bioventus®

Innovations For Active Healing

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EC REP

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Rx Only

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CLASSIFIED C UL US

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

L100 Go®

Functional Electrical Stimulation System

USER'S GUIDE

bioness®

A Bioventus Rehab Company

Rx Only

Bioness Patents
This product is covered by one or more US and international patents. Additional patents pending.

Disclaimer
Bioness Inc. and its affiliates shall not be liable for any injury or damage suffered by any person, either directly or indirectly, as a result of the unauthorized use or repair of Bioness Inc. products. Bioness Inc. does not accept any responsibility for any damage caused to its products, either directly or indirectly, as a result of use and/or repair by unauthorized personnel.

Environmental Policy

Service personnel are advised that when changing any part of the L100 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.

List of Symbols

	Caution
	Warning
	Double Insulated (Equivalent to Class II of IEC 536)
	Type BF Applied Part(s)
	Non-Ionizing Radiation
	Date of Manufacture
	Manufacturer
	This Product Must Not Be Disposed of with Other Household Waste
	Refer to Instruction Manual/Booklet
REF	Re-Order Number
LOT	Lot Number
SN	Serial Number
	Single Patient Use - To Prevent Cross Contamination
	Single Patient Multiple Use
MD	Medical Device
	Storage Temperature
	Humidity Limitation
	Atmospheric Pressure Limitation
	Keep Dry
IP42	Degree of Ingress Protection (for EPG)
LT	Left
RT	Right
	Underwriters Laboratories (UL) is an independent, globally recognized agency that certifies, validates, tests, inspects and audits corporations and products.
EC REP	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.

The L100 Go System is designed to improve gait in people suffering from foot drop secondary to upper motor neuron pathology. This may include patients suffering from stroke, Cerebral palsy (CP), Traumatic Brain Injury (TBI), Spinal Cord Injury (SCI), and Multiple Sclerosis (MS) that are otherwise ambulatory. The L100 Go System consists of a Lower Leg Cuff with an Electronic Pulse Generator (EPG). These components communicate wirelessly to electrically stimulate muscles in the affected leg to raise the foot.

The intended purpose of the L100 Go System when used in “gait mode” is to improve gait in patients with foot drop. When used in “training mode” the intended purpose of the L100 Go System is to allow correct fitting of the device and also to train muscles using pre-set stimulation cycles when the patient is not walking.

The L100 Go System is designed to be used in a Residential/Home Healthcare environment. The intended user of the L100 Go system is the patient. It is intended that a trained clinician configures the system and ensures optimal fitting to the patient. If required, adult caregivers and/or healthcare professionals may assist the patient with using the L100 Go System.

Note: The L100 Go System uses L300 Go System components with L300 Go labels with the exception of Lower Leg Cuff and personal panel. In many sections of this guide, statements about the L100 Go System are based on testing and evaluation of the L300 Go System components.

Lower Leg Cuff with EPG

Figure 1-1: L100 Go System

This L100 Go User's Guide describes:

- Important safety information about the L100 Go System.
- The components of the L100 Go System.
- How to set up, operate, and maintain your L100 Go System.
- Troubleshooting information.

Be sure to review this guide with your clinician before using your L100 Go System. If you have any questions contact Bioness Technical Support at 800.211.9136, Option 3. You can also visit the Bioness website at: www.bioness.com.

Caution: Do not put on or operate the L100 Go System before being properly fitted and trained by a certified clinician.

Safety Information

Indications for Use

The L100 Go System is indicated for use in adults with foot drop secondary to upper motor neuron pathology in patients otherwise ambulatory. The device electrically stimulates muscles in the affected leg to provide ankle dorsiflexion of the foot; thus, it also may improve gait.

Contraindications

- Patients with a demand-type cardiac pacemaker, defibrillator or any electrical implant should not use the L100 Go System.

⚠ Warnings

- The L100 Go System should not be used on a leg where a metallic implant is directly underneath the electrodes.
- The L100 Go System should not be used on a leg where a cancerous lesion is present or suspected.
- The L100 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 should not be worn over swollen, infected, or inflamed areas or skin eruptions, such as phlebitis, thrombophlebitis, and varicose veins.
- Simultaneous connection of the L100 Go System to the patient and high-frequency surgical equipment may result in skin burns where the stimulator electrodes touch and damage to the EPG.

- Do not use the L100 Go System within three feet of short wave or microwave therapy equipment. Such equipment may produce instability in the EPG output.
- The L100 Go System should only be configured by an authorized clinician.
- In case of any inconvenience, turn off stimulation and remove the Lower Leg Cuff. If the stimulation cannot be turned off, remove the cuff to stop stimulation.

Precautions

- Inflammation in the region of the Lower Leg Cuff may be aggravated by motion, muscle activity, or pressure from the cuff. Stop using the L100 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 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 patients 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 L100 Go System without electrodes.
- After removing the Lower Leg 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 L100 Go System until any inflammation is gone.
- Stop using the L100 Go System and consult your clinician if stimulation does not start at the correct time during gait.

- Turn off the L100 Go System when at a refueling place. Do not use the L100 Go System near flammable fuel, fumes, or chemicals.
- Only your treating clinician should determine electrode placement and stimulation settings.
- Use only the L100 Go System electrodes supplied by Bioness Inc.
- Turn off the L100 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 L100 Go System during pregnancy has not been established.
- Skin problems, on the leg where the Lower Leg Cuff is worn, may be aggravated by the L100 Go System.
- Adult supervision and assistance should be provided for anyone needing help while using the L100 Go System.
- The patient is the intended operator of the L100 Go System.
- Protect all electronic components from contact with water, such as from sinks, bathtubs, shower stalls, rain, snow, etc.
- Do not leave the L100 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 L100 Go System. Contact Bioness if you experience a technical problem not covered in this guide.
- The Lower Leg Cuff is to be worn only on the leg of the patient for whom it is fitted. It should not be worn by anyone else or on any other part of the body.
- Turn off the L100 Go System before putting on the Lower Leg Cuff. Do not turn on the L100 Go System until the Lower Leg Cuff is fastened in place.
- Shut off the L100 Go System before driving, operating machinery, or performing any activity in which involuntary muscle contractions could injure you.

