charger (with charging adapters) 
- Magnetic Charging Cord 
- Small Lower Leg Cuff Strap (XXS) 
- L300 Go User's Guide
- L300 Go User's Reference Card

L300 Go System, Lower Leg

- Box Container
- Regular Lower Leg Cuff, Right or Left, with (Medium) Strap 
- Central External Pulse Generator (EPG) 
- System Charger (with charging adapters) 
- Magnetic Charging Cable 
- Cuff Snap Covers (attached to the Lower Leg Cuff) 
- L300 Go User's Guide
- L300 Go User's Reference Card

L300 Go System, Thigh Plus (Used with the Lower Leg System Kit)

- Box Container
- Thigh Cuff, Right or Left 
- Peripheral External Pulse Generator (EPG) 
- Magnetic 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 
- L300 Go User's Guide
- L300 Go User's Reference Card

L300 Go System, Thigh Stand-Alone

- 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) 
- Magnetic 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)
- L300 Go Control Unit (optional, not included)
- Replacement Battery for use with the Control Unit or Foot Sensor (optional, not included)
- L300 Go User's Guide
- L300 Go User's Reference Card



Small Lower Leg
Cuff with EPG



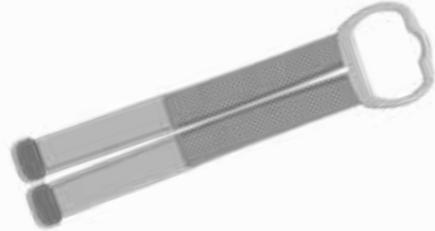
Regular Lower Leg
Cuff with EPG



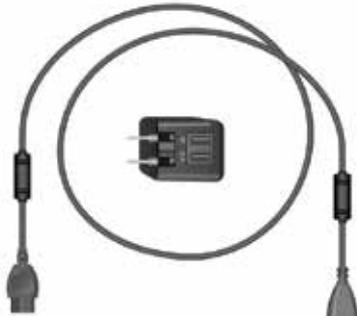
Control Unit



Foot Sensor



Lower Leg Cuff Strap
(example shown)



System Charger with
Magnetic Charging Cord



Wire Concealers



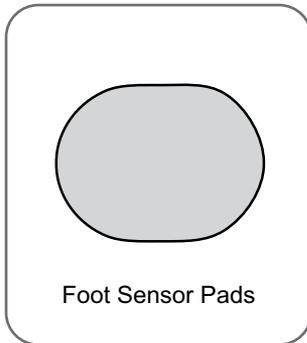
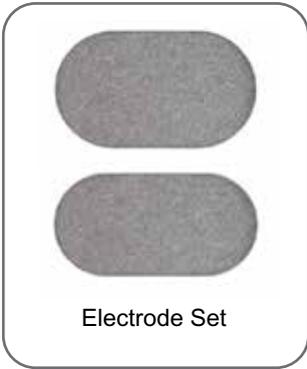
Cuff Snap Covers



Control Unit Neck Strap



Replacement Battery



Device Description

Lower Leg Cuff

The Lower Leg Cuff is an orthosis that fits on the leg below the knee and is designed to facilitate upward movement of the foot and toes. See Figure 5-1. The Lower Leg Cuff is available in right and left configurations and in two sizes (regular and small). The Lower Leg Cuff houses the EPG cradle, the lower leg EPG, and integrated electrodes. It also provides an anatomically designed locator to ensure repeatable electrode contact and a strap that can be fastened with one hand.



Figure 5-1: Lower Leg Cuff

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 5-2. The Thigh Cuff is available in right and left configurations.

The Thigh Cuff houses the EPG cradle, the thigh 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. The Thigh Cuff can be used on its own or in conjunction with the Lower Leg Cuff.



Figure 5-2: Thigh Cuff

Lower Leg EPG and Thigh EPG

The lower leg EPG generates the electrical stimulation used to contract the muscles in the leg that lift the foot and toes. The lower leg EPG features a built-in motion sensor, that detects the position of the foot and it communicates via Bluetooth® Low Energy (BLE) wireless signals with the Control Unit (optional) and Foot Sensor (optional). If a user is wearing both the Lower Leg Cuff and the Thigh Cuff, the lower leg EPG will also send wireless signals to the thigh EPG.

The thigh EPG generates the electrical stimulation used to flex or extend the knee. The thigh EPG responds to wireless signals from the Control Unit, lower leg EPG (for users that are using the Lower Leg Cuff with the Thigh Cuff), and the Foot Sensor to turn stimulation on or off.

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 respective 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 5-3, 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.

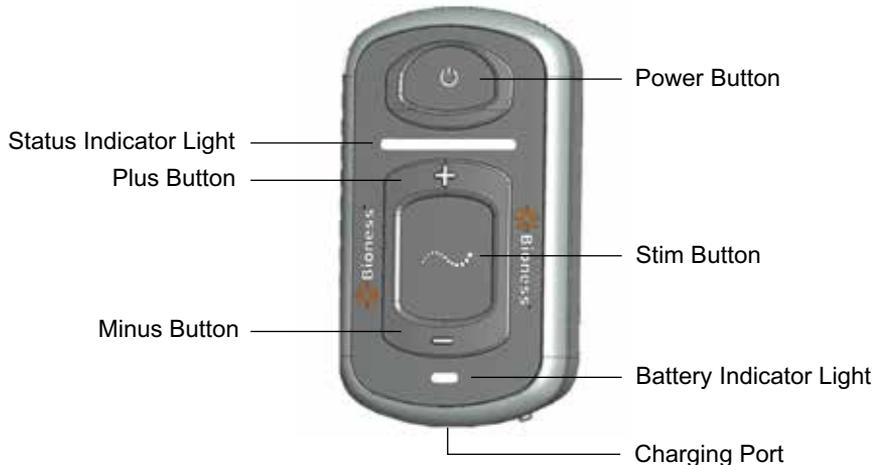


Figure 5-3: EPG

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
	 (Solid)	Solid 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 L300 Go 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 5-4, 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.

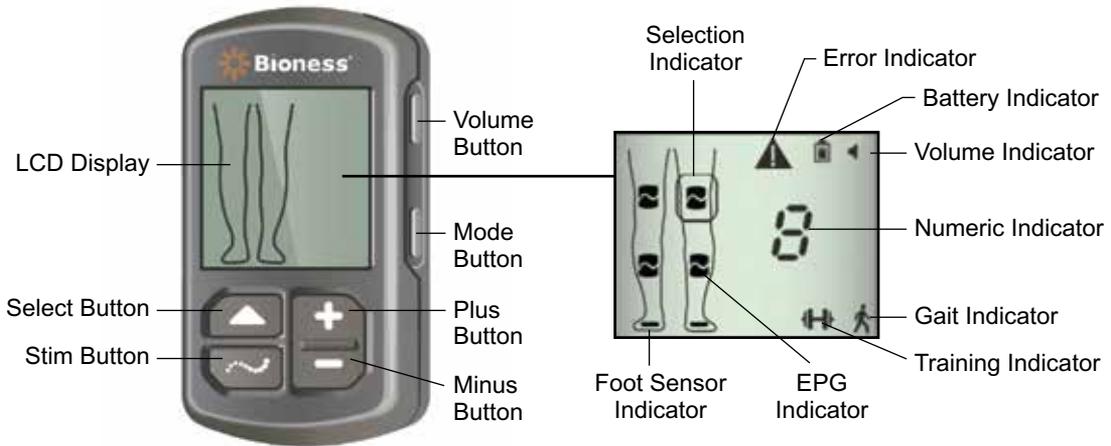


Figure 5-4: Control Unit

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

Control Unit Button	Description	Function
	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
 (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

LCD Display Icons	Description	Function
	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

L300 Go System Operating Modes

The L300 Go 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 lower leg EPG detect the position of the lower leg and then send the appropriate signal to that EPG. For users wearing the Lower Leg Cuff and the Thigh Cuff, this signal is then sent from the lower leg EPG to the thigh 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 achieve dorsiflexion and 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 L300 Go 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 lower leg EPG. Stimulation is delivered in cycles pre-set by your clinician.

For Lower Leg Cuff users, Training mode is designed to facilitate muscle re-education, prevent or retard disuse atrophy of the lower leg muscles, maintain or improve range of motion of the ankle joint, and improve local blood circulation. Training mode can also be used to check if the Lower Leg Cuff is positioned properly. If your foot does not respond to the stimulation as it should, reposition the Lower Leg Cuff.

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.

Foot Sensor

The Foot Sensor is an optional component of the L300 Go System. Your clinician will determine if you need to use the Foot Sensor with your L300 Go 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 L300 Go system while using Cycle Training mode.

The Foot Sensor features a pressure sensor, transmitter, and a clip. See Figure 5-5. 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 5-5 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 L300 Go 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 Bioness Technical Support at 800.211.9136, Option 3 (USA & Canada) or your local 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.

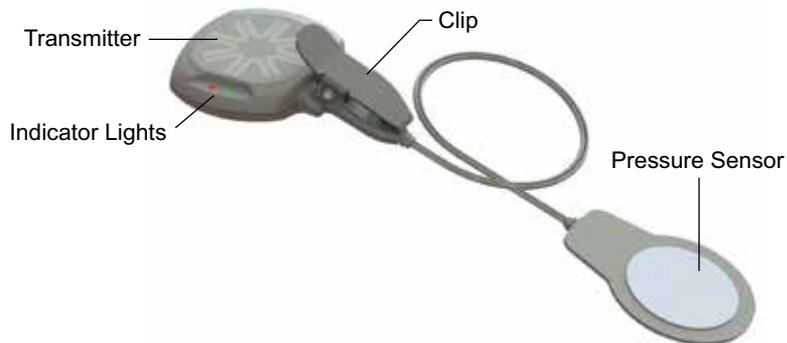


Figure 5-5: Foot Sensor

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

Lower Leg Cuff Electrodes and Electrode Bases

There are four different types of electrodes that can be used with the Lower Leg Cuff to deliver stimulation. The electrodes either adhere to electrode bases, which snap onto the Lower Leg Cuff liner or the electrode snaps directly into the Lower Leg Cuff liner.

