L100 Go®

Functional Electrical Stimulation System

CLINICIAN'S GUIDE

bioness®

A Bioventus Rehab Company

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

Table of Contents

Introduction

Central nervous system (CNS) injuries/diseases 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. The L100 Go System communicates wirelessly to deliver electrical pulses over the common peroneal nerve and to the motor point of the tibialis anterior muscle, causing ankle dorsiflexion in the swing phase of gait to prevent foot drop. The L100 Go System also can deliver stimulation to the muscles in the 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 L100 Go System consists of a Lower Leg Cuff with an External Pulse Generator (EPG).

The L100 Go System is designed to be used in a Hospital/Professional Healthcare Facility or Residential/ Home Healthcare environment.

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: L100 Go System

This L100 Go Clinician'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 the L100 Go System.
- The Bioness Clinician Application software.
- How to fit the L100 Go System.
- How to program the L100 Go System.
- Troubleshooting information.

The L100 Go System includes components and accessories required for fitting and programming the L100 Go System. This Clinician's Guide describes the fitting accessories and instructions for use. The L100 Go Clinician Application is intended to be used by a trained clinician. The Clinician Kit is intended to be used by a trained clinician. A brief description of the L100 Go System components is provided for reference. Refer to the L100 Go User’s Guide for comprehensive information on the L100 Go System Kit contents and instructions for use.

Be sure to review the User's Guide, including all safety information, with your patients before they use the L100 Go System. If you have any questions contact the Bioness Client Support Department at 800.211.9136, Option 3 (USA & Canada) or your local distributor. You may also visit www.bioness.com.

Safety Information

Indications for Use

The L100 Go System is intended to provide ankle dorsiflexion in adults with foot drop or muscle weakness related to upper motor neuron disease/injury (e.g., stroke, damage to pathways to the spinal cord). The L100 Go System electrically stimulates muscles in the affected leg to provide ankle dorsiflexion of the foot; thus, it also may improve the adult's gait.

The L100 Go System may also:

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

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
- 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. Advise patients to stop using the L100 Go System until any inflammation is gone.
- Use caution when treating patients with suspected or diagnosed heart problems.
- Advise patients to use the cuff with caution:
  - If the patient has a tendency to hemorrhage 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 the patient has 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 changing 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. Advise patients to stop using their L100 Go System until any inflammation is gone and to alert their clinician.
- Advise patients to stop using their L100 Go System and consult their clinician if stimulation does not start at the correct time during gait.
- Advise patients to 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 a treating clinician should determine electrode placement and stimulation settings.
- Use only the L100 Go System electrodes supplied by Bioness.
- Turn off the L100 Go System before removing or replacing the electrodes.
- Specific physician clearance should be obtained before using the L100 Go System on patients who have an alteration of normal arterial or venous flow in the region of the cuff because of arterial or venous thrombosis, local insufficiency, occlusion, arteriovenous fistula for the purpose of hemodialysis, or a primary disorder of the vasculature.
- Specific physician clearance should be obtained before using the L100 Go System when patients have a structural deformity in the area to be stimulated.
- 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.
- Advise patients to shut off the L100 Go System before operating machinery, or performing any activity in which involuntary muscle contractions could cause injury (e.g. driving a car, riding a bicycle, etc.).
- 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.
- Advise patients to remove the L100 Go System before undergoing any diagnostic or therapeutic medical procedure such as x-ray examination, ultrasound, MRI, etc.

Adverse Reactions

In the unlikely event that any of the following occurs, advise patients to stop using their L100 Go System immediately and consult their 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. Skin irritation tends to occur after approximately three months of use. 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 every two weeks or more frequently, 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,patients should stop using their L100 Go System immediately and contact their clinician or dermatologist. They can also contact Bioness Client Support Department at 800.211.9136, Option 3 (USA & Canada) or your local distributor. Patients should resume use only when the skin is completely healed, and then follow a skin conditioning protocol per the recommendation of their 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 can 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 blades is compatible with Australian, U.K., European Union, and U.S. voltages: 100-240V, 50/60 Hz.

Advise patients to turn off their L100 Go System before going through airport security and to wear loose clothing so they can easily show the security person their L100 Go System. The L100 Go System will likely set off the security alarm. Patients should be prepared to remove the L100 Go System so that security can scan it, or ask for the system to be scanned if they do not want to remove it. It is recommended that patients carry a copy of their L100 Go System prescription.

Patients can request a copy of their prescription by contacting Bioness or their 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 15.

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.

The L100 Go System

The L100 Go System consists of a Lower Leg Cuff with an External Pulse Generator (EPG).

The components in the Lower Leg System Kit communicate wirelessly to stimulate the common peroneal nerve (normally found posterior and slightly distal to the head of the fibula) to contract the tibialis anterior and peroneal muscles, thus causing balanced dorsiflexion (without excessive inversion or eversion).

Lower Leg Cuff

The Lower Leg Cuff is an orthosis that fits on the leg directly under the patella and is designed to facilitate upward movement of the foot and toes. See Figure 4-1. 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 includes an anatomically designed locator for accurate placement on the leg and a strap that can be fastened with one hand.

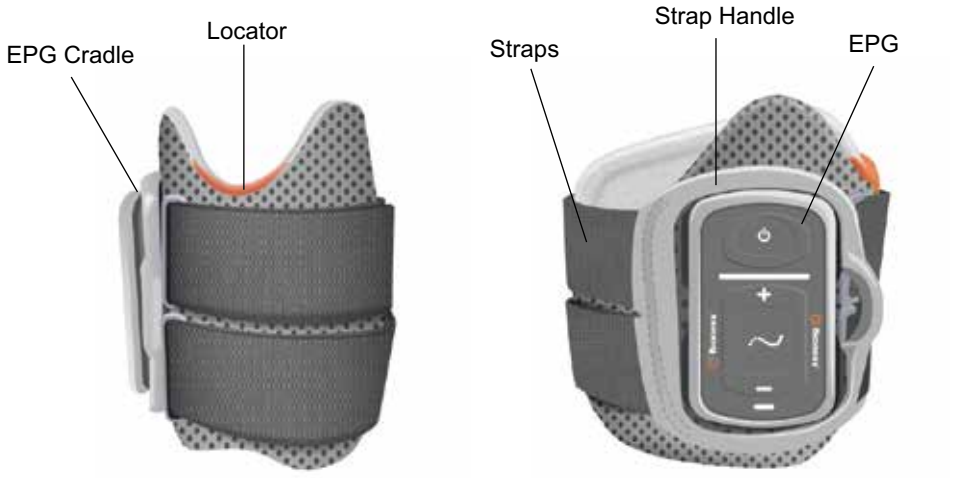


Figure 4-1: Lower Leg Cuff

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. In addition, 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.

The effectiveness of eliciting muscle contraction force depends on amplitude, duration, frequency, and waveform of the electrical stimulation signal. The clinician can impact the force, efficiency, and timing of the muscle contraction by adjusting stimulation and gait parameters. Refer to the "Patient Programming" chapter in this guide for more information.

Patients can also adjust the electrical stimulation using control buttons on the EPG. The EPG includes four buttons, two indicator lights, and a rechargeable battery (lithium ion 1000 mAh battery). See Figure 4-2, Table 4-1, and Table 4-2. The EPG emits an audio alert when wireless communication fails or the component malfunctions.

The EPG snaps into the cradle on the cuff and should only be removed from the cradle for maintenance and when cleaning the cuff. The battery charging port is located at the bottom of the EPG.

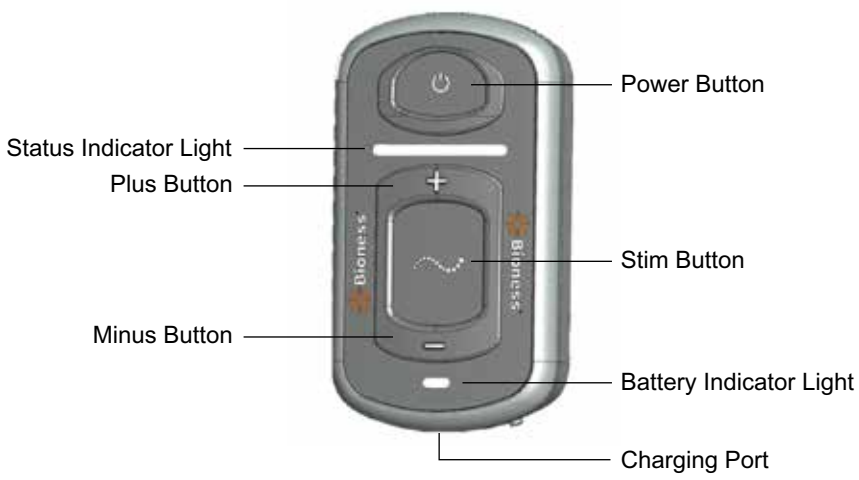


Figure 4-2: EPG

The EPG emits visual (see Table 4-1) and/or audio feedback when: an EPG button is pushed, stimulation is being delivered, an error has been detected, or when the battery level is low. The EPG provides vibration feedback when: an EPG button is pushed, stimulation is being delivered, or when an error is detected.

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 4-1: 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 4-2: 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 for walking. In Gait mode, the stimulation is synchronized with gait events, using the EPG integrated motion sensors, to achieve dorsiflexion and knee extension or flexion when the heel or forefoot leaves the ground and relaxation after the heel or forefoot makes contact with the ground.

During gait, the stimulation of the lower leg EPG is controlled by the motion sensor in the lower EPG at the appropriate phase of gait.

Training Mode

Training mode is used to train muscles when the patient is not walking (e.g., sitting, standing, or lying down). Training mode works independently of the motion sensors in the lower leg EPG. Stimulation is delivered in pre-set cycles.

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.

Charging the L100 Go System

The lower leg EPG is the only L100 Go System component that can be charged. The EPG must be charged daily and Bioness recommends charging the EPG(s) while attached to the cuff.

The EPG needs to be charged with the system charger set that is included in the L100 Go System Kit. 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.

To charge the L100 Go System:

1. Remove the System Charger Set from the packaging and select the proper adapter for your country or region.
2. Insert the USB end on the magnetic charging cable into either of the two available USB ports on the AC adapter. See Figure 4-6.

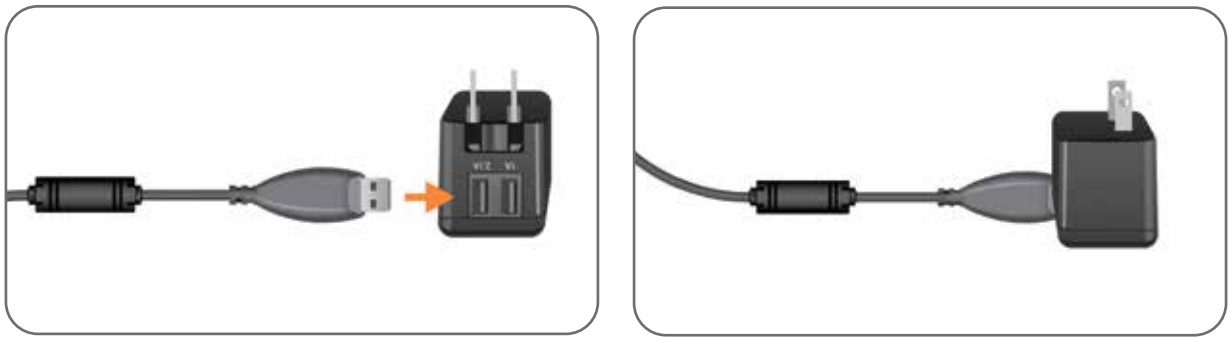


Figure 4-6: Inserting USB Charging Cable into AC Adapter

3. Connect the magnetic end on the charging cable to the charging port on the lower leg EPG. The charging port is located at the bottom of the EPG. See Figure 4-7.
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.

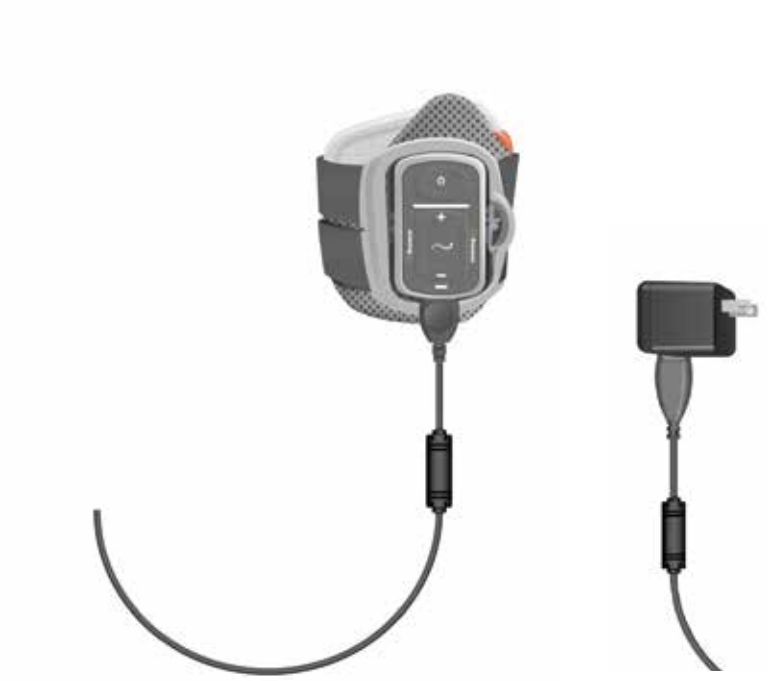


Figure 4-7: L100 Go System Charging Setup

⚠ **Caution:** Use only the charger included in the L100 Go System Kit. Use of any other charger could 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.

