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Rx Only

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**NESS
L300[®]**

Clinician's Guide

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L300[®]**



Clinician's Guide

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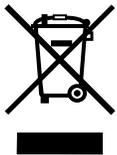
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Patents Pending

Aspects of this device are covered by several patents and patent applications including US Pat 7,899,556.

Disclaimer

Bioness Inc and its affiliates shall not be liable for any injury or damage suffered by any person, either directly or indirectly, as a result of the unauthorized use or repair of Bioness Inc products. Bioness Inc and its affiliates do 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 NESS L300, care should be taken to dispose of those parts in the correct manner; where applicable, parts should be recycled. When the life cycle of the NESS L300 has been completed, the product should be discarded according to the laws and regulations of the local authority.

For more detailed information regarding these recommended procedures, please contact Bioness Inc. Bioness Inc is committed to continuously seeking and implementing the best possible manufacturing procedures and servicing routines.

Conformity Certification

The NESS L300 complies with the following standards:

Safety of Medical Equipment. General Requirements - UL 60601-1: 2003-04-25 (Ed.1) with Revisions up to 2003/06/30, and CSA C22.2 No.:601.1-1M90

Standard For Safety of Medical Equipment. Particular Requirements for Safety of Nerve and Muscle Stimulators - IEC 60601-2-10:1987+A1:2001



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List of Symbols

	Caution
	Complies with United States and Canadian Product Safety Standards
	Complies with the European Union Medical Device Directive
	Serial Number
	Double Insulated (Equivalent to Class II of IEC 536)
	Type BF Applied Part(s)
	Non-Ionizing Radiation
	European Authorized Representative
	Date of Manufacture
	Manufacturer
	This Product Must not be Disposed of with Other Household Waste
	Consult Instructions for Use
	Re-Order Number
	Lot Number
	Certification of Radio Products for the Japanese Market
	Left
	Right
	Single Use Only

Introduction

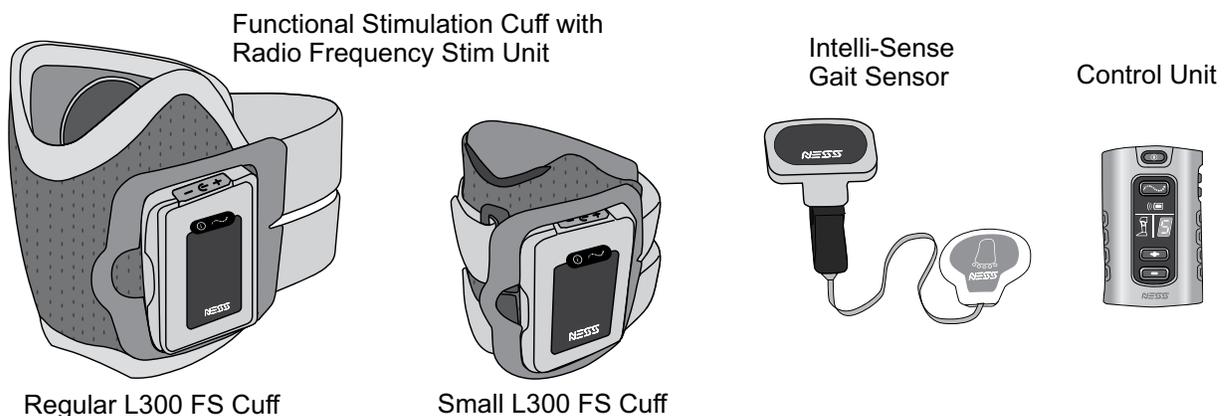
The NESS L300 Foot Drop System is an advanced neuroprosthesis designed to improve gait in people suffering from foot drop—the dragging of the forefoot while walking—as a result of a central nervous system injury or disease.

The NESS L300 Foot Drop System communicates wirelessly to deliver electrical pulses over the common peroneal nerve and to the motor point of the tibialis anterior muscle, causing ankle dorsiflexion in the swing phase of gait to prevent foot drop.

The NESS L300 Foot Drop System may facilitate muscle re-education, prevent disuse atrophy of the muscles that dorsiflex the foot, maintain or improve range of motion in the ankle joint, and improve local blood circulation.

System Components:

- A Functional Stimulation (FS) Cuff (available in regular and small sizes) with a Radio Frequency (RF) Stim Unit
- An Intelli-Sense Gait Sensor
- A Control Unit



System Features:

- The unique ergonomic design of the FS Cuff may allow the FS Cuff to be put on with one hand, and ensures constant and snug contact between the user’s limb and the FS Cuff’s integrated electrodes.
- The Intelli-Sense Gait Sensor detects whether the foot is in the air or on the ground. When the user is walking, the Gait Sensor transmits this information to the rest of the system, which implements algorithms to synchronize activation of the foot accordingly.
- The wireless Control Unit displays real-time information regarding the system’s status and manages the system components.

In addition, the NESS L300 features a gait mode for use when walking and a therapeutic training mode for therapeutic muscle training when not walking.

The NESS L300 Clinician's Kit contains the components and accessories for fitting and programming the NESS L300 Foot Drop System. This Clinician's Guide describes the Clinician's Kit contents and instructions for use. A brief description of the NESS L300 system components is provided for reference. Refer to the NESS L300 User's Guide for comprehensive information on the NESS L300 System Kit contents and instructions for use, including set-up, operation, battery charging and replacement, cleaning, component electronic registration, and troubleshooting.

General Warnings and Precautions

Indications for Use

The NESS L300 Foot Drop System is intended to provide ankle dorsiflexion in individuals (adults and pediatrics) who have foot drop following an upper motor neuron injury or disease. During the swing phase of gait, the NESS L300 electrically stimulates muscles in the affected leg to provide dorsiflexion of the foot; thus, it may improve the individual's gait. The NESS L300 may also facilitate muscle re-education, prevent or retard disuse atrophy, maintain or increase joint range of motion, and increase local blood flow.

Contraindications

- Patients with a demand-type cardiac pacemaker, defibrillator, or any electrical or metallic implant should not use the NESS L300.
- The NESS L300 should not be used where a cancerous lesion is present or suspected.
- The NESS L300 should not be used on a leg where a regional disorder, such as a fracture or dislocation, would be adversely affected by motion from the stimulation.
- The NESS L300 should not be used on a leg where strength testing or strength training is planned.

Warnings

- The long-term effects of chronic electrical stimulation are unknown.
- The FS 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 NESS L300 to the patient and high-frequency surgical equipment may result in skin burns where the stimulator electrodes adhere and damage to the RF Stim Unit.
- Do not use the NESS L300 within three feet of short wave or microwave therapy equipment. Such equipment may produce instability in the RF Stim Unit output.
- The NESS L300 should only be configured by an authorized clinician.
- The Clinician's Programmer should only contain the Windows Mobile for Pocket PC operating system and Bioness Inc proprietary software. Third-party software packages are not supported and may interfere with proper operation of the NESS L300, thus voiding the warranty.

Precautions

- Inflammation in the region of the FS Cuff may be aggravated by motion, muscle activity, or pressure from the FS Cuff. Advise patients to stop using the NESS L300 until any inflammation is gone.
- Use caution when treating patients with suspected or diagnosed heart problems.
- Advise patients to use the FS 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.
- Use caution with patients who have suspected or diagnosed epilepsy.
- Some patients may experience skin irritation, an allergic reaction, or hypersensitivity to the electrical stimulation or the electrical conductive medium. In some cases, irritation may be avoided by changing the stimulation parameters or altering electrode placement.
- Do not use the NESS L300 without electrodes.
- After removing the FS 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. Use of the NESS L300 should be temporarily halted until any inflammation is resolved completely.
- Advise patients to stop using the NESS L300 and consult their clinician if stimulation does not start at the correct time during gait.
- Patients should not wear the NESS L300 during x-ray examinations.
- Patients should turn off the NESS L300 when at a refueling place. They should not use the NESS L300 near flammable fuel, fumes, or chemicals.
- Only the treating clinician should determine electrode placement and stimulation settings.
- Use only NESS L300 electrodes supplied by Bioness Inc.
- Specific physician clearance should be obtained before using the NESS L300 on patients who have an alteration of normal arterial or venous flow in the region of the FS 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 NESS L300 when patients have a structural deformity in the area to be stimulated.
- The safe use of the NESS L300 during pregnancy has not been established.