With a Small L300 Go System the following electrodes and electrode bases can be used (See Figure 5-6):

- Small Quick Fit Electrode - Size A or B (as fitted by your clinician)
- Small Round Cloth Electrodes
- Small Electrode Base set (used with the Small Round Cloth Electrodes)

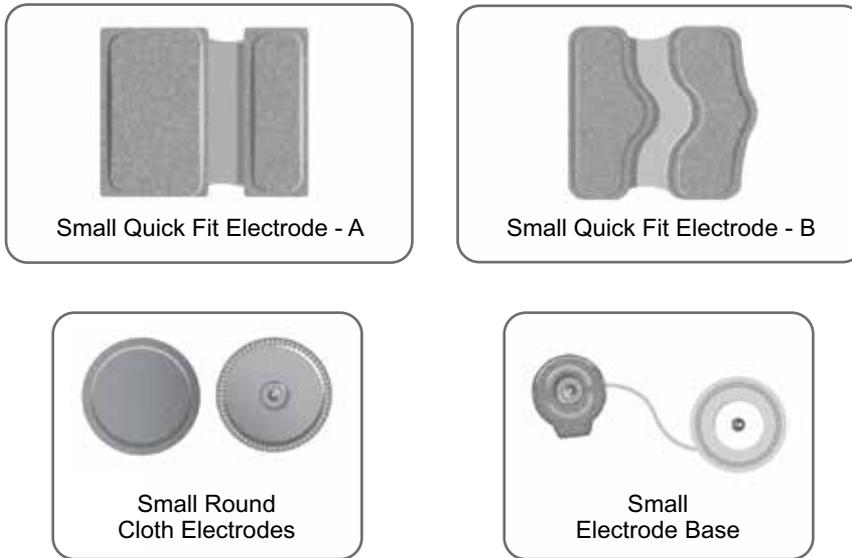


Figure 5-6: Electrodes and Bases for the Small Lower Leg Cuff

With a regular L300 Go System the following electrodes and electrode bases can be used (See Figure 5-7):

- Steering Cloth Electrode, left or right
- Quick Fit Electrode, left or right
- Hydrogel Electrodes/Bases
- Round Cloth Electrodes/Bases

Your clinician will fit you with the appropriate electrode option and attach them to your Lower Leg Cuff. Afterward, you will need to replace the electrodes every two weeks. Only the hydrogel electrodes carry an expiration date, therefore verify the expiration date is outside the two week period before use. To re-order all electrodes, contact your local representative or visit www.bioness.com

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

 **Caution:** Do not use the L300 Go System without the electrodes attached to the Lower Leg Cuff.

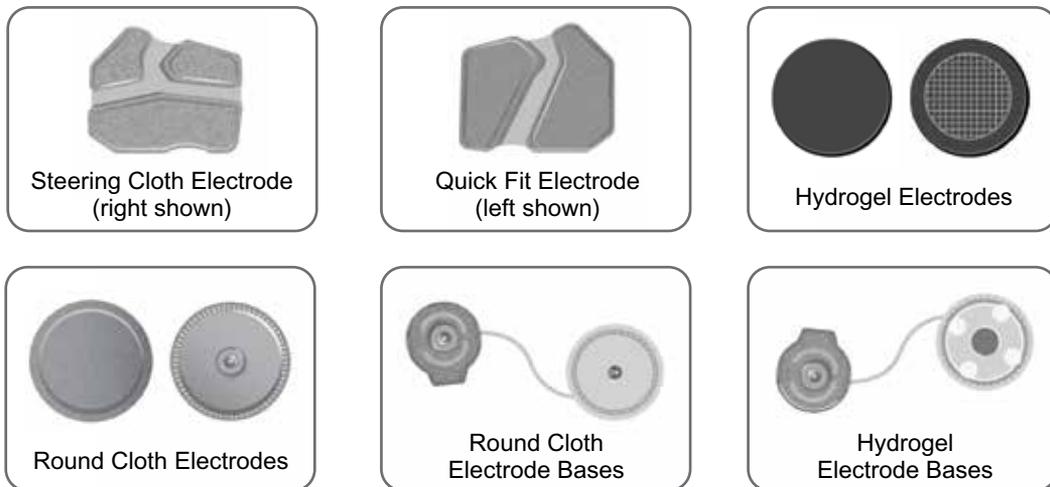


Figure 5-7: Electrodes and Bases for the Regular Lower Leg Cuff

Thigh Cloth Electrodes

The Thigh Cuff uses two cloth electrodes to provide electrical stimulation to the muscles in the upper leg. 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.

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

 **Caution:** Do not use the L300 Go System without the electrodes attached to the Thigh Cuff.

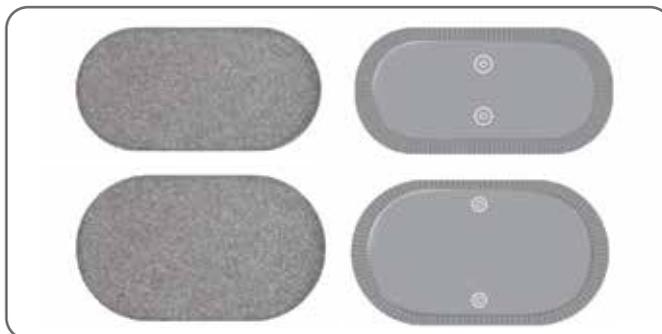


Figure 5-8: Electrodes for the Thigh Cuff

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 5-9. The Home Use Cuff Cover touches the user's skin and is designed to increase aesthetics and comfort throughout the day.

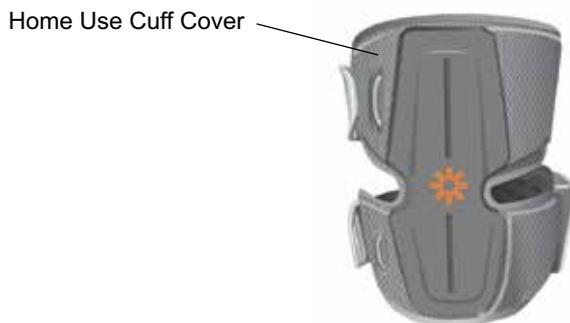


Figure 5-9: Thigh Cuff Home Use Cuff Cover

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 5-10. The Home Use Strap Holder is designed to assist with keeping the straps in place while on the user's thigh.



Figure 5-10: Thigh Cuff Home Use Strap Holder

System Charger Set

The system charger set includes a dual USB 3.1A 15w AC adapter, charging adapters for U.S. and international outlets, and a magnetic USB charging cable. The system charger set connects to a main power supply and is used to charge the EPG battery. See Figure 5-11.



Figure 5-11. System Charger Set

⚠ Caution: Use only the System Charger Set included in your L300 Go 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.

Snap Covers

The Snap Covers are used to close two of the Lower Leg Cuff plug holes when using the Regular Quick Fit Electrode, Hydrogel Electrodes, or Round Cloth Electrodes. Refer to the "Setup Instructions" section of this guide for more information.

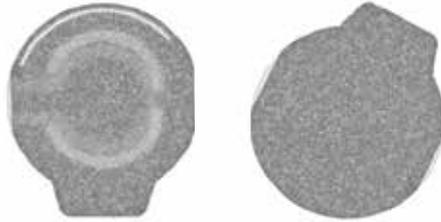


Figure 5-12: Snap Covers

Foot Sensor Pads

The Foot Sensor Pads are an accessory item that is not included with the L300 Go System Kit. 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.

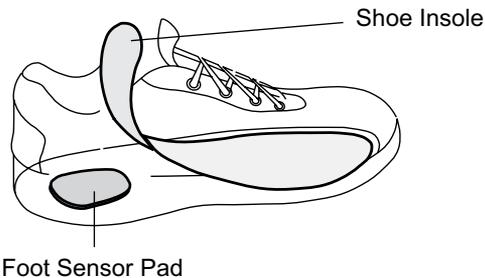


Figure 5-13: Foot Sensor Pad Placement

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, or learn more at www.L300Go.com. You may also contact Bioness Technical Support at 800.211.9135, Option 3 (USA & Canada) or your local distributor to request a paper copy."

Setup Instructions

Charging the L300 Go System

The lower leg EPG and thigh EPG are the only L300 Go System components 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 cuff(s).

To charge the L300 Go 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 magnetic charging cable into any of the two available USB ports on the AC adapter. See Figure 6-1.

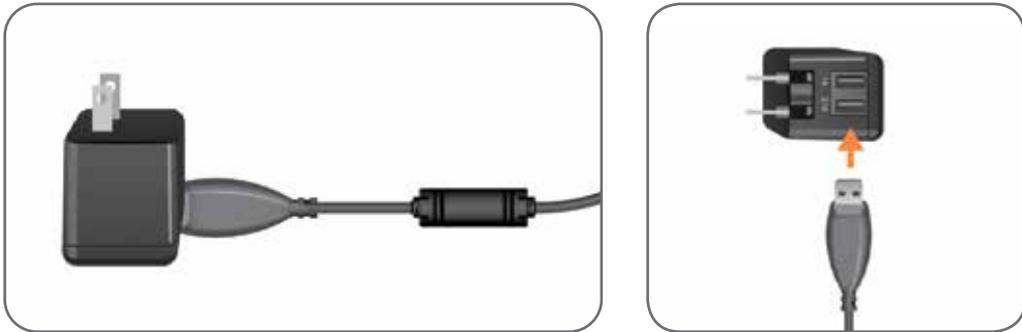


Figure 6-1: Inserting USB Charging Cable into AC Adapter

3. Connect the magnetic end on the charging cable to the charging port on the lower leg EPG and/or thigh EPG. The charging port is located at the bottom of the EPG. See Figure 6-2.



Figure 6-2: L300 Go System Charging Setup
(Example of a Lower Leg Cuff and Thigh Cuff Configuration)

4. Plug the AC adapter with connected magnetic 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 L300 Go System Kit. Use of any other charger will damage the system.

⚠ Caution: Do not use the Lower Leg Cuff and/or 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 Lower Leg Cuff and/or Thigh Cuff, always check your skin for signs of irritation. If any irritation is present, do not put on the Lower Leg Cuff or Thigh Cuff and contact your clinician. Wait for complete healing before using the L300 Go System. For optimal stimulation, the skin under the 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.

 **Caution:** Do not use your L300 Go System without the electrodes attached.

Quick Fit Electrode

To attach the Quick Fit Electrode to the Lower Leg Cuff:

1. Make sure the lower leg EPG and Control Unit are turned off.
2. If the Quick Fit Electrode is attached to the Lower Leg Cuff gently remove it.
3. Wet the entire Quick Fit Electrode with water. See Figure 6-3.
4. Remove excess water from the Quick Fit Electrode with a cloth. See Figure 6-3.