⚠ **Caution:** Do not use the L100 Go System while the EPG is charging.

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 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 vibrate when turning off.

Turning Stimulation Off Using the EPG

To turn stimulation off using the EPG:

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

Note: Once the Stim button on the EPG is pressed to turn off stimulation, the EPG 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.

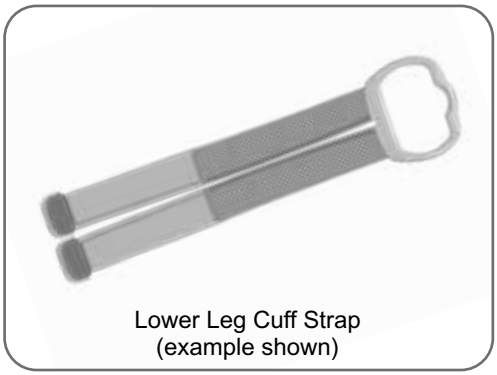
L100 Go System Kit, Accessories, and Programmer

L100 Go System Kit Contents

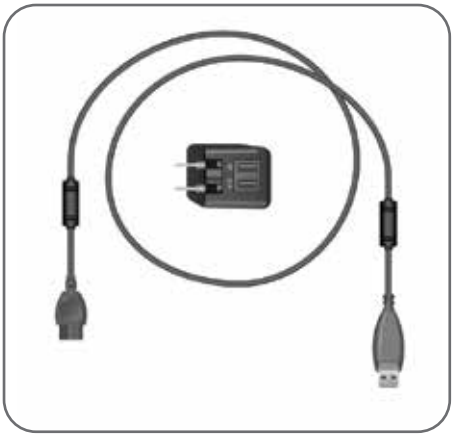
L100 Go System, Lower Leg

- 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



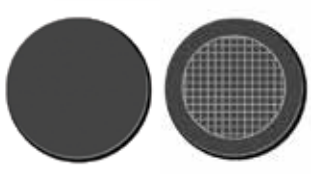
Lower Leg Cuff Strap
(example shown)



L100 Go System Accessories

The following accessories are not included in the L100 Go System Kit but may be ordered through a Bioness representative or by calling 1.800.211.9136, option 2.

Quick Fit Electrode
(right shown) CE

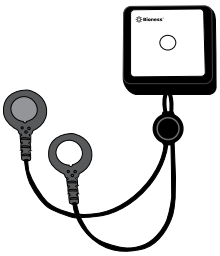


Hydrogel
Electrodes CE

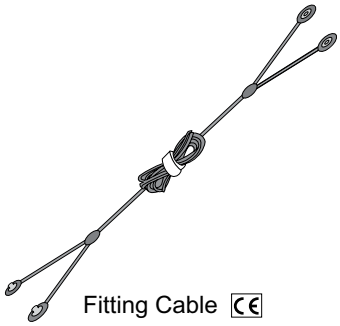
Hydrogel Electrode
Base Set, 45mm CE

Round Cloth
Electrode, 45mm CE

Round Cloth Electrode
Base Set, 45mm CE



Tester



Fitting Cable CE

Lower Leg Cuff Straps CE

Personal Panels CE

Bioness Clinician Programmer

- Bioness Clinician Programmer Tablet with Stylus
- Bioness Clinician Programmer Application
- Bluetooth® Dongle
- Bioness Clinician Programmer Charger

Bioness Clinician Programmer Tablet CE 2797

Fitting and Testing Accessories Descriptions

Lower Leg Cuff Straps

The Lower Leg Cuff Strap is used to hold the Lower Leg Cuff in place on the leg. The Lower Leg Cuff Strap is elastic, and fastens around the leg and the EPG Cradle. See Figure 6-1.

To attach the Lower Leg Cuff Strap to the Lower Leg Cuff:

- Slide the strap through the strap leads and buckles on the Lower Leg Cuff. Make sure the hook and loop fasteners face away from the Lower Leg Cuff. Press on the hook and loop fasteners to secure the strap. See Figure 6-2.

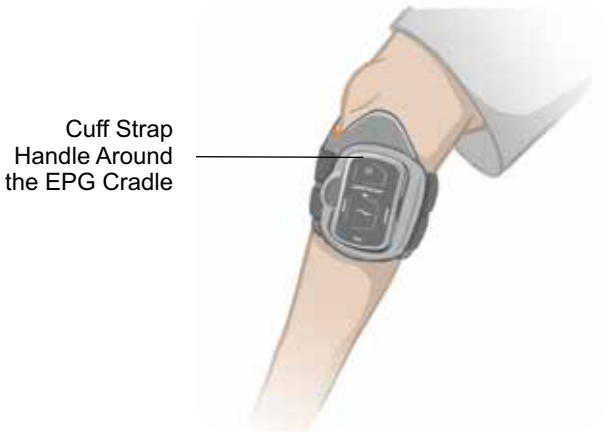


Figure 6-1: Regular Lower Leg Cuff fastened on the right leg.

Personal Panels (Lower Leg Cuff)

The Personal Panel is a removable inner lining for the Lower Leg Cuff for use in the clinic when the Lower Leg Cuff is used by multiple patients. The Regular Personal Panel is used with the Regular Lower Leg Cuff and features two buttonholes.

⚠ **Caution:** The Personal Panel is for single patient use only to prevent cross contamination.

To attach the Personal Panel to the Lower Leg Cuff for initial fittings:

1. For the Regular Personal Panel, align the buttenholes on the panel over the two electrode plug holes on the Regular Lower Leg Cuff. See Figure 6-2.

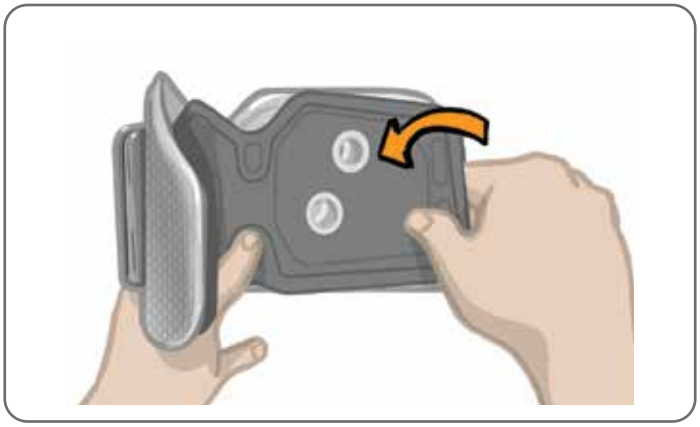


Figure 6-2: Attaching the Personal Panel

To remove the Personal Panel from the Lower Leg Cuff:

1. Remove the Personal Panel from the Lower Leg Cuff.
2. Write the patient's name and strap size on the Personal Panel label. If using Hydrogel Electrodes, re-adhere the electrode covers. If using Round Cloth Electrodes allow the electrodes to air dry.
3. Store the Personal Panel and electrodes for the patient's next session.

Note: When the patient returns to the clinic for a follow-up visit, attach the Personal Panel (with the electrode bases and electrodes attached) onto the Lower Leg Cuff inner liner.

Electrode Bases

The electrode bases are used to:

- Elevate the electrodes from the inner liner of the Lower Leg Cuff to optimize electrode contact.
- Ensure accurate positioning of the electrodes with every application.

The electrode bases feature a snap for attachment to the Lower Leg Cuff plug holes.

The following electrode bases can be used with the Regular Lower Leg Cuff: (See Figure 6-3)

- Regular L100 Round Cloth Electrode Bases (used with the Regular L100 Round Cloth Electrodes)
- Hydrogel Electrode Bases (used with the Hydrogel Electrodes)

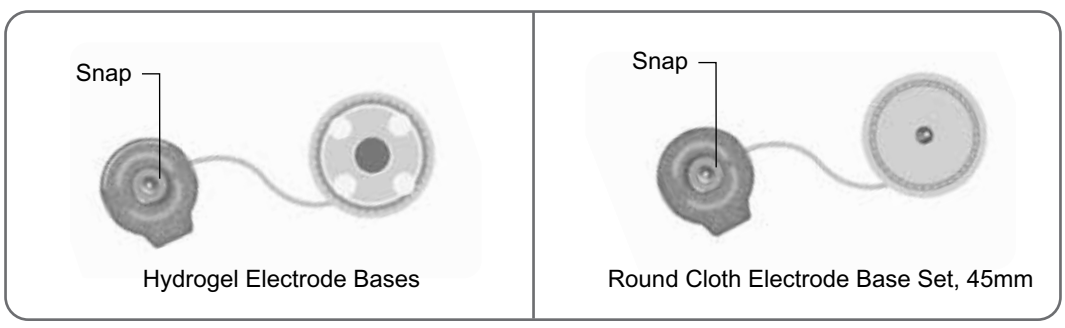


Figure 6-3: Regular Lower Leg Cuff Electrode Base Options

Note: The electrode bases are re-usable. Clean the electrode bases with cool water to remove any hydrogel residue, if applicable. Then disinfect the electrode bases with alcohol. See the "Maintenance and Cleaning" chapter in this guide for more information.

⚠ **Caution:** Only a clinician should replace or reposition the electrode bases.

Electrodes

The electrodes transmit the electrical signal from the EPG to the target nerve and there are three types of electrodes that can be used with the Lower Leg Cuff.

⚠ **Caution:** The electrodes are to be used by no more than one individual patient. The L100 Go electrodes are for single patient use only to prevent cross contamination. 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.

⚠ **Caution:** Do not use the L100 Go System without the electrodes attached to the cuff.

With the Lower Leg Cuff the following electrodes can be used: (See Figure 6-4)

- Quick Fit Electrode, left or right
- Hydrogel Electrodes
- Round Cloth Electrodes, 45mm

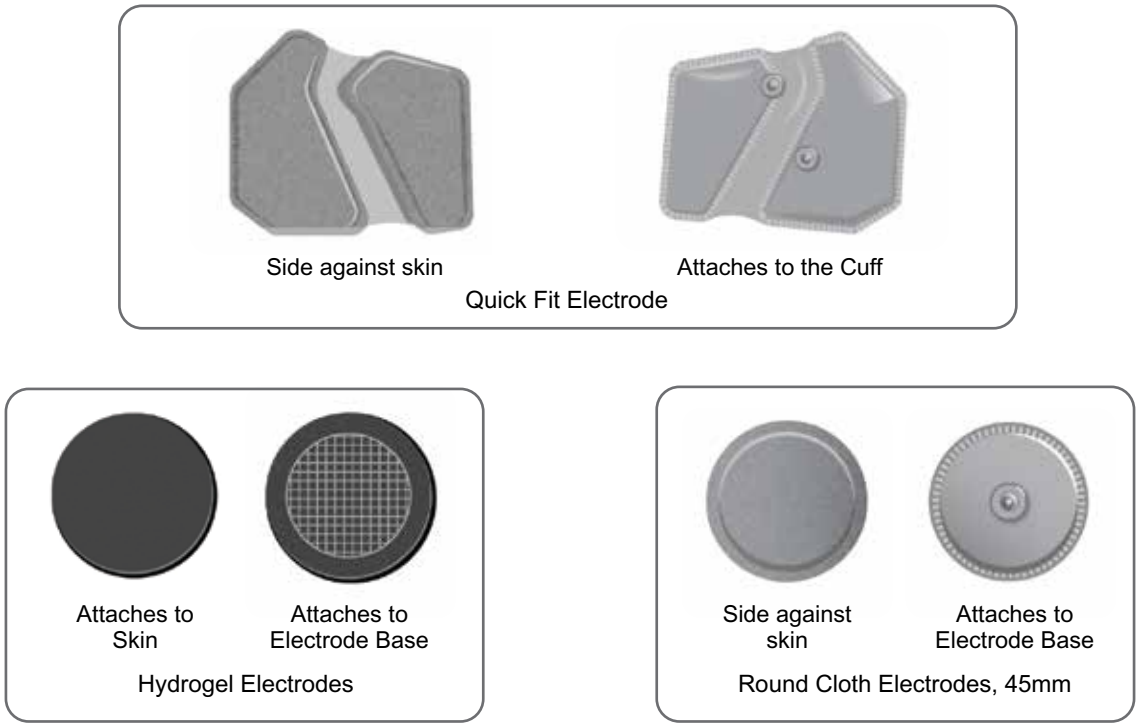


Figure 6-4: Lower Leg Cuff Electrode Options

Wire Concealers

The Wire Concealers are used to cover the wires and snaps of the electrode bases when attached to the Lower Leg Cuff. The Wire Concealers are used with patients that are using the Hydrogel Electrodes or Round Cloth Electrodes. See Figure 6-5.

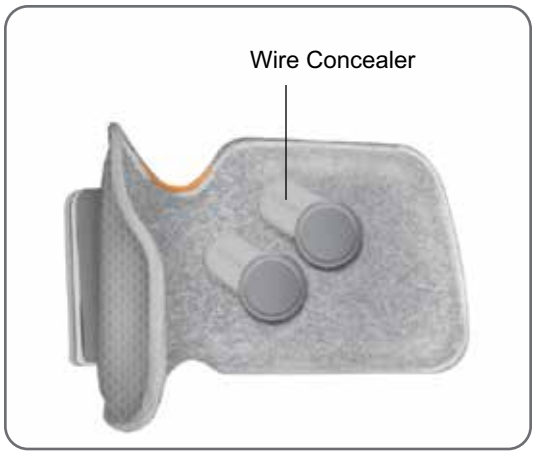


Figure 6-5: Lower Leg Cuff with Wire Concealers

Fitting Cable

The Fitting Cable is used to electrically connect the electrode base snaps to the Lower Leg Cuff plug holes during fitting. See Figure 6-6. The Fitting Cable is used with the Hydrogel or Round Cloth Electrodes during the initial fitting session.