- Skin problems where the FS Cuff is worn may be aggravated by the NESS L300.
- Turn off the NESS L300 before removing or replacing the electrodes.
- Adult supervision and assistance should be provided for anyone needing help while using the NESS L300 system.
- Protect all electronic components from contact with water, such as from sinks, bathtubs, shower stalls, rain, snow, etc.
- Do not leave the NESS L300 stored where temperatures may exceed the recommended storage temperature range: -20°C to +60°C (-4°F to +140°F). Temperature extremes can damage the components.
- Should any technical problem occur that is not covered in this guide, contact Bioness Inc. Do not attempt to repair the NESS L300.
- The FS 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 NESS L300 before putting on the FS Cuff. Do not turn on the NESS L300 until the FS Cuff is fastened in place.
- Advise patients to turn off the NESS L300 before driving, operating machinery, or performing any activity in which involuntary muscle contractions may put the patient at undue risk of injury.
- Avoid the formation of condensation on the NESS L300 electronic components. 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.

Adverse Reactions

In the unlikely event that any of the following occurs, advise patients to stop using the NESS L300 immediately and consult their physician:

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

Skin irritations and burns 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 FS Cuff. Skin irritation tends to occur after approximately three months of use. To ensure healthy skin with long-term use of the NESS L300, it is important that patients 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 FS Cuff.
- Replace the electrodes at least every two weeks, even if they appear to be in good condition.
- After taking off the FS Cuff, always re-cover hydrogel electrodes with the protective plastic covers, where applicable.
- Excess body hair where the electrodes adhere may reduce electrode contact with the skin. If necessary, remove excess body hair with an electric shaver or scissors. Do not use a razor. A razor can irritate the skin.
- When positioning the FS Cuff, make sure the electrodes uniformly contact the skin.
- Ventilate the skin by removing the FS Cuff for at least 15 minutes every three to four hours.

If skin irritation or a skin reaction occurs, patients should stop using the NESS L300 immediately and contact their clinician, dermatologist, or Bioness Clinical Specialist. They should resume use only when the skin is completely healed, and then follow a skin-conditioning protocol per the recommendation of a health-care specialist.

Environmental Conditions that Affect Use

Radio Communication Information

Several components of the NESS L300 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 (Radio Frequency Devices) of the FCC (Federal Communications Commission) Rules. These limits are designed to provide reasonable protection against harmful interference in a residential environment. This equipment generates, uses, and can radiate radio frequency energy and, if not operated 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 environment. 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.

Changes or modifications to this equipment not expressly approved by Bioness Inc could void the user's authority to operate the equipment.

Portable and mobile RF communications equipment can affect the NESS L300 System.

Conformity Certification

The NESS L300 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, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Travel

The NESS L300 System charger set with interchangeable blades is compatible with both European and U.S. voltage: 110/220 V, 50/60 Hz.

Turn off your L300 system before going through airport security. Wear loose clothing so that you can easily show the security person your NESS L300. The NESS L300 will likely set off

the security alarm. Either ask for a “hand scan” or be prepared to remove your NESS L300 so that security can scan it. You may want to carry a copy of your NESS L300 prescription. A prescription can be useful when passing through customs as well.

To request a copy of your prescription, call Bioness Customer Support: telephone: (800) 211-9136, Option 2; or (661) 362-4850, Option 2. A Bioness representative can fax or mail you a copy.

Note: The NESS L300 contains radio transmitters. The Federal Aviation Administration (FAA) rules require that all radio-transmitting devices be turned off during flight.

Electromagnetic Emissions

The NESS L300 System needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this manual.

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

- DC power supply as provided by Bioness Inc, manufactured by Friwo, Part No. FW7555M/05.
- “Y” cable (2-way splitter) as provided by Bioness Inc. Manufactured by Tamuz Electronics Ltd.

Warnings

- The use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the NESS L300 System as replacement parts for internal components, may result in increased emissions or decreased immunity of the NESS L300 System.
- The NESS L300 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 the accessory, transducer, or cable with equipment and systems other than those specified may result in increased emissions or decreased immunity of the NESS L300 System.
- The NESS L300 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 (IEC)) emission requirements.

The NESS L300 Foot Drop System

The NESS L300 Foot Drop System consists of an FS Cuff with RF Stim Unit, a Control Unit, and an Intelli-Sense Gait Sensor. See Figure 4-1. These components communicate wirelessly to stimulate the common peroneal nerve (normally found posterior and slightly distal to the head of the fibula) to contract the tibialis anterior and peroneal muscles, thus causing balanced dorsiflexion (without excessive inversion or eversion).

Stimulation Features:

- The NESS L300 uses electrodes for stimulation of the common peroneal nerve and the motor point of the tibialis anterior muscle.
- Stimulation is controlled by wireless communication at the appropriate phase of gait.

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 (for example, amplitude) and gait (for example, ramp) parameters to provide sufficient foot clearance during walking.

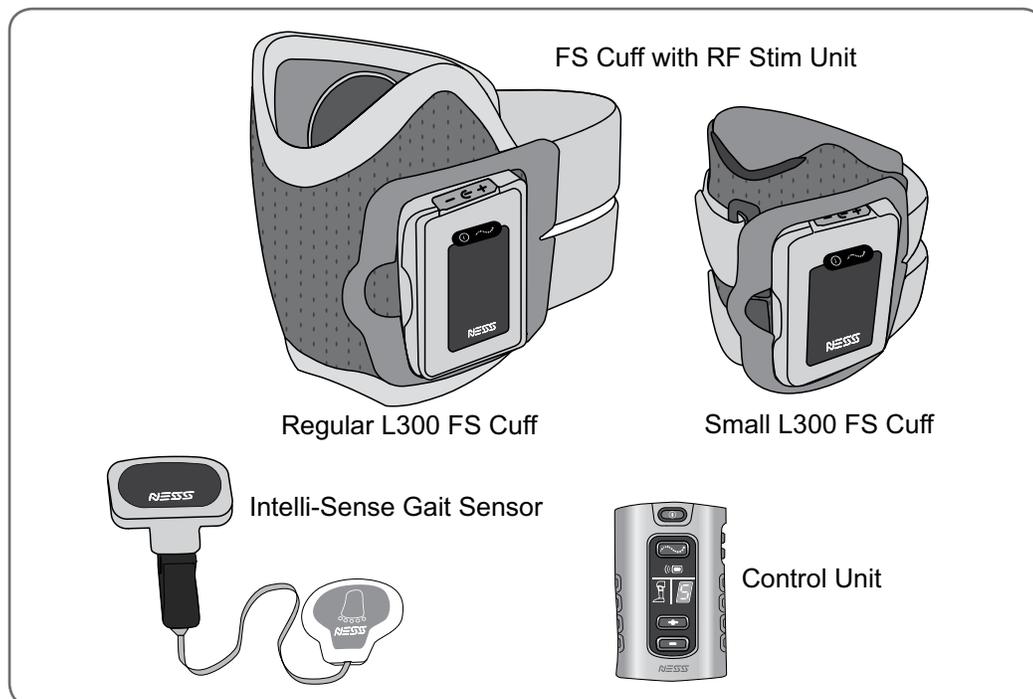


Figure 4-1: NESS L300 system components.

Functional Stimulation (FS) Cuff

The L300 FS Cuff is a lightweight, low-profile neuroprosthesis that straps onto the leg directly under the patella.