- Protect the L100 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 L100 Go System before undergoing any diagnostic or therapeutic medical procedure such as Xray examination, ultrasound, MRI, etc.
- Keep away from pets and pests. While not in use, keep away from children. Care should be taken when removing small parts from the system, which may be accidentally swallowed. If swallowed, consult a doctor immediately.
- Do not modify or alter the system in any way and only use Bioness supplied or approved components and parts.

Adverse Reactions

In the unlikely event that any of the following occurs, stop using your L100 Go System immediately and consult your physician:

- Signs of significant irritation or pressure sores where the Lower Leg 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 of the Lower Leg Cuff. To promote healthy skin with long-term use of the L100 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.
- Replace the electrodes at least every two weeks, even if they appear to be in good condition.
- Wet cloth based electrodes before use and after every 3-4 hours for optimal performance.

- After taking off the Lower Leg 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, make sure the electrodes uniformly contact the skin.
- Ventilate the skin by removing the Lower Leg Cuff for at least 15 minutes every three to four hours.

If skin irritation or a skin reaction occurs, stop using your L100 Go System immediately and contact your clinician or dermatologist. You can also contact Bioness Technical Support at 800.211.9136, Option 3. 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 medical device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established if within the European Union.

Chapter 3

Environmental Conditions that Affect Use

Radio Frequency (RF) Communication Information

Several components of the L100 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 L100 Go System

Conformity Certification

The L100 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 L100 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 L100 Go System before going through airport security. Wear loose clothing so that you can easily show the security person your L100 Go System. The L100 Go System will likely set off the security alarm. Be prepared to remove the L100 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 L100 Go System prescription.

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

Note: The L100 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 L100 Go system in flight.

Electromagnetic Emissions

The L100 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 L100 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 L100 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 L100 Go System before undergoing any diagnostic or therapeutic medical procedure such as Xray examination, ultrasound, Magnetic Resonance Imaging (MRI), etc.
- The L100 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 L100 Go System as replacement parts for internal components) may result in increased emissions or decreased immunity of the L100 Go System.
- The L100 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.

Chapter 4

L100 Go System Kits

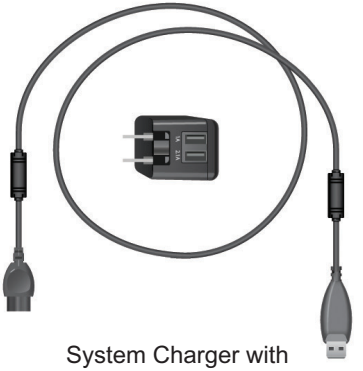
Contents

L100 Go System, Lower Leg

- Box Container
- Regular Lower Leg, Right or Left, with (Universal) Strap CE 2797
- Central Electronic Pulse Generator (EPG) CE 2797
- System Charger (with charging adapters) CE
- Magnetic Charging Cable CE
- L100 Go User's Guide

Regular Lower Leg FS
Cuff with EPG

Lower Leg Cuff Strap
(example shown)



System Charger with
Magnetic Charging Cord

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. 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.

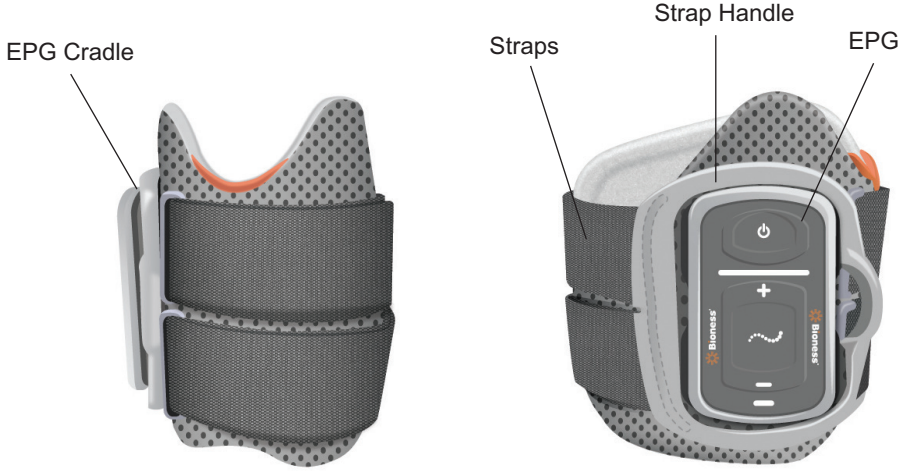


Figure 5-1: Lower Leg Cuff

Lower Leg 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.

Electrical stimulation can be controlled from controls on the EPG. The EPG snaps into the EPG cradle and should only be removed from the cradle for maintenance and when cleaning the cuffs.

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

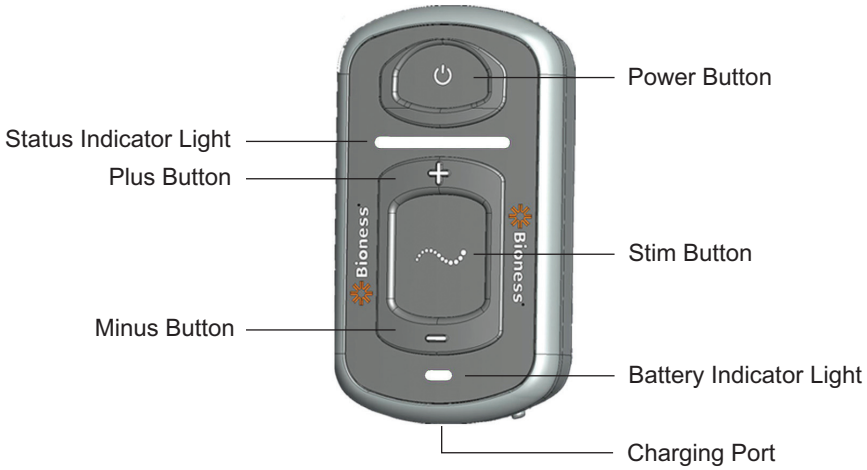


Figure 5-2: EPG

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

- An EPG button is pushed

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

The EPG provides vibration feedback when:

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

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

Table 5-1: EPG Displays

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

Table 5-2: EPG Button Functions

L100 Go System Operating Modes

The L100 Go System has two operating modes: gait and training.