5. Make sure the Cuff Snap Covers are in place. Align the orange and blue snaps on the Quick Fit Electrode with the orange and blue plug holes on the Lower Leg Cuff. See Figure 6-4.
6. Press firmly to snap the Quick Fit Electrode into the Lower Leg Cuff. See Figure 6-4.

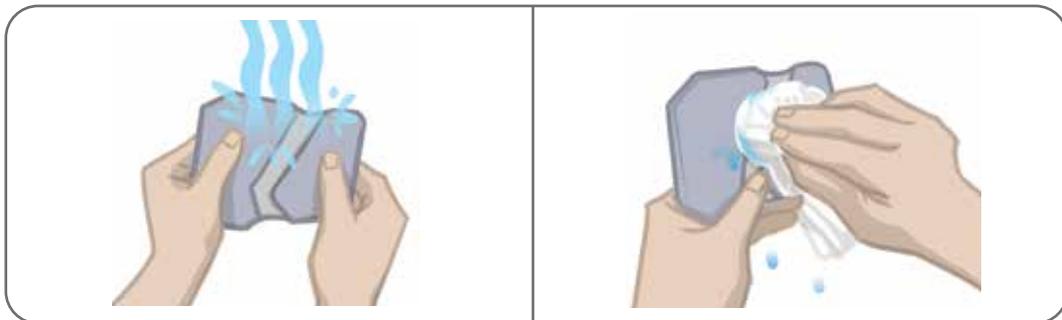


Figure 6-3: Wetting the Electrode and Removing Excess Water

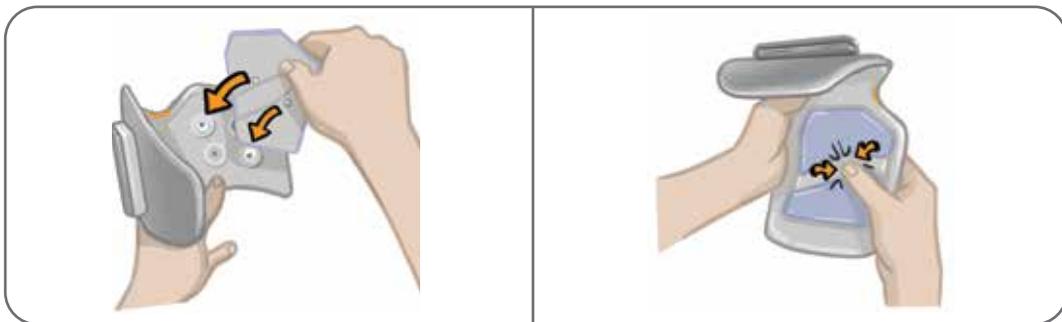


Figure 6-4: Aligning and Attaching the Quick Fit Electrode

Note: Remove and re-wet the entire Quick Fit Electrode every time you remove the Lower Leg Cuff from your leg for more than one hour, and after every three to four hours of use. When wetting the Quick Fit Electrode, always remove it from the Lower Leg Cuff.

Round Cloth Electrodes

To attach the Round Cloth Electrodes:

1. Make sure the lower leg EPG is turned off.
2. If attached, gently pull the Cloth Electrodes from the electrode bases. Be careful not to detach the electrode bases from the Lower Leg Cuff.
3. Wet the Round Cloth Electrodes with water until they are saturated. See Figure 6-5.
4. Use a washcloth to gently wipe or blot excess water off the back (side with the snap) of the electrodes. See Figure 6-5.
5. Attach the Round Cloth Electrodes to the electrode bases. See Figure 6-6. For regular Lower Leg Cuff users make sure the Cuff Snap Covers are in place.

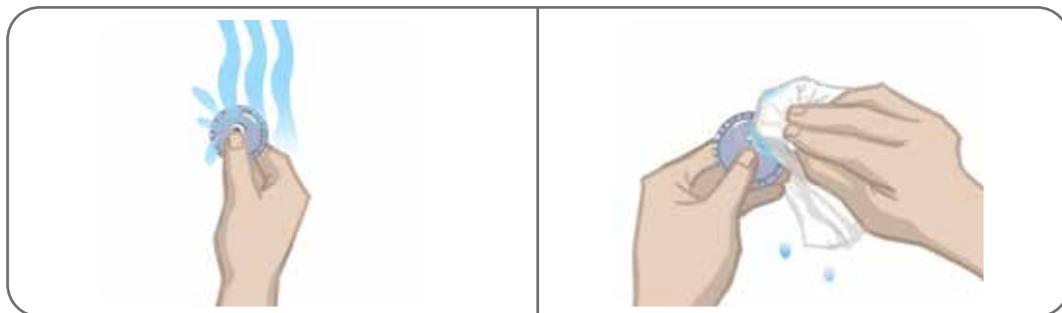


Figure 6-5: Wetting the Electrode and Removing Excess Water

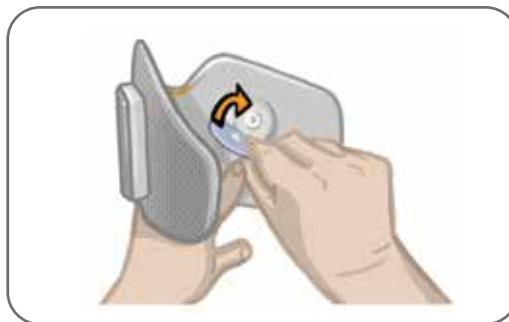


Figure 6-6: Attaching the Round Cloth Electrodes

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

Hydrogel Electrodes

For Lower Leg Cuff users with the Hydrogel Electrodes, your clinician has already attached them to the electrode bases on your regular Lower Leg Cuff.

Remove the covers from the electrodes. Set aside the covers to reapply between uses.

Steering Electrode

To attach the Steering Electrode to the Lower Leg Cuff:

1. Make sure the lower leg EPG is turned off.
2. If the Steering Electrode is attached to the Lower Leg Cuff, gently remove it.
3. Wet the entire Steering Electrode with water. See Figure 6-7.
4. Remove excess water from the Steering Electrode with a cloth. See Figure 6-7.

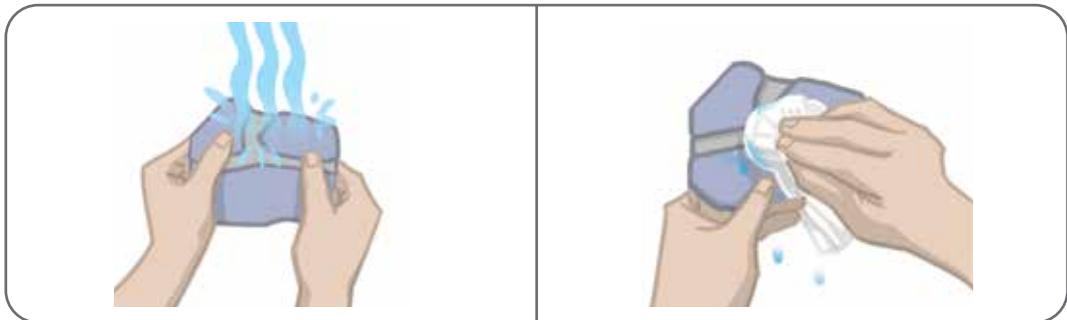


Figure 6-7: Wetting the Electrode and Removing Excess Water

5. Align the snaps on the Steering Electrode with the plug holes on the Lower Leg Cuff. See Figure 6-8.
6. Press firmly to snap the Steering Electrode into the Lower Leg Cuff. Make sure to press on the areas above all four snaps. See Figure 6-8.

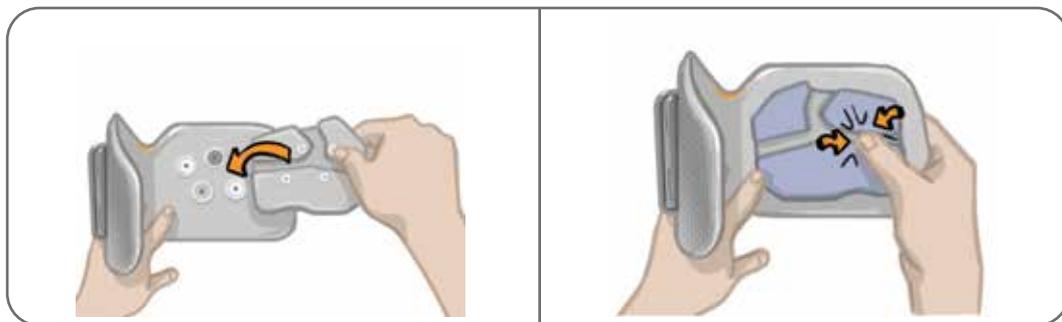


Figure 6-8: Aligning and Attaching the Steering Electrode

Note: Remove and re-wet the entire Steering Electrode every time you remove the Lower Leg Cuff from your leg for more than one hour, and after every three to four hours of use. When wetting the Steering Electrode, always remove it from the Lower Leg Cuff.

Thigh Cloth Electrodes

To attach the Thigh Cloth Electrodes to the Thigh Cuff:

1. Make sure the thigh 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 6-9. 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 6-9.

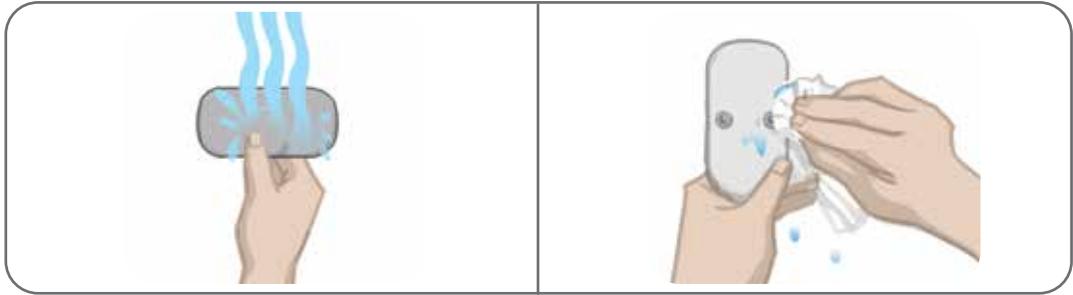


Figure 6-9: Wetting the Electrode and Removing Excess Water

5. Align the snaps on the Thigh Cloth Electrodes to the plug holes on the Thigh Cuff. See Figure 6-10.
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 6-10.