The L300 FS Cuff features an ergonomically designed locator for accurate placement, a cradle for the RF Stim Unit, and an adjustable elastic strap. See Figure 4-2. The Regular L300 FS Cuff strap is available in three sizes: small (S), medium (M), and large (L). The Small L300 FS Cuff strap is available in two sizes: extra small (XS) and extra extra small (XXS). The electrodes and electrode bases attach to the inner liner of the L300 FS Cuff.

The Regular L300 System Kit comes with a medium (M) strap attached to the Regular L300 FS Cuff. The Small L300 System Kit comes with an extra small (XS) strap attached to the Small L300 FS Cuff. The other available strap sizes are included in the system kits as an accessory item.

The L300 FS Cuff can easily be worn under most clothing, and is available in right and left configurations. The Regular L300 FS Cuff is used for leg circumferences ranging from 29 cm to 51 cm (11 in. to 20 in.). The Small L300 FS Cuff is used for leg circumferences ranging from 22 cm to 31 cm (8 in. to 12.2 in.).

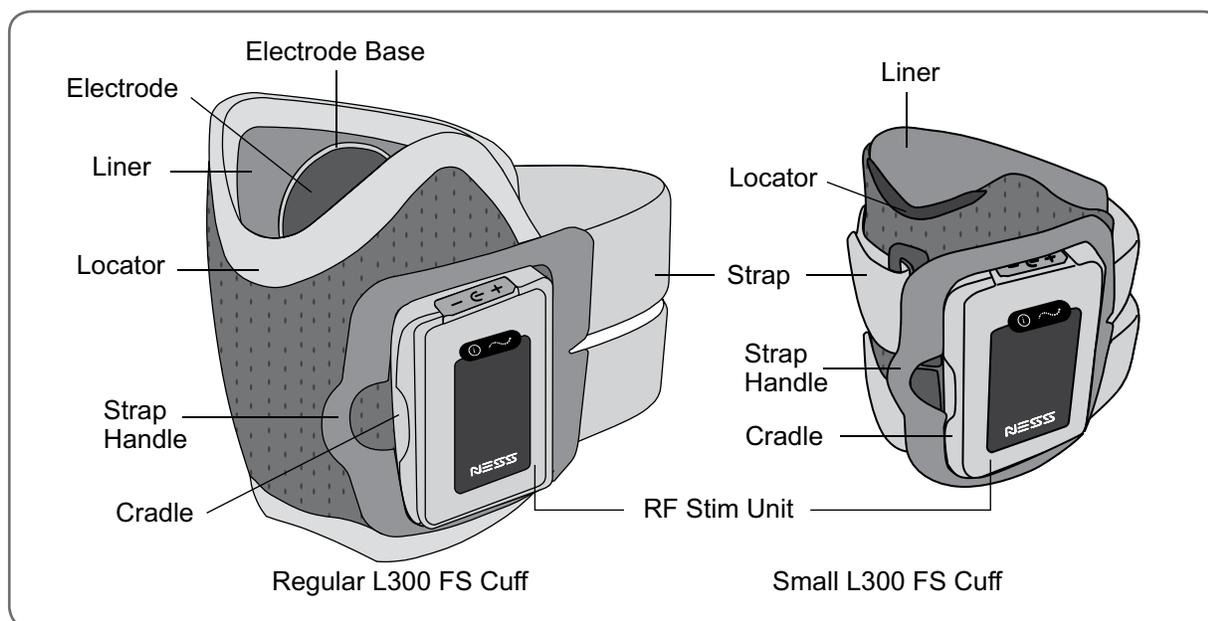


Figure 4-2: Regular L300 FS Cuff and Small L300 FS Cuff.

Radio Frequency (RF) Stim Unit

The RF Stim Unit snaps into the cradle of the L300 FS Cuff and should only be removed for maintenance and when cleaning the L300 FS Cuff.

The RF Stim Unit responds to wireless signals from the Control Unit and Intelli-Sense Gait Sensor to turn stimulation on and off. It has a rechargeable battery and two indicator lights: a status light and a stimulation light. See Table 4-1. The RF Stim Unit emits visual and audio alerts when radio communication fails or the component malfunctions.

The NESS L300 System Kit includes a system charger set for charging the RF Stim Unit and Control Unit.

RF Stim Unit	Display	Description	Definition
Status Light 		Flashes GREEN	System is On
		Flashes YELLOW	Low Battery
		Alternately Flashes YELLOW and GREEN	Battery Charging
		Solid GREEN	Battery Fully Charged
		Flashes RED	Radio Communication Failure
		Solid RED	RF Stim Unit Malfunction
Stimulation Light 		Flashes YELLOW SLOWLY	Stimulation is Off
		Flashes YELLOW RAPIDLY	Stimulation is On

Table 4-1: RF Stim Unit displays and definitions.

Intelli-Sense Gait Sensor

The Intelli-Sense Gait Sensor detects when the foot is in the air and on the ground, and wirelessly signals the RF Stim Unit and Control Unit to synchronize movement of the foot accordingly during the gait cycle.

The Intelli-Sense Gait Sensor features a pressure sensor and a transmitter. The pressure sensor is worn under the insole of the shoe of the involved lower extremity, attached to a Gait Sensor pad. See Figure 4-3. The transmitter is worn clamped to the inner rim of the shoe.

The Intelli-Sense Gait Sensor can be transferred to a different shoe, or additional Gait Sensors can be purchased for different shoes. There is no need to detach the Intelli-Sense Gait Sensor between uses.

The Intelli-Sense Gait Sensor is powered by a small non-rechargeable battery. The battery will need to be replaced after approximately six months of use.

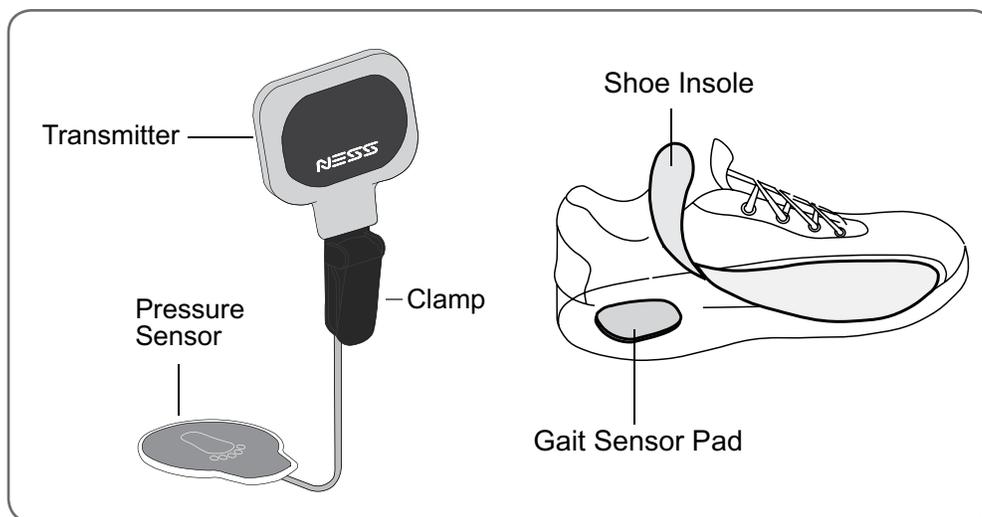


Figure 4-3: Intelli-Sense Gait Sensor (left) and placement of the Gait Sensor (right).

Control Unit

The Control Unit is used to turn on/off the NESS L300 system, select an operating mode (gait, training, standby, or clinician), fine-tune stimulation intensity, adjust audio alert volume, and monitor system performance. See Figure 4-4 and tables 4-2, 4-3, and 4-4.