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. Stimulation in the EPG(s) responds as programmed by the clinician.

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 motion sensors in the lower leg EPG. Stimulation is delivered in cycles pre-set by your clinician.

Training mode is utilized to cyclically activate and condition the muscles under the lower cuff. 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.

Lower Leg Cuff Electrodes and Electrode Bases

There are three 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.

With a regular L100 Go System the following electrodes and electrode bases can be used (See Figure 5-3):

- 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 L100 Go System without the electrodes attached to the Lower Leg Cuff.

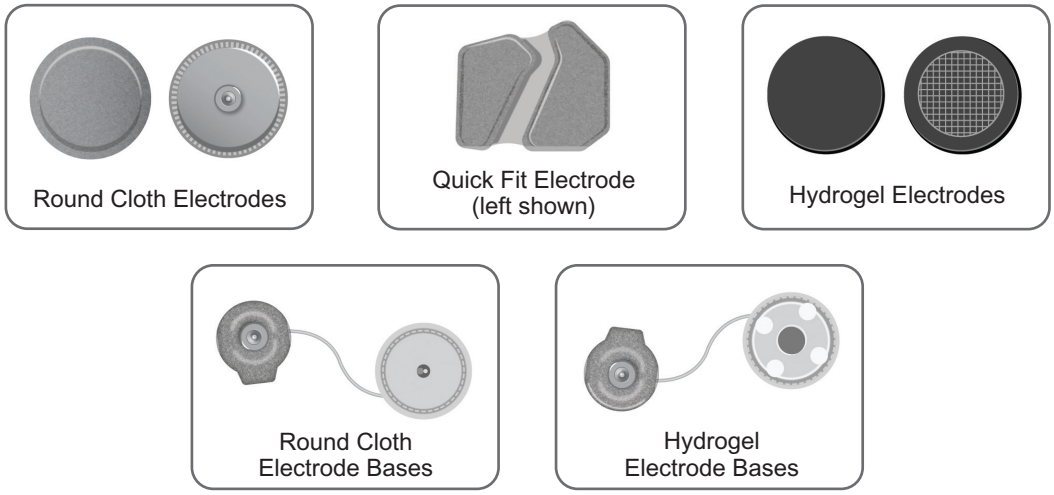


Figure 5-3: Electrodes and Bases for the Regular Lower Leg Cuff

System Charger Set

The system charger set includes a USB AC adapter, charging adapters for U.S. and international outlets, and a USB charging cable. The system charger set connects to a main power supply and is used to charge the EPG battery. See Figure 5-4.

Figure 5-4. System Charger Set

⚠ **Caution:** Use only the System Charger Set included in your L100 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

myBioness™ Mobile Application

The myBioness™ Mobile Application is an optional application that can be downloaded onto a mobile device (smart phone/tablet). More information is available in the user instructions provided with the myBioness™ Mobile Application. You may also contact Bioness Technical Support at 800.211.9136, (USA & Canada) or your local distributor to request a paper copy.

Setup Instructions

Charging the L100 Go System

The lower leg EPG is the only L100 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 Lower Leg Cuff(s).

To charge the L100 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 charging cable into the USB port on the AC adapter. See Figure 6-1.

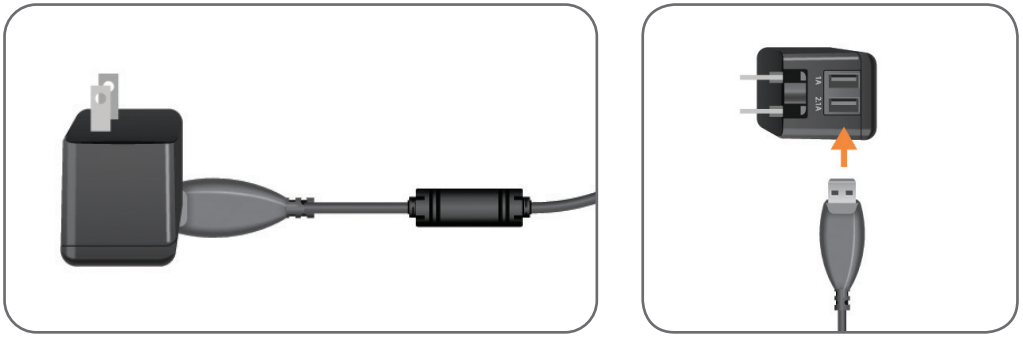


Figure 6-1: Inserting USB Charging Cable into AC Adapter

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

Figure 6-2: L100 Go System Charging Setup

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 L100 Go System Kit. Use of any other charger will damage the system.

⚠ Caution: Do not use the Lower Leg 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, always check your skin for signs of irritation. If any irritation is present, do not put on the Lower Leg Cuff and contact your clinician. Wait for complete healing before using the L100 Go System. For optimal stimulation, the skin under the Lower Leg 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 L100 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 is 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. 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.