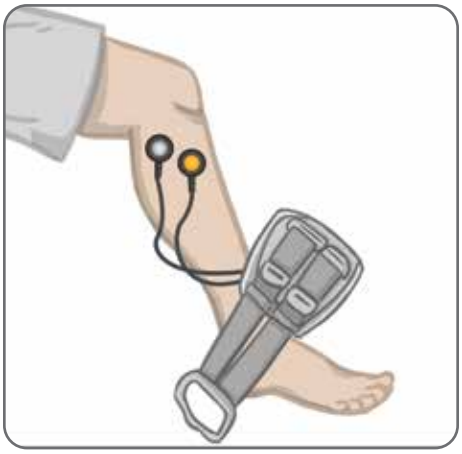


Figure 6-6: Fitting Cable Connected to the Lower Leg Cuff and Electrode Bases

Tester

The Tester is used for troubleshooting to confirm that stimulation is being delivered. It tests if there is a disconnection in the Lower Leg Cuff or the EPG. The Tester provides audio feedback when connected to the Lower Leg Cuff or EPG and stimulation is applied. For more information on the Tester, refer to the "Troubleshooting" chapter in this guide.

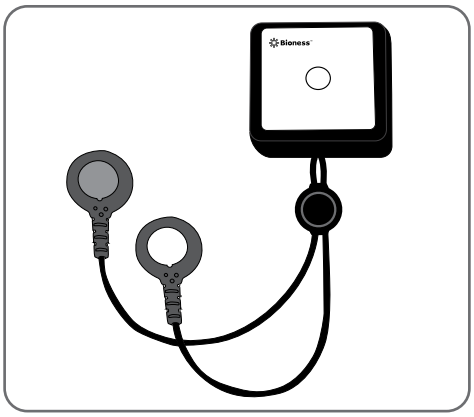


Figure 6-7: Tester

Bioness Clinician Programmer Software Navigation

The Bioness Clinician Programmer Application uses proprietary software that enables the clinician to configure stimulation parameters and programs for the patient. The Bioness Clinician Programmer Application uses a Windows® based tablet PC platform and uses standard Bluetooth® Low Energy (BLE) wireless signals to communicate with the L100 Go System. The Bioness Clinician Programmer Application is used in the clinic for patient programming. The Bioness Clinician Programmer Application also enables the clinician to retrieve patient's activity logs.

The Bioness Clinician Programmer Application consists of six main screens the Login, Patient Database, Patient Dashboard, Programming Settings, Reports, and Logout/Settings screens.

Login Screen

The Login Screen is used to login into the Bioness Clinician Programmer Application software. The Login Screen appears after the software has been launched. From this screen, the user must enter their username and password and press the Login button. See Figure 7-1.

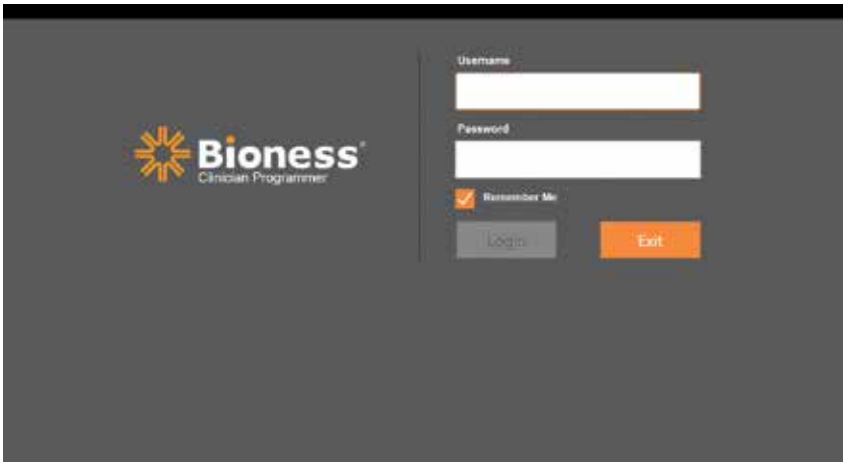


Figure 7-1: Login Screen

Patient Database Screen

After the Login screen, the Bioness Clinician Programmer Application will display the Patient Database Screen. The Patient Database screen lists all patient files that are stored on the Bioness Clinician Programmer Application. From this screen, the clinician can search for a patient file, import or export the patient file, or edit the patient file. This screen is also used to create new patient files.

The Patient Database Screen consists of four icons and a searchable text field. See Figure 7-2.

- Add New Patient icon - used to add a new patient file to the Bioness Clinician Programmer Application.
- Upload Patient icon - used to upload a patient file to a paired EPG.
  Note: Upload Patient icon is disabled until the EPG's are connected to the Bioness Clinician Programmer Application.

- Export Patient icon - used to export a patient file and load onto another Bioness Clinician Programmer Application.
- Import Patient icon - used to import a patient file from another Bioness Clinician Programmer Application.

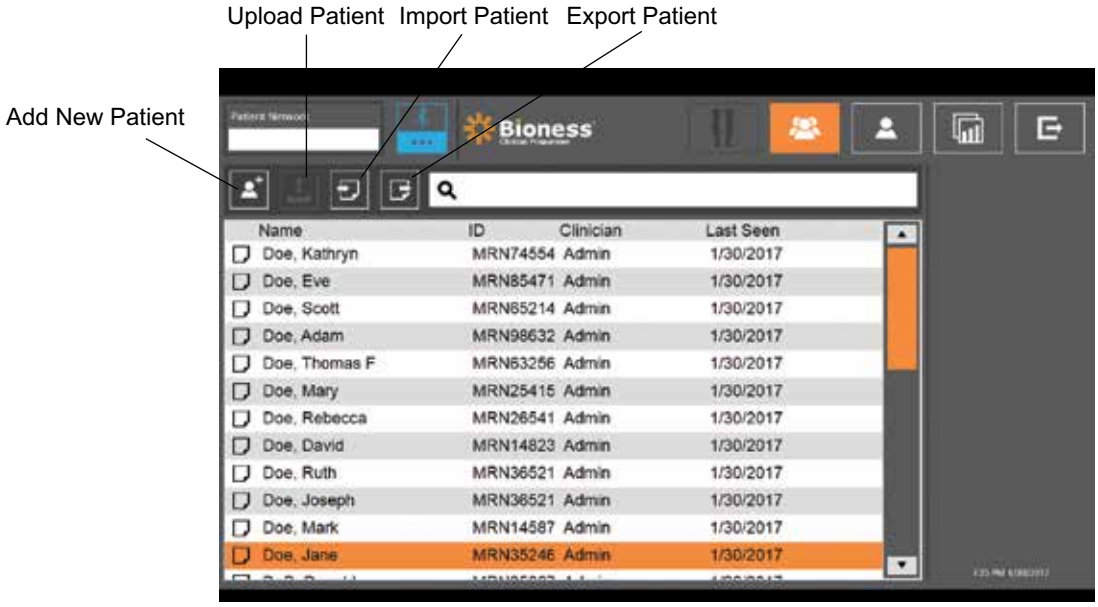


Figure 7-2: Patient Database Screen

Navigation Bar

The navigation bar appears along the top of each screen in the Bioness Clinician Programmer Application software. It consists of five menu icons, patient network field and link state button. See Figure 7-3 and Figure 7-4.

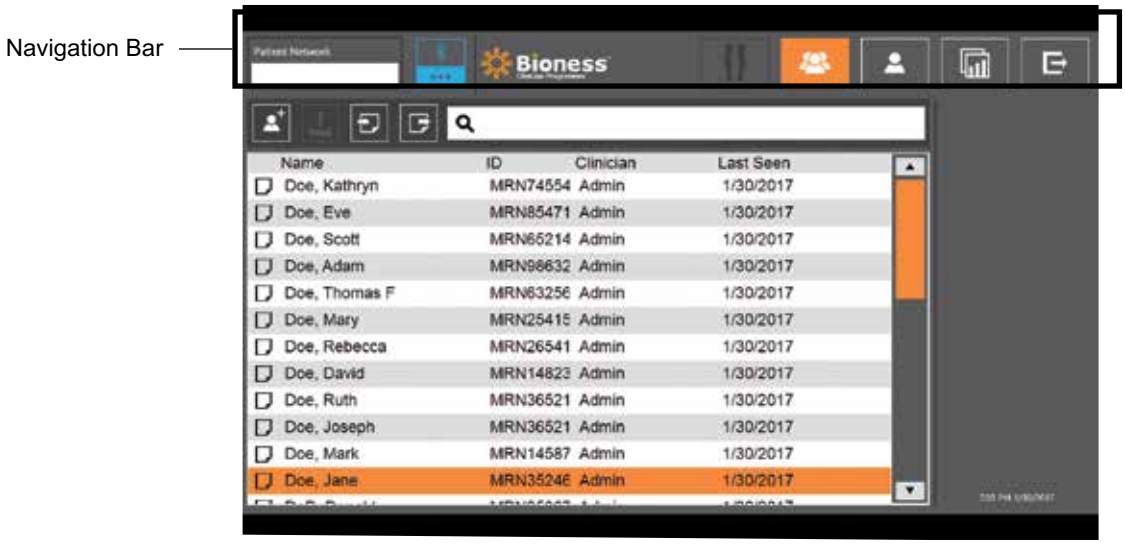


Figure 7-3: Navigation Bar on the Programming Screen

When the Bioness Clinician Programmer Application is paired with a patient's L100 Go System, the patient's name will appear in the patient network field with an orange outline and the active screen's icon will also appear in orange. See Figure 7-4.

When the Bioness Clinician Programmer Application is not paired with a patient's L100 Go System, the patient network field will be empty with a blue outline and the active screen's icon will also appear in blue.

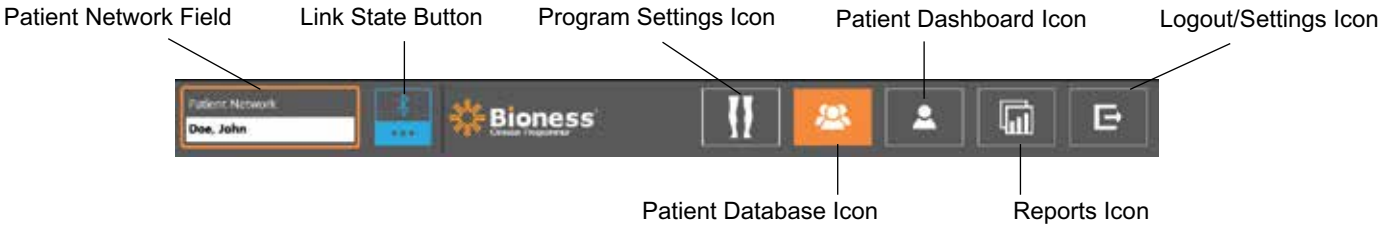


Figure 7-4: Navigation Bar - Linked to a Patient's System

Programming Setting Screen

The Programming Setting screen can only be accessed if the Bioness Clinician Programmer Application is paired with a L100 Go System and a patient file has been uploaded to the patient network. This screen is used by the clinician to program the stimulation parameter settings, programs, and advance settings on a patient's L100 Go System. The Programming Settings Screen consists of four sub-menu screens: Parameter, Gait, Cycle Training, and Training Screens. See Figure 7-5.

Figure 7-5: Programming Setting Screen (Stim (sub-menu) Screen Displayed)

Parameter Screen

The Parameter Screen is used to program the stimulation settings for the selected EPG. The advanced setting window can also be accessed from this screen by pressing the Advanced Settings icon. See Figure 7-6.

Figure 7-6: Parameter Screen with Advanced Settings Displayed

Gait Screen

The Gait screen is used to program Gait mode settings. See Figure 7-7. This screen also controls the audio and vibration feedback during stimulation settings. To access this screen press the Gait screen icon. See Figure 7-5.

Cycle Training Screen

Cycle Training mode is not available for the L100 Go System.

Training Screen

The Training screen is used to program the settings that are used in training mode. See Figure 7-8. To access this screen press the Training screen icon. See Figure 7-5.

Figure 7-7: Gait Screen

Figure 7-8: Training Screen

Patient Dashboard Screen

The Patient Dashboard Screen allows the clinician to view all relevant information about a specific patient, including session settings history, data logs, and notes. See Figure 7-9. To access the Patient Dashboard Screen press the Patient Dashboard icon located in the navigation bar. See Figure 7-4.

You can review and upload setting from a previous session to use for the current session. Select a previous session from the list and press the Upload icon to load the settings to the patient network.