The Control Unit digital display and indicator lights indicate stimulation intensity level, operating mode, battery charge status, electronic registration status, and error messages. See tables 4-3 and 4-4.

The Control Unit beeps to indicate:

- The system is on.
- A button was pressed.
- Low battery.
- An error (usually accompanied by a visual indicator).

The Control Unit communicates wirelessly with the RF Stim Unit and the Intelli-Sense Gait Sensor. It is powered by a single rechargeable AAA battery.

The NESS L300 System Kit includes a system charger set for charging the Control Unit and RF Stim Unit, and a belt pouch, wrist strap, and neck strap for carrying the Control Unit.

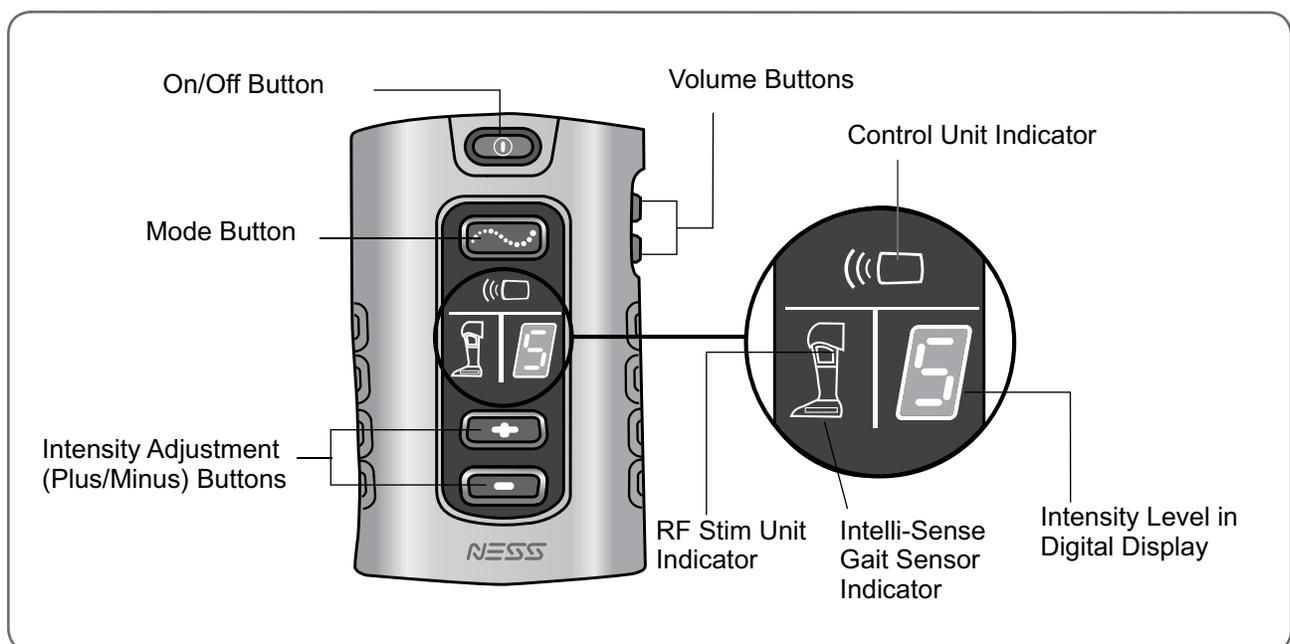


Figure 4-4: Control Unit operating buttons and visual displays.

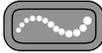
Control Unit	Operating Button	Description	Function
		On/Off	Turns On/Off the System
		Mode	Selects Gait, Training, Standby, and Clinician Mode
	 	Volume	Adjusts Volume of Audio Alerts and Turns On/Off Audio Feedback for Stimulation
	 	Intensity Adjustment (Plus/Minus)	Adjusts Stimulation Intensity Level

Table 4-2: Control Unit operating buttons and functions.

Control Unit	Display	Description	Definition
		On/Off Button Flashes GREEN	System is On
		Mode Button Flashes YELLOW SLOWLY	System is in Gait/Training/Clinician Mode, Stimulation is Off
		Mode Button Flashes YELLOW RAPIDLY	System is in Gait/Training/Clinician Mode, Stimulation is On
		Displays 0–9	Intensity Level
		Intensity Level and “t” Alternate in the Digital Display	Training Mode
		Intensity Level and “C” Alternate in the Digital Display	Clinician Mode
		A Component Indicator Flashes YELLOW	Component Low Battery
		Rotating GREEN Circle	Control Unit Charging
		Horizontal GREEN Line	Control Unit Fully Charged

Table 4-3: Control Unit visual displays and definitions.

Control Unit	Display	Description	Definition
		RF Stim Unit Indicator Flashes RED and Intensity Level Flashes	Faulty Electrode Contact
		Control Unit and RF Stim Unit Indicators Alternately Flash RED and "E" Flashes	Radio Communication Failure Between the Control Unit and RF Stim Unit
		Gait Sensor and RF Stim Unit Indicators Alternately Flash RED and "E" Flashes	Gait Sensor Hibernation or Radio Communication Failure between the Gait Sensor and RF Stim Unit
		A Component Indicator is Solid RED and "E" Appears	Component Malfunction

Table 4-4: Control Unit error displays and definitions.

Turning On/Off the Control Unit

To turn on the Control Unit:

- Press the  on/off button once. The Control Unit will start in standby mode. All display indicators will light up for a few seconds while the system performs a self-test. The  on/off button will then flash GREEN to indicate the system is on.

To turn off the Control Unit:

- Press the  flashing GREEN on/off button once.

Selecting Gait Mode

Gait mode is used for walking. In gait mode, the stimulation is synchronized by the Intelli-Sense Gait Sensor to achieve dorsiflexion in the swing phase of gait when the heel or forefoot leaves the ground and relaxation after heel or forefoot contact during the stance phase of gait.

To select gait mode:

- Turn on the Control Unit, and then press the  mode button *briefly*. The unit will beep and the  mode button will start flashing YELLOW SLOWLY (indicating that stimulation is off). When stimulation is on, the  mode button will flash YELLOW RAPIDLY.

Selecting Training Mode

Training mode is used to train the muscles while the patient is not walking. Patients can be standing, sitting, or lying down. It is also used to condition patients to stimulation, and it provides extra stimulation time for patients with limited ambulation.

Training mode works independently of the Intelli-Sense Gait Sensor. In training mode, stimulation is delivered in cycles pre-set by the clinician. Training mode is designed to facilitate muscle re-education, prevent or retard disuse atrophy of the lower leg muscles, maintain or improve range of motion of the ankle joint, and improve local blood circulation. Training mode also can be used to check if the L300 FS Cuff is positioned properly. If the foot does not respond to the stimulation as it should, reposition the L300 FS Cuff.

To select training mode:

- Turn on the Control Unit. Press and *hold* the  mode button until the Control Unit beeps, the  mode button starts flashing YELLOW SLOWLY (indicating that stimulation is off), and  ("t" for training) alternates with the intensity level in the digital display. When stimulation is on, the  mode button will flash YELLOW RAPIDLY.

Note: To achieve maximum benefit in training mode, have patients attempt to contract the muscle simultaneously with stimulation.

Returning to Standby Mode

The Control Unit turns on in standby mode. In standby mode, the Control Unit is on and waiting for commands. Stimulation is off.

To return to standby mode from gait or training mode:

- Press the  flashing mode button briefly. The Control Unit will beep, and the  mode button will stop flashing.

Selecting Clinician Mode

Clinician mode is used to start and pause stimulation while programming the NESS L300, or to enhance clinical training. Select clinician mode to enhance clinical training to include, for example, balance training in acute and sub-acute patients. Clinician mode uses the stimulation parameters set for gait mode.

To select clinician mode:

- Press the  on/off button to turn off the Control Unit. Press and hold the  minus button and then press the  on/off button briefly. The Control Unit will beep twice and the  mode button will begin to flash YELLOW SLOWLY, indicating that stimulation is off. The digital display will alternately show  (“C” for Clinician) and the intensity level.