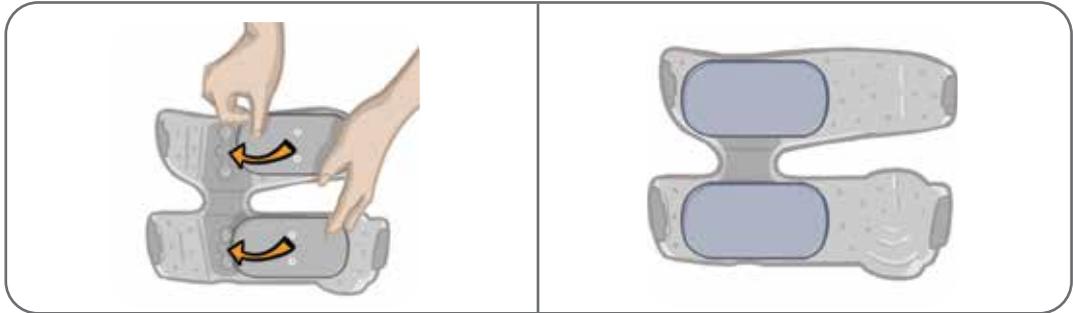


Figure 6-10: Aligning and Attaching the Thigh Cloth Electrodes

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 Lower Leg Cuff

To position the Lower Leg Cuff:

1. While seated, slightly straighten your leg as shown in Figure 6-11. The outline of your kneecap should be clearly defined. (Place your foot on a footrest, if necessary.)

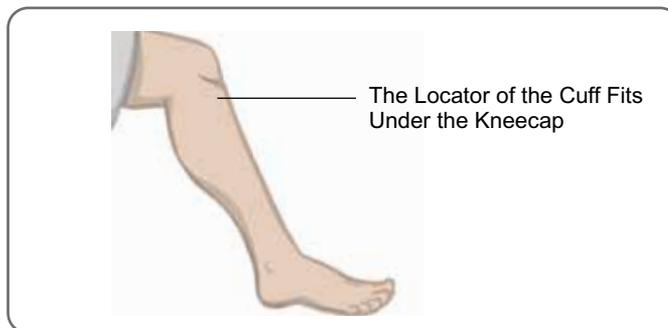


Figure 6-11: Recommended Knee Angle for Positioning the Lower Leg Cuff

2. Make sure the electrodes are securely attached. Then, grasp the front of the Lower Leg Cuff by the cradle and tilt the bottom of the cuff up. Slide the locator up your leg until it rests snugly and comfortably below your kneecap. See Figure 6-12.



Figure 6-12: Positioning the Lower Leg Cuff on the Leg

3. Hold the locator in place and lower the Lower Leg Cuff until it rests flush against your leg.
4. Grasp the handle of the Lower Leg Cuff strap. See Figure 6-13. With your thumb on the cuff cradle, fasten the strap handle around the cradle. If using the small Lower Leg Cuff, you may need to use your other hand to stabilize the cuff on the leg.

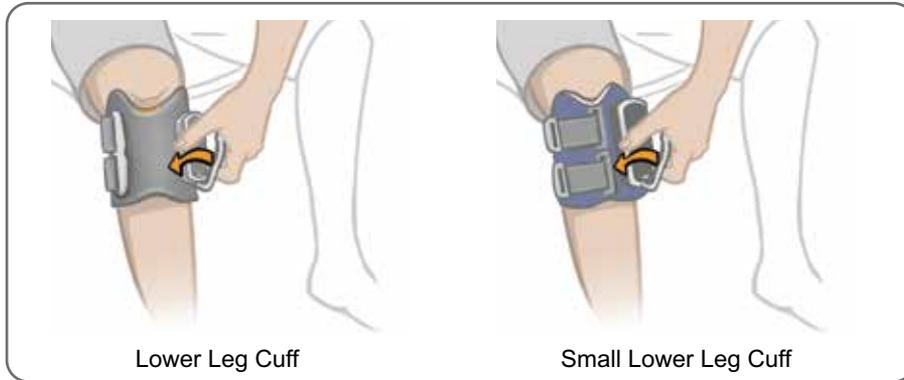


Figure 6-13: Fastening the Lower Leg Cuff Strap

5. Make sure the Lower Leg Cuff is correctly positioned. See Figure 6-14. Reposition the Lower Leg Cuff as necessary. Adjust the hook and loop fasteners to ensure a snug fit. See Figure 6-12.



Figure 6-14: Lower Leg Cuff fastened on the leg

Testing the Position of the Lower Leg Cuff

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

Removing the Lower Leg Cuff

1. Turn off the lower leg EPG.
2. Unhook the Lower Leg Cuff strap handle from the cradle.
3. Slowly lift the Lower Leg Cuff away from your skin.
4. If using hydrogel electrodes (Lower Leg Cuff users only), gently peel the electrodes from your skin, and reapply the electrode covers to the electrodes.

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

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 6-15. 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 6-16.
5. Fasten the straps by inserting the strap buckle into the hook attached to the Thigh Cuff panels. See Figure 6-16. If needed, tighten the strap tension by adjusting the strap fasteners.

- 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.

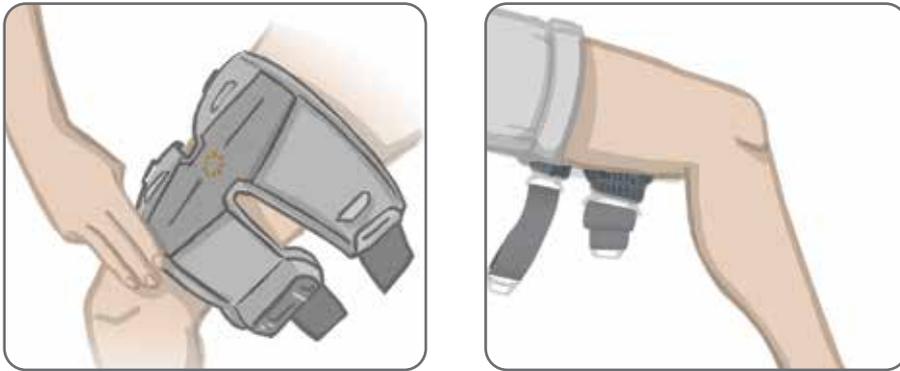


Figure 6-15: Correct Position of the Thigh Cuff Locator
(Left) Quadriceps Position Shown, (Right) Hamstrings Position Shown

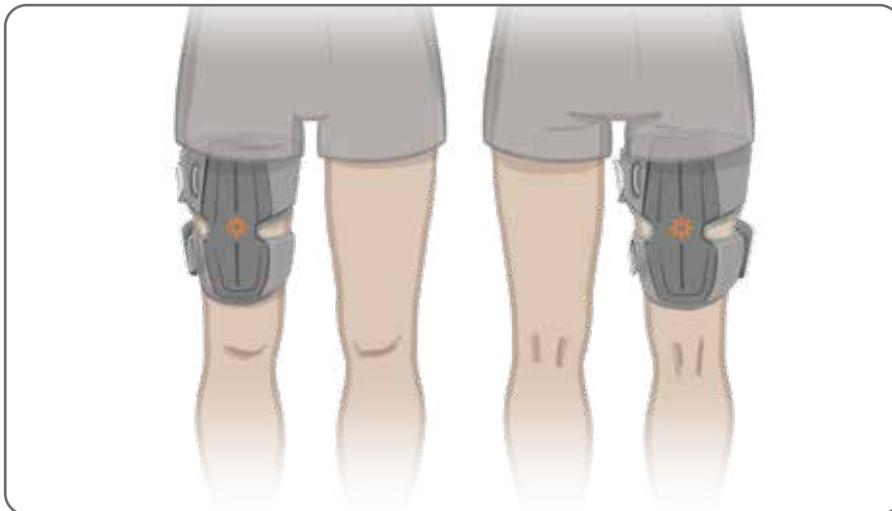


Figure 6-16: Correct Position of the Thigh Cuff
(Left) Quadriceps Fitting Position on Right Leg,
(Right) Hamstring Fitting Position on Right Leg

Testing the Position of the Thigh Cuff

1. Press the Power button on the thigh EPG. The EPG will give vibration and audio feedback when turned on.
2. Press and hold the Stim button on the thigh 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 thigh 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 6-17.
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 6-18. Refer to the foot image on the pressure sensor for positioning.

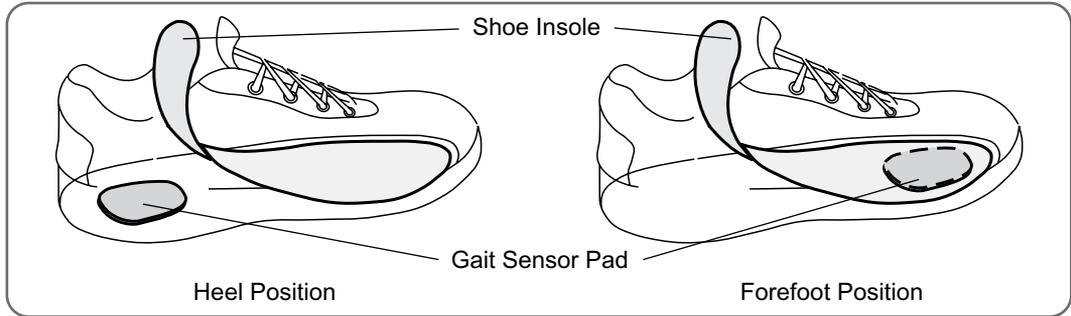


Figure 6-17: Placement of the Foot Sensor Pad

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

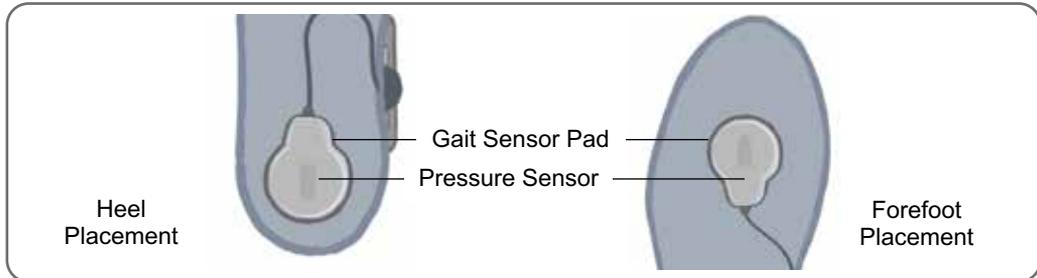


Figure 6-18: Positioning the Foot Sensor in the Shoe

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 6-19.
5. Cover the pressure sensor with the insole. Tuck any excess wire under the insole. See Figure 6-19.