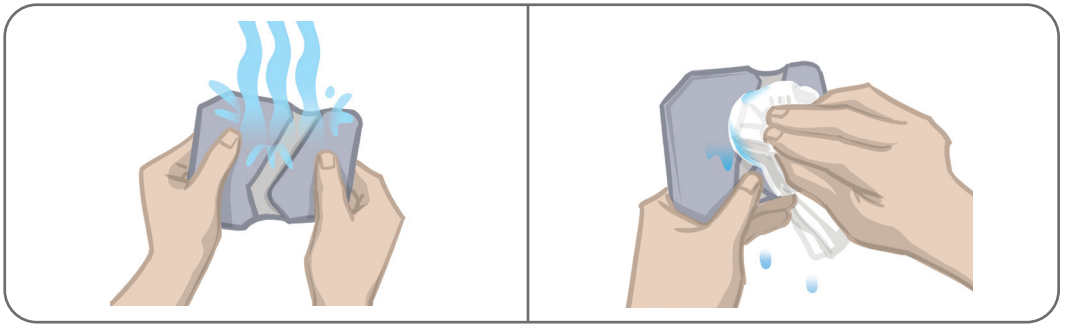


Figure 6-3: Wetting the Electrode and Removing Excess Water

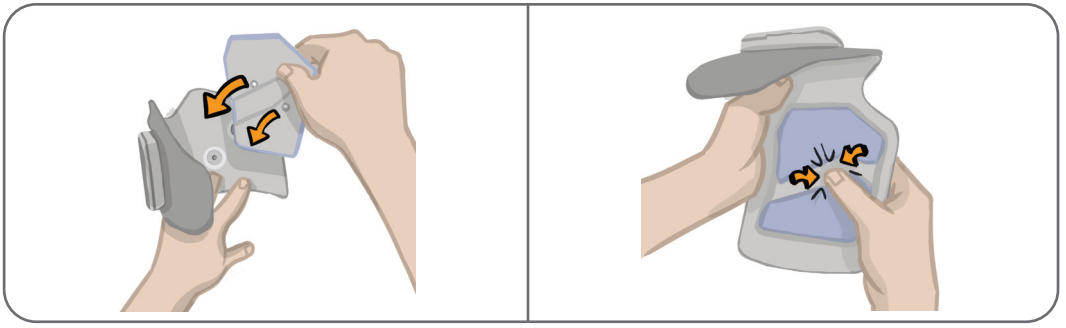


Figure 6-4: Aligning and Attaching the Quick Fit Electrode

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 Round 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.

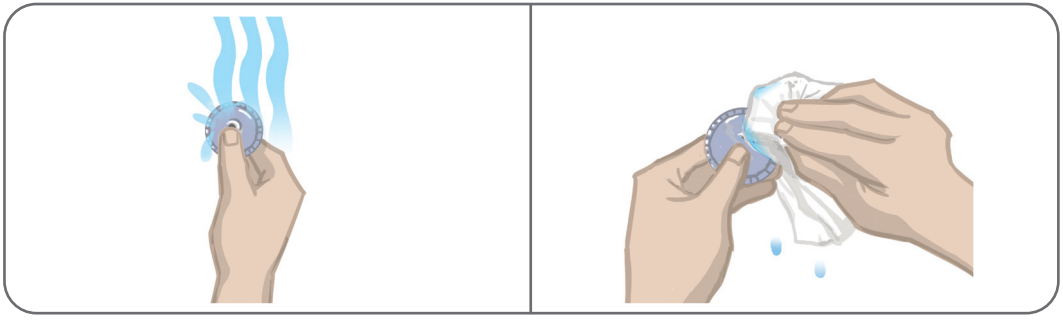


Figure 6-5: Wetting the Electrode and Removing Excess Water

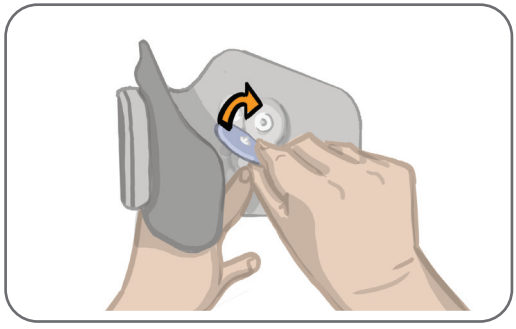


Figure 6-6: Attaching the Round Cloth Electrodes

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 patients that are using the L300 Hydrogel Electrodes, your clinician has already attached them to the electrode bases on your regular Lower Leg Cuff.

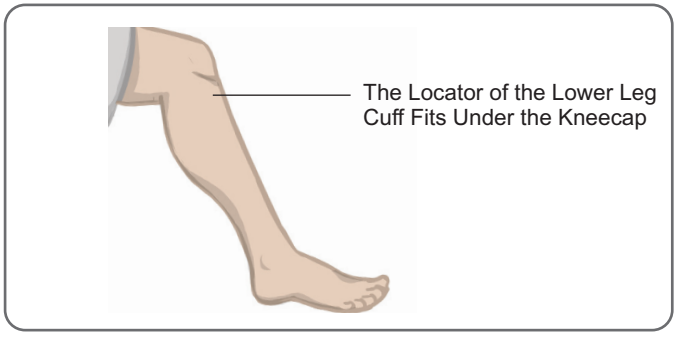
Remove the covers from the electrodes. Set aside the covers to reapply between uses.

Positioning the Lower Leg Cuff

To position the Lower Leg Cuff:

1. While seated, slightly straighten your leg as shown in Figure 6-7. The outline of your kneecap should be clearly defined. (Place your foot on a footrest, if necessary.)

Figure 6-7: 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 Lower Leg Cuff up. Slide the cuff up your leg until it rests snugly and comfortably below your kneecap. See Figure 6-8.

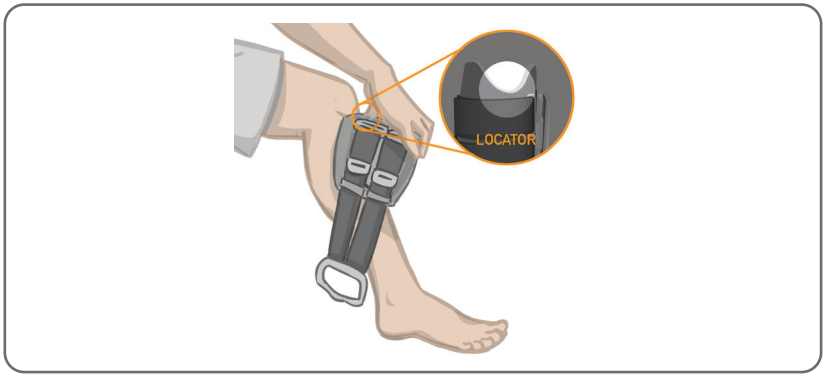


Figure 6-8: Positioning the Lower Leg Cuff on the Leg

3. Hold the cuff 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 6-9. With your thumb on the Lower Leg Cuff cradle, fasten the strap handle around the cradle. If using the Lower Leg Cuff, you may need to use your other hand to stabilize the cuff on the leg.