To apply stimulation:

- Continuously press the  flashing mode button to apply stimulation. While stimulation is on, the  mode button flashes YELLOW RAPIDLY.

To stop stimulation:

- Release the  flashing mode button to stop stimulation. While stimulation is off, the  mode button flashes YELLOW SLOWLY.

To exit clinician mode:

- Press the  on/off button briefly to exit clinician mode.

Fine-Tuning Stimulation Intensity

When patients first turn on the Control Unit the stimulation intensity level will be “5”, which is the level set by the clinician. Normally patients will not need to adjust stimulation intensity other than when walking on different surfaces or in different shoes.

To fine-tune stimulation intensity:

- Press the  plus or  minus intensity adjustment button on the Control Unit once for each level of change. The Control Unit will beep with each level of change, and the new level will show in the digital display.

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

To increase dorsiflexion:

- If the patient’s foot slightly drags or catches on the floor while walking, increase the stimulation intensity level by pressing the  plus button.

To decrease dorsiflexion:

- If the patient’s foot rises too high while walking or if the stimulation is unpleasant, reduce the stimulation intensity level by pressing the  minus button. Be sure the patient’s foot does not drag or catch on the floor.

Adjusting the Volume of the Audio Alerts

To adjust the volume of the audio alerts:

- Use the   volume adjustment buttons to adjust the volume of the audio alerts.

Each time one of the buttons is pressed, the volume level will change. The Control Unit will beep to demonstrate the new level. When the system is turned off, the active volume level is saved. If the active volume level is “mute”, the default volume level is automatically restored.

To mute the audio alerts:

- Lower the volume to the lowest setting by pressing the  down volume adjust button.

Turning On Audio Feedback During Stimulation

To receive an audio alert when stimulation turns on:

- Turn on the Control Unit and press the  up volume adjustment button for three seconds.

To turn off audio feedback during stimulation:

- Press the  down volume adjust button or turn off the Control Unit.

System Safety Features

To communicate wirelessly, the NESS L300 Control Unit, RF Stim Unit, and Intelli-Sense Gait Sensor must be within RF communication range of each other. If the components become separated, RF communication will be lost and the system will stop working until RF communication is restored.



If RF communication fails, or if a battery is discharged:

- The Control Unit and RF Stim Unit indicators will flash RED and “E” will flash in the digital display.
- The Control Unit will emit an audio alert.
- The NESS L300 will deliver a warning default stimulation to lift the foot for six seconds before shutting down.

The NESS L300 Clinician's Kit

The NESS L300 Clinician's Kit is a portable clinical workshop used to fit, program, test, and perform routine maintenance on the NESS L300 Foot Drop System.

The Regular L300 Clinician's Kit includes the following:

- Clinician's Programmer with Intelli-Gait Software
- Storage Card
- Configuration Cradle
- Clinician's Programmer Charger
- Gait Sensor Pads
- Gait Sensor Replacement Battery
- Fitting Cable
- Regular L300 Personal Panels, Right
- Regular L300 Personal Panels, Left
- Personal Strap Covers
- Regular L300 Hydrogel Electrode Bases
- Regular L300 Hydrogel Electrodes
- Regular L300 Cloth Electrode Bases
- Regular L300 Cloth Electrodes
- Regular L300 Quick Fit Electrode, Right - A
- Regular L300 Quick Fit Electrode, Left - A
- Wire Concealers
- Shoe Spacers
- Tester
- Clinician's Reference Card

The Small L300 Clinician's Kit includes the following:

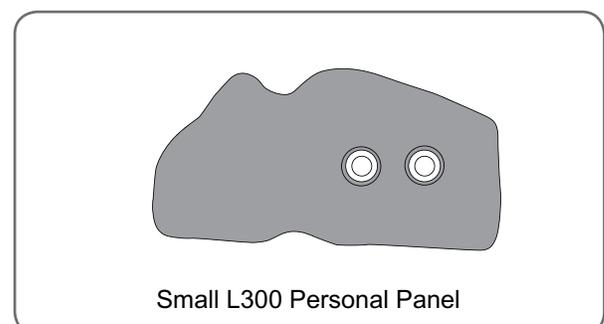
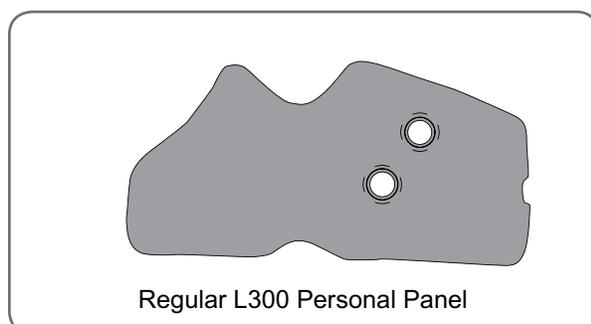
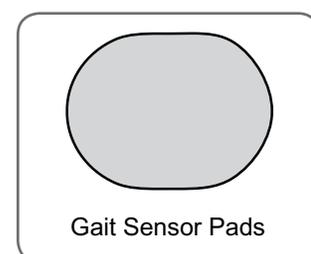
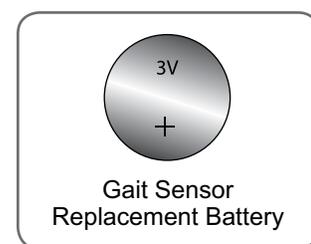
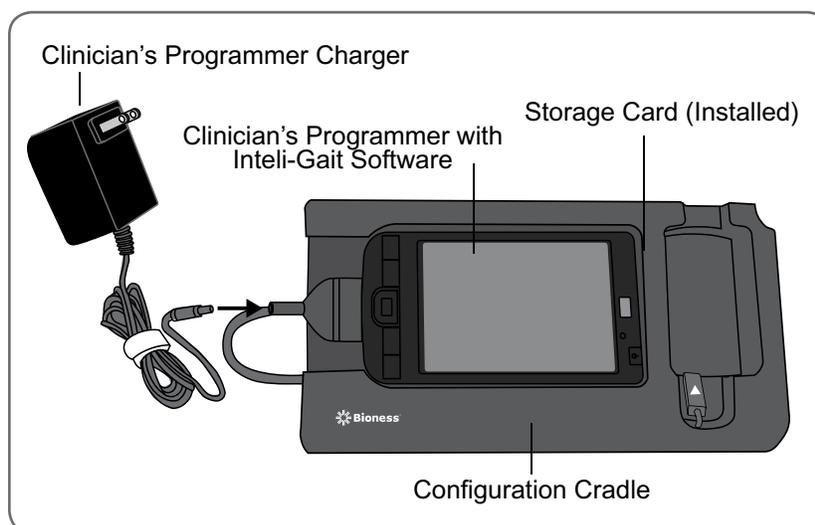
- Clinician's Programmer with Intelli-Gait Software
- Storage Card
- Configuration Cradle
- Clinician's Programmer Charger
- Gait Sensor Pads
- Gait Sensor Replacement Battery
- Fitting Cable
- Small L300 Personal Panels, Right
- Small L300 Personal Panels, Left
- Personal Strap Covers
- Small L300 Electrode Bases
- Small L300 Hydrogel Electrodes
- Small L300 Cloth Electrodes
- Small L300 Quick Fit Electrode - A
- Small L300 Quick Fit Electrode - B
- Shoe Spacers
- Tester
- Clinician's Reference Card

