bioventus®

Innovations For Active Healing

Bioness Inc.
25103 Rye Canyon Loop
Valencia, CA 91355 USA
Telephone: (800) 211-9136 or (661) 362-4850
Email: bionessrehab@bioventus.com
Website: www.bionessrehab.com

Rx Only

612-01232-001 Rev. B
09/2023

L360™

Thigh System

Functional Electrical Stimulation and
Neuromuscular Electrical Stimulation System

CLINICIAN'S GUIDE

bioventus®

Innovations For Active Healing

Disclaimer

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

Environmental Policy

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

List of Symbols

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

Table of Contents

Introduction

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

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

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

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

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

Figure 1-1: L360 Thigh System

This L360 Thigh System Clinician's Guide describes:

- Important safety information about the L360 Thigh System.
- The components of the L360 Thigh System.
- How to set up, operate, and maintain the L360 Thigh System.
- The Clinician Application software.
- How to fit the L360 Thigh System.
- How to program the L360 Thigh System.
- Troubleshooting information.

The L360 Thigh System includes components and accessories required for fitting and programming. This Clinician's Guide describes the system components and instructions for use. Refer to the L360 Thigh System User’s Guide for comprehensive information on the L360 Thigh 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 L360 Thigh System. If you have any questions contact Customer Service at 800-211-9136, Option 3 (USA & Canada) or your local distributor. You may also visit www.bionessrehab.com.

Safety Information

Indications for Use

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

The L360 Thigh System may also:

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

Contraindications

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

⚠ Warnings

- The L360 Thigh System should not be used on a leg where a metallic implant is directly underneath the electrodes.
- The L360 Thigh System should not be applied over, or in proximity to, cancerous lesions.
- The L360 Thigh System should not be used on a leg with a regional disorder, such as a fracture or dislocation, which could be adversely affected by motion from the stimulation.
- The long-term effects of chronic electrical stimulation are unknown.
- The Thigh Cuff should not be worn over swollen, infected, or inflamed areas or skin eruptions, such as phlebitis, thrombophlebitis, and varicose veins.
- Simultaneous connection of the L360 Thigh System to the 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 L360 Thigh System within three feet of short wave or microwave therapy equipment. Such equipment may produce instability in the EPG output.

- The L360 Thigh System should only be configured by an authorized clinician.
- In case of any inconvenience, turn off stimulation and remove the Thigh Cuff. If the stimulation cannot be turned off, remove the Thigh Cuff to stop stimulation.

Precautions

- Inflammation in the region of the Thigh Cuff may be aggravated by motion, muscle activity, or pressure from the cuff. Advise patients to stop using the L360 Thigh System until any inflammation is gone.
- Use caution when treating patients with suspected or diagnosed heart problems.
- Advise patients to use the Thigh 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 or electrode placement.
- Do not use the L360 Thigh System without electrodes.
- After removing the Thigh Cuff, it is normal for the areas under the electrodes to be red and indented. The redness should disappear in approximately one hour. Persistent redness, lesions, or blisters are signs of irritation. Advise patients to stop using their L360 Thigh System until any inflammation is gone and to alert their clinician.
- Advise patients to stop using their L360 Thigh System and consult their clinician if stimulation does not start at the correct time during gait.
- Advise patients to turn off the L360 Thigh System when at a refueling place. Do not use the L360 Thigh System near flammable fuel, fumes, or chemicals.
- Only a treating clinician should determine electrode placement and stimulation settings.
- The L360 Thigh System should be kept out of the reach of children.
- Use only the L360 Thigh System electrodes supplied by Bioventus.
- Turn off the L360 Thigh System before removing or replacing the electrodes.
- Specific physician clearance should be obtained before using the L360 Thigh System on patients who have an alteration of normal arterial or venous flow in the region of the Thigh Cuff because of 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 L360 Thigh System when patients have a structural deformity in the area to be stimulated.
- The safe use of the L360 Thigh System during pregnancy has not been established.

- Skin problems, on the leg where the Thigh Cuff is worn, may be aggravated by the L360 Thigh System.
- Adult supervision and assistance should be provided for anyone needing help while using the L360 Thigh System.
- The patient is the intended operator of the L360 Thigh System.
- The Control Unit neck strap is meant to be worn around the neck and if not used properly could cause bodily harm.
- Protect all electronic components from contact with water, such as from sinks, bathtubs, shower stalls, rain, snow, etc.
- Do not leave the L360 Thigh System stored where temperatures may exceed the acceptable environmental range: -25°C to 55°C (-13°F to 131°F). Temperature extremes can damage the components.
- Do not attempt to repair your L360 Thigh System. Contact Customer Service if you experience a technical problem not covered in this guide.
- The Thigh Cuff is to be worn only on the leg of the 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 L360 Thigh System before putting on the Thigh Cuff. Do not turn on the L360 Thigh System until the Thigh Cuff is fastened in place.
- Advise patients to shut off the L360 Thigh 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 L360 Thigh System electronic components from condensation. When moving the components between hot and cold temperatures, place them in an airtight plastic bag, and let them slowly (for at least two hours) adjust to the temperature change before use.
- Medical electrical equipment needs special precautions for electromagnetic compatibility.
- Advise patients to remove the L360 Thigh 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 L360 Thigh System immediately and consult their physician:

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

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

Skin Care Guidelines

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

- Clean the skin where the electrodes adhere with a wet washcloth. If any oils or lotions are on the skin, then clean with soap and water. Rinse well.
- Always check the skin for redness or a rash when putting on and taking off the Thigh Cuff.
- Replace the electrodes 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.
- Excess body hair where the electrodes adhere may reduce electrode contact with the skin. If necessary, remove excess body hair with an electric shaver or scissors. Do not use a razor. A razor can irritate the skin.
- When positioning the Thigh Cuff, make sure the electrodes uniformly contact the skin.
- Ventilate the skin by removing the Thigh Cuff for at least 15 minutes every three to four hours.

If skin irritation or a skin reaction occurs,patients should stop using their L360 Thigh System immediately and contact their clinician or dermatologist. They can also contact Customer Service 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.

Environmental Conditions that Affect Use

Radio Frequency (RF) Communication Information

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

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

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

Portable and mobile RF communications equipment can affect the L360 Thigh System.

Conformity Certification

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

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

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

Travel and Airport Security

The L360 Thigh 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 L360 Thigh System before going through airport security and to wear loose clothing so they can easily show the security person their L360 Thigh System. The L360 Thigh System will likely set off the security alarm. Patients should be prepared to remove the L360 Thigh 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 L360 Thigh System prescription.

Patients can request a copy of their prescription by contacting Customer Service or their physician.

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

Electromagnetic Emissions

The L360 Thigh System needs special precautions regarding electromagnetic compatibility (EMC). The system needs to be installed and put into service according to the EMC information provided in this manual. See Chapter 15.

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

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

⚠ Warnings

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

Incident Reporting

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

The L360 Thigh System

The L360 Thigh System consists of a Thigh Cuff with an External Pulse Generator (EPG), an optional Control Unit, and an optional Foot Sensor.

The components in the L360 Thigh System communicate wirelessly to stimulate the quadriceps or hamstrings in order to provide knee flexion or extension.

Thigh Cuff

The Thigh Cuff is a low-profile orthosis that fits above the knee, centered on the back or front of the thigh. It is designed to assist with knee flexion or extension. See Figure 4-1. The Thigh Cuff is available in right and left configurations.

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

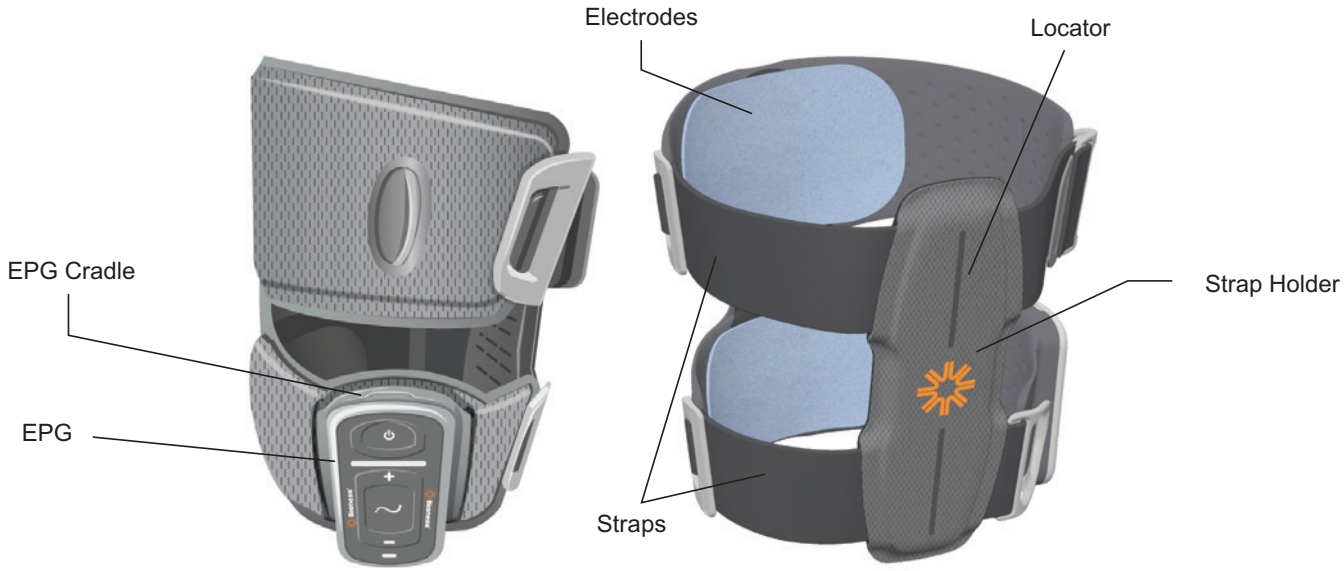


Figure 4-1: Thigh Cuff

The effectiveness of eliciting muscle contraction force in the Thigh Cuff 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 parameters to provide sufficient knee flexion or extension during walking.

External Pulse Generator (EPG)

The EPG contains an integrated motion sensor and gait detection algorithm to synchronize electrical stimulation with the gait events (heel on and heel off). The EPG also responds to standard Bluetooth® Low Energy (BLE) wireless signals from the optional Control Unit and Foot Sensor. The EPG generates the electrical stimulation used to flex or extend the knee.

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 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 myBioness™ App or the Control Unit. 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 EPG 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.

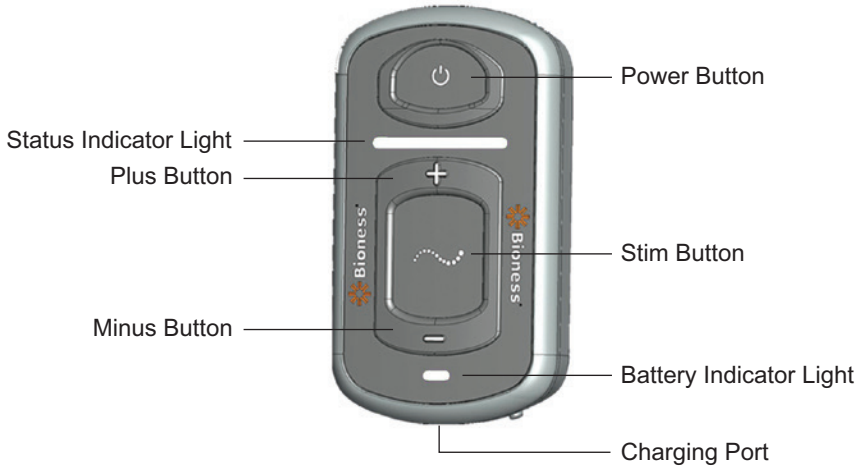


Figure 4-2: EPG

The EPG emits visual (See Table 4-1) and/or audio feedback when:

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

The EPG provides vibration feedback when:

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

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

Table 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

Control Unit

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

The Control Unit includes six buttons and an LCD display. See Figure 4-3, Table 4-3, and Table 4-4. It is powered by a single button cell lithium battery (CR2032 battery). The Control Unit LCD Display screen communicates the L360 Thigh System performance. It displays stimulation intensity level, operating mode, battery charge status, electronic registration status, and error messages. See Table 4-4.

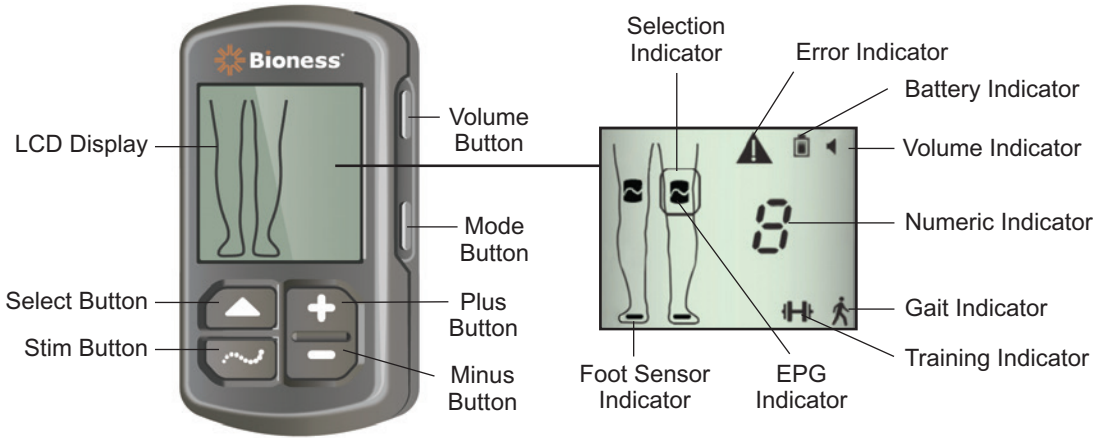


Figure 4-3: Control Unit

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

Table 4-3: Control Unit Button Functions

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

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

Table 4-4: Control Unit LCD Display Icon Descriptions

L360 Thigh System Operating Modes

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

Gait Mode

Gait mode is used for walking. In Gait mode, the stimulation is synchronized with gait events, using either the EPG integrated motion sensors or the Foot Sensor to assist 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 EPG is controlled by the same gait event detector: either via the motion sensor in the EPG or via the Foot Sensor, at the appropriate phase of gait.