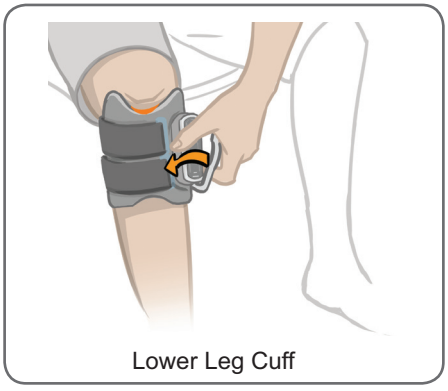


Figure 6-9: Fastening the Lower Leg Cuff Strap

5. Make sure the Lower Leg Cuff is correctly positioned. See Figure 6-10. Reposition the Lower Leg Cuff as necessary. Adjust the hook and loop fasteners (see Figure 6-9) to ensure a snug fit.

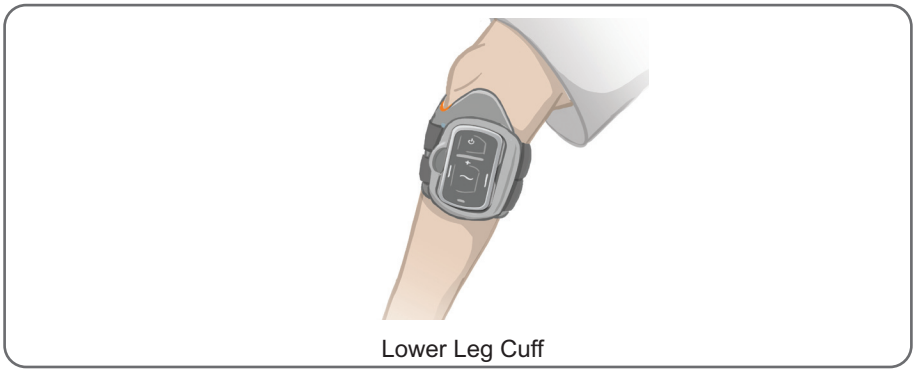


Figure 6-10: Lower Leg Cuff fastened on the leg

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 fifteen 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.

Chapter 7

Operating the L100 Go System

Turning the L100 Go System On/Off

To turn on the L100 Go System, press the Power button once on the lower leg 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 L100 Go System, press and hold the Power button, for three seconds, on the lower leg EPG. The EPG will provide vibration feedback when turning off.

Selecting an Operating Mode (Gait Mode and Training Mode)

To turn on an operating mode using the EPG:

1. Turn on the lower leg EPG by pressing the Power button on the EPG.
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 at least 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.

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 patients using the Lower Leg Cuff):

Press the Plus or Minus button on the EPG to increase or decrease the stimulation intensity.

Audio and Vibration Feedback During Stimulation

The EPG has the capability to provide audio and vibration feedback when stimulation is being delivered. The only way to turn off vibration feedback is to have your clinician disable the feature during the programming session for your L100 Go System.

Turning Stimulation Off (Gait Mode and Training Mode)

To turn stimulation off using the EPG:

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

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

Chapter 8

Maintenance and Cleaning

Daily Maintenance and Storage

1. 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 detach the electrode from the Lower Leg Cuff when not in use. Store the Quick Fit Electrode where it can air dry, to prevent mold growth.
4. Allow the Lower Leg Cuff to air dry, when not in use.
5. Fully charge the lower leg EPG batteries daily.
6. Check each component for wear or damage. Replace any components that appear old, worn, or damaged.

Charging

The lower leg EPG batteries should be charged daily. Charging instructions can be found in the "Charging the L100 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 Replacement

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

device, contact the Bioness Client Support Department, at 800.211.9136, Option 3 (USA & Canada) or your local distributor.

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 L100 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 Round Cloth 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.