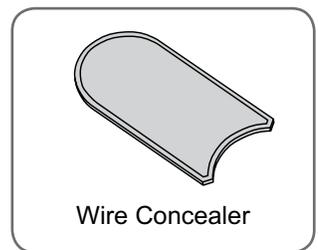
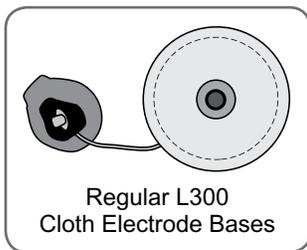
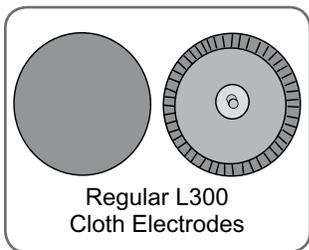
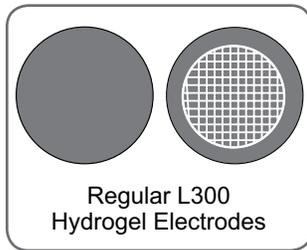
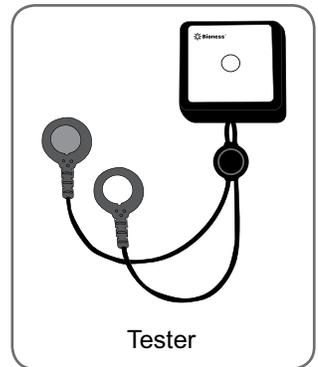
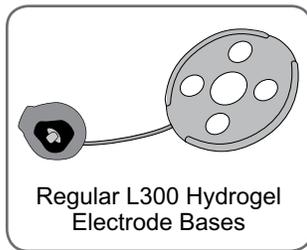
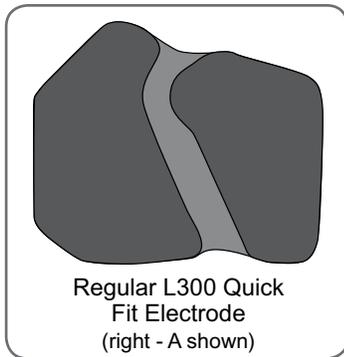
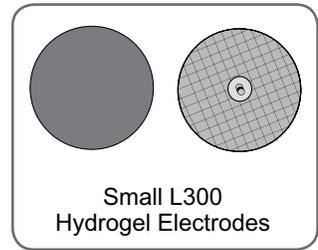
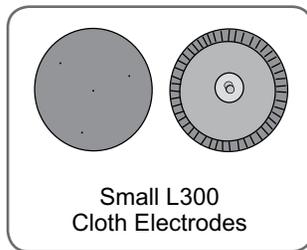
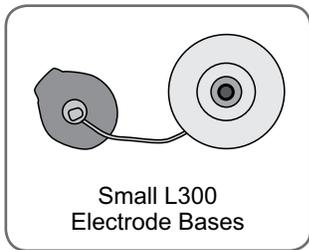
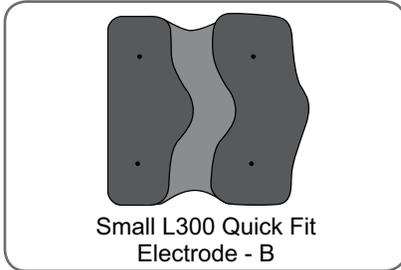
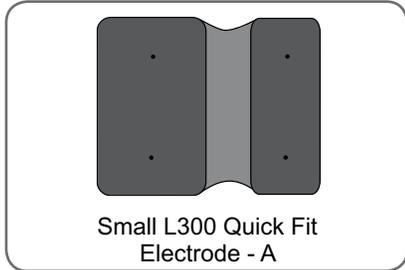
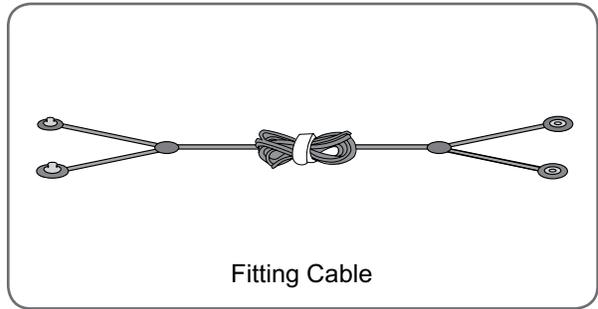
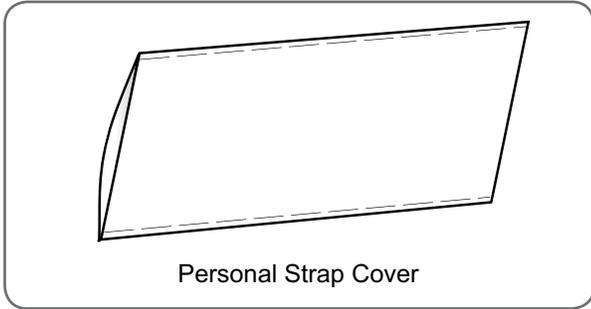
The Regular L300 Clinician's Pack includes the following:

- Regular L300 Personal Panels, Right
- Regular L300 Personal Panels, Left
- Regular L300 Hydrogel Electrode Bases
- Regular L300 Hydrogel Electrodes
- Regular L300 Cloth Electrode Bases
- Regular L300 Cloth Electrodes
- Regular L300 Quick Fit Electrode, Right - A
- Regular L300 Quick Fit Electrode, Left - A
- Wire Concealers
- Clinician's Reference Card

The Small L300 Clinician's Pack includes the following:

- Small L300 Personal Panels, Right
- Small L300 Personal Panels, Left
- Small L300 Electrode Bases
- Small L300 Hydrogel Electrodes
- Small L300 Cloth Electrodes
- Small L300 Quick Fit Electrode - A
- Small L300 Quick Fit Electrode - B
- Clinician's Reference Card





Programming Components and Software

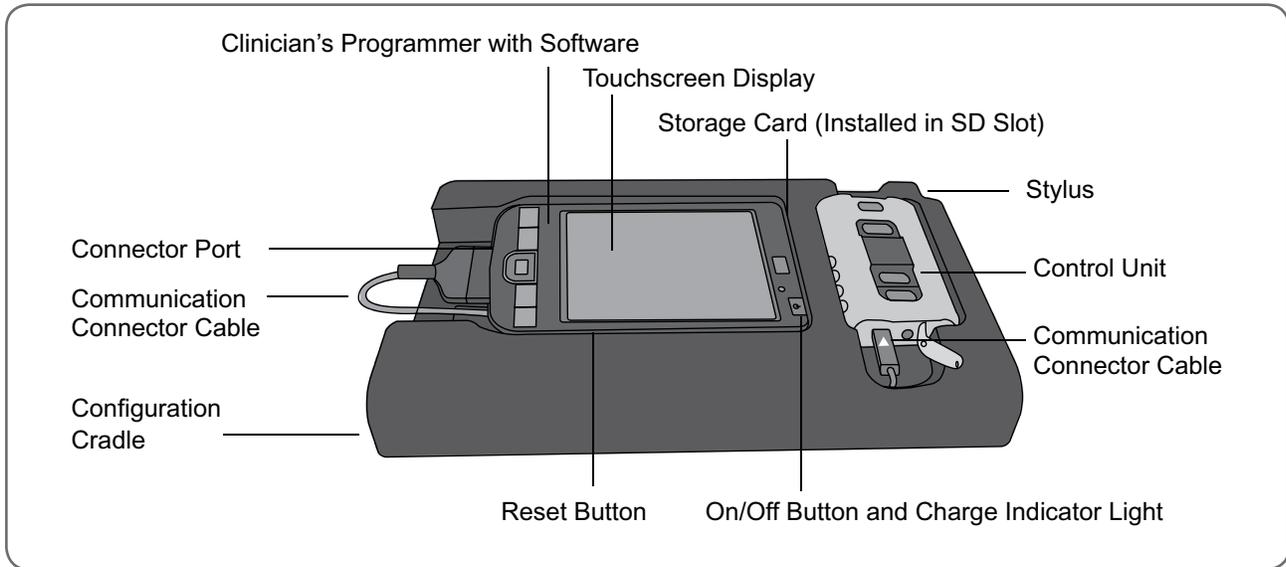


Figure 6-1: Programming components (and Control Unit).