Cycle Training Mode

Cycle Training mode is used to train muscles while the patient is using a stationary bicycle. In Cycle Training mode, the stimulation is synchronized with the cycle of the crank position to assist knee extension or flexion. Stimulation during Cycle Training mode is patient-initiated and requires the patient to engage in the motion of pedaling.

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

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 Foot Sensor and the motion sensors in the EPG. Stimulation is delivered in pre-set cycles.

Training mode is designed to facilitate muscle re-education, prevent or retard disuse atrophy of the thigh muscles, maintain or improve range of motion of the knee joints, and improve local blood circulation. It may also provide early post-surgical quadricep and hamstring strengthening, improve post-surgical knee stability secondary to quadricep and hamstring strengthening, and relax muscle spasms.

Clinician Mode

Clinician mode allows the clinician to apply enhanced training. Clinician mode is used to start/pause stimulation in the Thigh Cuff independently or simultaneously. For example, the clinician may select Clinician mode to enhance training to include balance training in acute and sub-acute patients. Clinician mode uses the stimulation parameters set for Gait mode. The clinician can enable Clinician mode by pressing and holding the Stim and Minus buttons for five seconds on the Control Unit. Pressing the Stim button will deliver manual stimulation to the selected Cuffs while the Stim button is pressed. To exit Clinician mode, press the Mode button.

Foot Sensor

The Foot Sensor is an optional component of the L360 Thigh System. The Foot Sensor uses a dynamic gait tracking algorithm to detect whether the foot is on the ground or in the air and transmits wireless signals to the EPG(s) to synchronize stimulation according to the gait pattern.

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

The Foot Sensor features a pressure sensor, transmitter, and clip. See Figure 4-4. The pressure sensor fits under the insole of the patient's shoe. The transmitter is worn clipped to the inner rim of the shoe. The Foot Sensor also includes two indicator lights and is powered by a single button cell lithium battery (CR2032 battery). See Figure 4-4 and Table 4-5.

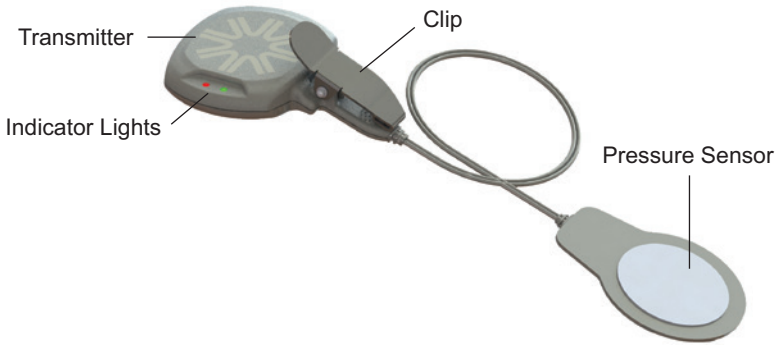


Figure 4-4: Foot Sensor

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

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

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

Table 4-5: Foot Sensor Displays

Charging the L360 Thigh System

The EPG is the only L360 Thigh System component that can be charged. The EPG(s) must be charged daily and Bioventus recommends charging the EPG(s) while attached to the Thigh Cuff(s).

The EPG(s) will need to be charged with the system charger set that is included in the L360 Thigh System Kits. 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 L360 Thigh 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 any of the two available USB ports on the AC adapter. If you are charging both the right and left Thigh Cuff, connect an additional USB charging cable to the AC adapter. See Figure 4-5.

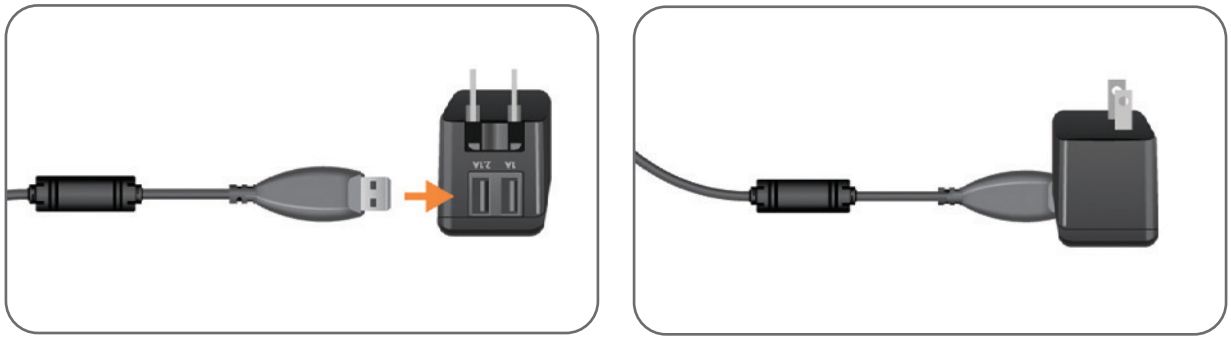


Figure 4-5: Inserting USB Charging Cable into AC Adapter

3. Connect the magnetic end on the charging cable to the charging port on the EPG. The charging port is located at the bottom of the EPG. See Figure 4-6.
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.

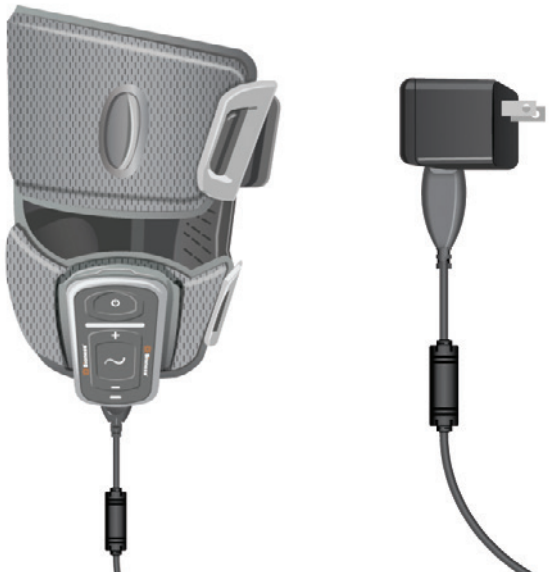


Figure 4-6: L360 Thigh System Charging Setup

⚠ **Caution:** Use only the charger included in the L360 Thigh 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 L360 Thigh System while the EPG is charging.

Turning the L360 Thigh System On/Off

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

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

Selecting an Operating Mode Using the Control Unit

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

To select an operating mode using the Control Unit:

1. Turn on the EPG by pressing the power button on the EPG(s).
2. Turn on the Control Unit by pressing any button.
3. The paired EPG(s) will appear in the digital display on the Control Unit with the Selection Indicator icon around the EPG Indicator icon(s). See Figure 4-7. Refer to "Pairing a New Control Unit to the EPG" section for pairing instructions.
4. For patients using both right and left Thigh Cuffs, the Select button on the Control Unit can be used to toggle between the right and left EPG or to select both EPGs. See Figure 4-7.

5. To select Gait mode, press the Mode button on the Control Unit until the Gait Indicator icon appears in the lower right corner of the digital display. See Figure 4-7.
6. To select Training mode, press the Mode button on the Control Unit until the Training Indicator icon appears in the lower right corner of the digital display. See Figure 4-7.

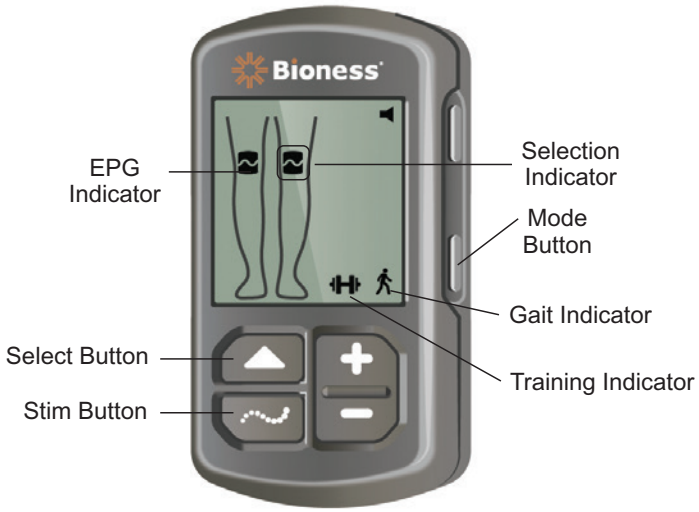


Figure 4-7: Selecting a Operating Mode on the Control Unit

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

To turn on an operating mode using the EPG:

10. Turn on the EPG(s) by pressing the Power button on each of the EPG(s).
11. Press the Stim button on one of the EPG(s) to activate Gait mode.
12. Press and hold the Stim button on the EPG(s) for three seconds to activate Training mode. Press Stim button for an additional three seconds to return to Gait mode.

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

Adjusting Stimulation Intensity Using the Control Unit

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

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

To adjust stimulation intensity (for patients using one Thigh Cuff):

1. Press the Plus or Minus button on the Control Unit or on the EPG to increase or decrease the stimulation intensity. See Figure 4-8.
2. The new level number will appear in the digital display on the Control Unit.

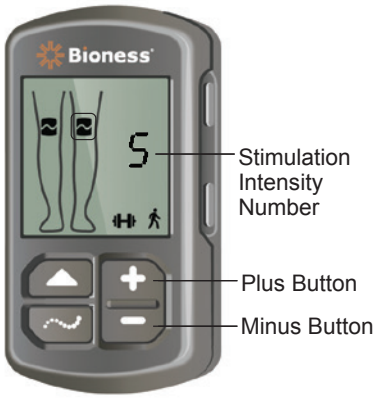


Figure 4-8: Adjusting Stimulation Intensity

To adjust stimulation intensity (for patients using both the right and left Thigh Cuffs):

1. The stimulation intensity will need to be adjusted separately for each connected EPG. Press the Select button on the Control Unit to select the desired EPG. See Figure 4-8.
2. Press the Plus or Minus button on the Control Unit to increase or decrease the stimulation intensity. See Figure 4-8.
3. The new level number will appear in the digital display on the Control Unit.
4. Repeat steps one through three for the other connected EPG.

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

Changing Audio and Vibration Feedback Using the Control Unit

The EPG has the capability to provide audio and vibration feedback when stimulation is being delivered. The audio and vibration feedback setting is adjusted by the Clinician Application. If audio feedback during stimulation is enabled, the patient can turn it off using the Control Unit.

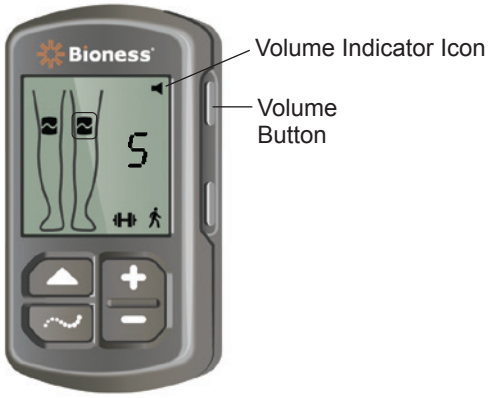


Figure 4-9: Volume Button on Control Unit

To turn off audio feedback during stimulation:

1. Press the Volume button on the Control Unit. See Figure 4-9. The Volume Indicator icon in the upper right corner of the digital display will disappear.

To turn on audio feedback during stimulation:

1. Press the Volume button on the Control Unit. See Figure 4-9. The Volume Indicator icon in the upper right corner of the digital display will appear.

Turning Stimulation Off Using the Control Unit and EPG

To turn stimulation off using the Control Unit:

1. Turn on the Control Unit by pressing any button.
2. The stimulating EPG(s) will appear in the digital display on the Control Unit as an EPG- Stim State icon.
3. To stop stimulation, press the Stim button on the Control Unit. See Figure 4-7.

To turn stimulation off using the EPG:

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

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

L360 Thigh System, Components and Accessories

Clinician Programmer

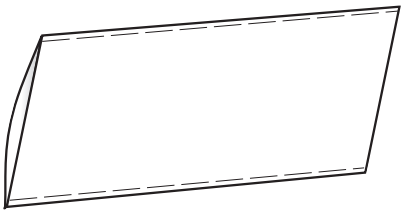
The Clinician Programmer is used to program the L360 Thigh System and consists of the following items:

- Clinician Programmer, Tablet with Software and Stylus
- Bluetooth® Dongle
- Clinician Programmer Charger

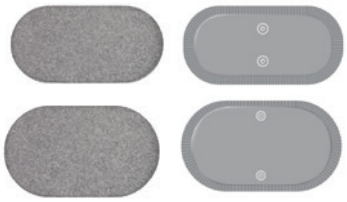
L360 Thigh System Components and Accessories

Note: Items sold separately.

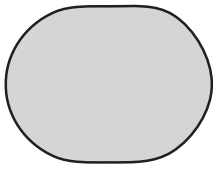
Clinician Programmer



Strap Covers



Thigh Electrodes



Foot Sensor Pads
(optional)

Tester

Fitting and Testing Accessories Descriptions

Thigh Cloth Electrodes

The thigh cloth electrodes transmit the electrical signal from the EPG to the target nerve.

The Thigh Cuff uses two cloth electrodes to provide electrical stimulation to the muscles in the upper leg. See Figure 6-1. The Thigh Electrodes snap to the Thigh Cuff proximal and distal panels.

⚠ **Caution:** The electrodes are to be used by no more than one individual patient. The L360 Thigh System electrodes are for single patient use only to prevent cross contamination. To re-order electrodes, contact your local representative or visit www.BionessRehab.com

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

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

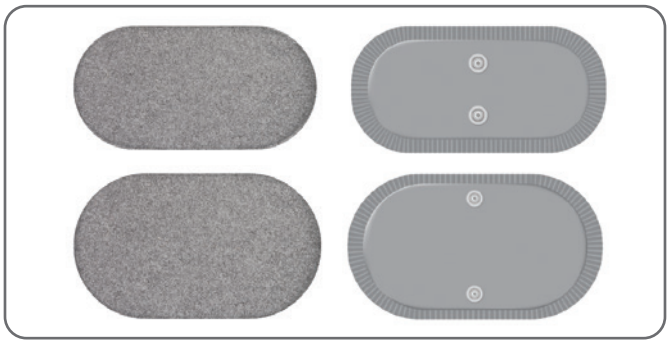


Figure 6-1: Thigh Electrodes

Foot Sensor Pads

The Foot Sensor Pad is used to secure the Foot Sensor pressure sensor to the inside of the patient's shoe. The Foot Sensor pad is placed under the insole, and the Foot Sensor pressure sensor is placed on top of the Foot Sensor pad. See Figure 6-2.