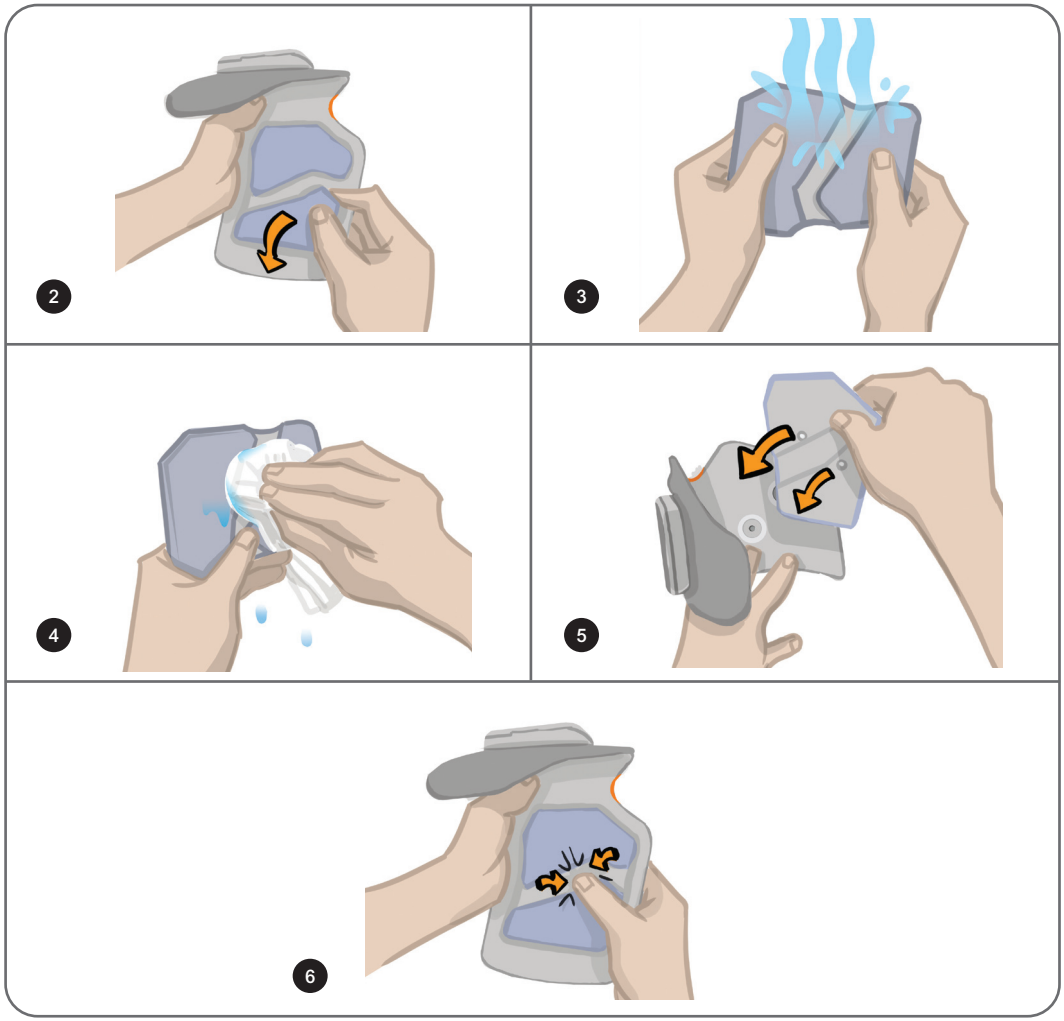


Figure 8-3: Replacing the Quick Fit Electrode

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 L100 Go System without electrodes.

To replace the Round 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.

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.

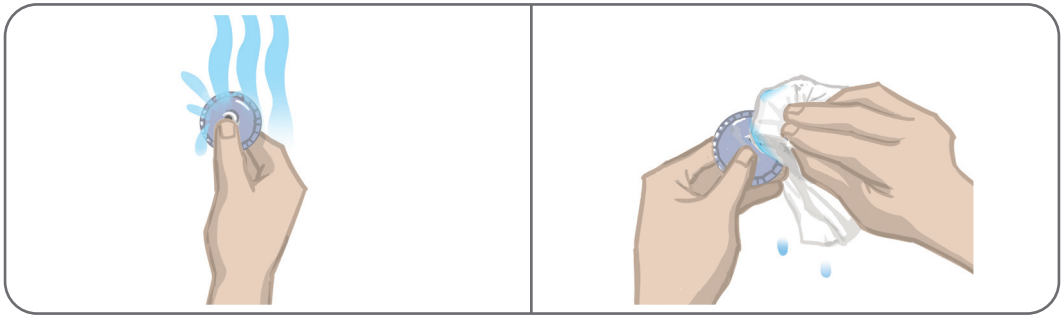


Figure 8-4: Wetting and Removing Excess Water

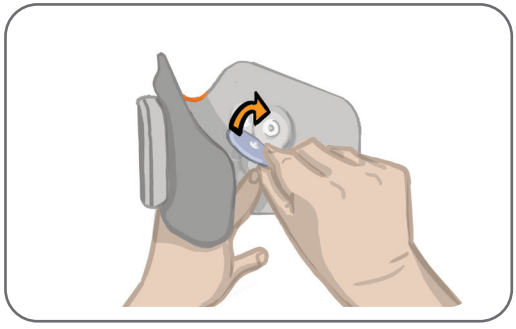


Figure 8-5: Attaching the Round Cloth Electrodes

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 L100 Go System without electrodes.

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

1. Make sure the lower leg EPG is 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. Remove the cover 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.

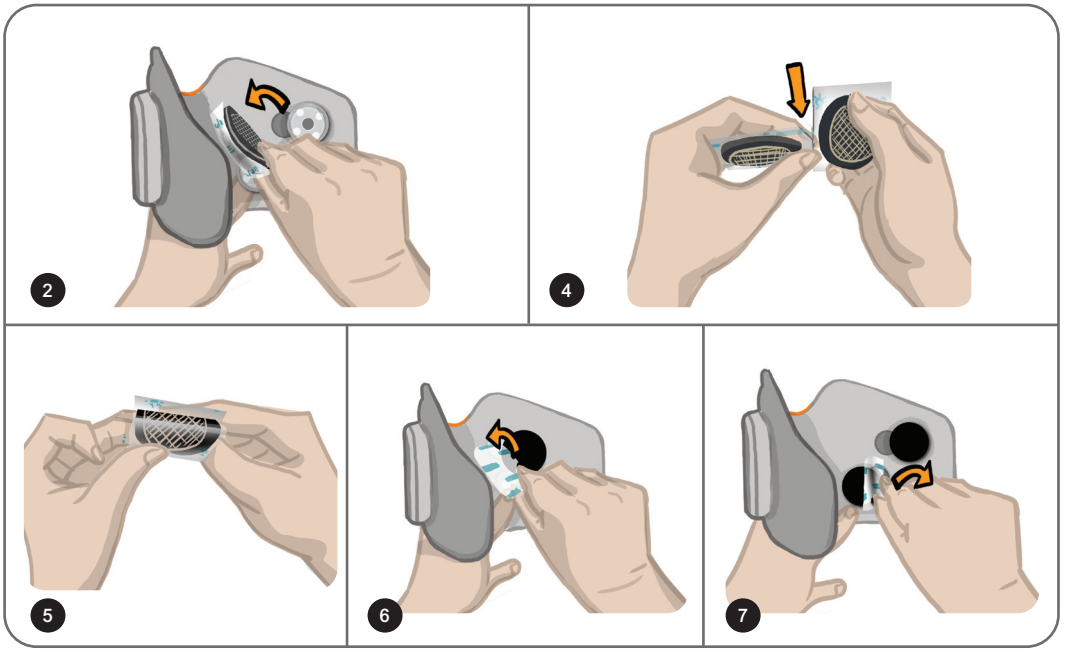


Figure 8-6: Replacing the Hydrogel Electrodes

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 Electrodes to Round Cloth Electrodes, or from Round 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 Lower Leg Cuff liner with a permanent marker. See Figure 8-7.
3. Disconnect the electrode base snaps from the plug holes. See Figure 8-8.