Clinician's Programmer

The Clinician's Programmer is used to program the NESS L300 Foot Drop System. The Clinician's Programmer is a portable personal digital assistant (PDA) that comes with the NESS L300 Intelli-Gait Software and a storage card installed. When connected to the Configuration Cradle and the Control Unit, the Clinician's Programmer can wirelessly communicate with the RF Stim Unit. See Figure 6-1.

On/Off Button

The on/off button is used to turn the Clinician's Programmer on and off.

Reset Button

The reset button is used to soft reset the Clinician's Programmer.

Charge Indicator Light

The charge indicator light is AMBER when the Clinician's Programmer is charging and GREEN when the Clinician's Programmer battery charge is complete.

SD (Secure Digital) Slot

The SD slot contains the storage card.

Battery

The Clinician's Programmer contains a removable/rechargeable 2200 mAh Lithium-Ion battery.



Risk of explosion if battery is replaced with an incorrect type. Dispose of used batteries according to local regulation.

Touchscreen Display

The touchscreen display is used to navigate the NESS L300 Intelli-Gait Software, read statuses, and enter data. Use the pointed end of the stylus on the Configuration Cradle to make contact with the display screen. Use only the stylus.

Connector Port

The connector port is used to connect the Clinician's Programmer with the communication connector cable on the Configuration Cradle.



The Clinician's Programmer should only contain the Windows Mobile® operating system and Bioness Inc proprietary software. Third-party software packages are not supported and may interfere with proper operation of the NESS L300 system, thus voiding the warranty.

Configuration Cradle

The Configuration Cradle is used to connect the Clinician's Programmer to the Control Unit and to the Clinician's Programmer Charger. While the Clinician's Programmer is connected to the Control Unit, it communicates via the Control Unit with the RF Stim Unit. The Configuration Cradle contains a stylus for software navigation.

Storage Card

The storage card is used to back up and restore the Clinician's Programmer database. The storage card is provided installed in the SD slot of the Clinician's Programmer.

Clinician's Programmer Charger

The Clinician's Programmer Charger is used to recharge the Clinician's Programmer battery.

Intelli-Gait Software

The NESS L300 Intelli-Gait Software is used to program the NESS L300 Foot Drop System. The software features an information icon, six navigation menus, and numerous navigation buttons to aid in navigating the software. Data entry options include an on-screen keyboard and drop-down lists.

Information Icon

The information icon indicates system status and, when pressed, can open error messages and troubleshooting solution screens. The information icon is positioned in the top right corner of the navigation screens. See Figure 6-2.



Figure 6-2: Information icon.

The information icon is GREEN when the Clinician’s Programmer is connected to a Control Unit. The information icon is GRAY when the Clinician’s Programmer is not connected to a Control Unit.

When the information icon is RED or YELLOW:

- Press the information icon with the stylus to open a message window. See Table 6-1.

Information Icon	Display Description	Definition
	Solid GREEN	Control Unit Connected
	Solid GRAY	Control Unit Disconnected
	Flashing YELLOW	Low Battery in One or More of the Components
	Flashing RED	Error Alert, Such as Radio Communication Failure or Faulty Electrode Contact
	Solid RED	Hardware Malfunction Error in One or More of the Components

Table 6-1: Information icon displays and definitions.

Navigation Menus

The Intelli-Gait Software has six navigation menus: **Exit**, **Patients**, **Settings**, **History**, **Admin** (accessible to administrators only), and **(i)**, which opens the Intelli-Gait Software information screen. Press on the navigation menu with the stylus to open the navigation menu. See Figure 6-3 and Table 6-2.



Location of
Navigation Menus



Figure 6-3: Navigation menus.

Navigation Menu	Function
Exit	Exit the Intelli-Gait Software
Patients	Open the Patients List Window to Open, Add, Modify, or Remove a Patient Record
Settings	Open the Stim, Gait, Training, and Advanced Settings Windows for Viewing and to Program Settings
History	View Patient Usage (Gait Log) and Session History
Admin	Back Up and Restore the Database, and Add and Remove Users
(i)	View the Intelli-Gait Software Information Screen

Table 6-2: Navigation menus and functions.

Navigation Buttons

The Intelli-Gait Software has numerous navigation buttons that, when pressed, open a new screen or execute a command. Buttons common to the Stim, Gait, Training, and Advanced Settings windows are shown in Figure 6-4 and Table 6-3.

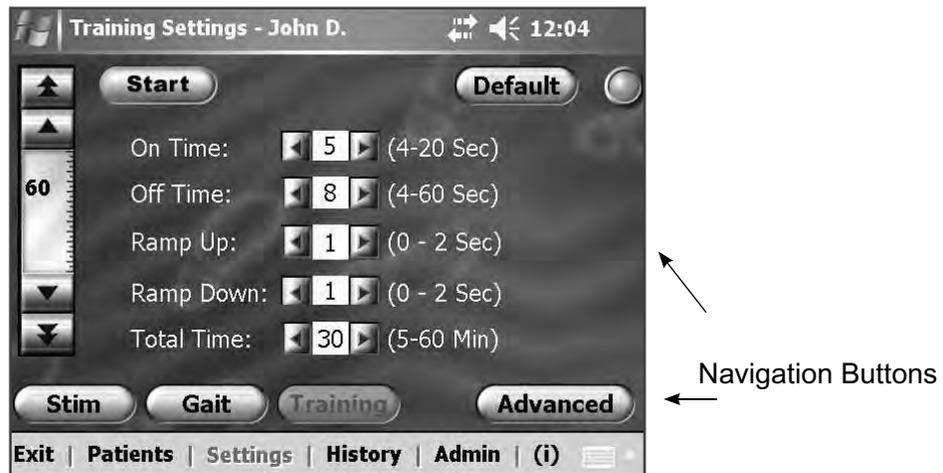


Figure 6-4: Navigation buttons, Training Settings window.

Navigation Button	Function
Start/Stop	Starts/Stops Stimulation
Stim	Opens the Stim Settings Window
Gait	Opens the Gait Settings Window
Training	Opens the Training Settings Window
Advanced	Opens the Advanced Settings Window
Default	Restores Stimulation, Gait, and Training Settings to their Default Values (Pressing Default will only affect the window that the button is pressed in and reduces the intensity level in all three settings windows to zero.)
?	Opens a Help Screen

Table 6-3: Navigation buttons common to the Stim, Gait, Training, and Advanced Settings windows.

Keyboard

Use the on-screen keyboard to enter characters in a field that requires alphanumeric input. The keyboard appears collapsed at the bottom right of most screens. To enlarge or reduce the keyboard, touch the keyboard with the stylus. To enter data, select each character using the stylus. See Figure 6-5.

Drop-Down Lists

To use a drop-down list:

- Press the down arrow to display the values in a drop-down list. Use the stylus to select a value. See Figure 6-5.