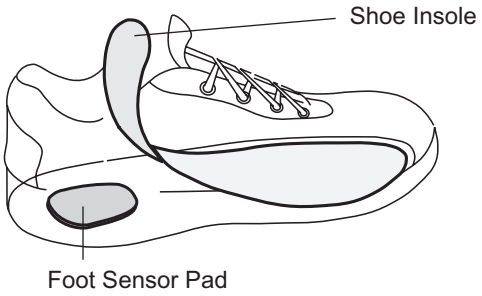


Figure 6-2: Foot Sensor Pad Placement

Tester

The Tester is used for troubleshooting to confirm that stimulation is being delivered. It tests if there is a disconnection in the Thigh Cuff or the EPG. The Tester provides audio feedback when connected to the Thigh Cuff and EPG, and stimulation is applied. For more information on the Tester, refer to the "Troubleshooting" chapter in this guide. See Figure 6-3.

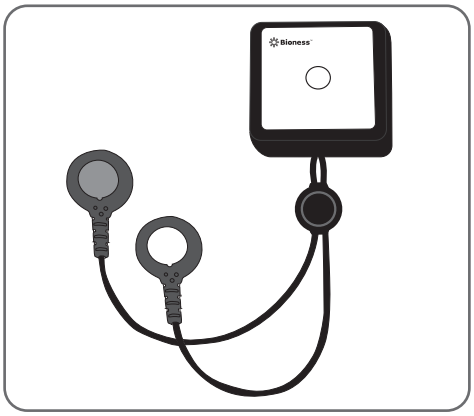


Figure 6-3: Tester

Personal Strap Covers

The Personal Strap Covers slide over the two Thigh Cuff straps and are used as an hygienic cover when the Thigh Cuff is used by multiple patients.

⚠ **Caution:** The Personal Strap Covers are for single patient use only to prevent cross contamination.

To attach the Personal Strap Covers:

1. Slide one Personal Strap Cover over each of the straps on the Thigh Cuff. See Figure 6-4.
2. If the Personal Strap Cover is too long, cut to size.

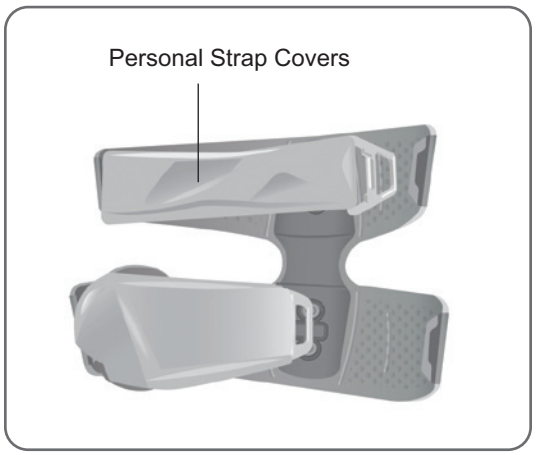


Figure 6-4: Personal Strap Covers on the Thigh Cuff

Clinician Application Software Navigation

The Clincian Application uses proprietary software that enables the clinician to configure stimulation parameters and programs for the patient. The Clinician Application uses a Windows® based tablet PC platform and uses standard Bluetooth® Low Energy (BLE) wireless signals to communicate with the L360 Thigh System. The Clinician Application is used in the clinic for patient programming. The Clinician Application also enables the clinician to retrieve patient's activity logs.

The Clinician 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 Clinician 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.

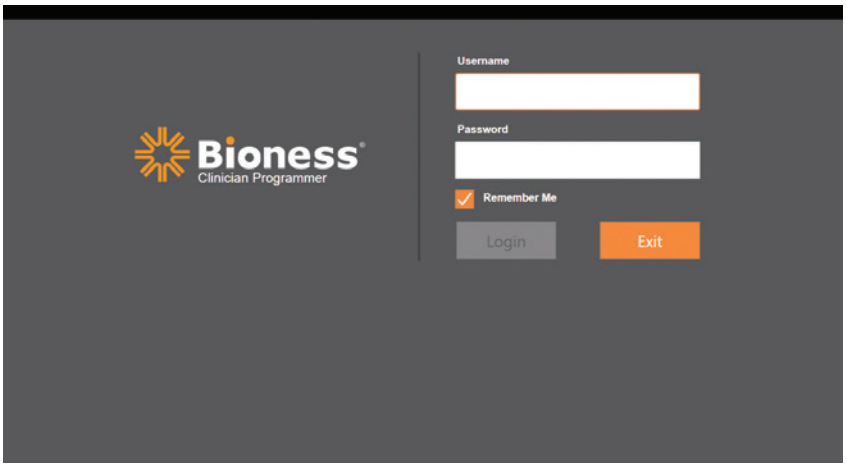


Figure 7-1: Login Screen

Patient Database Screen

After the Login screen, the Clinician Application will display the Patient Database Screen. The Patient Database screen lists all patient files that are stored on the Clinician 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 Clinician 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 Clinician Application.
- Export Patient icon - used to export a patient file and load onto another Clinician Application.

- Import Patient icon - used to import a patient file from another Clinician Application.

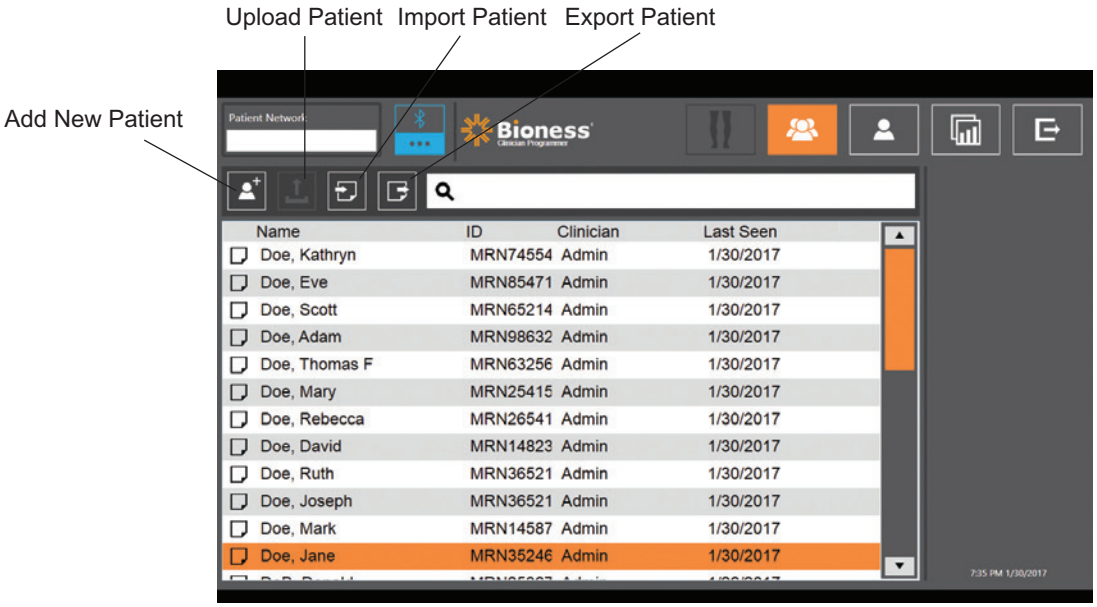


Figure 7-2: Patient Database Screen

Navigation Bar

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

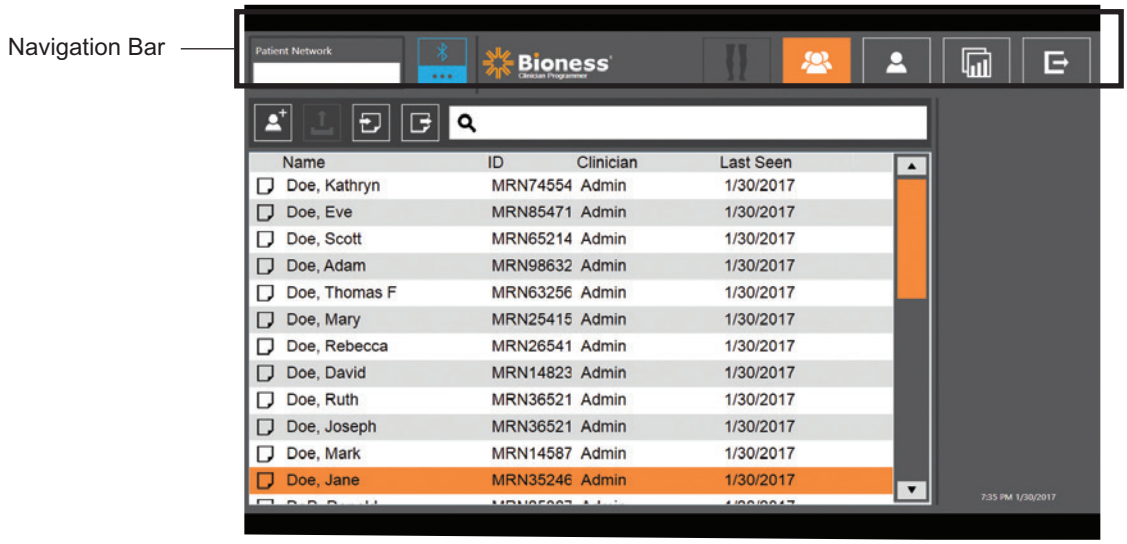


Figure 7-3: Navigation Bar on the Programming Screen

When the Clinician Application is paired with a patient's L360 Thigh 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 Clinician Application is not paired with a patient's L360 Thigh System, the patient network field will be empty with a blue outline and the active screen's icon will also appear in blue.

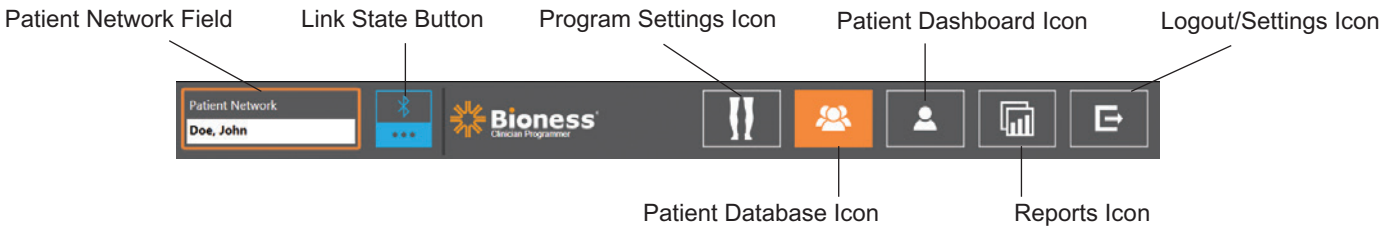


Figure 7-4: Navigation Bar - Linked to a Patient's System

Programming Setting Screen

The Programming Setting screen can only be accessed if the Clinician Application is paired with a L360 Thigh 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 L360 Thigh System. The Programming Settings Screen consists of four sub-menu screens: Parameter, Gait, Cycle Training, and Training Screens. See Figure 7-5.

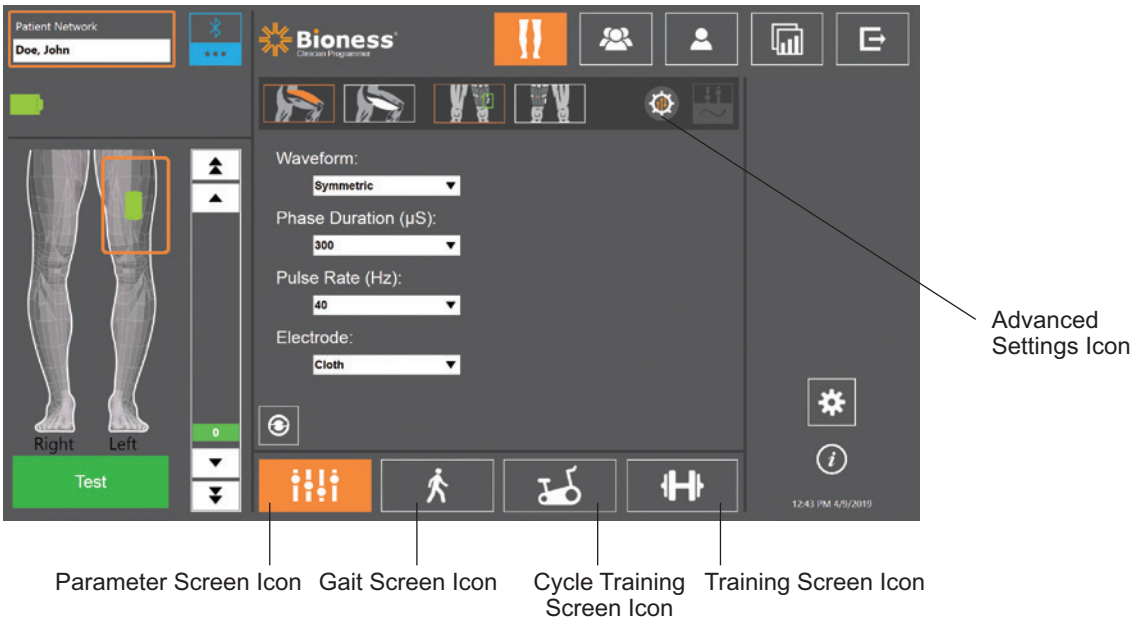


Figure 7-5: Programming Setting Screen (Stim (sub-menu) Screen Displayed)

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

The Cycle Training screen is used to program Cycle Training mode settings. See Figure 7-8. The stimulation amplitude settings on this screen are independent of those used for Gait mode. To access this screen, press the Cycle Training screen icon. See Figure 7-5.