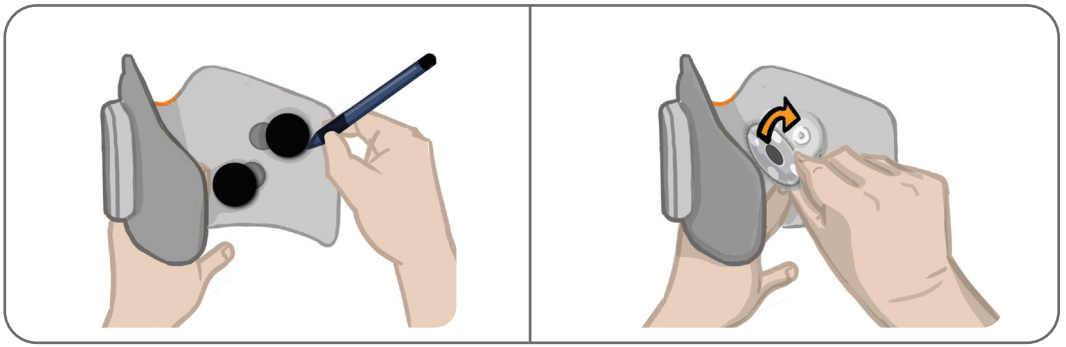


Figure 8-7: Mark Position of Electrode Base (Left)
Disconnect Electrode Base Snaps (Right)

4. Remove the used electrode bases from Lower Leg 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.

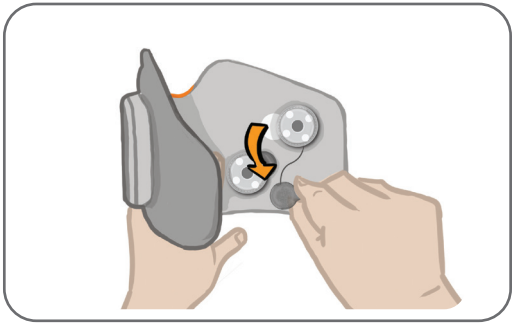


Figure 8-8: Removing the Used Electrode Bases

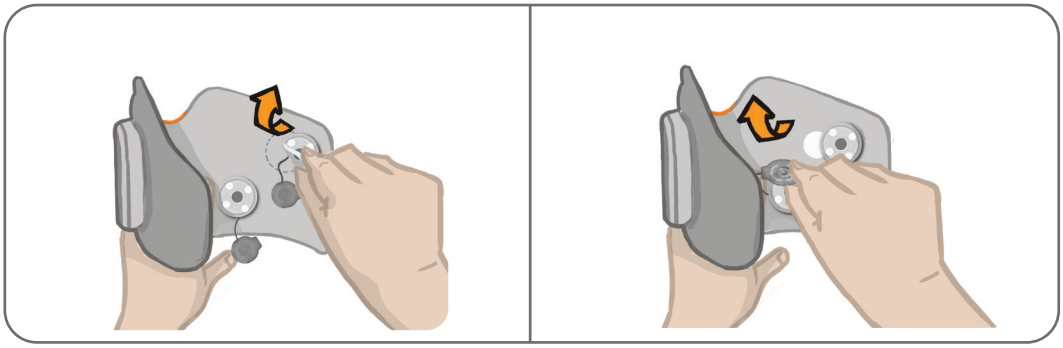


Figure 8-9: Attaching New Electrode Bases (Left)
Connecting Electrode Base Snaps (Right)

Removing the EPG

The lower leg EPG should only be removed for maintenance and to clean the Lower Leg Cuff.

To remove the EPG:

1. Make sure the EPG is turned off.
2. Pull the top of the EPG away from the cradle. See Figure 8-10.
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.

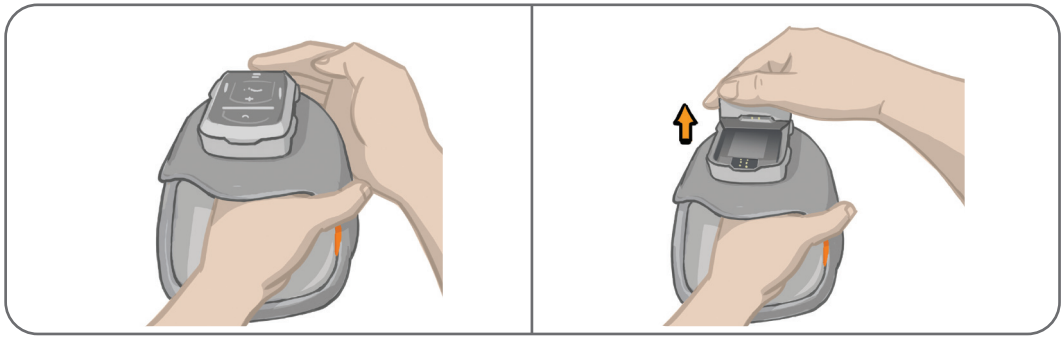


Figure 8-10: Removing the EPG

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 L100 Go System Components

All L100 Go System components may be cleaned by carefully by wiping them with a damp cloth. The electrical components are not waterproof. **Do not immerse them in water.**

Cleaning the 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 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 Lower Leg Cuff. Lay the Lower Leg 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 Lower Leg 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.

Disinfecting Your L100 Go System Components

Disinfecting the EPG

The lower leg 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 L100 Go System components.

Troubleshooting

If you have any questions or concerns, please contact the Bioness Client Relations Department at 800.211.9136, Option 3 or visit the Bioness website at www.bioness.com.