Figure 6-19: 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 lower leg EPG, and/or thigh 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 lower leg EPG, and/or thigh EPG, and the Control Unit is turned off.
2. Switch shoes.
3. Register the new Foot Sensor to the lower leg EPG. Refer to the "Pairing Replacement Part Components" section in this guide for more information.

Note: For L300 Go System, Thigh Stand-Alone users who require the use of the optional Foot Sensor, register the new Foot Sensor to the thigh EPG. Refer to the "Pairing Replacement Part Components" section in this guide for more information.

Operating the L300 Go System

Turning the L300 Go System On/Off

To turn on the L300 Go System, press the Power button once on the lower leg EPG and/or thigh 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 L300 Go System, press and hold the Power button, for three seconds, on the lower leg EPG and/or thigh 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 lower leg EPG and/or thigh 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 the Lower Leg Cuff and Thigh Cuff, the Select button on the Control Unit can be used to toggle between the lower leg EPG and thigh 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 lower leg EPG and/or thigh EPG 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 for three seconds to activate Training mode. Press Stim button for 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 the Lower Leg 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 the Lower Leg Cuff and the Thigh Cuff):

1. The stimulation intensity will need to be adjusted separately for each connected EPG. Press the Select button on the Control Unit to select either the lower leg EPG or thigh 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 L300 Go 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.

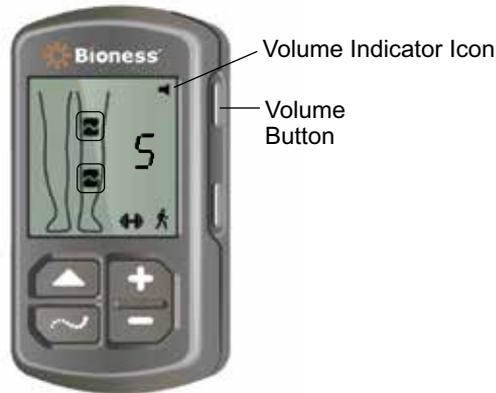


Figure 7-3: Volume Button on Control Unit

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.

Maintenance and Cleaning

Daily Maintenance and Storage

1. For the Hydrogel Electrodes, reapply the covers to the hydrogel electrodes when the Lower Leg Cuff is not in use.
2. For the Round Cloth Electrodes, detach the electrodes from the electrode bases when the Lower Leg Cuff is not in use. Store the Round Cloth Electrodes where they can air dry, to prevent mold growth.
3. For the Quick Fit Electrode or Steering, Round Cloth Electrode, detach the electrode from the Lower Leg Cuff when not in use. Store the Quick Fit Electrode or Steering Electrode where it can air dry, to prevent mold growth.
4. For the Thigh Cloth Electrodes, detach the electrodes from the Thigh Cuff panels when not in use. Store the Thigh Cloth Electrodes where they can air dry, to prevent mold growth.
5. Allow the Lower Leg Cuff and/or Thigh Cuff to air dry, when not in use.
6. Fully charge the lower leg EPG and/or thigh EPG batteries daily.
7. Check each component for wear or damage. Replace any components that appear old, worn, or damaged.

Charging

The lower leg EPG and/or thigh EPG batteries should be charged daily. Charging instructions can be found in the "Charging the L300 Go System" section on page 35 of this guide.

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

EPG Battery Maintenance

The lower leg EPG and thigh EPG have 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 the Bioness Client Support Department, at 800.211.9136, Option 3 (USA & Canada) or your local distributor.

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 L300 Go 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 8-1.

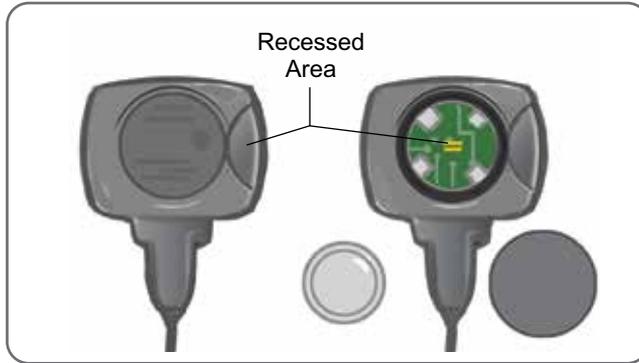


Figure 8-1: Replacing the Foot Sensor Battery

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.

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 L300 Go 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 Quick Fit Electrodes

You will need to replace the Quick Fit Electrodes at least every two weeks or sooner if they become worn.

⚠ Caution: Use only the electrodes supplied by Bioness.

 **Caution:** Do not use your L300 Go System without electrodes.

 **Caution:** Do not fold or twist the Quick Fit Electrode.

To replace the Quick Fit Electrodes: (See Figure 8-3)

1. Make sure the lower leg EPG is turned off.
2. Gently remove the used Quick Fit Electrode from the Lower Leg Cuff.
3. Wet the Quick Fit Electrodes with water until they are saturated.
4. With a cloth, gently wipe or blot excess water off the electrode.
5. Align the orange and blue snaps on the Quick Fit Electrode with the orange and blue plug holes on the Lower Leg Cuff.
6. Press firmly to snap the Quick Fit Electrode into the Lower Leg Cuff.



Figure 8-3: Replacing the Quick Fit Electrode

Remove and re-wet the entire Quick Fit Electrode every time you remove the Lower Leg Cuff from your leg for more than one hour, and after every three to four hours of use. When wetting the Quick Fit Electrode, always remove it from the Lower Leg Cuff.

If the Quick Fit Electrode dries out, your response to the stimulation may change. If you need to adjust stimulation intensity more often than usual, try re-wetting or replacing the electrode.

Note: When not in use, store the Quick Fit Electrode where it can air dry.

Replacing the Round Cloth Electrodes

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

 **Caution:** Use only Round Cloth Electrodes supplied by Bioness.

 **Caution:** Do not use your L300 Go System without electrodes.

To replace the Cloth Electrodes:

1. Make sure the lower leg EPG is turned off.
2. Gently pull the used Round Cloth Electrodes from the electrode bases. Be careful not to detach the electrode bases from the Lower Leg Cuff.
3. If necessary, clean the electrode bases with a damp cloth. Do not use a chemical-based cleaning substance.
4. Wet the Round Cloth Electrodes with water until they are saturated. See Figure 8-4.
5. With a cloth, gently wipe or blot excess water off the back (side with the snap) of the electrodes. See Figure 8-4.
6. Attach the Round Cloth Electrodes to the electrode bases. See Figure 8-5. For regular Lower Leg Cuff users make sure the Cuff Snap Covers are in place.

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

If the Round 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.

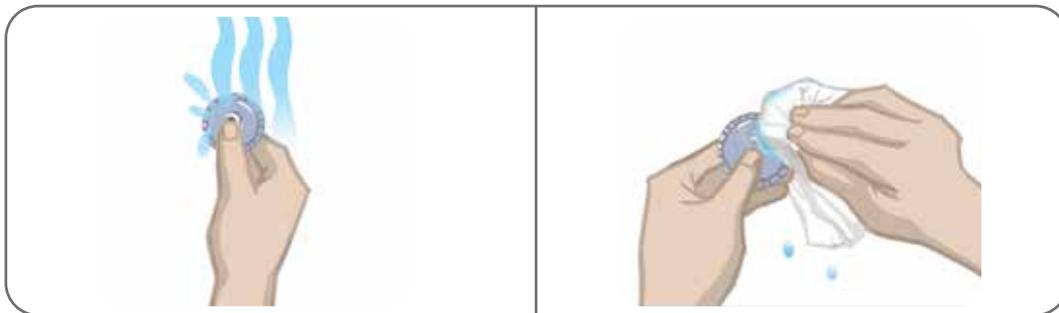


Figure 8-4: Wetting and Removing Excess Water



Figure 8-5: Attaching the Cloth Electrodes

Note: When not in use, store the Round Cloth Electrodes where they can air dry.

Replacing the Hydrogel Electrodes

For Lower Leg Cuff users the Hydrogel Electrodes are one of the electrode options for home use. You need to replace the hydrogel electrodes at least every two weeks.

⚠ Caution: Use only Hydrogel Electrodes supplied by Bioness.

⚠ Caution: Do not use your L300 Go System without electrodes.

To replace the Hydrogel Electrodes: (See Figure 8-6)

1. Make sure the lower leg EPG and Control Unit are turned off.

2. Gently pull the used Hydrogel Electrodes from the electrode bases. Be careful not to detach the electrode bases from the Lower Leg Cuff.
3. If necessary, clean the electrode bases with a damp cloth. Do not use a chemical-based cleaning substance.
4. Separate the two new electrodes along the perforation.
5. Split the two-piece covers on each new electrode and discard them.
6. Attach the grid side of the electrodes to the electrode bases, then press firmly.
7. Remove the covers from the electrodes.

Note: Save the covers to protect the electrodes between uses. When reapplying the covers, make sure the Bioness logo faces up.

Note: If the electrode gel becomes dry, replace with a new electrode set.

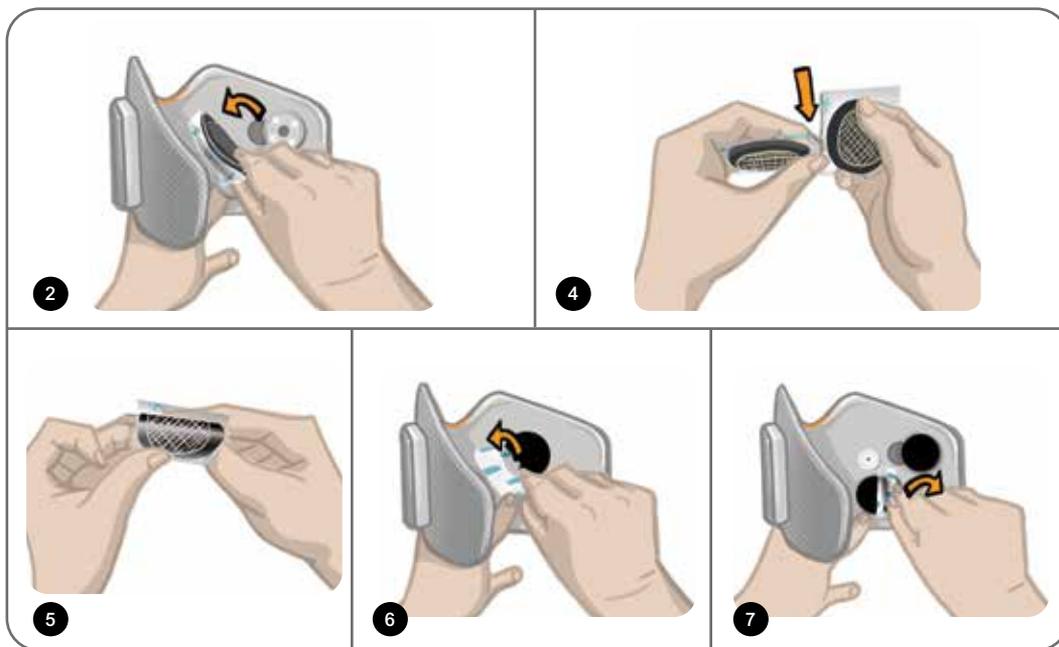


Figure 8-6: Replacing the Hydrogel Electrodes

Replacing the Electrode Bases

Depending on use, it may be necessary to replace the electrode bases after one year of use. Contact Bioness to purchase replacement electrode bases.