Training Screen

The Training screen is used to program the settings that are used in training mode. See Figure 7-9. To access this screen press the Training screen icon. See Figure 7-5.

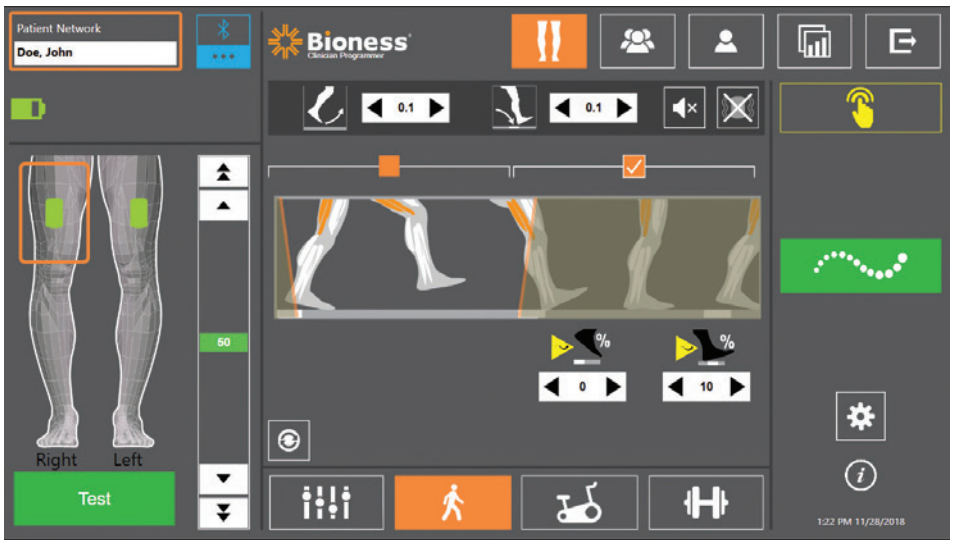


Figure 7-7: Gait Screen

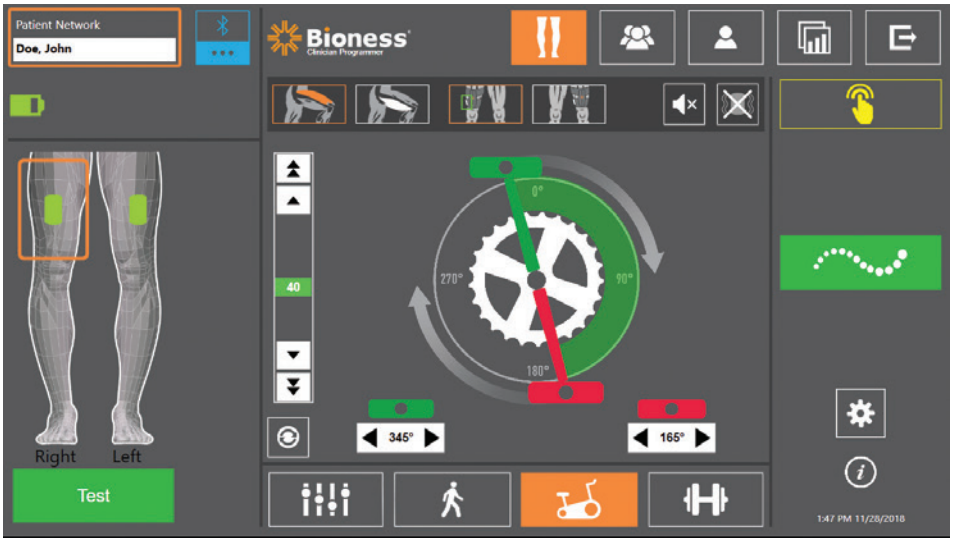


Figure 7-8: Cycle Training Screen

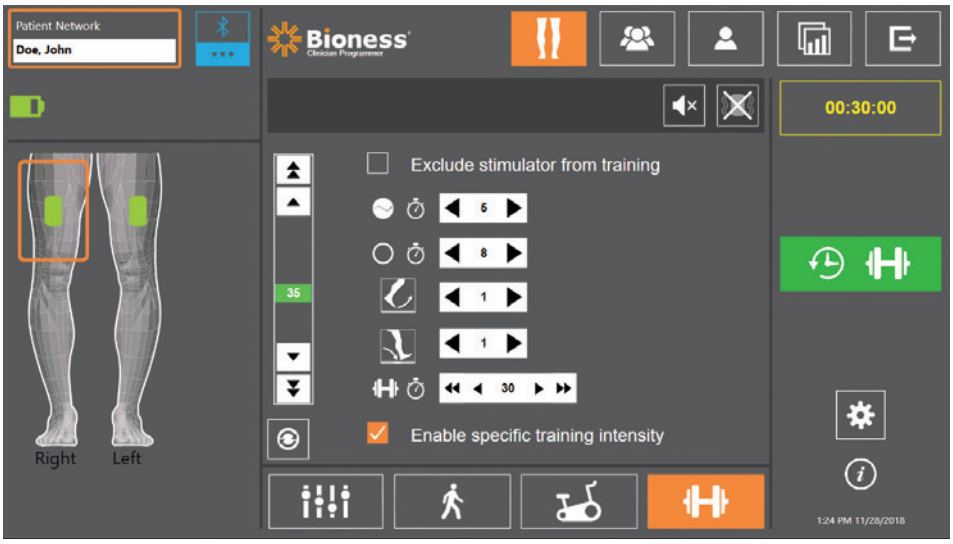


Figure 7-9: Training Screen

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 7-10. 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.

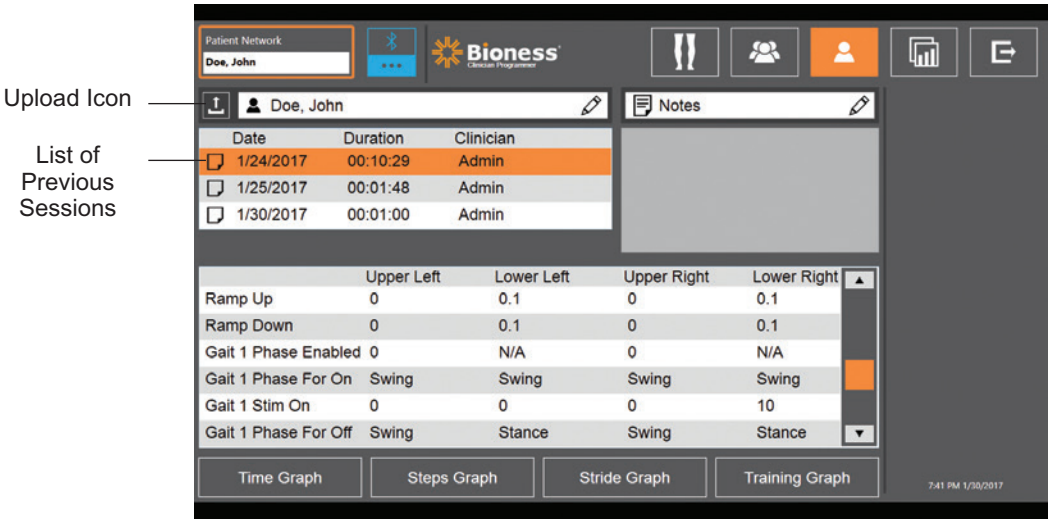


Figure 7-10: Patient Dashboard Screen

Reports Screen

The clinician can access the Reports screen to view previous data and generate new test reports. See Figure 7-11. To access the Reports screen press the Reports icon located in the navigation bar. See Figure 7-4.

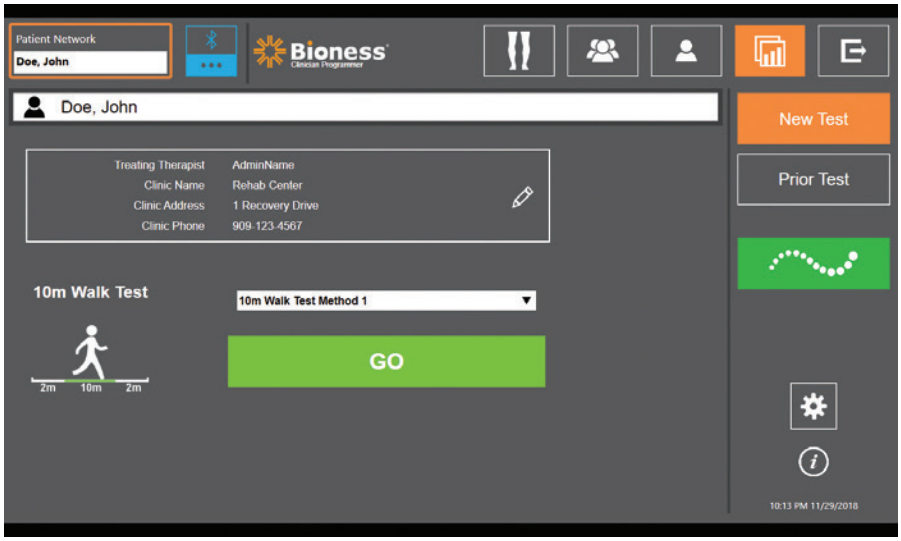


Figure 7-11: Reports Screen

Ten Meter Walk Test

The Clinician Programmer 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 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.

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.

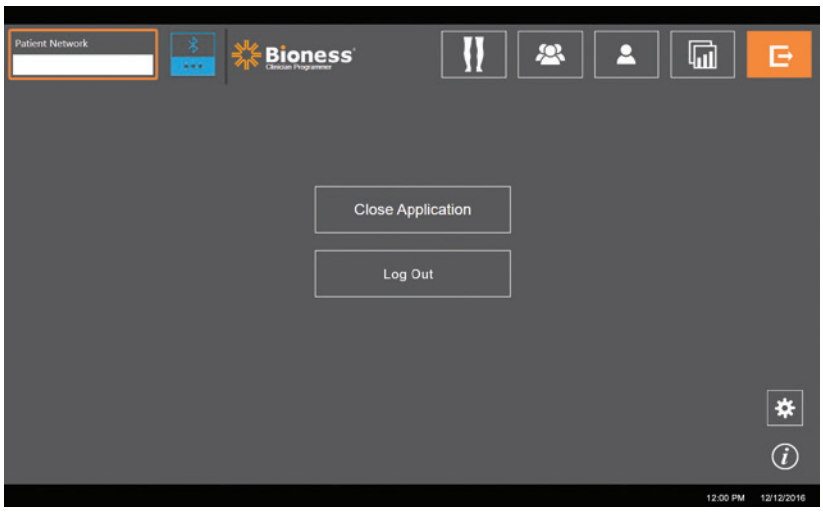
Note: The saved data includes the therapist name, clinic name, contact information, total time, gait speed, ambulatory category, and fall risk.

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 Clinician Application software, and close the application.

Figure 7-12: 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 7-13.

- 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 7-13 and Figure 7-14.
- 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

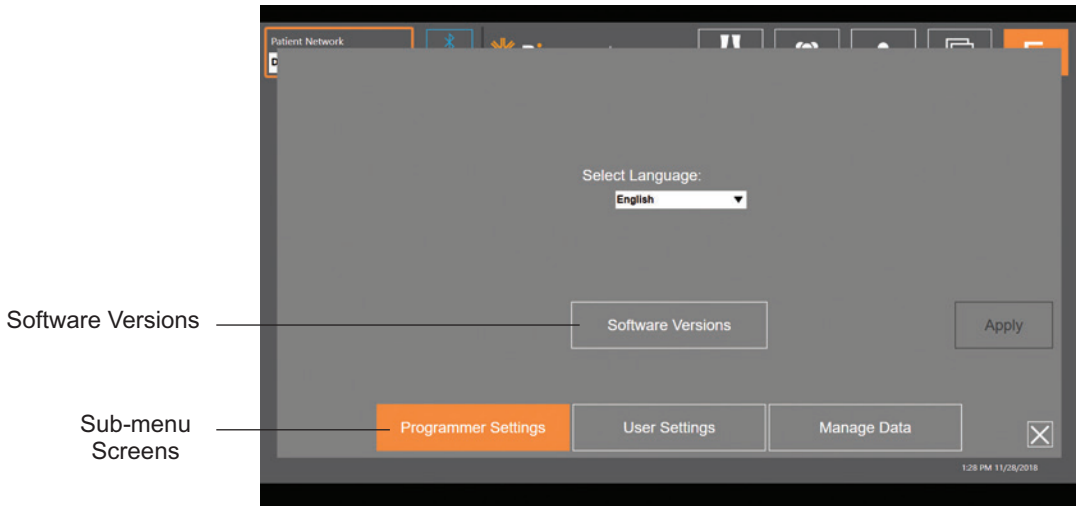


Figure 7-13: Application Settings Screen - Change Languages

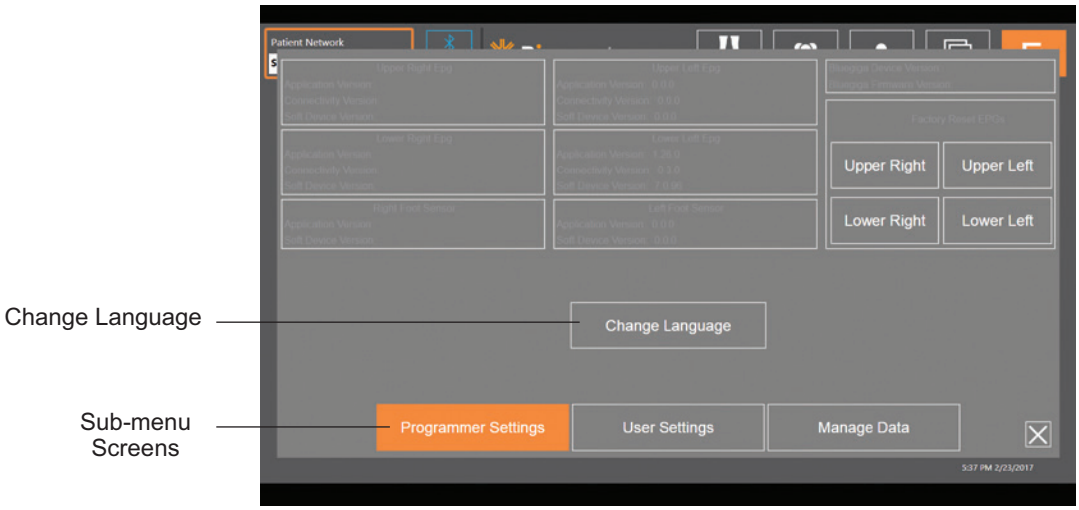


Figure 7-14: Application Settings Screen - Software Versions

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). The example below explains how to reset a left thigh cuff to a right thigh cuff. A similar process can be followed to reset a right Thigh Cuff to a left Thigh Cuff.