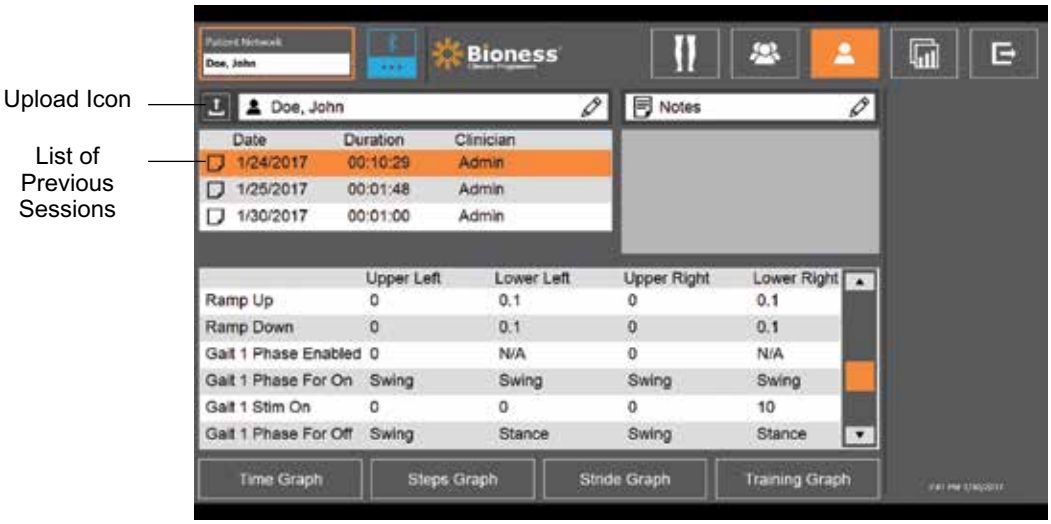


Figure 7-9 Patient Dashboard Screen

Reports Screen

The clinician can access the Reports screen to view previous data and generate new test reports. See Figure 7-10. To access the Reports screen press the Reports icon located in the navigation bar. See Figure 7-4.

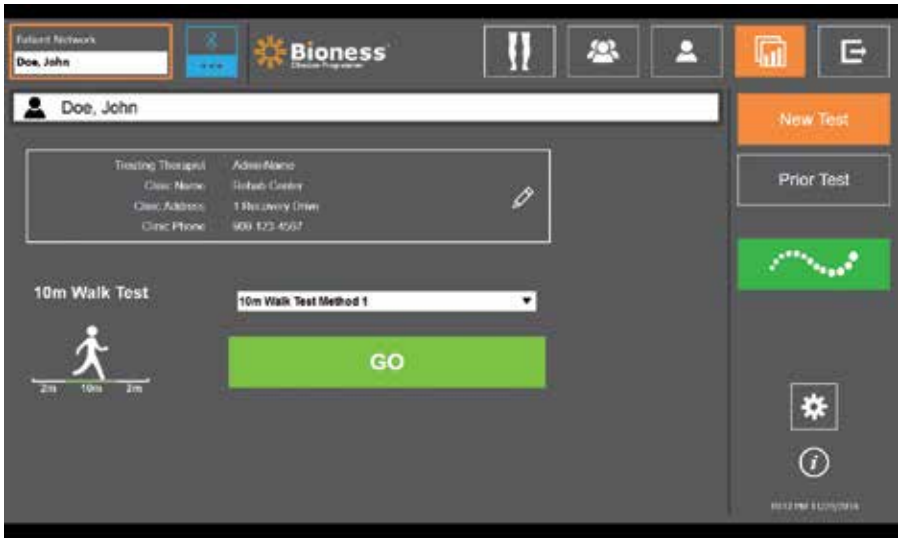


Figure 7-10: Reports Screen

Ten Meter Walk Test

The Bioness Clinician Programmer Application supports the 10 meter Walk Test which assesses patient gait speed in meters per second over a set distance. This test allows a clinician to set ambulatory category and fall risk. There are two common methods for conducting the 10m Walk Test. The software calculates patient gait speed by dividing the distance walked by the patient by the total time taken.

Method 1

Method 1 is the default setting. During this test, the patient walks unassisted for a total of 14 meters. The software calculates gait speed over a distance of ten meters.

1. On the New Test screen, press the Pencil icon to enter therapist name, clinic name, and contact information. Press the Save icon to continue.
2. Press the Stimulation button to turn on Gait mode.
3. Instruct the patient to walk two meters (allowing the patient to accelerate to a normal comfortable walking speed).
4. Press Go to begin the stopwatch.
5. Press Done to stop the stopwatch once the patient has walked ten meters.
6. Allow the patient to decelerate over the remaining two meters.
7. Once the gait speed is determined, the clinician must assign the Perry Ambulatory Category (Household, Community, or Limited Community) and Fall Risk (Low, Moderate, or High) from the drop down menus.
8. Press the Save Results button to save results, or press Redo Test button to discard results and begin a new test.

Note: The saved data includes the therapist name, clinic name, contact information, total time, gait speed, ambulatory category, and fall risk.

9. The result can be exported by pressing the Export button on the Prior Test screen.

Method 2

Method 2 is a second method for conducting the 10m Walk Test. During this test, the patient walks unassisted for a total of 10 meters. The software calculates gait speed over a distance of six meters.

1. On the New Test screen, press the Pencil icon to enter therapist name, clinic name, and contact information. Press the Save icon to continue.
2. Press the Stimulation button to turn on Gait mode.
3. Instruct the patient to walk two meters (allowing the patient to accelerate to a normal comfortable walking speed).
4. Press Go to begin the stopwatch.
5. Press Done to stop the stopwatch once the patient has walked six meters.
6. Allow the patient to decelerate over the remaining two meters.
7. Once the gait speed is determined, the clinician must assign the Perry Ambulatory Category (Household, Community, or Limited Community) and Fall Risk (Low, Moderate, or High) from the drop down menus.
8. Press the Save Results button to save results, or press Redo Results button to discard results and begin a new test.

Note: The saved data includes the therapist name, clinic name, contact information, total time, gait speed, ambulatory category, and fall risk.

9. The result can be exported by pressing the Export button on the Prior Test screen.

Logout/Settings Screen

The Logout/Settings screen is used to logout of the Bioness Clinician Programmer Application software, and close the application.

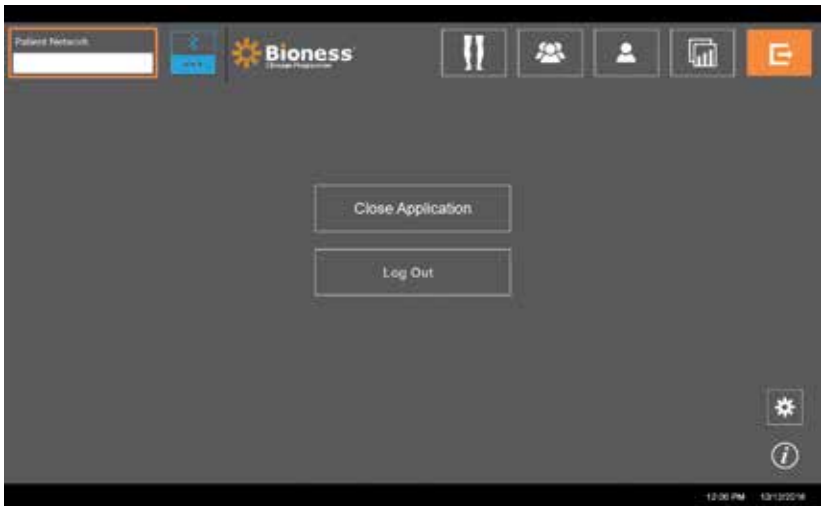


Figure 7-11: Logout/Settings Screen

Application Settings Screen

The Application Settings screen, accessed via the icon ⚙ available on each screen on the right lower corner of the screen, is used to adjust language settings, manage user profiles, and manage data. The Application Settings Screen consists of three sub-menu screens. See Figure 7-12.

- Programmer Settings: used to select a language setting, display software versions, and factory reset the EPGs. Press the Software Versions or Change Language button to toggle between the two available screens. See Figure 7-12 and Figure 7-13.
- User Settings: used to manage user (clinician) profiles including adding new user accounts, editing profiles, disabling user accounts, and resetting passwords
- Manage Data: used to load system data and export EPG system logs

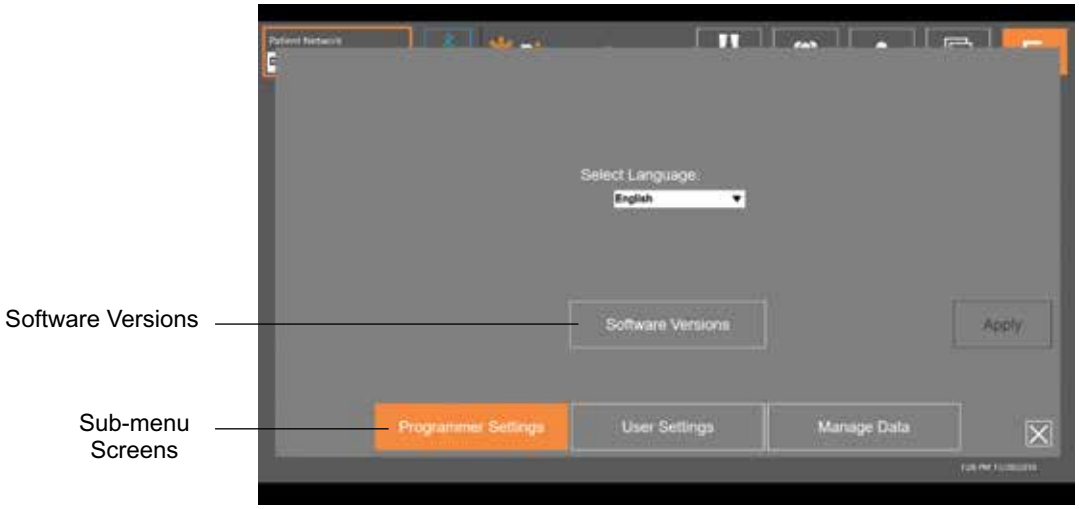


Figure 7-14: Application Settings Screen - Change Languages

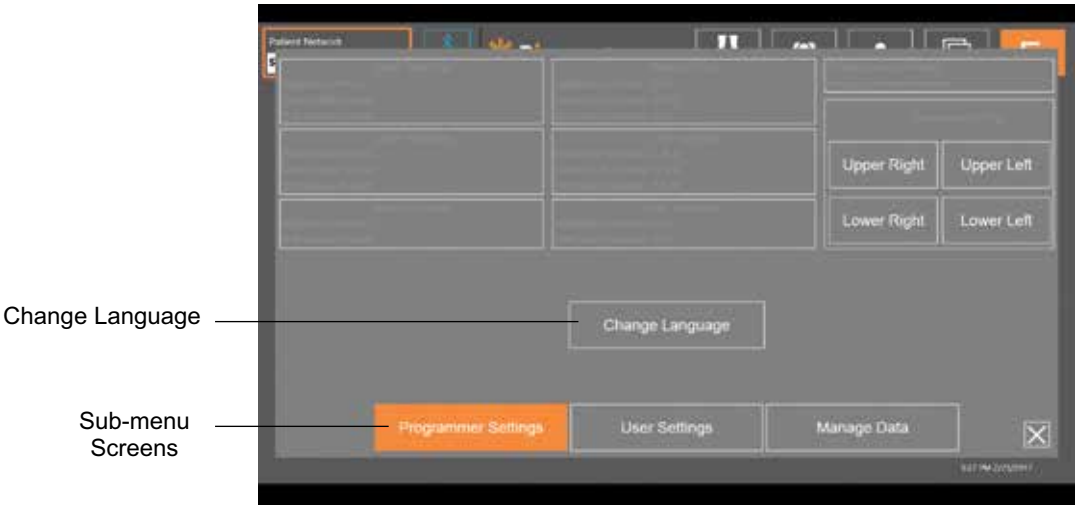


Figure 7-15: Application Settings Screen - Software Versions

EPG Factory Reset

To factory reset an EPG, access the application settings screen then click on Software Versions to view the factory reset buttons. Follow the steps below to factory reset an EPG for use with a different cuff type

(e.g. right or left) cuff. The example below explains how to reset an EPG from a Left Lower Leg Cuff for use with a Small Right Lower Leg Cuff.

To factory reset an EPG:

1. Remove central EPG from previous cuff (e.g. Left Lower Leg Cuff) and place it into the desired cuff (e.g. Right Lower Leg Cuff).
2. Pair the right Right Lower Leg to Bioness Clinician Programmer Application as if it were a Left Lower Leg Cuff and allow to run through syncing sequence.
3. Click on Application Settings and select Software Version to view the factory reset options. See Figure 7-14.
4. Under the factory reset section, select the location where the EPG had been previously (e.g. Left Lower Leg). This will initiate the factory reset with red status bar flashing on the EPG. Once done, silence the alarm by pressing the power button. Turn off the EPG and turn it back on and it will recognize it's new location.

Information Screen

The Information screen is accessed via the information icon available on each screen on the far right below the Application Settings icon. The Information screen provides information about the features available on the screens of Bioness Clinician Programmer Applicationlication. The Information screen is dynamic as the information displayed is dependent on the screen in which it is accessed. See Figure 7-14.

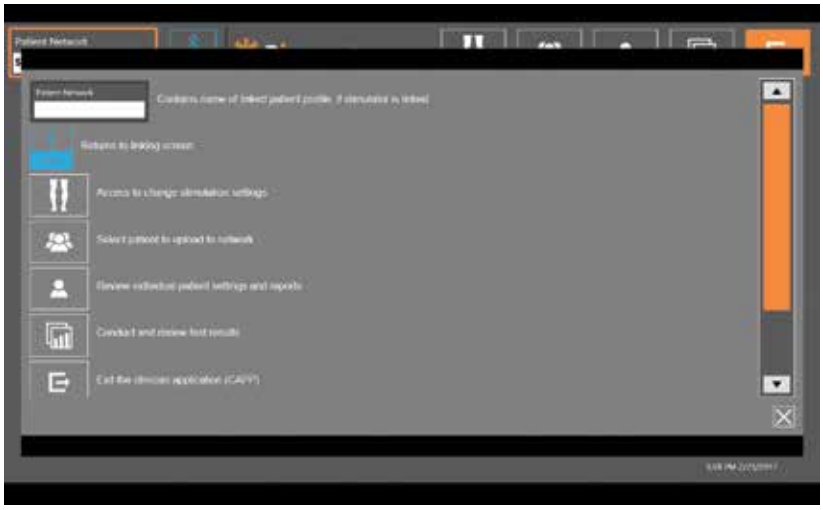


Figure 7-16: Information Screen

Patient Fitting

Skin Preparation

Before fitting the Lower Leg Cuff on a patient, always check the patient's skin for signs of irritation. If any irritation is present, wait for complete healing before using the L100 Go System. For optimal stimulation, the skin under the cuff should be clean and healthy.