For regular Lower Leg Cuff users, if you are switching from hydrogel to cloth electrodes, or from cloth electrodes to hydrogel electrodes, you will need to be seen by a trained clinician for a first fitting. Your clinician will need to fit the electrode bases and adjust your stimulation settings.

To replace the electrode bases:

1. If your clinician installed wire concealers over the electrode base wires, remove the wire concealers.
2. Mark the position of the used electrode bases on the cuff liner with a permanent marker. See Figure 8-7.
3. Disconnect the electrode base snaps from the plug holes. See Figure 8-8.

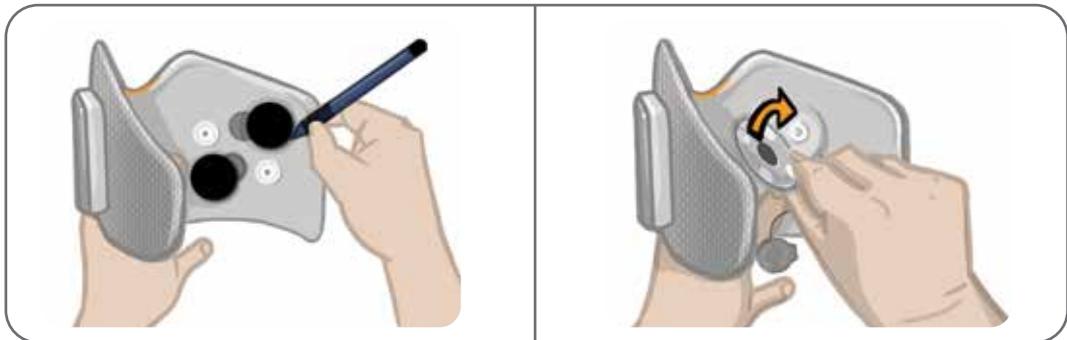


Figure 8-7: Mark Position of Electrode Base (Left)
Disconnect Electrode Base Snaps (Right)

4. Remove the used electrode bases from the cuff. See Figure 8-8.
5. Attach the new electrode bases where the previous bases were attached. See Figure 8-9.
6. Connect the electrode base snaps to the plug holes. See Figure 8-9.

7. Recover the wires and snaps with the wire concealers, if desired.

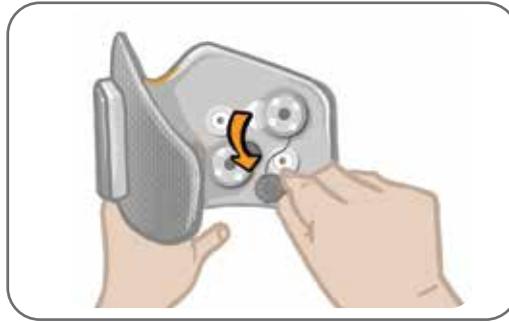


Figure 8-8: Removing the Used Electrode Bases

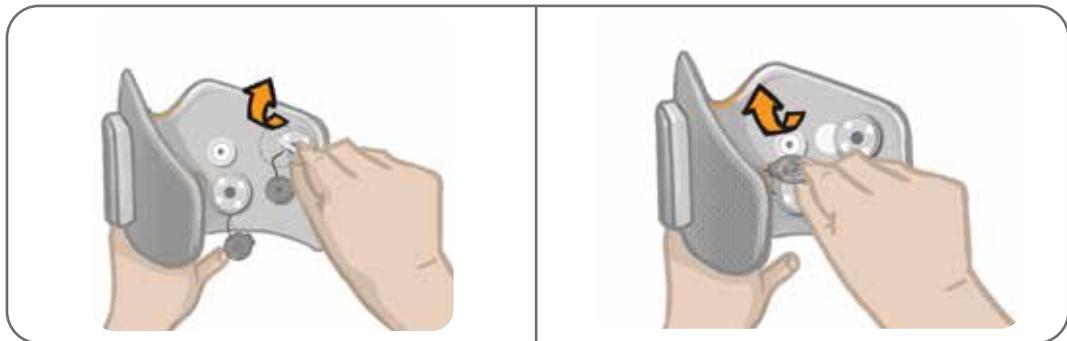


Figure 8-9: Attaching New Electrode Bases (Left)
Connecting Electrode Base Snaps (Right)

Replacing the Steering Electrodes

You will need to replace the Steering Electrodes at least every two weeks or sooner if they become worn.

⚠ Caution: Use only the electrodes supplied by Bioness.

⚠ Caution: Do not use your L300 Go System without electrodes.

⚠ Caution: Do not fold or twist the Steering Electrode.

To replace the Steering Electrodes: (See Figure 8-10)

1. Make sure the lower leg EPG and Control Unit are turned off.
2. Gently remove the used Steering Electrode from the Lower Leg Cuff.
3. Wet the electrode with water until they are saturated.
4. With a cloth, gently wipe or blot excess water off the electrode.
5. Align the four snaps on the Steering Electrode with the four plug holes on the Lower Leg Cuff.
6. Press firmly to snap the Steering Electrode into the Lower Leg Cuff.

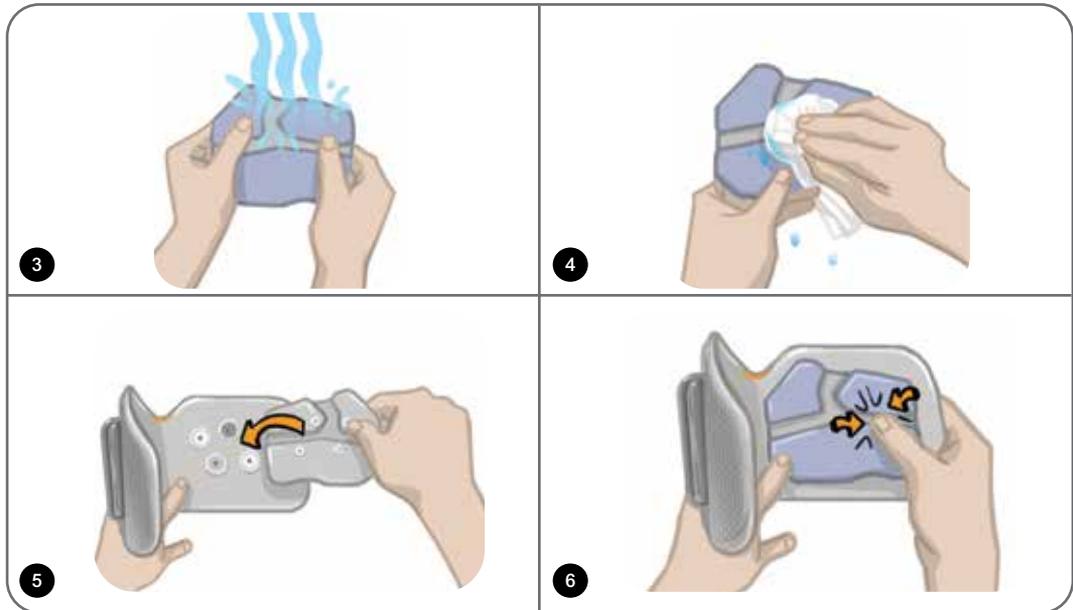


Figure 8-10: Replacing the Steering Electrode

Remove and re-wet the entire Steering Electrode every time you remove the Lower Leg Cuff from your leg for more than one hour, and after every three to four hours of use. When wetting the Steering Electrode, always remove it from the Lower Leg Cuff.

If the Steering Electrode dries out, your response to the stimulation may change. If you need to adjust stimulation intensity more often than usual, try re-wetting the electrode.

Note: When not in use, store the Steering Electrode where it can air dry.

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 L300 Go System without the electrodes attached.

To replace the Thigh Cloth Electrodes: (See Figure 8-11)

1. Make sure the thigh 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.

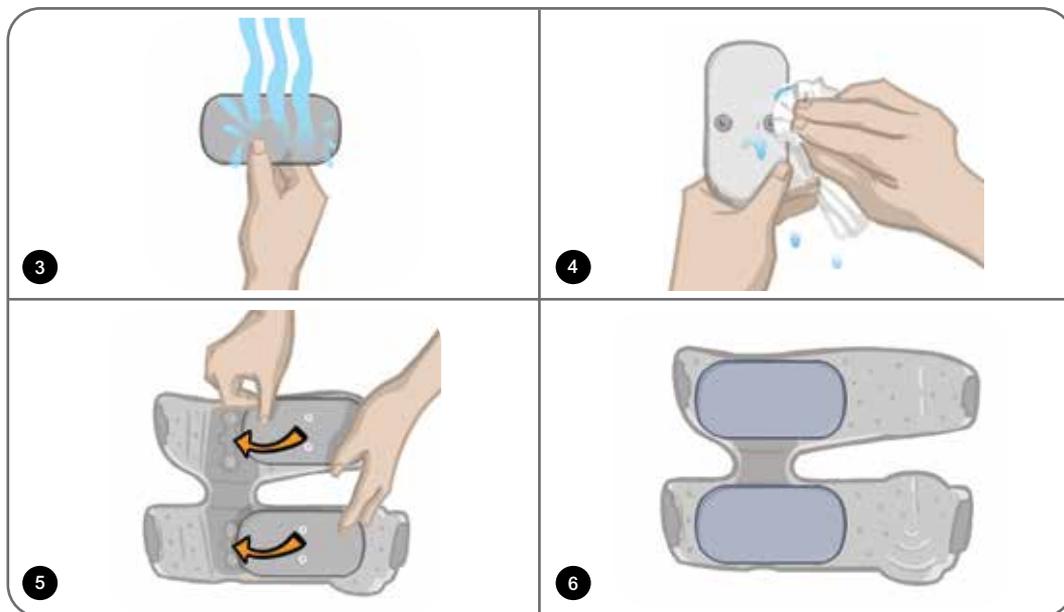


Figure 8-11: Replacing the Thigh Cloth Electrodes

Removing the EPG

The lower leg EPG and the thigh EPG should only be removed for maintenance and to clean the Lower Leg Cuff and/or 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 8-12.
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.