To factory reset an EPG:

1. Remove EPG from previous cuff (e.g. left Thigh Cuff) and place it into desired cuff (e.g. right Thigh Cuff).
2. Pair the right Thigh Cuff to the Clinician Application as if it were a left Thigh 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 7-13.
4. Under the factory reset section, select the location where the EPG had been previously (e.g. upper

left). 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 Clincian Application. The Information screen is dynamic as the information displayed is dependent on the screen in which it is accessed. See Figure 7-15.

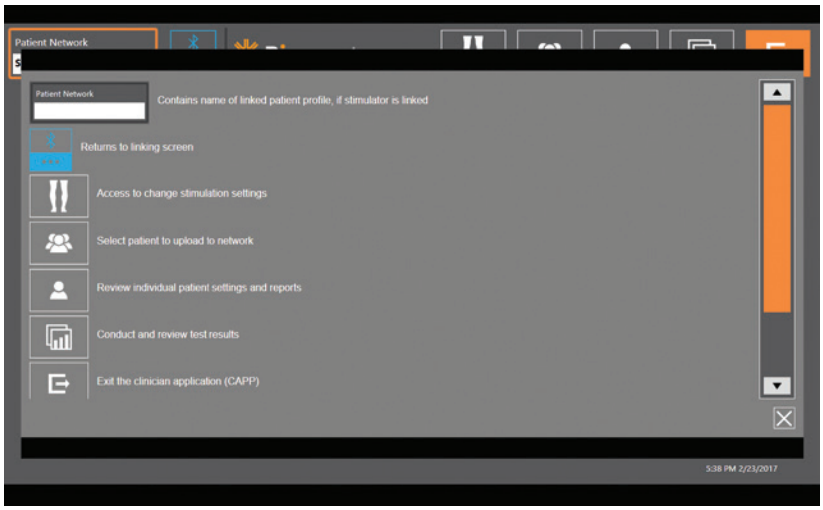


Figure 7-15: Information Screen

Patient Fitting

Skin Preparation

Before fitting the Thigh 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 L360 Thigh System. For optimal stimulation, the skin under the Thigh 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 Thigh Cloth Electrodes

The Thigh Cloth Electrodes attach to the snaps on the Thigh Cuff panels. The larger Thigh Cloth Electrode attaches to the proximal panel on the Thigh Cuff. The smaller Thigh Cloth Electrode attaches to the distal panel on the Thigh Cuff. See Figure 8-1.

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

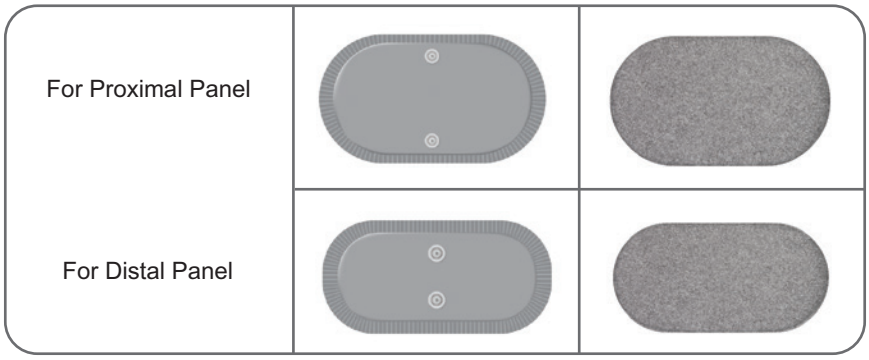


Figure 8-1: Thigh Cloth Electrodes

To fit the Thigh Cloth Electrodes: (See Figure 8-2)

1. Make sure the EPG is turned off.
2. Wet the Thigh Electrodes with water. Gently squeeze the Thigh Electrodes together.
3. Remove excess water from the snap side of the Thigh Electrodes with a cloth.
4. Align the snaps on the Thigh Cloth Electrodes to the plug holes on the Thigh Cuff.
5. Press firmly to snap Thigh Cloth Electrodes to the proximal and distal panels on the Thigh Cuff.

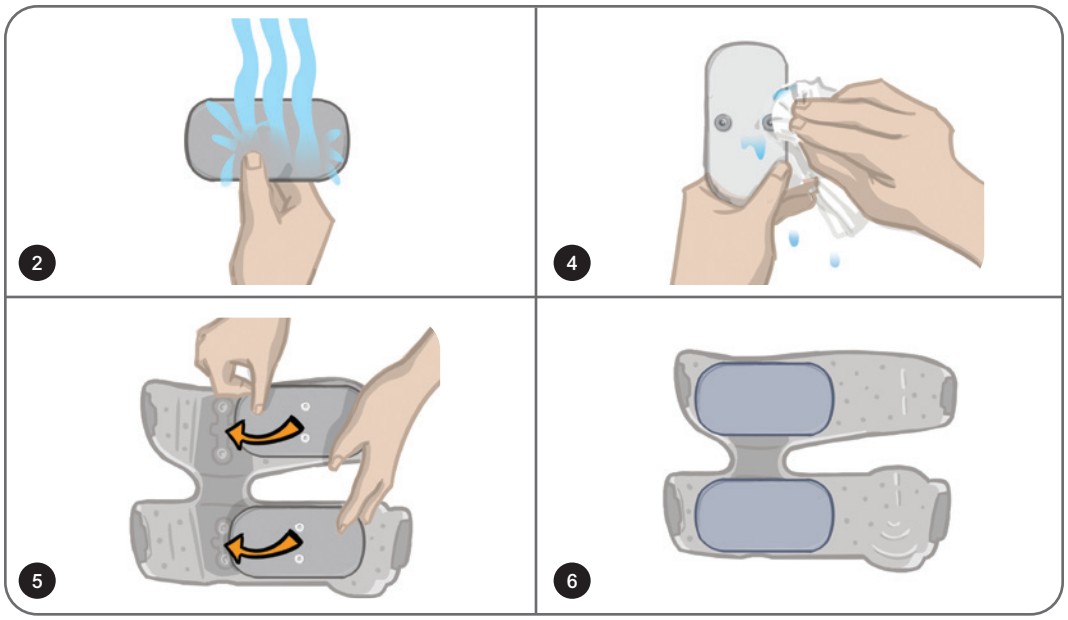


Figure 8-2: Fitting the Thigh Cloth Electrodes

Donning the Thigh Cuff

To don the Thigh Cuff:

1. Have the patient sit in a stable position on the edge of a chair.
2. Make sure the Thigh Cloth Electrodes are securely attached to the Thigh Cuff panels.
3. For in-patient use, attach an Thigh Cuff strap cover to the Thigh Cuff.
4. Place the Thigh Cuff locator (a tactile finger mark) on the midline of the thigh, approximately three finger widths proximal from the patella if stimulating the quadriceps or from the popliteal fossa if stimulating the hamstrings. See Figure 8-17.

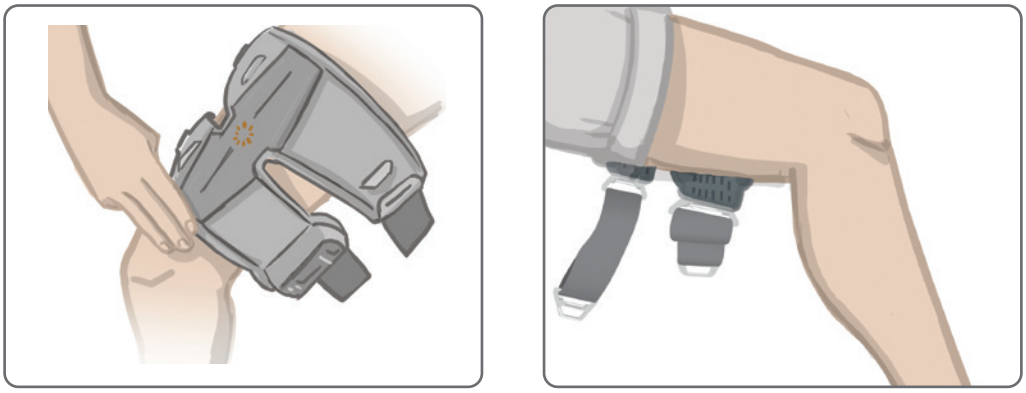


Figure 8-3: Correct Position of the Thigh Cuff Locator
(Left) Quadriceps Position Shown, (Right) Hamstrings Position Shown

5. Center the bridge on the midline of the thigh. See Figure 8-18.
6. Fasten the straps by inserting the strap buckle into the hook attached to the Thigh Cuff panels. See Figure 8-18. If needed, tighten the strap tension by adjusting the strap fasteners.

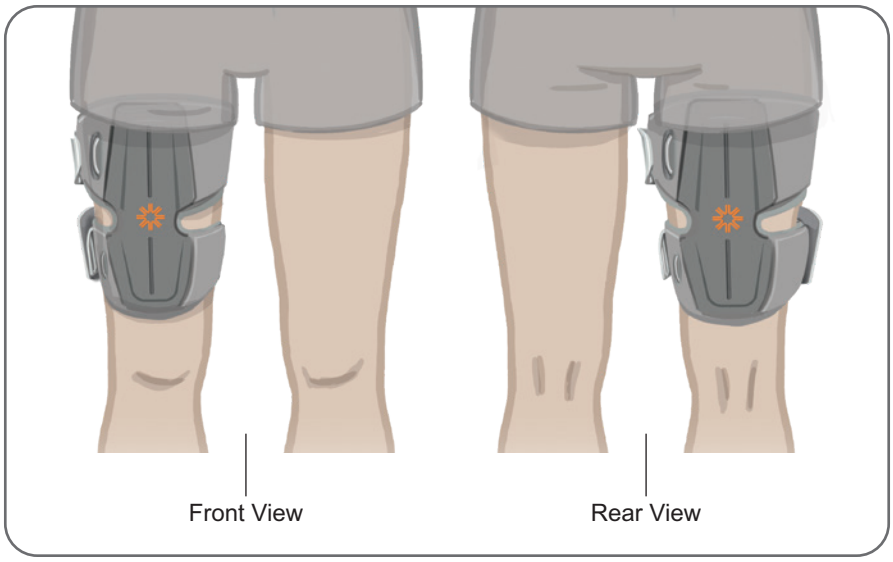


Figure 8-4: Correct Position of the Thigh Cuff
(Left) Quadriceps Fitting Position on Right Leg, (Right) Hamstring Fitting Position on Right Leg

Testing Electrode Placement: Patient Sitting and Standing

To test electrode placement:

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

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

Testing the Position of the Thigh Cuff: Patient Sitting and Standing

To check the position of the Thigh Cuff:

1. Have the patient sit with the lower leg dangling unobstructed. Make sure the EPG is turn on and paired to the Control Unit.
2. For new patients, press and hold the Stim and Mode buttons on the Control Unit for five seconds to enable the default parameter settings.

Note: If desired, these default parameter settings can be used as the patient's L360 Thigh System settings. If different parameter settings are desired, the clinician will need to access the Clinician Application software for programming.

3. The default stimulation intensity level is set to 0. Press the Stim button on the EPG to enable stimulation.
4. Press the Plus button on the EPG to gradually increase stimulation intensity to achieve the desired extension or flexion at the knee.

5. After proper extension or flexion is achieved with the patient seated, retest with the patient standing with the knee at an adjustable angle and the foot in the air.

6. If necessary, adjust the stimulation intensity to achieve knee extension or flexion in this position.

Fitting the Foot Sensor

The Foot Sensor is an optional component of the L360 Thigh System. The clinician can determine if the Foot Sensor is needed based on patient presentation.

Note: For instructions on pairing a new Foot Sensor with the EPG, refer to the "Pairing a New Foot Sensor to the EPG" section of this guide.

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

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

The placement of the Foot Sensor can be adjusted based on patient's initial contact point. For the majority of patients the Foot Sensor should be placed at the heel. For patients that have initial contact with the ground near the toes, the Foot Sensor may be placed at the forefoot.

Note: The Foot Sensor pad and Foot Sensor pressure sensor should be placed under the insole of the shoe. If the shoe does not have a detachable insole, place the Foot Sensor pad and pressure sensor on top of the insole. Then, place a soft, thin (one layer versus two) generic insole over them.

To place the Foot Sensor in the shoe:

1. For new patients the Foot Sensor will need to be paired with their EPG. For pairing instructions, please refer to the "Pairing a New Foot Sensor to the EPG" section of this guide.

2. Determine the appropriate placement (heel position or forefoot position) of the Foot Sensor based on patient presentation.

3. Lift the shoe insole, and attach a Foot Sensor pad to the heel or forefoot of the shoe.

4. For heel position placement point the wire of the Foot Sensor toward the toe of the shoe. For forefoot position placement point the wire of the Foot Sensor toward the heel of the shoe. Attach the pressure sensor to the Foot Sensor pad. See Figure 8-5.

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

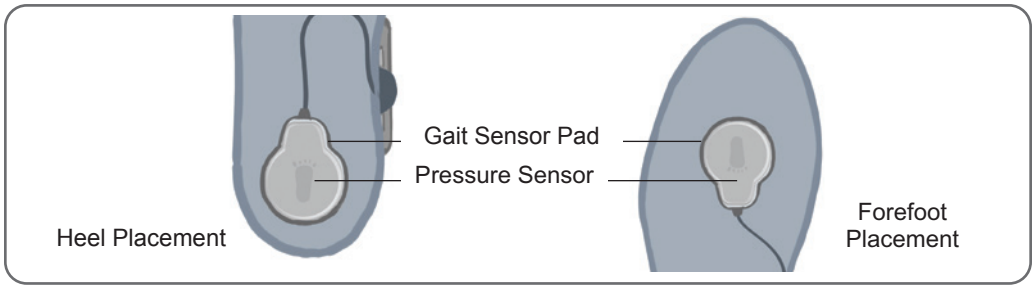


Figure 8-5: Positioning the Foot Sensor in the Shoe

5. Clamp the Foot Sensor transmitter on to the inner rim of the shoe. Face the starburst logo on the transmitter away from the ankle. See Figure 8-6.