To prepare the skin:

1. Use a wet cloth to clean the skin where the electrodes will touch. 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.

Fitting the Quick Fit Electrodes

For first fittings, it is recommended to use quick fit electrodes before using other electrode types.

The Lower Leg Cuff can use one type of Quick Fit Electrode, which is available in left and right configurations.

To fit the Quick Fit Electrode: **(See Figure 8-1)**

1. Make sure the EPG is turned off and then remove the Lower Leg Cuff from patient's leg.
2. Wet the entire new Quick Fit Electrode with water until saturated.
3. Remove excess water from the Quick Fit Electrode with a cloth.
4. Align the orange and blue snaps on the Quick Fit Electrode with the orange and blue plug holes on the Lower Leg Cuff.
5. Press firmly to snap the Quick Fit Electrode into the Lower Leg Cuff.
6. Don the Lower Leg Cuff.
7. Adjust the stimulation settings to achieve the desired dorsiflexion response.

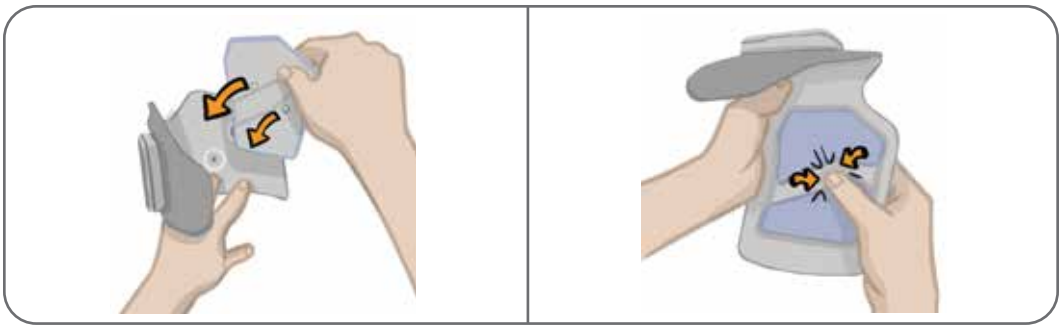


Figure 8-1: Fitting the Quick Fit Electrode
(Quick Fit Electrode and Lower Leg Cuff Shown)

Attaching the Hydrogel Electrodes and Electrode Bases

⚠ **Caution:** The Hydrogel Electrodes are to be used by no more than one individual patient. The electrodes are for single patient use only to prevent cross contamination.

To attach the Hydrogel Electrodes to the leg:

1. Make sure the lower leg EPG is turned off.
2. Separate the two new Hydrogel Electrodes along the perforation. See Figure 8-2.
3. Split the two-piece covers on each electrode and discard them. See Figure 8-2.

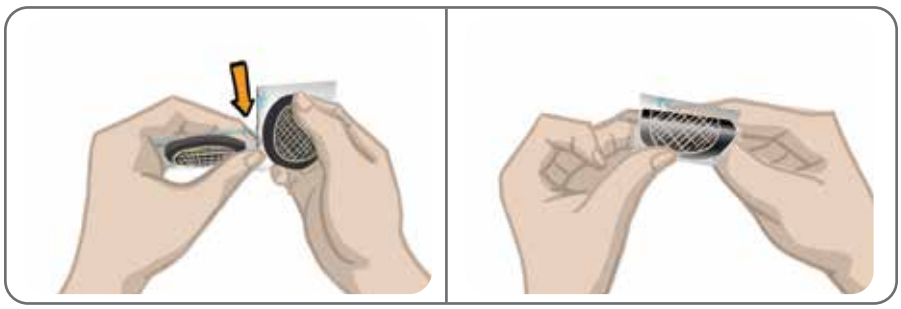


Figure 8-2: Separating the Hydrogel Electrodes and Splitting the Two-Piece Covers

4. For patients using the Lower Leg Cuff, attach the grid side of the electrodes to the Hydrogel Electrode Bases and then press firmly.
5. Remove the larger covers (with the Bioness logo) from the electrodes and save them. (Always cover the Hydrogel Electrodes between uses. Make sure the Bioness logo on the cover faces up.)
6. Have the patient sit and extend the leg to between 15 and 20 degrees of flexion. (The patient should maintain this position throughout the fitting process.) The heel should be elevated, if possible.
7. Position one electrode (the nerve electrode) over the common peroneal nerve, distal and slightly posterior to the fibular head. See Figure 8-3.
8. Position the other electrode (the muscle electrode) approximately 5 cm (2 in.) distal and anterior to the nerve electrode, over the belly of the tibialis anterior muscle.

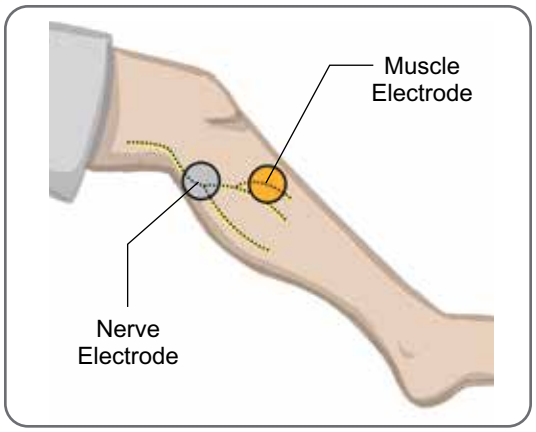


Figure 8-3: Positioning the Electrodes on the Leg

Note: The Small Hydrogel Electrodes are for fitting purposes only and not for patient home use.

Connecting the Fitting Cable

To connect the fitting cable:

1. Make sure the EPG is attached to the EPG cradle on the Lower Leg Cuff.
2. Connect the fitting cable to the electrode bases and to the Lower Leg Cuff plug holes.
3. Connect the orange ends of the fitting cable to the muscle electrode base and the orange cuff plug hole. See Figure 8-4.

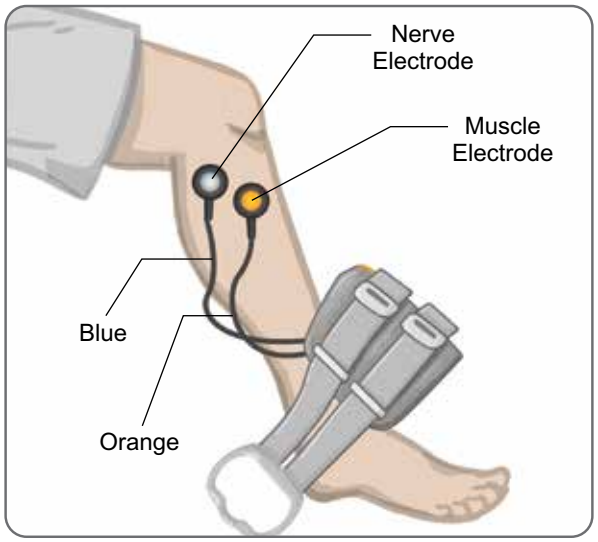


Figure 8-4: Fitting Cable Connected

4. Connect the blue ends of the fitting cable to the nerve electrode base and the blue cuff plug hole. See Figure 8-4.
5. Place the Lower Leg Cuff next to the patient's foot. See Figure 8-4.

Adjusting the Electrode Position While Stimulating: Patient Sitting

Note: When applying stimulation, observe the patient's foot for proper dorsiflexion.

1. Press the Plus button on the EPG to gradually increase stimulation intensity to achieve dorsiflexion with a small amount of eversion.
2. **If inversion is excessive:** Move the nerve electrode posterolaterally to increase eversion.
3. **If eversion is excessive:** Move the nerve electrode slightly anteriorly to decrease eversion.

The muscle electrode can also be moved to balance dorsiflexion. Bring the muscle electrode anteriorly to decrease eversion of the foot or posterolaterally to increase eversion. Avoid stimulation directly above the tibial shaft, as it can be uncomfortable and less effective.

Test the Effect of a Positional Change

1. To test the effect of a positional change, gently move the electrode and skin as a unit over the common peroneal nerve area. (Do not leave stimulation on for long. Fatigue may result.)

Note: Press gently on the electrode bases while testing to simulate pressure from the cuff.

Adjusting the Position of the Electrode While Stimulating: Patient Standing

Once proper dorsiflexion is achieved with the patient seated, if possible, retest with the patient standing, the knee extended, and the foot in the air. If necessary, adjust the stimulation or electrode position to achieve proper dorsiflexion in this position.

Transfer the Electrodes to the Lower Leg Cuff

To transfer the electrodes to the Lower Leg Cuff:

1. Press the Stim button on the EPG to stop stimulation.
2. Using a marker, make four small, evenly spaced marks on the patient's leg around the electrode bases for reference.
3. Disconnect the fitting cable from the electrode bases and Lower Leg Cuff, making sure not to move the electrodes.
4. For in-patient use, attach an cuff strap cover and personal panel to the Lower Leg Cuff.
5. Grasp the Lower Leg Cuff on each side to flare the Orthosis slightly open. Then tilt the bottom of the Cuff away from the leg about 30 degrees.
6. Position the locator of the Lower Leg Cuff below the patella, over the tibial plateau. See Figure 8-5. Make sure the cuff does not touch the electrode bases. The locator should fit snugly but comfortably under the inferior pole of the patella.

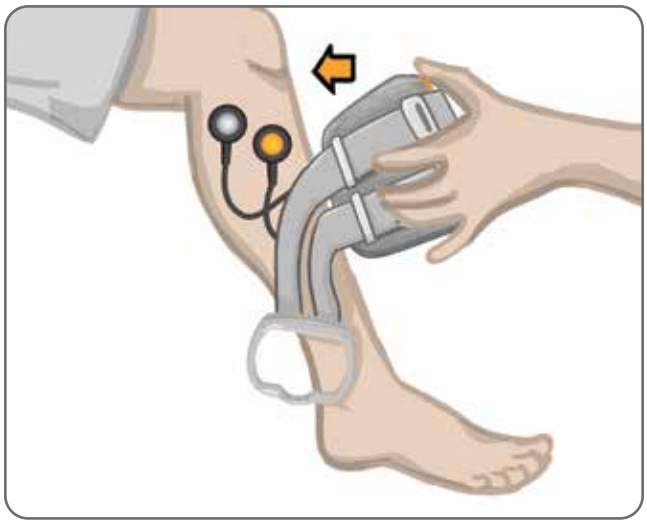


Figure 8-5: Positioning the Locator Below the Patella

7. Keeping the Lower Leg Cuff open, lower the bottom of the cuff, allowing only the front of the cuff to contact the anterior surface of the tibia. Then wrap the ends of the Lower Leg Cuff around the leg to “capture” the electrode bases. See Figure 8-6.
8. Gently remove the Lower Leg Cuff from the leg. See Figure 8-7.
9. Press firmly on the electrode bases to secure them to the Lower Leg Cuff. Plug the electrode base snaps into the cuff plug holes.

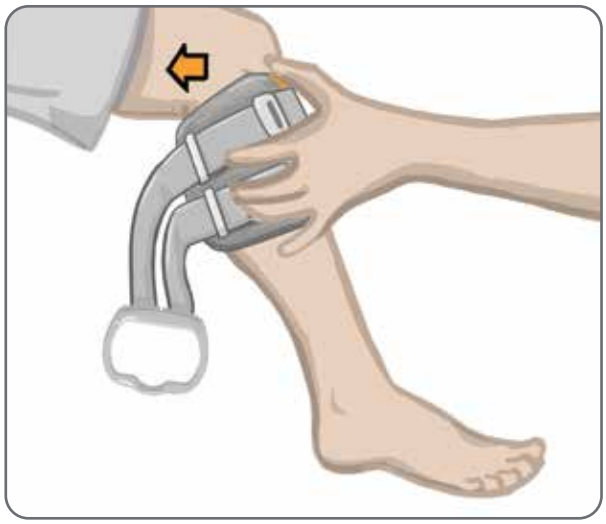


Figure 8-6: Capturing the Electrode Bases

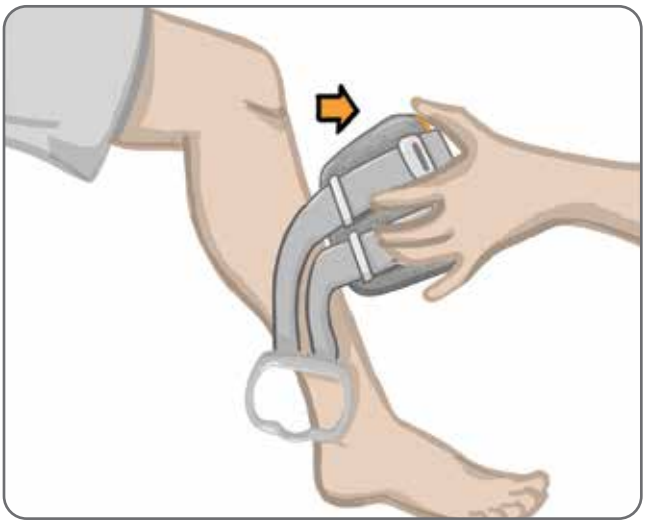


Figure 8-7: Removing the Lower Leg Cuff with Captured Electrode Bases

Donning the Lower Leg Cuff

To don the Lower Leg Cuff:

1. Wipe the leg with lukewarm water.
2. Have the patient sit and extend the knee so that the patella is clearly defined. Use a footrest if needed.
3. Tilt the top of the Lower Leg Cuff toward the leg. Gently slide the locator up to the base of the patella. Lower the bottom of the cuff until it is flush with the leg. The Lower Leg Cuff should gently grip the leg.
4. Pull the strap handle around the leg and the Lower Leg Cuff cradle to fasten it.
5. Make sure the fastened cuff fits comfortably, with the locator below the patella and the strap handle around the cradle, as shown in Figure 8-8.