Error Code Descriptions

When an error occurs with the L100 Go System the EPG will emit an audio alert and the Status Indicator Light on the EPG will display a flashing red light. The Mobile Application 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, E2	Overstimulation Fault	Stimulation being delivered is higher than expected or is not being delivered correctly. Possible hardware issue. Stop using the L100 Go System and contact Bioness.
E3, E4	Understimulation Fault	Stimulation being delivered is lower than expected. Possible hardware issue. Stop using the L100 Go System and contact Bioness.
E10	Parameter Corrupted	Patient will need to have their L100 Go System reprogrammed by their clinician. Stop using the L100 Go System and contact Bioness.

Error Code	Description of Error	Solution
E11	Incorrect Cuff Fault	Make sure EPG is correctly inserted into the EPG cradle on the Lower Leg Cuff. For patients using the Lower Leg Cuff make sure the correct EPG is inserted into the EPG cradle. The lower leg EPG must be in the Lower Leg 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 L100 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.
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 Lower Leg Cuff.
E15	EPG Battery Empty	Charge the EPG. Refer to the "Charging the L100 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 Lower Leg Cuff. Remove the Lower Leg Cuff before starting the test.

To test the functionality of the alert indicator:

1. Remove the electrodes from the Lower Leg Cuff.
2. Press the Power button on the EPG.
3. Press and hold the Stim button on the EPG for at least five 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 Client Relations Department at 800.211.9136, Option 3.

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.

What should I do if the electrodes or electrode bases are frayed, peeling, damaged, or falling off the Lower Leg 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 L100 Go System is not indicating any errors?

- Make sure the EPG(s) is turned off.
- Reposition the L100 Lower Leg 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.

Why is the stimulation inconsistent when I am walking, but the L100 Go System is not indicating any errors?

Stop walking and shift your weight from side to side.

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

- Stop using the L100 Go System immediately.
- Contact your clinician or dermatologist, and the Bioness Client Relations Department at 800.211.9136, Option 3
- Resume use only when the skin is completely healed.
- Ask your clinician or dermatologist for a skin conditioning protocol.

Technical Specifications

EPG Specifications	
Classification	Internally powered, continuous operation with type BF applied part(s)
Battery Type	Rechargeable lithium ion battery, 3.7V, 1000 mAh
Controls	• Power button - turns system on/off • Stim button- to turn stimulation on/off • Minus and Plus buttons- to decrease or increase stimulation intensity level
Indications	• Status Indicator Light and Battery Indicator Light • Audio and vibration feedback • “Beeps” for audio alerts
Dimensions	• Length: 82 mm (3.2 in.) • Width: 47 mm (1.9 in.) • Height: 15 mm (0.6 in.)
Weight	60 grams
Environmental Ranges	Transport and Storage Conditions: • Temperature: -25°C to +55°C • Relative humidity: 5% to 90% • Pressure: 20 kPa to 106 kPa Operating Conditions: • Temperature: 5°C to 40°C • Relative humidity: 5% to 75% • Operating pressure: 80 kPa to 106 kPa

EPG Specifications	
Ingress Protection Rating	IP42 Protection Against: • >1mm Solids Ingress • Dripping Water When Tilted up to 15° Effective Against: • Most wires, screws, etc. • Vertical dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position.
Product Lifetime (Given Intended Use)	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					
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.					

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.

Lower Leg Cuff Specifications	
	Regular L100 Lower Leg Cuff
Material	Fabric - Polymer
Fits Limb Circumference	29 - 51 cm (11-20 in.)
Dimensions	• Height: 160 mm (6.3 in.) • Width: 100 mm (3.9 in.) • Depth: 125 mm (4.9 in.)
Weight	Approximately 127 grams (4.5 oz)

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	•USB 1: 2.1 A •USB 2: 1.0 A

Note: Do not use the L100 Go System while charging. Do not wear the Lower Leg Cuff while charging.

Electrode and Electrode Base Specifications–Lower Leg Cuff	
Hydrogel Electrodes	•Two, 45-mm (1.77-in.) diameter, surface area 15.8 cm^2 hydrogel electrodes •Transport and storage temperature: 5°C to 27°C (41.0°F to 80.6°F) •Relative humidity: 35% to 50% **Note:** Use only electrodes provided by Bioness Inc
Hydrogel Electrode Bases, 45mm	•Two, 45-mm (1.77-in.) diameter, relocatable polymer electrode bases for individual fitting
Round Cloth Electrode Bases, 45mm	•Two, 45-mm (1.77-in.) diameter, relocatable Thermoplastic elastomer (TPE) electrode bases
Round Cloth Electrodes, 45mm	•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 cm^2
Quick Fit Electrode (right - A and left - A)	•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 cm^2 \ 55.3 cm^2

Wireless Information

System Characteristics

The L100 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 L100 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 L100 Go System was designed and tested to not have interference from other RF devices (including other L100 Go Systems, WiFi networks, Cellular Devices, Microwaves and other Bluetooth® devices).

L100 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 L100 Go System is affected by other equipment, the user should turn the L100 Go System off, and move away from the interfering equipment.

Electromagnetic compatibility (EMC) Information

Guidance and Manufacturer's Declaration—Electromagnetic Emissions		
The L100 Go System is intended for use in the electromagnetic environment specified below. The customer or the user of the L100 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 L100 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 L100 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 L100 Go System is intended for use in the electromagnetic environment specified below. The customer or the user of the L100 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 L100 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.
Note: UT is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
The L100 Go System is intended for use in the electromagnetic environment specified below. The customer or the user of the L100 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 L100 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 L100 Go System is used exceeds the applicable RF compliance level above, the L100 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 L100 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 L100 Go System			
The L100 Go System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the L100 Go System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the L100 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√P	**80 MHz to 800 MHz d = 0.4√P**	**800 MHz to 2700 MHz d = 0.7√P**
0.01	0.12 m	0.04 m	0.07 m
0.1	0.38 m	0.13 m	0.22 m
1	1.2 m	0.4 m	0.7 m
10	3.8 m	1.3 m	2.2 m
100	12 m	4 m	7 m

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

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

Note: All calculations were made according to tables 204 and 206 of IEC 60601-1-2 for not life-supporting equipment using factors of 3.5 in 0.15–800 MHz and 7 in 800–2500 MHz. There are no requirements for ISM bands in these tables.