6. Cover the pressure sensor with the insole. Tuck any excess wire under the insole. See Figure 8-6.

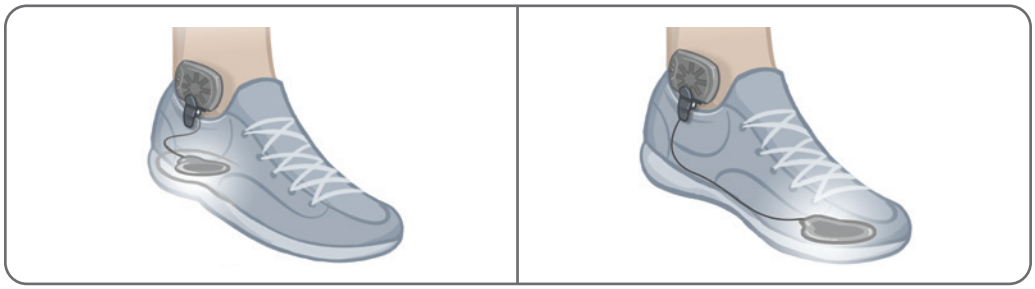


Figure 8-6: Final Position of the Foot Sensor Attached to the Shoe

Doffing the Thigh Cuff

1. Press the Power button on the EPG to turn off the system.
2. Unhook both sets of straps.
3. Slowly lift the Thigh Cuff away from the patient's skin.
4. Remove the Thigh Cloth Electrodes from the Thigh Cuff and store them were they can air dry, to prevent mold.

Note: Make sure to instruct patients who will be using the L360 Thigh System at home to ventilate the skin by removing the Thigh Cuff for at least 15 minutes every three to four hours.

Patient Programming

Before programming the L360 Thigh System make sure the electrodes and Thigh 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 Clinician Application to the L360 Thigh System

Before pairing the Clinician Application to the L360 Thigh System, make sure the patient's components (EPG(s), Foot Sensor, and/or Control Unit) have already been paired together. Refer to the "Pairing Replacement Part Components" chapter in this guide for pairing instructions.

When an EPG is paired to the Clinician Application, the Clinician Application will automatically recognize the other components that are paired to that EPG, such as a Foot Sensor.

To pair the Clinician Application to the L360 Thigh System:

1. Turn on the Clinician Programmer, and launch the Clinician Application by pressing the Clinician 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 9-1.

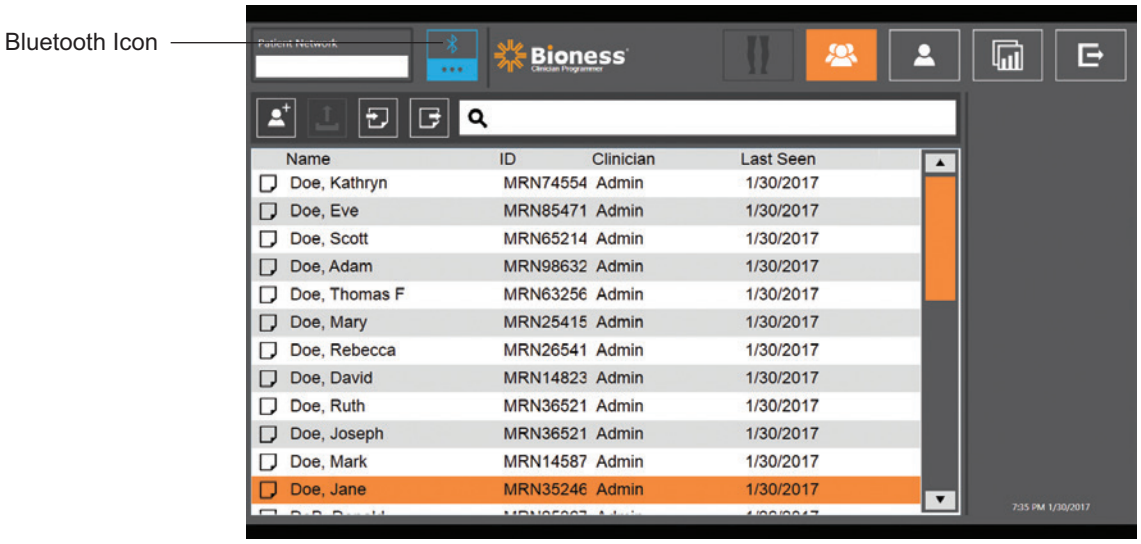


Figure 9-1: Bluetooth® Icon

4. Click on the Linking icon located above the desired leg. See Figure 9-2.
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 9-2: 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 L360 Thigh System is paired with the Clinician Application.
2. From the Patient Database Screen, press the Add New Patient icon. See Figure 9-3.

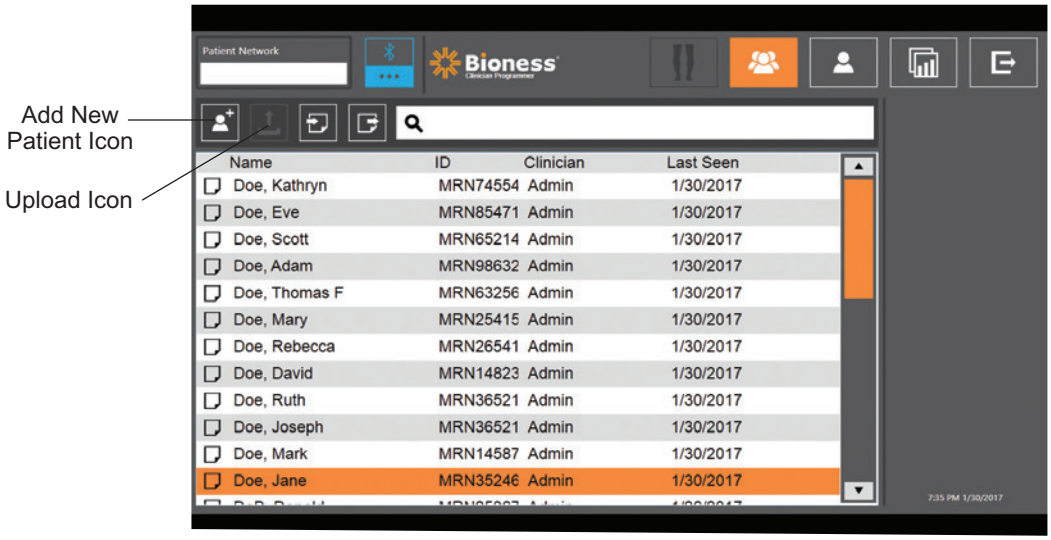


Figure 9-3: Add New Patient Icon

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 L360 Thigh 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 L360 Thigh System is paired with the Clinician Application.
2. Open the Patient Database Screen and highlight the patient from the Patient List. See Figure 9-3.
3. Press the Upload icon. See Figure 9-3. A window will appear stating "Program all stimulators with patient: X,X". Press the Continue button.
4. The Clinician 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 Clinician Application has been paired to a L360 Thigh 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 9-4.
4. The selected EPG will have an orange box outline around it.
5. Use the drop down lists to adjust the Waveform, Phase Duration and Pulse Rate 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 9-4.

Figure 9-4: 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 Clinician 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: Cloth

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 9-4 and Figure 9-5.

2. Adjust the Interphase Period, Max Stim Time, and Foot Sensor 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 knee extension or flexion, the L360 Thigh 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 L360 Thigh System is in the air and 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.
Advanced Stim Parameter	**Definition**

Foot Sensor	When the Clinician Application is connected to a system that uses a Foot Sensor. The Foot Sensor setting will be enabled. Use the drop down list to select: Contrallateral vs. Same Side. Foot Sensor Required Box - when the box is unchecked this turns on the motion sensing backup feature. If the Foot Sensor is not communicating to the EPG, the EPG will use the integrated motion sensors for gait detection.

Table 9-2: Advanced Stim Parameter Setting Definitions

Figure 9-5: 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.
4. Adjust the Ramp Up, Ramp Down, Extended, Delayed and Intensity Settings. See Table 9.3.

Figure 9-6: Programming Stimulation, Gait Settings Screen

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. This setting can provide a more biomechanically matched contraction as loading and unloading occurs when walking on a slope. 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. This setting can provide a more biomechanically matched contraction as loading and unloading occurs when walking on a slope. Values are from 0 to 0.5 seconds in 0.1-second increments.
Extended	The percentage of time that the stimulation continues after a terminating heel on or heel off event. Once the calculated percentage is met, the stimulation begins to ramp down. The extended percentage provides the ability to customize the timing of the functional electrical stimulation contraction to a patient's gait and loading. For example, this setting can be used to prevent knee hyperextension while stimulating hamstrings or prevent knee buckling when stimulating quadriceps. In addition, using percentages allows for automated adjustment to a patient's gait speed.
Delayed	The percentage of time that the stimulation continues after the initiating heel on or heel off event. Once the calculated percentage is met, the stimulation begins to ramp up. The delayed percentage provides the ability to customize the timing of the functional electrical stimulation contraction to a patient's gait and loading. For example, this setting can be used to prevent pre-mature hip extension while stimulating hamstrings or allow for initial loading response (knee flexion) when stimulating quadriceps. In addition, using percentages allows for automated adjustment to a patient's gait speed.
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

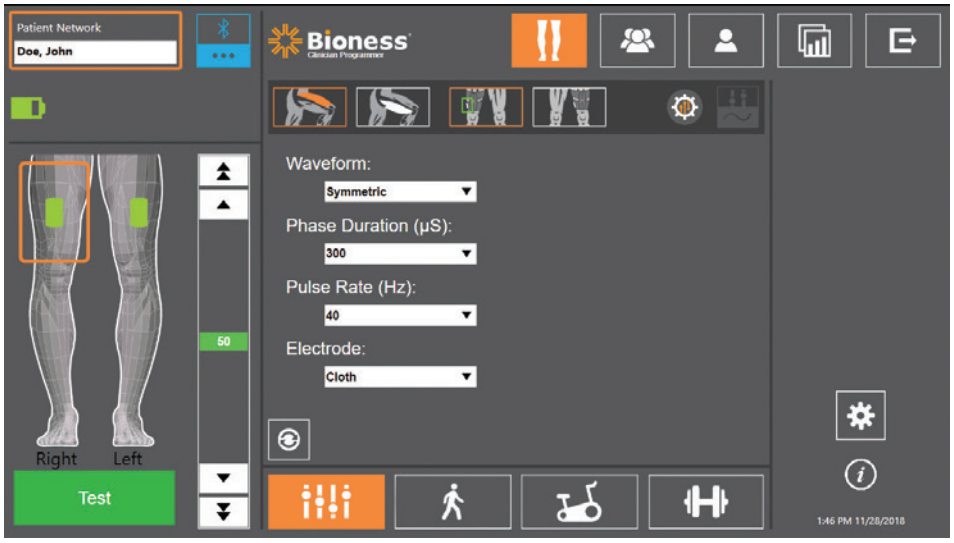
5. Press the Stimulation button to test and save the settings. Stimulation will respond to gait activity input from either the Foot Sensor (if applicable), or from the EPG integrated motion sensor.
6. Fine-tune settings while the patient is walking.
7. Press the Stimulation button again to stop stimulation.

Programming Cycle Training Settings

To program cycle training settings:

1. Seat the patient in a chair or on a therapy mat.
2. Press the Program Settings icon in the navigation bar to open the Parameter Screen. See Figure 9-7.

Figure 9-7: Programming Stimulation, Parameter Settings Screen



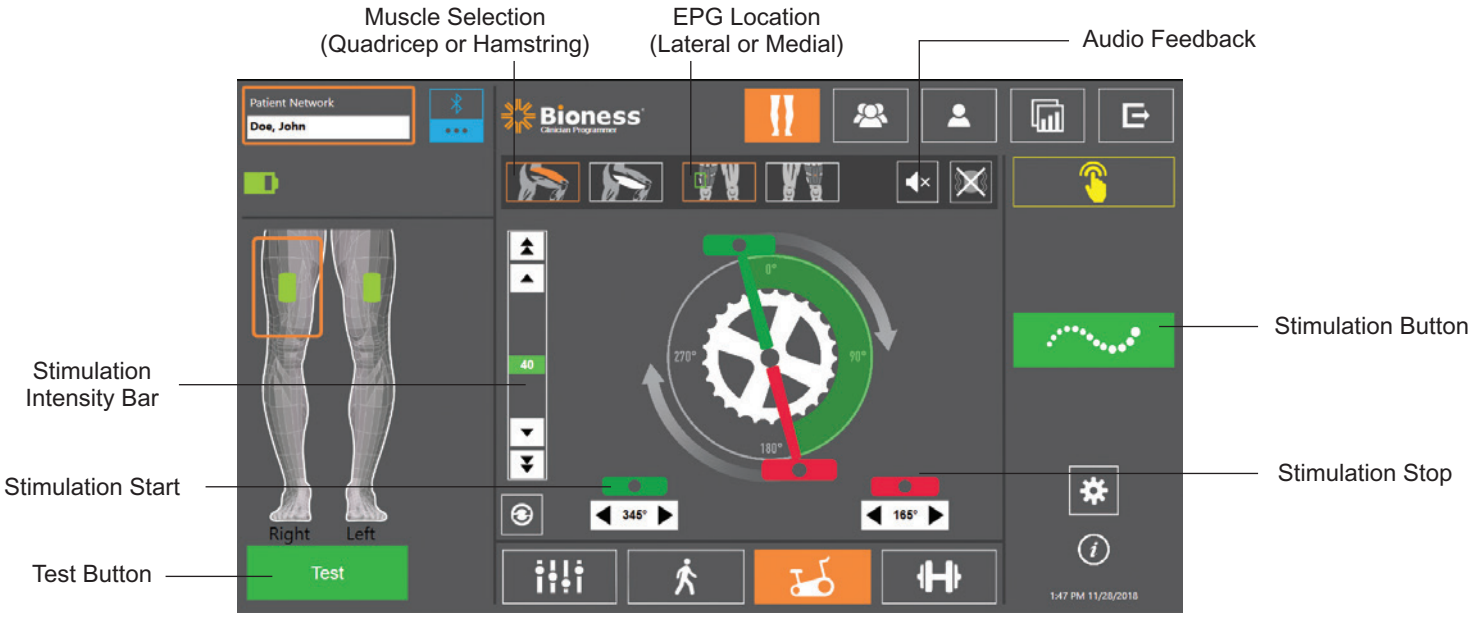
3. The screen will show the linked EPG(s) as a green icon on the leg diagram located on the left side of the Parameter Screen. See Figure 9-7. The selected EPG will have an orange box outline around it.