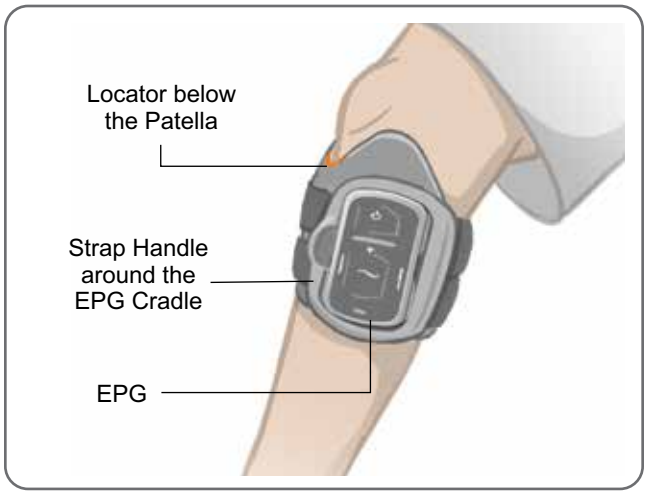


Figure 8-8: Lower Leg Cuff on the Right Leg

Retesting Electrode Placement: Patient Sitting and Standing

To retest electrode placement:

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.
3. If patient response is not accurate or is inconsistent with the original response, reposition the Lower Leg Cuff and assess the response to stimulation. Do not leave stimulation on for long, as fatigue may result.

Fitting the Round Cloth Electrodes

To fit the Round Cloth Electrode Bases: (See Figure 8-9)

1. Make sure the EPG is turned off and then remove the Lower Leg Cuff from patient's leg.
2. Mark the position of the Hydrogel Electrode Bases on the cuff liner.
3. Disconnect the snap on the Hydrogel Electrode bases from the cuff plug holes.
4. Remove the Hydrogel Electrode bases.
5. Attach the Round Cloth Electrode bases where the Hydrogel Electrode bases were attached.

Note: The Round Cloth Electrode base is 2mm smaller in height than the Hydrogel Electrode base.

6. Connect the snaps on the Round Cloth Electrode bases to the plug holes on the cuff.

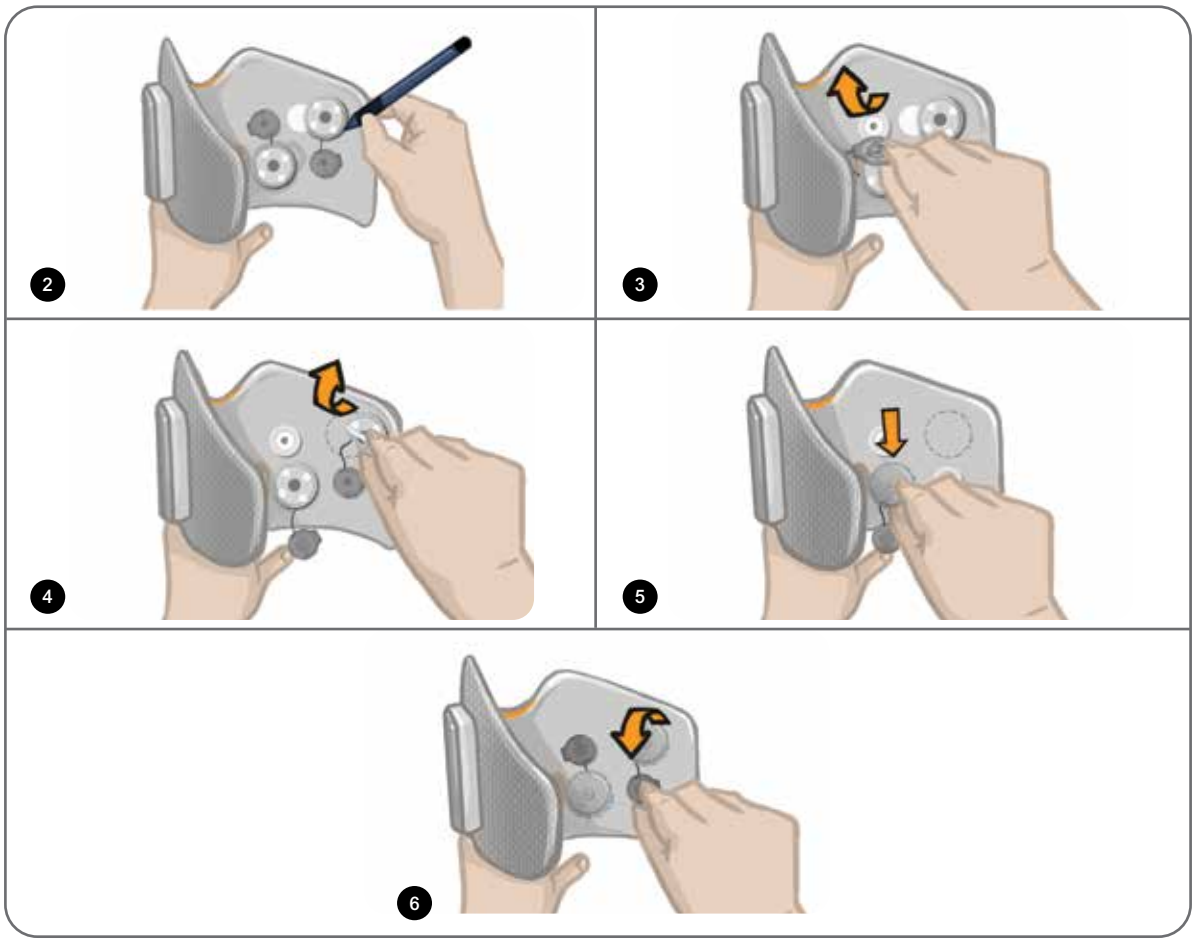


Figure 8-9: Fitting the Round Cloth Electrode Bases

To fit the Round Cloth Electrodes: (See Figure 8-10)

1. Wet the new Round Cloth Electrodes with water until saturated.
2. With a soft cloth, gently wipe or blot excess water from the back (side with the snap) of the Round Cloth Electrodes.
3. Attach the Round Cloth Electrodes to the Round Cloth Electrode bases on the cuff.
4. Don the lower leg Cuff and verify that the desired dorsiflexion response. If needed, optimize the stimulation settings and the position of the Round Cloth Electrodes.

Figure 8-10: Fitting the Round Cloth Electrode

Doffing the Lower Leg Cuff

To doff the Lower Leg Cuff:

1. Press the Power button on the EPG to turn off the system.
2. With a marker, mark the location of the Lower Leg Cuff locator on the leg for reference.
3. Unhook the cuff strap handle from the EPG Cradle, and slowly lift the Lower Leg Cuff away from the skin.

Note: For patients using the Hydrogel Electrodes with the Lower Leg Cuff, gently peel the electrodes from the skin, and reapply the electrode covers to the electrodes.

4. With a marker, make small, evenly spaced marks around the electrode bases on the liner of the Lower Leg Cuff (or on the personal panel) for reference.
5. If appropriate, cover the electrode base wires and snaps with the wire concealers. Make sure the wires are tucked under the wire concealers.

Note: Make sure to instruct patients who will be using the L100 Go System at home to ventilate the skin by removing the Lower Leg Cuff for at least 15 minutes every three to four hours.

Patient Programming

Before programming the L100 Go System make sure the electrodes and cuff have been properly fitted on the patient, and the patient is in a seated position. Refer to the "Patient Fitting" chapter in this guide for fitting instructions.

Pairing the Bioness Clinician Programmer Application to the L100 Go System

When a lower leg EPG is paired to the Bioness Clinician Programmer Application, the Bioness Clinician Programmer Application will automatically recognize the other components that are paired to that EPG.

To pair the Bioness Clinician Programmer Application to the L100 Go System:

1. Turn on the Bioness Clinician Programmer Tablet, and launch the Clinician's Application by pressing the Bioness Clinician Programmer Application (CAPP) icon.
2. The Login Screen will appear. Enter a username and password and then press the Login button.
3. The Patient Database Screen will appear. In the navigation, press the Bluetooth® icon. See Figure 9-0.

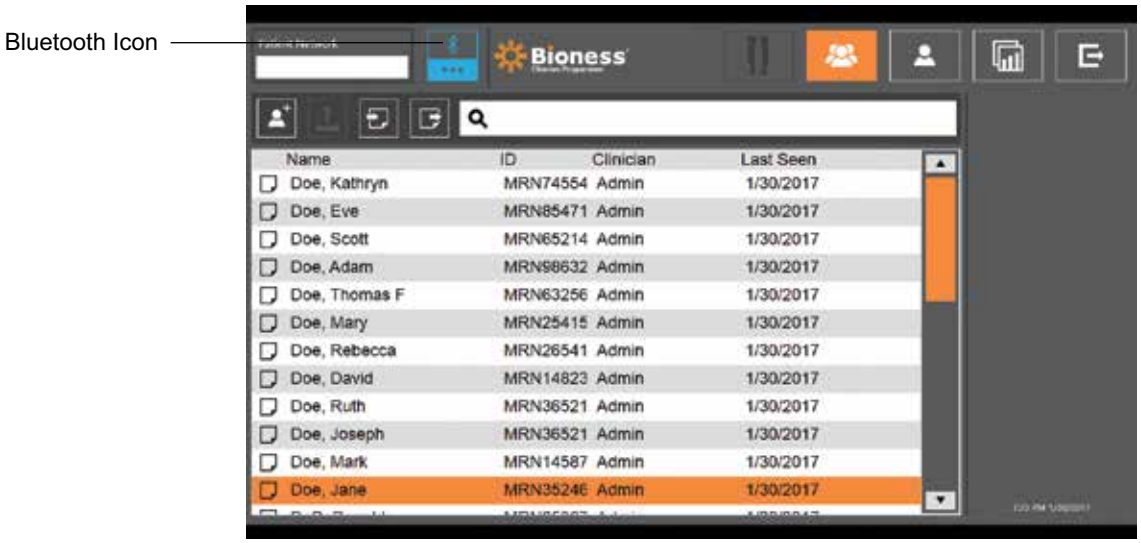


Figure 9-0: Bluetooth® Icon

4. Click on the Linking icon located above the desired leg. See Figure 9-1.
5. Place the desired EPG into Pairing mode by simultaneously pressing the plus (+) and minus (-) buttons on the EPG.
6. When paired, the Linking icon will change to a orange Unlinked icon .

Figure 9-1: Linking Screen

7. Exit the linking screen by clicking on the Bluetooth Exit Icon.
8. Once pairing has been completed, a window will be displayed prompting the user to create a new patient profile, select and upload an existing patient profile from the Patient List, or work with a patient profile already loaded onto the EPG.

Creating a New Patient Profile

To create a new patient profile:

1. Make sure a L100 Go System is paired with the Bioness Clinician Programmer Application.
2. From the Patient Database Screen, press the Add New Patient icon. See Figure 9-2.

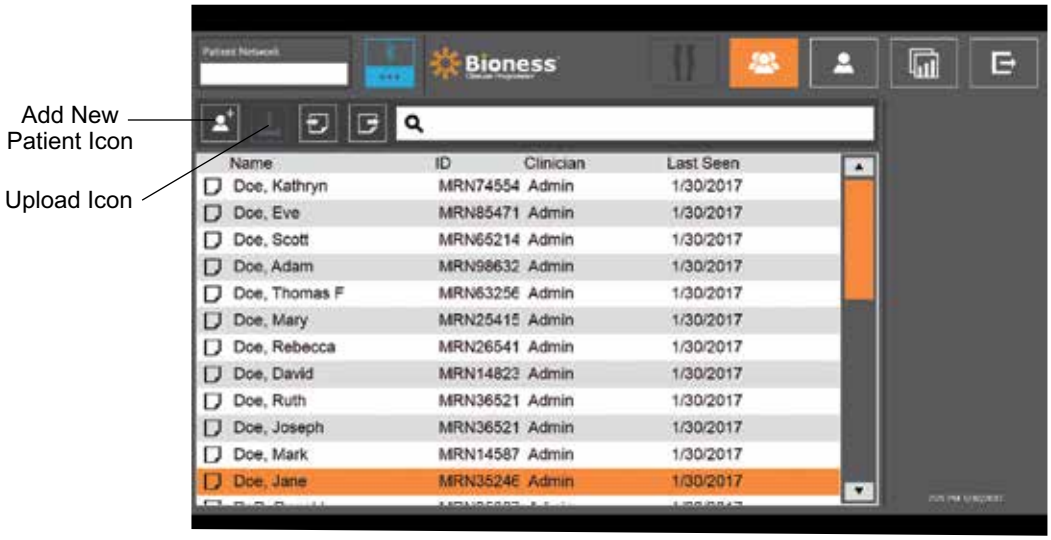


Figure 9-2: Add New Patient Icon

3. Enter in the patient demographic information (Patient ID, Legal Name, Date of Birth [MM/DD/YYYY], and Gender.
4. Press the Save button to save the new patient profile.