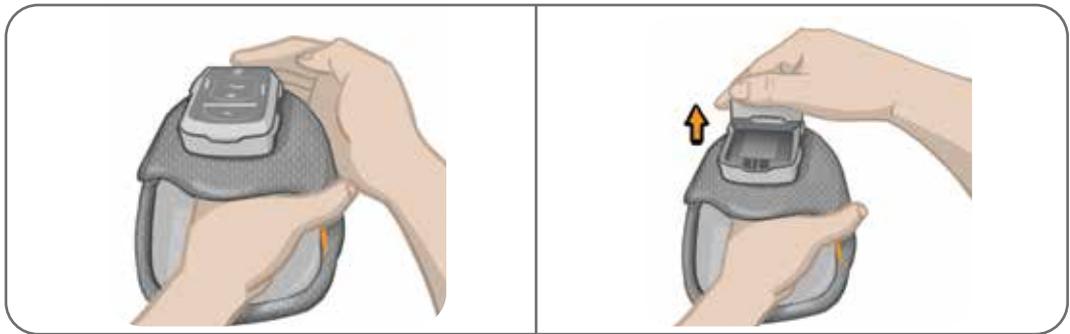


Figure 8-12: Removing the EPG

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 8-13.
2. Slide the thigh strap out away from the Thigh Cuff to detach.



Figure 8-13: 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 8-14.
3. The strap buckle will snap into the Thigh Cuff panel hook.

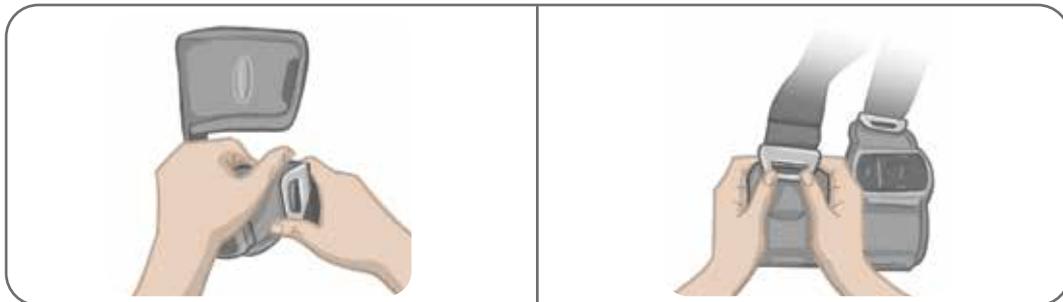


Figure 8-14: Reattaching the Thigh Straps

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 8-15.

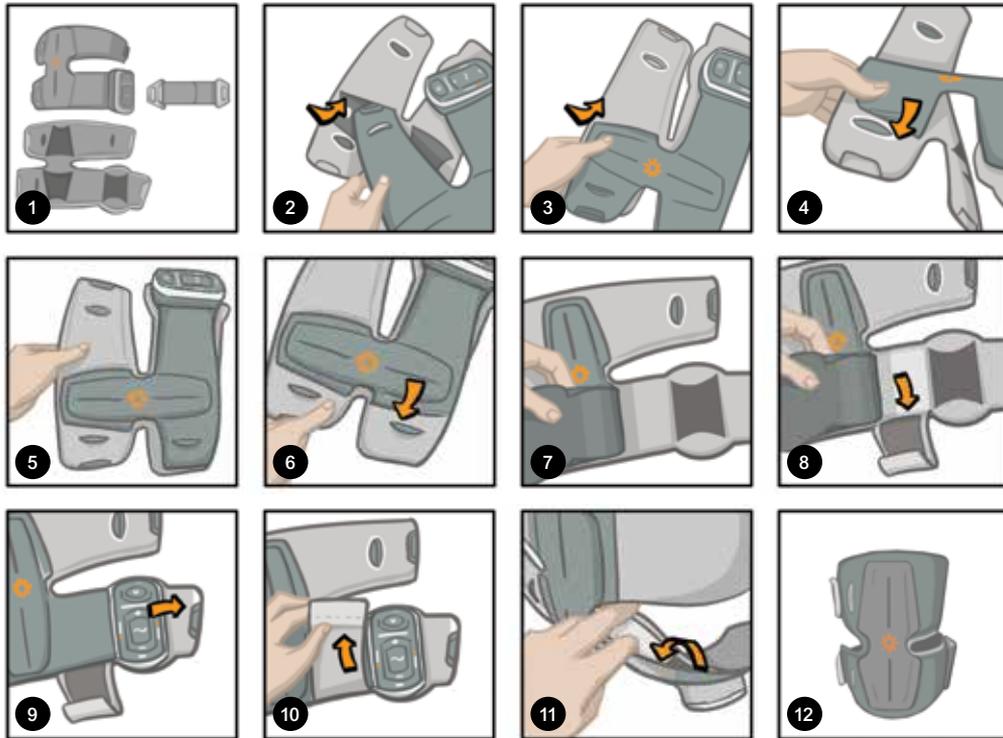


Figure 8-15: Attaching the Home Use Thigh Cuff Cover

The system consists of mechanical and electronic components. Inadequate handling of those components may cause health hazards. Disposal of the system must comply with local regulations.

Cleaning Your L300 Go System Components

All L300 Go System components may be cleaned by carefully wiping them with a damp cloth. The electrical components are not waterproof. **Do not immerse them in water.**

Cleaning the Lower Leg Cuff

The Lower Leg Cuff is the only component that can be immersed in water to clean. Clean the Lower Leg Cuff when replacing the electrodes.

To clean the Lower Leg Cuff:

1. Remove the lower leg EPG from the cradle.
2. Gently remove the electrodes from the electrode bases. Leave the electrode bases and snap covers attached to the Lower Leg Cuff. For hydrogel electrodes, reapply the electrode covers.

Note: For individuals using the Steering Electrode or Quick Fit Electrode, remove the electrode directly from the Lower Leg Cuff plug holes.

3. Immerse the Lower Leg Cuff for 30 minutes in lukewarm water and mild detergent. Do not use a washing machine.
4. Rinse the Lower Leg Cuff thoroughly under running water.
5. Immerse the Lower Leg Cuff for an additional 15 minutes in clean, lukewarm water.
6. Rinse the Lower Leg Cuff again under running water.
7. Gently blot excess moisture from the Lower Leg Cuff with a towel. Do not wring the cuff. Lay the cuff flat in the shade to air dry. (Do not hang dry.) Drying time will vary from four to twelve hours depending on climate and humidity. For faster drying, place the cuff in front of a circulating cold-air fan. Do not use a hot-air dryer or other heat source to dry.
8. When the Lower Leg Cuff is completely dry, insert the lower leg EPG into the cradle and attach the electrodes.

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 L300 Go 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 thigh 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 Control Unit and EPG

The Control Unit, lower leg EPG, and thigh EPG 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 Bioness 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 L300 Go System components.

Pairing Replacement Part Components

The L300 Go 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 cuff.
3. Turn on the EPG by pressing the Power button on the EPG.

Pairing a Lower Leg EPG to a Thigh EPG

1. Make sure both EPGs are turned on.
2. Place the Lower Leg Cuff and Thigh Cuff, with EPGs attached, within a few inches of each other.
3. Simultaneously press and hold for three seconds the Plus and Minus buttons on the lower leg EPG. The EPG will go into pairing mode and the EPG State Indicator Light will display an alternating green, yellow, and red light.
4. Immediately simultaneously press and hold for three seconds the Plus and Minus buttons on the thigh EPG. The EPG will go into pairing mode and EPG State Indicator Light will display an alternating green, yellow, and red light.

5. Once paired, the EPG State Indicator Light will flash green on both EPGs.

Pairing a New Control Unit to the EPG

1. For individuals using the Lower Leg Cuff, make sure the lower leg EPG is turned on. For individuals using the Thigh Stand-Alone Cuff, make sure the thigh EPG is turned on.
2. Place the 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. For individuals using the Lower Leg Cuff, simultaneously press the Plus and Minus buttons on the lower leg EPG. The EPG will go into pairing mode and the EPG State Indicator Light will display an alternating green, yellow, and red light.
5. For individuals using the Thigh Stand-Alone Cuff, simultaneously press and hold for three seconds the Plus and Minus buttons on the thigh 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. The connected EPG/s will appear on the display screen on the Control Unit.

Pairing a New Foot Sensor to the EPG

1. For individuals using the Lower Leg Cuff, make sure the lower leg EPG is turned on. For individuals using the Thigh Stand-Alone Cuff, make sure the thigh EPG is turned on.
2. Place the 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. For individuals using the Lower Leg Cuff, simultaneously press the Plus and Minus buttons on the lower leg EPG. The EPG will go into pairing mode and the EPG State Indicator Light will display an alternating green, yellow, and red light.
6. For individuals using the Thigh Stand-Alone Cuff, simultaneously press and hold for three seconds the Plus and Minus buttons on the thigh EPG. The EPG will go into pairing mode and the EPG State Indicator Light will display an alternating green, yellow, and red light.
7. Once paired the EPG State Indicator Light on the EPG will flash green and the indicator light on the Foot Sensor will flash green.
8. 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 4-6.

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 Bioness Technical Support at 800.211.9136, Option 3 (USA & Canada) or your local distributor.

Error Code Descriptions

When an error occurs with the L300 Go 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 L300 Go System and contact Bioness.
E2	Overstimulation Fault	Stimulation is being delivered at a higher frequency than expected. This is a possible hardware issue. Stop using the L300 Go System and contact Bioness.
E3	Understimulation Fault	Stimulation is being delivered at a lower intensity than expected. This is a possible hardware issue. Stop using the L300 Go System and contact Bioness.
E4	Understimulation Fault	Stimulation is being delivered at a lower frequency than expected. This is a possible hardware issue. Stop using the L300 Go System and contact Bioness.