Note: The location of the green EPG icon may or may not correspond to the physical location of the EPG on the patient. The green EPG icon is used to denote the use of a "left" or "right" cuff type. However, a "left" or "right" cuff type may be used on the either leg.

4. Use the drop down list to adjust the parameter settings on the Parameter Screen. Refer to Table 9-1 for parameter setting definitions.
5. Press the Cycle Training Screen icon . See Figure 9-8.

6. Select the appropriate muscle group (quadricep or hamstring) by pressing the appropriate Muscle Selection button  . The selection will be highlighted in orange. See Figure 9-8.

Figure 9-8: Programming Stimulation, Cycle Training Settings Screen



7. Select the physical location (lateral or medial) of the EPG by pressing the EPG Location icon  . The selection will be boxed in green. See Figure 9-8.
8. For new patients, make sure the stimulation intensity is set to 0 using the arrows on the Stimulation Intensity Bar. See Figure 9-8.
9. Press the Test button to save setting and turn on stimulation. Gradually increase the stimulation intensity to the desired level using the arrows on the Stimulation Intensity Bar. See Figure 9-8.

Note: Cycle Training mode stimulation intensity is independent of intensity settings on the Parameter, Gait, and Training Screens. When stimulation is being delivered, the Test button will appear red and the EPG icon will turn yellow with stimulation wave. Do not leave stimulation on for long because fatigue may result.

10. If the patient is using more than one EPG, program the settings for each additional EPG. Select the desired EPG icon from the Parameter Screen and repeat steps 4-9.
11. Seat the patient on a stationary bicycle.
12. Instruct the patient to begin with feet on the pedals with the foot of the affected side positioned at the top of the crank or in the 12 o'clock position.
13. If the patient is using the L360 Thigh System bilaterally, position the pedals at the top and bottom of the crank.

Note: Depending on the starting position of the patient's foot while using Cycle Training mode, the L360 Thigh System motion detection algorithm may delay stimulation for up to 3 rotations of the crank before initiating stimulation.

14. Press the Stimulation button to save settings and turn on stimulation. Stimulation will respond to cycling activity input from the EPG integrated motion sensor.

15. Fine-tune the Stimulation Intensity while the patient is cycling. See Figure 9-8.

16. Fine-tune the Stimulation Start and Stop settings while the patient is cycling. See Table 9-4.

Note: Enabling the Audio Feedback indicator may assist in optimizing the Stimulation Start and Stop settings. See Figure 9-8. Palpating the muscle may assist in determining when muscle contraction occurs.

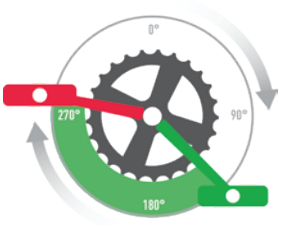
Cycle Training Parameter	Definition
 Stimulation Timing	Allows for adjustment of the stimulation timing while in Cycle Training mode. The green pedal indicates where stimulation starts in the cycle, and the red pedal indicates where stimulation stops. When stimulation is inactive, pressing and dragging the pedals allows gross control of stimulation start and stop timing. Gross control of stimulation start and stop timing is not available when stimulation is active to ensure patient safety. The clockwise rotation of the controls will always represent rotation toward the front of the stationary bicycle. Advancing the pedal clockwise will result in the stimulation event occurring later in the cycle, and moving the pedal counterclockwise will result in the event occurring sooner.
 Stimulation Start	Allows for fine control of stimulation start timing while Cycle Training mode stimulation is active. The arrows advance or delay the start of stimulation by 5 degrees.
 Stimulation Stop	Allows for fine control of stimulation stop timing while Cycle Training mode stimulation is active. The arrows advance or delay the stop of stimulation by 5 degrees.

Table 9-4: Cycle Training Mode Parameter Definitions

17. If the patient is using more than one EPG, select each EPG and repeat steps 14-16 to fine-tune the settings.
18. 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 9-9.

Figure 9-9: 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. 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 Clinician Application

The Programming Stimulation Gait Settings, Cycle Training 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 Cycle Training Settings Screen control audio and vibration feedback when the EPG is in Cycle Training 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 L360 Thigh 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 L360 Thigh System User Guide:

- General safety information, including the Skin Care Guidelines
- An overview of the L360 Thigh System
- Donning and doffing the Thigh Cuff
- Replacing the electrodes
- Placing the Foot Sensor in a shoe (for patients using this option)
- Operating the Control Unit or myBioness™ app
- The system component buttons, displays, and audio alerts: their definitions and functions
- Using Gait, Cycle Training, and Training modes
- Maintenance and cleaning instructions
- Review of basic troubleshooting
- How to contact Technical Support

Maintenance and Cleaning

Charging

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

EPG Battery Maintenance

The EPG has a rechargeable battery that is not removable. Do not attempt to replace the EPG battery. Maintain a routine of daily charging if using the system regularly, and at minimum, once monthly if your system is in storage. Avoid leaving your EPG uncharged indefinitely to minimize the risk of decreased battery longevity. Refer to the technical specifications section in this manual for appropriate operating and storage conditions. An EPG battery can be expected to last several years when maintained accordingly. For support with your device, contact Customer Service at 800-211-9136, Option 3 (USA & Canada) or your local distributor.

Replacing the Thigh Cloth Electrodes

The Thigh Cloth Electrodes will need to be replaced at least every two weeks or sooner if they become damaged.

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

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

To replace the Thigh Cloth Electrodes: (See Figure 11-1)

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

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

If the Thigh Cloth Electrodes dry out, 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. Store the Thigh Cloth Electrodes where they can air dry, when not in use.

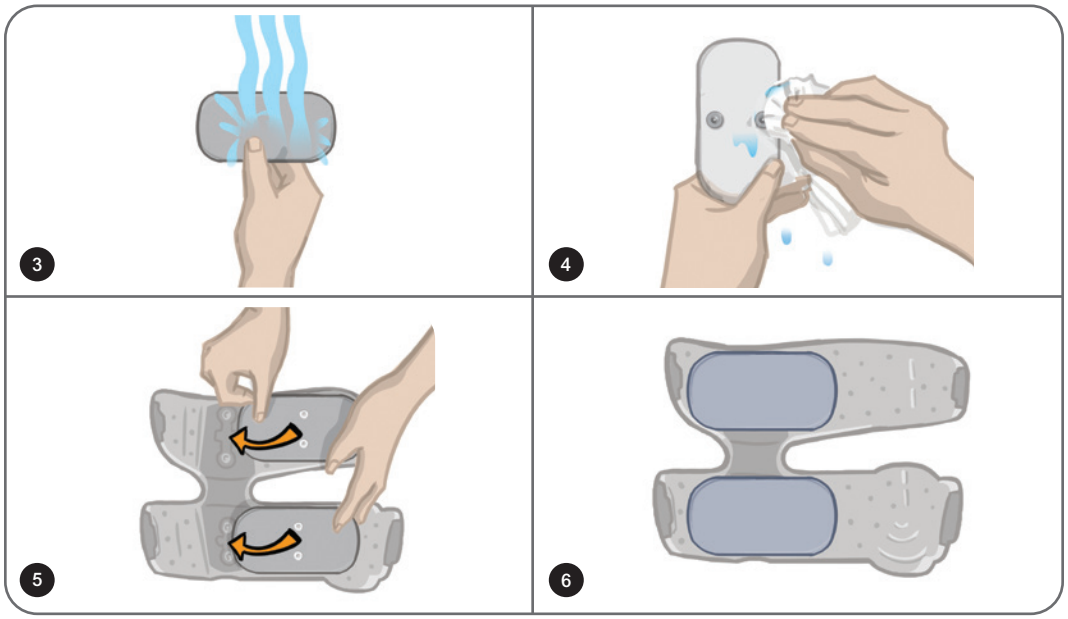


Figure 11-1: Replacing the Thigh Cloth Electrodes

Removing the EPG

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

To remove the EPG:

1. Make sure the EPG is turned off.
2. Pull the top of the EPG away from the cradle. See Figure 11-2.
3. Remove the bottom of the EPG from the cradle.

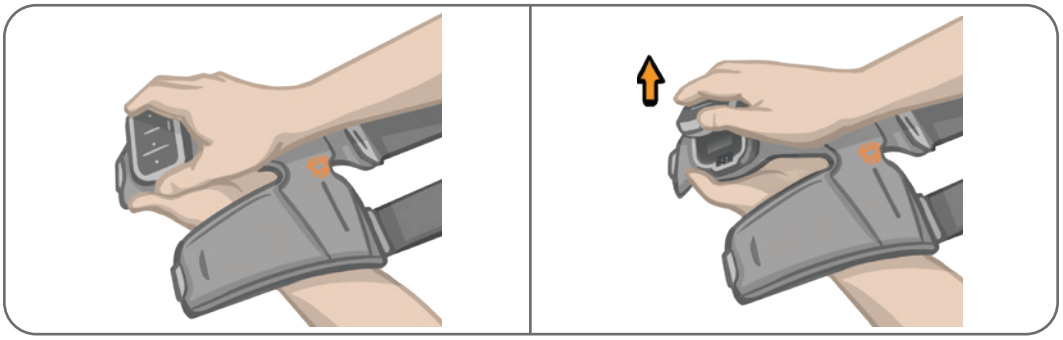


Figure 11-2: Removing the EPG

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.

Removing the Thigh Cuff Straps

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

To remove the thigh straps:

1. Push the attached thigh strap buckle toward the Thigh Cuff while making a twisting motion. See Figure 11-3.
2. Slide the thigh strap out away from the Thigh Cuff to detach.

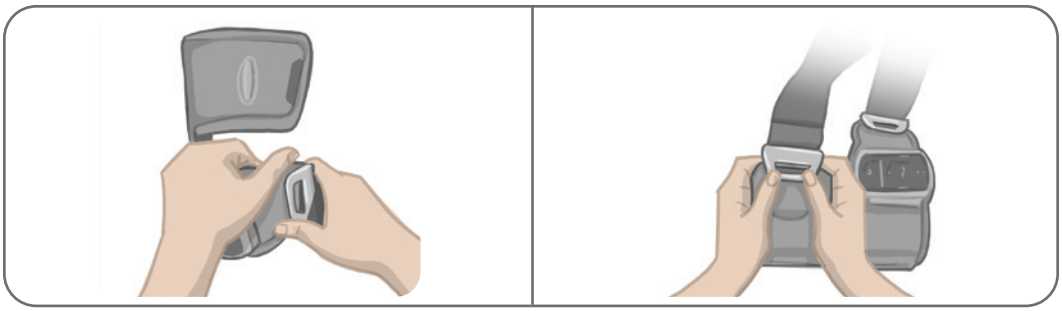


Figure 11-3: Removing the Thigh Straps

To reattach the thigh straps:

1. Align the strap buckle to the hook attached to the Thigh Cuff panels.
2. Push the strap buckle with your thumbs toward the strap (direction away from the Thigh Cuff). See Figure 11-4. The strap buckle will snap into the Thigh Cuff panel hook.

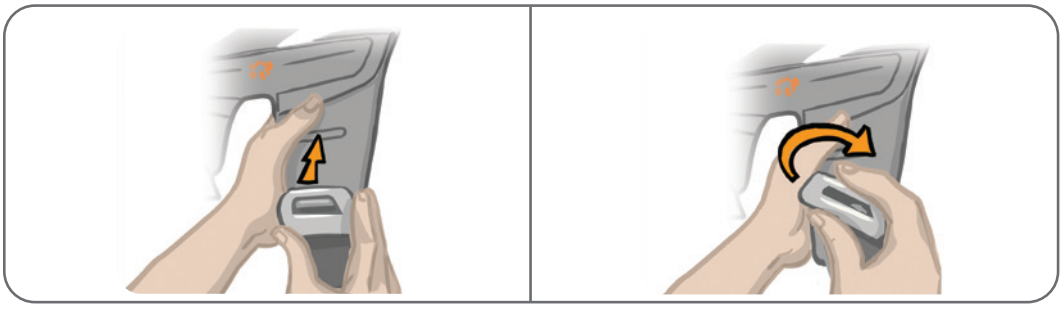


Figure 11-4: Reattaching the Thigh Straps

Replacing the Foot Sensor Battery

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

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

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

To replace the Foot Sensor battery:

1. Use the recess area on the back of the Foot Sensor to pop out the battery lid cover. See Figure 11-5.

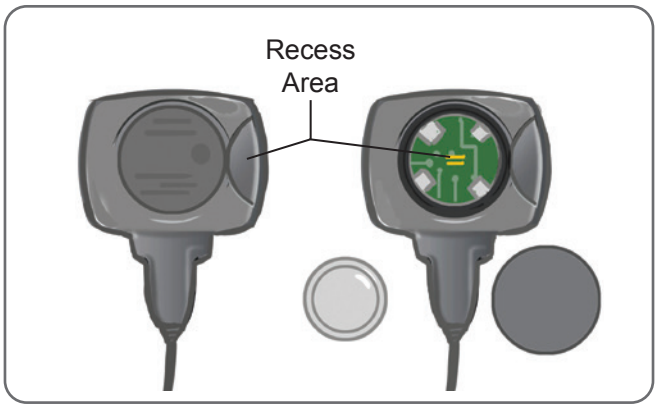


Figure 11-5: Replacing the Foot Sensor Battery

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

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

Replacing the Control Unit Battery

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

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

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

To replace the Control Unit battery:

1. Use the recess area on the back of the Control Unit to pop out the battery lid cover. If you find it difficult to remove the cover a coin (quarter) may be used to open the cover. See Figure 11-6.