Uploading a Patient Profile to the L100 Go System

An existing patient profile can be uploaded to the patient network and onto the paired EPG.

To upload an existing patient profile:

1. Make sure a L100 Go System is paired with the Bioness Clinician Programmer Application.
2. Open the Patient Database Screen and highlight the patient from the Patient List. See Figure 9-2.
3. Press the Upload icon. See Figure 9-2. A window will appear stating "Program all stimulators with patient: X,X". Press the Continue button.
4. The Bioness Clinician Programmer Application will upload patient demographics to the patient network and paired EPG.
5. A window will appear stating: "X,X has been loaded onto the Programmer". Press the OK button.

Programming Stimulation Settings

Once the Bioness Clinician Programmer Application has been paired to a L100 Go System and a patient has been uploaded to the patient network the clinician then can program the stimulation settings.

To program stimulation settings:

1. Make sure the patient is in seated position.
2. Press the Program Settings icon in the navigation bar to open the Parameter Screen.
3. The screen will show the linked EPG(s) as a green icon on the diagram located on the left side of the Parameter Screen. See Figure 9-3.
4. The selected EPG will have an orange box outline around it.
5. Use the drop down lists to adjust the Waveform, Phase Duration, Pulse Rate, and Electrode parameter settings. Refer to Table 9-1 for parameter setting definitions.
6. For new patients, make sure the Stimulation Intensity Bar is set to 0. See Figure 9-3.

Figure 9-3: Programming Stimulation, Parameter Screen

7. Press the Test button to turn on stimulation. Gradually increase the stimulation intensity to the

desired level using the arrows on the Stimulation Intensity Bar. Stimulation will start with a ramp up time (time it takes for the stimulation to increase from zero to the maximum level set) equal to the ramp up time set on the Gait Screen. Do not leave stimulation on for long. Fatigue may result.

Note: When stimulation is being delivered, the Test button will appear red and the EPG icon will turn yellow with a stimulation wave.

8. If the patient is using more than one EPG, the settings will also have to be programmed to the additional EPG. Select the desired EPG icon from the Parameter Screen and repeat steps 5-7.

Any changes made to the Bioness Clinician Programmer Application settings will not be implemented and saved until the Test button has been pressed. This activates the settings and saves the information to the paired EPG.

Stim Parameter	Definition
Intensity	Strength of Stimulation: 0 mA to 100 mA, in 1mA Steps
Waveform	Type of Stimulation: Symmetric or Asymmetric
Phase Duration	Length of Time of the Pulse: 100 µsec to 300 µsec, in 50 µsec Steps.
Pulse Rate	Frequency of Stimulation: 10 Hz to 45 Hz, in 5Hz Steps
Electrode	Type of Electrode: Quickfit (default), Round Cloth, Hydrogel

Table 9-1: Stim Parameter Setting Definitions

Programming Advanced Stimulation Settings

1. From the Parameter Screen, press the Advanced Stim Setting icon to open the Advanced Stim Settings Window. See Figure 9-3 and Figure 9-4.

2. Adjust the Interphase Period and Max Stim Time advanced settings.

Advanced Stim Parameter	Definition
Interphase Period	This setting defaults to 50 to increase force production, providing the strongest contraction with minimal discomfort. Ranges vary from 20, 50, 100 and 200. Symmetric waveform default is 50, Asymmetric waveform default is 20.
Max Stim Time	To avoid excessive fatigue of the muscles that activate dorsiflexion, the L100 Go System is designed to automatically stop stimulation after a set number of seconds (the maximum duration of stimulation). This safety feature is useful when a patient sits or lies down, and the leg wearing the L100 Go System is in the air and the system is in Gait mode. It limits the duration of stimulation. To adjust the maximum duration of stimulation, press the arrows to change the duration. **For fast and stable users:** This setting can be relatively low (default setting is 4 seconds). The lowest setting should be the maximum time it takes the patient to lift the leg to climb a stair or avoid an obstacle. **For slow walkers or patients who are just beginning rehabilitation:** This setting may need to be higher than 4 seconds for a patient that requires more time to advance their leg during the swing phase of gait.

Table 9-2: Advanced Stim Parameter Setting Definitions

Figure 9-4: Programming Stimulation, Parameter Screen with Advanced Settings Window

Programming Gait Settings

To program gait settings:

1. Make sure the patient is in a standing position.
2. From the Parameter Screen, press the Gait Screen icon  .
3. The Gait Settings Screen will open. See Figure 9-6.

Figure 9-6: Programming Stimulation, Gait Settings Screen

4. Adjust the Ramp Up, Ramp Down, Extended, Delayed, and Intensity Settings. See Table 9.3.

Gait Parameter	Definition
 Ramp Up	The time, in seconds, that it takes for the stimulation to increase from zero to the maximum level set. A gradual buildup of the current makes the stimulation more comfortable, helps avoid stretch reflexes, and delays the start of muscle contraction. Values are from 0 to 0.5 seconds in 0.1-second increments.
 Ramp Down	The time, in seconds, that it takes for the stimulation to decrease from the maximum level set to zero. The current is reduced slowly to gradually reduce the muscle contraction. Increase this setting to prevent foot slap. Values are from 0 to 0.5 seconds in 0.1-second increments.
 Extended	The percentage of total time from heel on to heel off that the stimulation continues after heel contact with the ground. This parameter determines the length of time before the stimulation starts to ramp down. Increase this setting to prevent foot slap and genu recurvatum (knee hyperextension/knee snapping) or to increase ankle stability during stance.
 Delayed	The percent of total time that the stimulation is delayed after a gait event is detected. Used to prevent premature lifting of the foot. This parameter determines the length of time before the stimulation starts to ramp up. (The delay % is calculated from total time of "heel off" to "heel on".)
Gait Parameter	**Definition**
Intensity	The strength of the electrical stimulation. Values are from 0 to 100 mA. The initial value appearing on the intensity bar will be the level established when configuring the stimulation settings. Changes can be made to the intensity level while in Gait mode and will be maintained in Training mode unless you have activated the “Enable specific intensity level” for Training mode on the Training Screen.

Table 9-3: Gait Parameter Definitions

Note: To minimize genu recurvatum (knee hyperextension/knee snapping) and foot slap, use the Extended option to create an eccentric contraction of the dorsiflexors after heel contact.

5. Press the Stimulation button to test and save the settings. Stimulation will respond to gait activity input from the EPG integrated motion sensor.
6. Fine-tune settings while the patient is walking.
7. Press the Stimulation button again to stop stimulation.

Programming Training Settings

To program training settings:

1. From the Parameter Screen, press the Training Screen icon  .
2. The Training Settings Screen will open. See Figure 9-7.

Figure 9-7: Programming Stimulation, Training Settings Screen

3. Select Include stimulator in Training by clicking on the box to add a check mark.
4. Adjust On Time, Off Time, Ramp Up, Ramp Down, and Total time settings. See Table 9-5.
5. If a stimulation intensity different than the one set for the gait intensity is desired, check the box next to "Enable Specific Training Intensity". Then adjust the stimulation intensity level.
6. Press the Training Stimulation button to start stimulation in Training mode.
7. Press the Training Stimulation button again to turn off stimulation or let the program run its allotted time.

Training Parameter	Definition
On Time	The amount of time that stimulation is applied.
Off Time	The amount of rest time between stimulations
Ramp Up	The time, in seconds, that it takes for the stimulation to increase from zero to the maximum level set. A gradual buildup of the current makes the stimulation more comfortable, helps avoid stretch reflexes, and delays the start of muscle contraction. Values are from 0 to 2 seconds in 0.5-second increments.
Ramp Down	The time, in seconds, that it takes for the stimulation to decrease from the maximum level set to zero. The current is reduced slowly to gradually reduce the muscle contraction. Increase this setting to prevent foot slap. Values are from 0 to 2 seconds in 0.5-second increments.
Total Time	The total amount of time for the training period. The training period consists of repeated cycles of the Ramp Up, On Time, Ramp Down, and Off Time parameters, until the total session time expires.

Table 9-5: Training Parameter Definitions

Changing Audio and Vibration Feedback Settings Using the Bioness Clinician Programmer Application

The Programming Stimulation Gait Settings, and Training Settings Screens feature an Audio Feedback icon and a Vibration Feedback icon. These icons enable or disable audio and vibration feedback during stimulation. The icons on the Gait Settings Screen control audio and vibration feedback when the EPG is in Gait mode. The icons on the Training Settings Screen control audio and vibration feedback when the EPG is in Training mode.

Icon	Definition
	Audio Feedback is Enabled
	Audio Feedback is Disabled
	Vibration Feedback is Enabled
	Vibration Feedback is Disabled

Patient Training

Clinicians and patients should know the limitations, warnings, and precautions associated with the L100 Go System. Clinicians should review the safety information with patients, and train patients on system set-up, operation, and maintenance. Patients should understand the system displays and indicators, and the troubleshooting solutions. Clinicians and patients should know whom to contact for clinical and technical support.

A training program should cover the following topics, which are described in this guide and in the L100 Go User Guide:

- General safety information, including the Skin Care Guidelines
- An overview of the L100 Go System
- Donning and doffing the cuff
- Replacing the electrodes and electrode bases
- The system component buttons, displays, and audio alerts: their definitions and functions
- Using Gait and Training modes
- Maintenance and cleaning instructions
- Review of basic troubleshooting
- How to contact Technical Support

Maintenance and Cleaning

Charging

Charge the Bioness Clinician Programmer Tablet daily. The lower leg EPG batteries should also be charged daily. EPG charging instructions can be found in the "Charging the L100 Go System" section of this guide.

EPG Battery Maintenance

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

The Quick Fit Electrodes will need to be replaced at least every two weeks or sooner if they become worn.

Caution: Use only the electrodes supplied by Bioness.

Caution: Do not use the L100 Go System without electrodes.

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

To replace the Quick Fit Electrodes: (See Figure 11-1)

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.

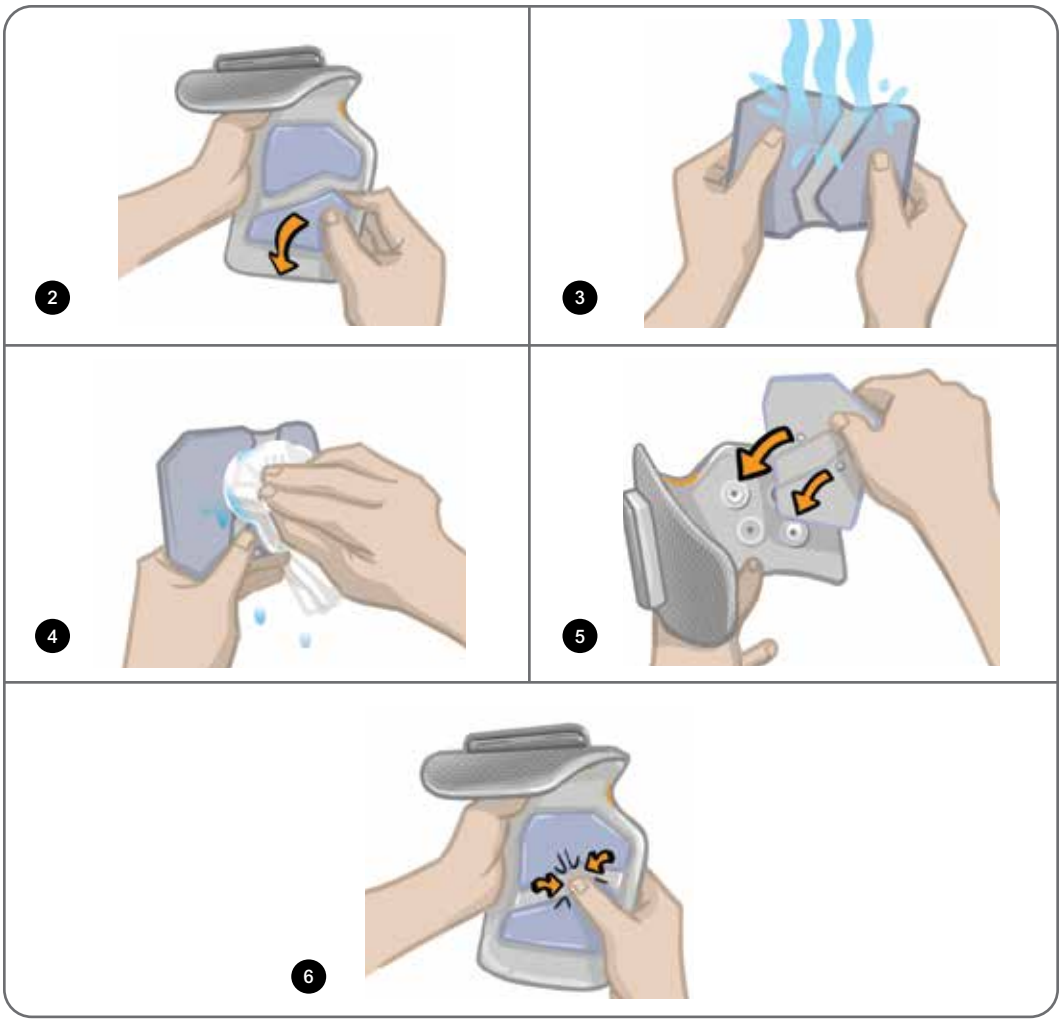


Figure 11-1: Replacing the Quick Fit Electrode

Instruct the patient to remove and re-wet the entire Quick Fit Electrode every time they remove the Lower Leg Cuff from their 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, the response to the stimulation may change. If the patient needs to adjust stimulation intensity more often than usual, try re-wetting or replacing the electrode.