Error Code	Description of Error	Solution
E5	Charge Imbalance	This is a possible hardware issue. Stop using the L300 Go System and contact Bioness.
E6	Communication Fault	The Foot Sensor and lower leg 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 L300 Go System and contact Bioness.
E10	Parameter Corrupted	The L300 Go System needs to be reprogrammed. Stop using the L300 Go System and contact Bioness.
E11, E22	Incorrect Cuff Fault	Make sure EPG is correctly inserted into the EPG cradle on the cuff. For users with both the Lower Leg Cuff and Thigh Cuff, make sure the correct EPG is inserted into the EPG cradle. The lower leg EPG must be in the Lower Leg Cuff and the thigh EPG must be in the Thigh Cuff for the system to function.
E12	Shorted Electrode Fault	Electrodes are shorted, cuff has an electrical short, or the hardware is not functioning correctly. Stop using the L300 Go System and contact Bioness.
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 cuff.
E15	EPG Battery Empty	Charge the EPG. Refer to the "Charging the L300 Go 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 cuff. Remove the cuff before starting the test.

To test the functionality of the alert indicator:

1. Remove the electrodes from the 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 Bioness Technical Support at 800.211.9136, Option 3 (USA & Canada) or your local 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 cuff?

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

What if my ankle is not moving (or my foot does not lift satisfactorily), and the L300 Go System is not indicating any errors?

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

- Reposition the L300 Go Cuff.
- Make sure the strap is snug and the Lower Leg Cuff is secure.
- Turn on the lower leg EPG by pressing the Power button on the EPG.
- Test the placement of the Lower Leg 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.

How come my knee is not moving satisfactorily, and the L300 Go 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 thigh 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 L300 Go 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 Bioness for a replacement part.

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

- Stop using the L300 Go System immediately.
- Contact your clinician or dermatologist, and Bioness Technical Support at 800.211.9136, Option 3 (USA & Canada) or your local 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 L300 Go 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<p>Transport and Storage Conditions:</p> <ul style="list-style-type: none"> •Temperature: -25°C to +55°C •Relative humidity: 5% to 90% •Pressure: 20 kPa to 106 kPa <p>Operating Conditions:</p> <ul style="list-style-type: none"> •Temperature: 5°C to 40°C •Relative humidity: 5% to 75% •Operating pressure: 80 kPa to 106 kPa
Ingress Protection Rating	<p>IP22</p> <p>Protection Against:</p> <ul style="list-style-type: none"> •Object Sized >12.5mm •Dripping Water When Tilted up to 15° <p>Effective Against:</p> <ul style="list-style-type: none"> •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	<ul style="list-style-type: none"> •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	<ul style="list-style-type: none"> • Status Indicator Light and Battery Indicator Light • Audio and vibration feedback • “Beeps” for audio alerts
Dimensions	<ul style="list-style-type: none"> • Length: 82 mm (3.2 in.) • Width: 47 mm (1.9 in.) • Height: 15 mm (0.6 in.)
Weight	60 grams
Environmental Ranges	<p>Transport and Storage Conditions:</p> <ul style="list-style-type: none"> • Temperature: -25°C to +55°C • Relative humidity: 5% to 90% • Pressure: 20 kPa to 106 kPa <p>Operating Conditions:</p> <ul style="list-style-type: none"> • Temperature: 5°C to 40°C • Relative humidity: 5% to 75% • Operating pressure: 80 kPa to 106 kPa
Ingress Protection Rating	<p>IP42</p> <p>Protection Against:</p> <ul style="list-style-type: none"> • >1mm Solids Ingress • Dripping Water When Tilted up to 15° <p>Effective Against:</p> <ul style="list-style-type: none"> • 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)	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	<ul style="list-style-type: none"> •Length: 65 mm (2.6 in.) •Width: 50 mm (2 in.) •Height: 10 mm (0.4 in.)
Weight	25 grams

Environmental Ranges	<p>Transport and Storage Conditions:</p> <ul style="list-style-type: none"> •Temperature: -25°C to +55°C •Relative humidity: 5% to 90% •Pressure: 20 kPa to 106 kPa <p>Operating Conditions:</p> <ul style="list-style-type: none"> •Temperature: 5°C to 40°C •Relative humidity: 5% to 75% •Operating pressure: 80 kPa to 106 kPa
Ingress Protection Rating	<p>IP52</p> <p>Protection Against:</p> <ul style="list-style-type: none"> •Dust •Dripping water when tilted up to 15° <p>Effective Against:</p> <ul style="list-style-type: none"> •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

Lower Leg Cuff Specifications		
	Regular Lower Leg Cuff	Small Lower Leg Cuff
Material	Fabric-Polymer	Fabric-Polymer
Fits Limb Circumference	29–51 cm (11–20 in.)	22–31 cm (8-12.2 in.)
Dimensions	<ul style="list-style-type: none"> •Height: 160 mm (6.3 in.) •Width: 100 mm (3.9 in.) •Depth: 125 mm (4.9 in.) 	<ul style="list-style-type: none"> •Height: 110.5 mm (4.5 in.) •Width: 80 mm (3 in.) •Depth: 100 mm (4 in.)
Weight	Approximately 150 grams (4.8 oz)	Approximately 104 grams (3.6 oz.)

Thigh Cuff Specifications	
Material	Fabric-Polymer
Fits Limb Circumference	<ul style="list-style-type: none"> •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): <ul style="list-style-type: none"> •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	<ul style="list-style-type: none"> •USB 1: 2.1 A •USB 2: 1.0 A
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Note: Do not use the L300 Go System while charging. Do not wear the Lower Leg Cuff or Thigh Cuff while charging.

Electrode and Electrode Base Specifications—Lower Leg Cuff	
Hydrogel Electrodes	<ul style="list-style-type: none"> •Two, 45-mm (1.77-in.) diameter, surface area 15.8 cm² hydrogel electrodes •Transport and storage temperature: 5°C to 27°C (41.0°F to 80.6°F) •Relative humidity: 35% to 50% <p>Note: Use only electrodes provided by Bioness Inc</p>
Hydrogel Electrode Bases, 45mm	<ul style="list-style-type: none"> •Two, 45-mm (1.77-in.) diameter, relocatable polymer electrode bases for individual fitting
Cloth Electrode Bases, 45mm	<ul style="list-style-type: none"> •Two, 45-mm (1.77-in.) diameter, relocatable Thermoplastic elastomer (TPE) electrode bases
Round Cloth Electrodes, 45mm	<ul style="list-style-type: none"> •Two, 45-mm (1.77-in.) diameter, relocatable non-woven polymer fabric (80% viscose, 20% polypropylene); conductive layer, stainless steel •Male snap connector •Low Density Polyethylene (LDPE) 10% + Ethylene Vinyl acetate (EVA) •Surface Area: 15.8 cm²
Quick Fit Electrode (right - A and left - A)	<ul style="list-style-type: none"> •Non-woven polymer fabric (80% viscose, 20% polypropylene); conductive layer, stainless steel •Male snap connector •Low Density Polyethylene (LDPE) 10% + Ethylene Vinyl acetate (EVA) •Surface area: 43.2 cm² \ 55.3 cm²

Steering Electrode (right and left)	<ul style="list-style-type: none"> • Non-woven polymer fabric (80% viscose, 20% polypropylene); conductive layer, stainless steel • Male snap connector • Low Density Polyethylene (LDPE) 10% + Ethylene Vinyl acetate (EVA) • Surface area: 21.2 cm² (proximal cathode) \ 19.5 cm² (distal cathode) \ 56.9 cm² (anode)
Small Round Cloth Electrodes, 36mm	<ul style="list-style-type: none"> • Two, 36-mm (1.41-in.) diameter, relocatable non-woven polymer fabric (80% viscose, 20% polypropylene); conductive layer, stainless steel • Male Snap Connector • Low Density Polyethylene (LDPE) 10% + Ethylene Vinyl acetate (EVA) • Surface area: 10.1 cm²
Small Electrode Bases, 36mm	<ul style="list-style-type: none"> • Two, 36-mm (1.41-in.) diameter, relocatable Thermoplastic elastomer (TPE) electrode bases
L300 Quick Fit Electrode, Small A	<ul style="list-style-type: none"> • Non-woven polymer fabric (80% viscose, 20% polypropylene); conductive layer, stainless steel • Male snap connector • Low Density Polyethylene (LDPE) 10% + Ethylene Vinyl acetate (EVA) • Surface area: 31.1 cm² \ 20.6 cm²
L300 Quick Fit Electrode, Small B	<ul style="list-style-type: none"> • Non-woven polymer fabric (80% viscose, 20% polypropylene); conductive layer, stainless steel • Male snap connector • Low Density Polyethylene (LDPE) 10% + Ethylene Vinyl acetate (EVA) • Surface area: 19.9 cm² \ 28.2 cm²

Thigh Cuff Cloth Electrode Specifications

Material	Non-woven cloth Note: Use only electrodes provided by Bioness Inc.
Dimensions	Proximal Oval: 130 mm x 75 mm Distal Oval: 120 mm x 63 mm

Wireless Information

System Characteristics

The L300 Go 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 L300 Go 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 L300 Go System was designed and tested to not have interference from other RF devices (including other L300 Go Systems, WiFi networks, Cellular Devices, Microwaves and other Bluetooth® devices).

L300 Go 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 L300 Go System is affected by other equipment, the user should turn the L300 Go System off, and move away from the interfering equipment.

Electromagnetic compatibility (EMC) Information

Guidance and Manufacturer's Declaration—Electromagnetic Emissions		
The L300 Go System is intended for use in the electromagnetic environment specified below. The customer or the user of the L300 Go System should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment — Guidance
RF emissions CISPR 11	Group 1	The L300 Go 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 L300 Go 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 L300 Go System is intended for use in the electromagnetic environment specified below. The customer or the user of the L300 Go 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 L300 Go 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.
<p>Note: UT is the AC mains voltage prior to application of the test level.</p>			

Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The L300 Go System is intended for use in the electromagnetic environment specified below. The customer or the user of the L300 Go 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 L300 Go 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: $d = 1.2\sqrt{P}$
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: $d = 0.4\sqrt{P}$, 80–800 MHz range $d = 0.7\sqrt{P}$, 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 L300 Go System is used exceeds the applicable RF compliance level above, the L300 Go 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 L300 Go 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 L300 Go System

The L300 Go System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the L300 Go System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the L300 Go 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 0.4\sqrt{P}$	800 MHz to 2700 MHz $d = 0.7\sqrt{P}$
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.



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MEDICAL - APPLIED CURRENT/ENERGY
EQUIPMENT AS TO ELECTRICAL SHOCK,
FIRE AND MECHANICAL HAZARDS ONLY IN
ACCORDANCE WITH:
ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012)
CAN/CSA-C22.2No. 60601-1 (2014)
E489148