Figure 11-6: Replacing the Control Unit Battery

2. Note the “+” orientation of the old battery.
3. Remove the old battery.
4. Insert the new battery by inserting the battery toward the back first and then carefully pressing down on the battery. The “+” should face up.
5. Reattach the battery lid cover to the back of the Control Unit by pressing firmly to snap the cover back on.

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

Cleaning the L360 Thigh System Components

All L360 Thigh 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 Thigh Straps

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

Disinfecting the L360 Thigh System Components

Disinfecting the Thigh Cuff

The plastic parts of the Thigh Cuff may be disinfected using a combination of CaviWipes™, per the manufacturer’s instructions, and 70% ethanol wipes.

To disinfect the Thigh Cuff:

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

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

3. Using one or more new CaviWipes, wipe the entire surface again for 1 minute. The surface should be visibly wet. Repeat this process again three times, using a new wipe each time.
4. Place a wipe saturated with 70% ethanol over each of the Thigh Cuff panels (on the side that faces the skin). Cover the entire surface and leave the saturated wipes on the Thigh Cuff for at least five minutes.
5. After five minutes, wipe the Thigh Cuff panels with the 70% ethanol wipes and remove them to allow the plastic surface to dry.

Disinfecting the EPG and Control Unit

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

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

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

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

Pairing Replacement Part Components

The L360 Thigh System components must be paired to each other to communicate wirelessly. The EPG and Control Unit in the System Kit are already paired. The Foot Sensor will need to be paired to the other components during a fitting session for patients that are using the optional Foot Sensor. When a Control Unit, EPG, or Foot Sensor is replaced, the new replacement component must be paired to the existing components.

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

Pairing Setup

1. If the replacement component is an EPG, make sure the new EPG is fully charged. See the "Charging the L360 Thigh System" section in this guide for more information.
2. Make sure the EPG is attached to the EPG Cradle on the Thigh Cuff.
3. Turn on the EPG by pressing the Power button on the EPG.

Pairing a New Control Unit to the EPG

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

Pairing an Existing Control Unit to a Different EPG

Note: If pairing to an EPG with different patient parameters, be sure to unpair the Control Unit first otherwise the previous patient's information will save onto the new EPG.

1. Make sure the EPG is turned on.
2. Place the Thigh Cuff, with EPG attached, and the Control Unit within a few inches of each other.
3. Turn on the Control Unit by pressing any button. Simultaneously press the Plus and Minus buttons on the Control Unit.
4. Simultaneously press the Plus and Minus buttons on the EPG. The EPG will go into Pairing mode and the EPG State Indicator Light will display an alternating green, yellow, and red light.
5. Once paired the EPG State Indicator Light on the EPG will flash green. The connected EPG will

appear on the display screen on the Control Unit.

6. The patient's parameters stored on the Control Unit will carry over onto the new EPG unless the Control Unit was unpaired.

Pairing a New Foot Sensor to the EPG

1. Make sure the EPG is turned on.
2. Place the Thigh Cuff, with EPG attached, and the Foot Sensor within a few inches of each other.
3. Remove the battery from the Foot Sensor, wait 120 seconds, and then insert the battery back into the Foot Sensor. Make sure to press firmly on the battery cover to snap back into place.
4. Press the Foot Sensor pressure sensor to activate the sensor.
5. Simultaneously press the Plus and Minus buttons on the EPG. The EPG will go into Pairing mode and the EPG State Indicator Light will display an alternating green, yellow, and red light.
6. Once paired the EPG State Indicator Light on the EPG will flash green and the indicator light on the Foot Sensor will flash green.

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

Troubleshooting

Using the Tester

The Tester is used in place of the Thigh Cloth Electrodes and can help to troubleshoot if there is a disconnection in the Thigh Cuff and the EPG. The Tester provides audio feedback when connected to the Thigh Cuff and EPG and stimulation is applied using the Clinician Programmer, EPG, Foot Sensor, or Control Unit. See Figure 13-1.

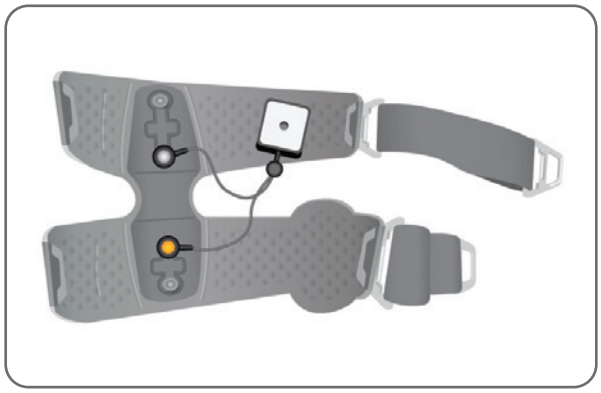


Figure 13-1: Tester Connected to Thigh Cuff

Error Code Descriptions

When an error occurs with the L360 Thigh System the EPG will emit an audio alert and the Status Indicator Light on the EPG will display a flashing red light. The Control Unit LCD display will show a flashing Error Indicator icon and a flashing Numeric Indicator communicating the error code. Refer to Table 13-1 for the error code descriptions and solutions.

Control Unit and Clinician Application Error Codes		
Error Code	**Description of Error**	**Solution**
E1	Overstimulation Fault	Stimulation is being delivered at a higher intensity than expected. This is a possible hardware issue. Stop using the L360 Thigh System and contact Customer Service.
E2	Overstimulation Fault	Stimulation is being delivered at a higher frequency than expected. This is a possible hardware issue. Stop using the L360 Thigh System and contact Customer Service.
E3	Understimulation Fault	Stimulation is being delivered at a lower intensity than expected. This is a possible hardware issue. Stop using the L360 Thigh System and contact Customer Service.
E4	Understimulation Fault	Stimulation is being delivered at a lower frequency than expected. This is a possible hardware issue. Stop using the L360 Thigh System and contact Customer Service.

Control Unit and Clinician Application Error Codes		
Error Code	**Description of Error**	**Solution**
E5	Charge Imbalance	This is a possible hardware issue. Stop using the L360 Thigh System and contact Customer Service.
E6	Communication Fault	The Foot Sensor and EPG are not communicating. Press the Foot Sensor pressure sensor to activate the Foot Sensor.
E7, E8, E9	Software Fault	Reset the EPG. If error persists, stop using the L360 Thigh System and contact Customer Service.
E10	Parameter Corrupted	The L360 Thigh System needs to be reprogrammed. Stop using the L360 Thigh System and contact Customer Service.
E11, E22	Incorrect Cuff Fault	Make sure EPG is correctly inserted into the EPG cradle on the Thigh Cuff.
E12	Shorted Electrode Fault	Electrodes are shorted, cuff has an electrical short, or the hardware is not functioning correctly. Stop using the L360 Thigh System and contact Customer Service.
E13	Bad Electrode Fault	Electrodes are worn or damaged. Replace any worn or damaged electrodes or electrode bases. Refer to the "Maintenance and Cleaning" chapter of this guide for instructions.
E14	Open Electrode Fault	Turn the EPG off by pressing the Power button on the EPG. Make sure the electrodes and/or electrode bases are snapped into the plug holes of the Thigh Cuff.
E15	EPG Battery Empty	Charge the EPG. Refer to the "Charging the L360 Thigh System" section in this guide.
E17	EPG Battery Temperature Fault	Battery temperature is too high. Disconnect the charger from the EPG. Place the EPG in a room within the operating conditions temperature range (5°C to 40°C/41°F to 104°F) for 30 minutes. After 30 minutes reconnect the EPG to the charger to continue charging.

Table 13-1: Control Unit and Clinician Application Error Codes

Frequently Asked Questions

If you have any questions or concerns, please contact Customer Service at 800-211-9136, Option 3 (USA & Canada) or your local distributor. You may also visit www.bionessrehab.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..

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

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

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

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

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

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

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

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

For patients using the Foot Sensor:

- Check for proper placement of the pressure sensor, reposition the pressure sensor slightly forward

in their shoe, or loosen the shoelace.

- Check the Foot Sensor wire for wear or fraying, and check the transmitter and pressure sensor for damage.
- If damaged contact Customer Service for a replacement part.

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

Have the patient stop using the L360 Thigh System immediately and contact Customer Service. The patient should resume use only when the skin is completely healed. Give patients the L360 Thigh System Skin Care Guidelines and a skin conditioning protocol.

How can I verify that current is flowing through the L360 Thigh System?

Connect the Tester to the Thigh 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

Control Unit Specifications	
Classification	Internally powered, continuous operation with type BF applied part(s)
Operation Modes	Gait, Training, and Clinician
Battery Type	Button cell lithium battery, CR2032, 3V, 240 mAh
Controls	•Select button- to select an EPG •Mode button- to select an operating mode •Stim button- to turn stimulation on/off •Minus and Plus buttons- to decrease or increase stimulation intensity level •Volume button- turns the EPG audio feedback on/off
Indications	•EPG icon (Ready, Stim, and Error State), Foot Sensor icon, Operating Mode icon, Battery Level icon, Error icon, and Volume (mute) icon •Numerical display for stimulation intensity and error code display
Carrying Options	In pocket or neck strap
Dimensions	•Length: 75 mm (2.9 in.) •Width: 40 mm (1.6 in.) •Height: 17 mm (0.7 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	IP22 Protection Against: •Object Sized >12.5mm •Dripping Water When Tilted up to 15° Effective Against: •Fingers or Similar Objects •Vertical dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position.
FCC ID Number	RYYEYSGJN

EPG Specifications	
Classification	Internally powered, continuous operation with type BF applied part(s)
Battery Type	Rechargeable lithium ion battery, 3.7V, 1000 mAh
Controls	•Power button - turns system on/off •Stim button- to turn stimulation on/off •Minus and Plus buttons- to decrease or increase stimulation intensity level
Indications	•Status Indicator Light and Battery Indicator Light •Audio and vibration feedback •“Beeps” for audio alerts
Dimensions	Length: 82 mm, Width: 47 mm, Height: 15 mm
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 Inter-Phase 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 Inter-Phase Interval of 50 µsec	450	650	850	1050	1250
Max. Load	80000 ohm (Subject to max. voltage limitation)				
Min. Load	100 ohm				
Pulse Repetition Rate	10–45 Hz, 5 Hz resolution				

Gait Parameters	
Swing Control Delay (%)	0–100% of phase* time, 5% resolution
Swing Control End (%)	0–100% of phase* time, 5% resolution
Stance Control Delay (%)	0–100% of phase* time, 5% resolution
Stance Control End (%)	0–100% of phase* time, 5% resolution
Ramp Up	0–0.5 seconds, 0.1-second resolution
Ramp Down	0–0.5 seconds, 0.1-second resolution
Extend (%)	0–100% of stance time, 5% resolution

Max. Duration of Stimulation	1–10 seconds, 1-second resolution
* Stimulation burst can start either on swing or stance phase.	

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

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

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

All logs are stored in EEPROM when the alert is generated. The logs are maintained as long as the EPG has power for at least a few seconds after an alert is activated. Once the contents of the logs reach maximum storage capacity, logs rollover and the oldest entries are overwritten.

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

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

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

System Charger Specifications	
Use the medical Class II safety approved power supply provided/approved by Bioventus 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 L360 Thigh System while charging. Do not wear the Thigh Cuff while charging.

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

Wireless Information

System Characteristics

The L360 Thigh System communicates wirelessly between components.

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

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

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

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

⚠ **Caution:** When controlling the L360 Thigh System on a patient using Clinician Application, make sure there is always line of site between the Clinician Application and the patient. In case of communication failure between the Clinician Application and the patient's L360 Thigh System, move the Clinician Application closer to the patient's L360 Thigh System.

Electromagnetic compatibility (EMC) Information

Guidance and Manufacturer's Declaration—Electromagnetic Emissions		
The L360 Thigh System is intended for use in the electromagnetic environment specified below. The customer or the user of the L360 Thigh System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment — Guidance**
RF emissions CISPR 11	Group 1	The L360 Thigh System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The L360 Thigh System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration— Electromagnetic Immunity for All Equipment and Systems			
The L360 Thigh System is intended for use in the electromagnetic environment specified below. The customer or the user of the L360 Thigh System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment— Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/-2 kV for power supply lines +/- 1 kV for Input/ output lines	+/- 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/-1 kV line to line +/-2 kV line to earth	+/-1 kV line to line +/-2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration— Electromagnetic Immunity for All Equipment and Systems			
The L360 Thigh System is intended for use in the electromagnetic environment specified below. The customer or the user of the L360 Thigh System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment—Guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the L360 Thigh System requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 Aa/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: U_T is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
The L360 Thigh System is intended for use in the electromagnetic environment specified below. The customer or the user of the L360 Thigh System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment—Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the L360 Thigh System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
The L360 Thigh System is intended for use in the electromagnetic environment specified below. The customer or the user of the L360 Thigh System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment—Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM and Amateur Radio Bands	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM and Amateur Radio Bands	**Recommended separation distance:** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz Proximity Fields per 60601-1-2 4th edition	$[E_1]$ = 10 V/m in 26 MHz to 2.7 GHz Proximity Fields per 60601-1-2 4th edition	**Recommended separation distance:** $d = 0.4\sqrt{P}$, 80–800 MHz range $d = 0.7\sqrt{P}$, 800-2700 MHz range

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the L360 Thigh System is used exceeds the applicable RF compliance level above, the L360 Thigh System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the L360 Thigh System.

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

Network Safety, Security, and Privacy

The security of Bioventus 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. Bioventus encourages customers to implement the following industry-standard practices:

- Physical Security (e.g. do not allow unauthorized individuals to use the Clinician Programmer tablet and application)
- Operational Security (e.g. do not leave sensitive information, such as exported files, on the 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 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 Clinician Programmer tablet, a remote possibility remains that the system can be hacked or altered. If such an occurrence is suspected, contact Customer Service 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 information can also be requested from this department.