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

Replacing the Round Cloth Electrodes

The Round Cloth Electrodes will need to be replaced 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 Round Cloth 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. The electrode bases may be cleaned and low-level disinfected using 70% isopropyl alcohol (IPA).
4. Wet the Round Cloth Electrodes with water until they are saturated. See Figure 11-2.
5. With a cloth, gently wipe or blot excess water off the back (side with the snap) of the electrodes. See Figure 11-2.

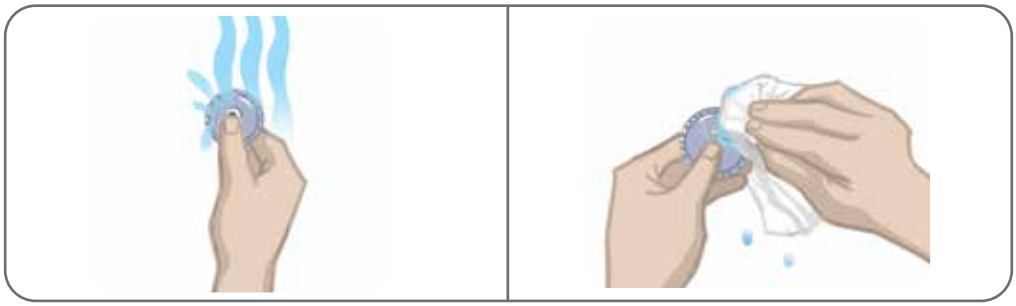


Figure 11-2: Wetting and Removing Excess Water

6. Attach the Round Cloth Electrodes to the electrode bases. See Figure 11-3.

Figure 11-3: Attaching the Round Cloth Electrodes

Instruct the patient to remove and re-wet the Round Cloth Electrodes every time they remove the Lower Leg Cuff from their 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, response to the stimulation may change. If the patient needs to adjust stimulation intensity more often than usual, try re-wetting or replacing the electrode. When not in use, store the Round Cloth Electrodes where they can air dry.

Replacing the Hydrogel Electrodes

The Hydrogel Electrodes will need to be replaced 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 L100 Hydrogel Electrodes: (See Figure 11-4)

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. The electrode bases may be cleaned and low-level disinfected using 70% isopropyl alcohol (IPA).
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, and then press firmly.
7. Remove the covers from the electrodes.

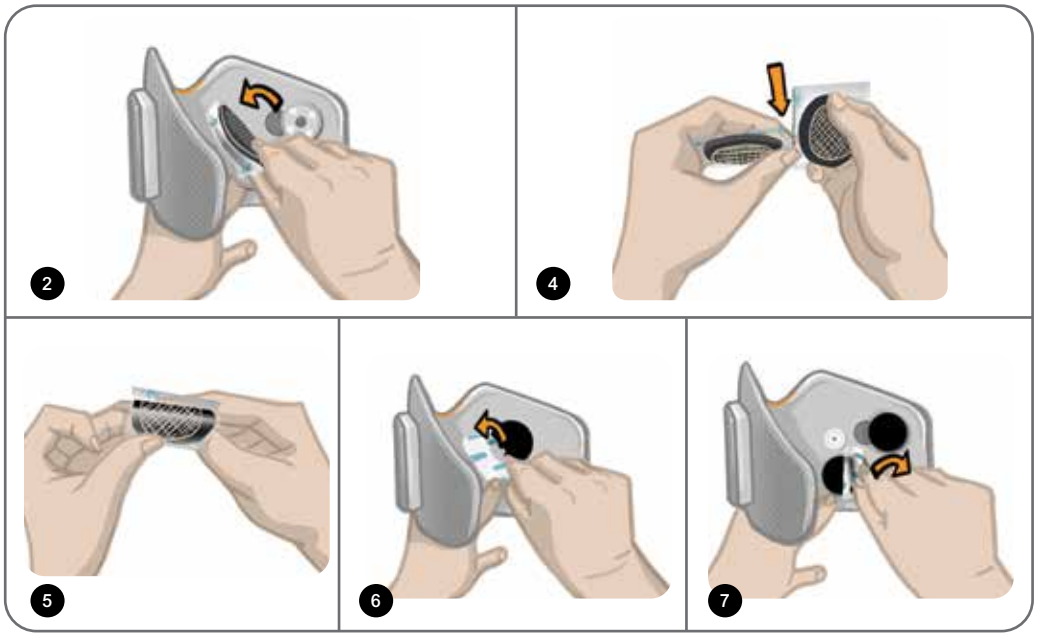


Figure 11-4: Replacing the Hydrogel Electrodes

Save the covers to protect the electrodes between uses. When reapplying the covers, make sure the Bioness logo faces up. If the electrode gel becomes dry, replace with a new electrode set.

Replacing the Electrode Bases

Depending on use it may be necessary to need to replace the electrode bases after one year of use.

To replace the electrode bases:

1. Remove the wire concealers and mark the position of the used electrode bases on the cuff liner with a permanent marker. See Figure 11-5.
2. Disconnect the electrode base snaps from the plug holes. See Figure 11-5.

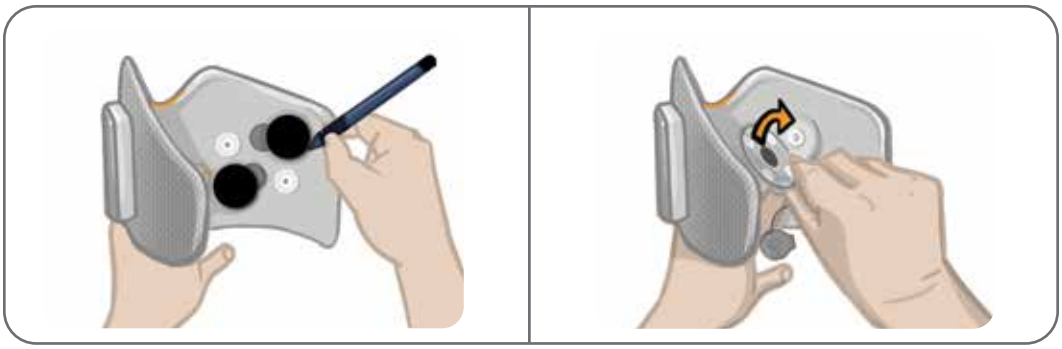


Figure 11-5: Mark Position of Electrode Base (Left)
Disconnect Electrode Base Snaps (Right)

3. Remove the used electrode bases from cuff. See Figure 11-6.
4. Attach the new electrode bases where the previous bases were attached. See Figure 11-7.
5. Connect the electrode base snaps to the plug holes. See Figure 11-7.
6. Recover the wires and snaps with the wire concealers, if desired.

Figure 11-6: Removing the Used Electrode Bases

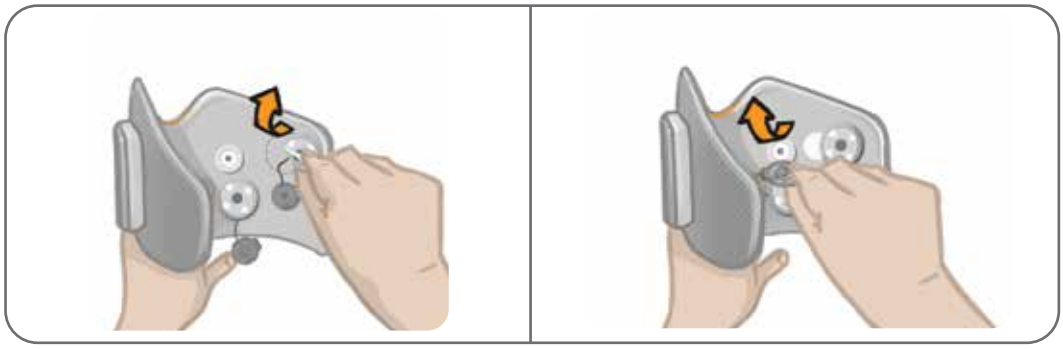


Figure 11-7: Attaching New Electrode Bases (Left)
Connecting Electrode Base Snaps (Right)

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.

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.

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 the L100 Go System Components

All L100 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. Bioness recommends cleaning 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, re-apply 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 in clean, lukewarm water for an additional 15 minutes.
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 4 to 12 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.

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.

Pairing a Replacement EPG

The L100 Go System components must be paired to each other to communicate wirelessly. When an EPG is replaced, the new replacement component must be paired to the existing component.

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

EPG Pairing Setup

1. Make sure the new EPG is fully charged. See the "Charging the L100 Go System" 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.

Troubleshooting

Using the Tester

The Tester is used in place of the electrodes and can help to troubleshoot if there is a disconnection in the Lower Leg Cuff or the EPG. The Tester provides audio feedback when connected to the Lower Leg Cuff. Audio feedback is delivered when stimulation is applied using the Bioness Clinician Programmer application or EPG. See Figure 12-1 for tester placement.

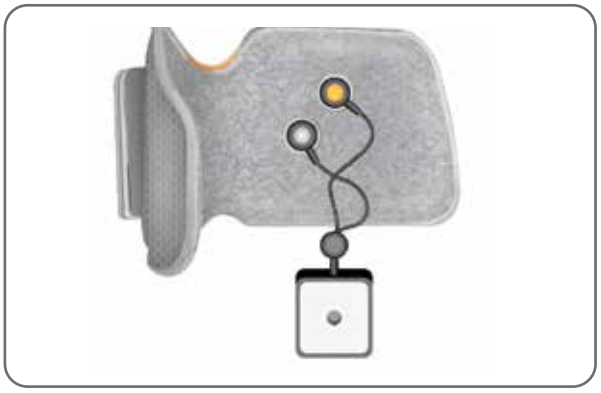


Figure 12-1: Tester Connected to Lower Leg Cuff

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 12-1 for the error code descriptions and solutions.

Error Code	Description of Error	Solution
E1	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.
E2	Understimulation Fault	Stimulation being delivered is lower than expected. Possible hardware issue. Stop using the L100 Go System and contact Bioness.
E4	Parameter Corrupted	Patient will need to have their L100 Go System reprogrammed by their clinician. Stop using the L100 Go System and contact Bioness.
E5	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.

Error Code	Description of Error	Solution
E6	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.
E7	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.
E8	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.
E9	EPG Battery Empty	Charge the EPG. Refer to the "Charging the L100 Go System" section in this guide.
E10	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.
E12	General Pairing Fault (Pairing Timeout Expires)	Repeat the pairing process. Refer to the "Pairing Replacement Part Components" chapter in this guide.

Table 12-1: Bioness Clinician Programmer Application Error Codes

Frequently Asked Questions

If you have any questions or concerns, please contact the Bioness Client Support Department at 800.211.9136, Option 3 (USA & Canada) or your local distributor. You may also visit www.bioness.com.

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 and the Status Indicator Light will flash red. When the battery is near empty the EPG will emit an audible alarm in addition to the low battery lights until it is completely discharged or connected to a power source.

What do 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 the patient’s ankle is not moving (or the 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 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 the patient is walking, but the L100 Go System is not indicating any errors?

Have the patient stop walking and shift their weight from side to side.

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

Have the patient stop using the L100 Go System immediately and contact Bioness. The patient should resume use only when the skin is completely healed. Give patients the L100 Go Skin Care Guidelines and a skin conditioning protocol.

How can I verify that current is flowing through the L100 Go System?

Connect the Tester to the cuff. The Tester will buzz when stimulation intensity is at least 10 mA.

What else can I use the Tester for?

The Tester can be used as an educational tool, to demonstrate when stimulation is on in the various stimulation modes.

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
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:** $d = 1.2\sqrt{P}$

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**
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz Proximity Fields per 60601-1-2 4th edition	[E1] = 10 V/m in 26 MHz to 2.7 GHz Proximity Fields per 60601-1-2 4th edition	**Recommended separation distance:** d = 0.4√P, 80–800 MHz range d = 0.7√P, 800-2700 MHz range

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
NOTE 3: *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
NOTE 4: Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
NOTE 5: Interference may occur in the vicinity of equipment marked with the following symbol: 

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 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.

Network Safety, Security, and Privacy

The security of Bioness products is an important factor in protecting information and systems from external and internal threats. Therefore, customers must take responsibility for maintaining a secure IT environment that is compliant with general IT standards. Bioness encourages customers to implement the following industry-standard practices:

- Physical Security (e.g. do not allow unauthorized individuals to use the Bioness Clinician Programmer tablet and application)
- Operational Security (e.g. do not leave sensitive information, such as exported files, on the Bioness Clinician Programmer tablet, and do not leave a logged-in tablet unattended, do not connect the tablet to the Internet and be careful inserting flash drives to the tablet, do not alter the tablet software and install unauthorized software on it including Virus scan software)
- Procedural Security (e.g. create awareness of the dangers of social engineering, create separate login credentials for each user for the Bioness Clinician Programmer application, and disable unused accounts)
- Risk Management
- Security Policies
- Contingency Planning

The implementation of security practices may vary by site and include many other technologies, such as firewalls, virus scanning, and anti-spyware software, etc. Although online functionality is disabled on the Bioness Clinician Programmer tablet, a remote possibility remains that the system can be hacked or altered. If such an occurrence is suspected, contact the Bioness Client Support Department at 800.211.9136, Option 3 (USA & Canada) or your local distributor. Additional information related to security, privacy, and available software upgrade to the system can also be requested from this department.

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Innovations For Active Healing

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AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL
HAZARDS ONLY IN ACCORDANCE WITH:
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