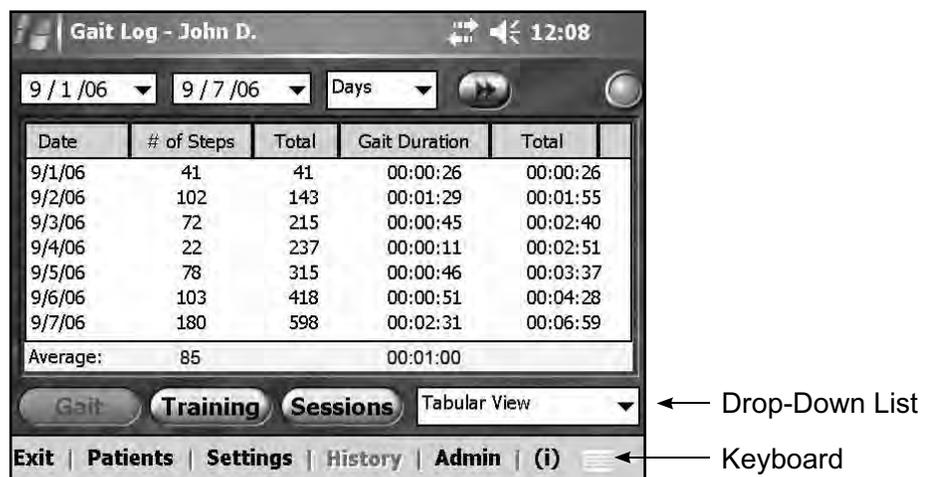


Figure 6-5: Data entry options: drop-down list and on-screen keyboard.

Fitting and Testing Accessories

FS Cuff Straps

The L300 FS Cuff strap is used to hold the L300 FS Cuff in place on the leg. The L300 FS Cuff strap is elastic, and fastens around the leg and the FS Cuff cradle. See Figure 7-1. The Regular L300 FS Cuff strap comes in three sizes: small (S), medium (M), and large (L). The Small L300 FS Cuff strap comes in two sizes: extra small (XS) and extra extra small (XXS).

To select an L300 FS Cuff strap:

- Measure the circumference of the patient’s leg at its broadest point (the gastrocnemius muscle belly) and refer to Table 7-1.

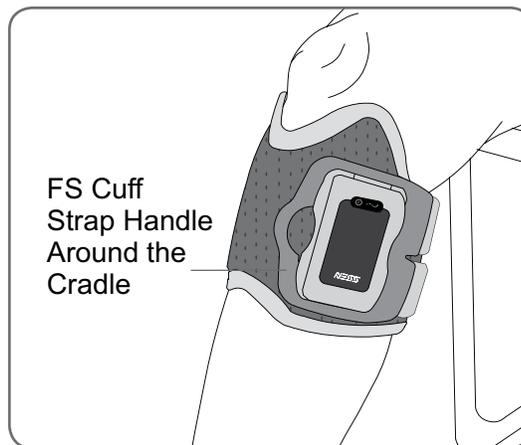


Figure 7-1: Regular L300 FS Cuff fastened on the right leg.

Regular L300 FS Cuff	
FS Cuff Strap Size	Leg Circumference
Small (S)	29–36 cm (11-14 in.)
Medium (M)	36-42 cm (14-16 in.)
Large (L)	42-51 cm (16-20 in.)
Small L300 FS Cuff	
FS Cuff Strap Size	Leg Circumference
Extra Extra Small (XXS)	21-26 cm (8-10 in.)
Extra Small (XS)	25-31 cm (9-12.2 in.)

Table 7-1: L300 FS Cuff strap fitting chart.

To attach the L300 FS Cuff strap to the L300 FS Cuff:

- Slide the strap through the strap leads and buckles on the L300 FS Cuff. Make sure the hook and loop fasteners face away from the L300 FS Cuff. Press on the hook and loop fasteners to secure the strap. See Figure 7-2.

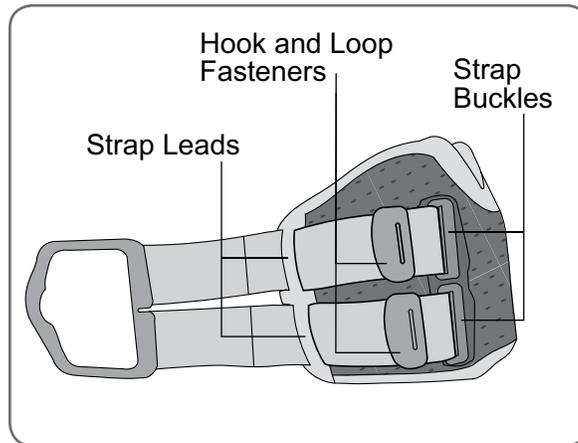


Figure 7-2: L300 FS Cuff strap attached to the L300 FS Cuff (Regular L300 FS Cuff shown).

Personal Strap Cover

The personal strap cover slides over the L300 FS Cuff strap and is used as a hygienic cover when the L300 FS Cuff is used by multiple patients. The personal strap cover can be cut to size if necessary. See Figure 7-3.

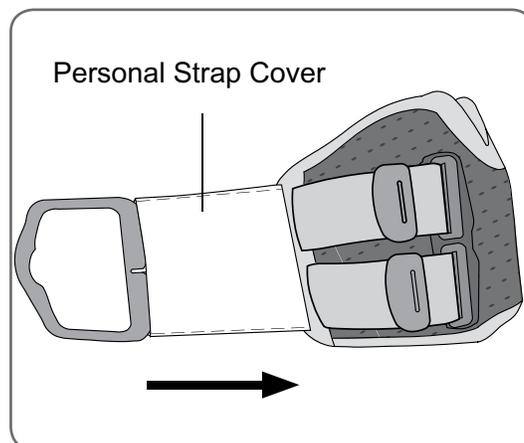


Figure 7-3: Personal strap cover on the L300 FS Cuff strap (Regular L300 FS Cuff shown).

Personal Panels

The personal panel is a removable inner lining for the L300 FS Cuff for use in the clinic when the L300 FS Cuff is used by multiple patients. The personal panel is available in small and regular sizes, as well as in right and left configurations. The regular personal panel is used with the Regular L300 FS Cuff and features two buttonholes that snap into the L300 FS Cuff plug holes. See Figure 7-4. The small personal panel is used with the Small L300 FS Cuff and is attached with velcro to the inner liner.

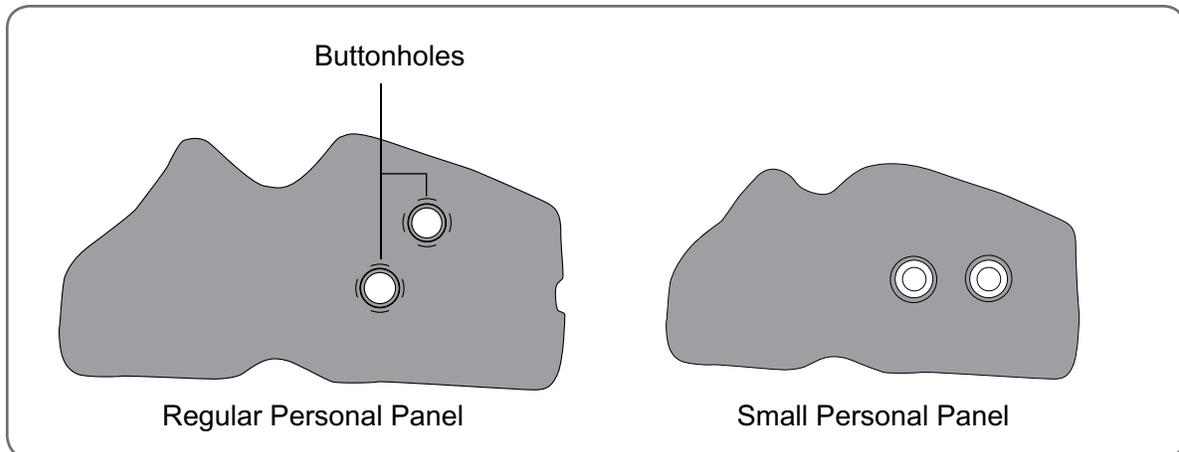


Figure 7-4: Right personal panel.

To attach the personal panel to the L300 FS Cuff for first fittings:

- For the Regular Personal Panel snap the personal panel buttonholes into the L300 FS Cuff plug holes. See Figure 7-5.
- For the Small Personal Panel align the position of the panel to the Small L300 FS Cuff and press down to attach the velcro to the cuff's inner liner.

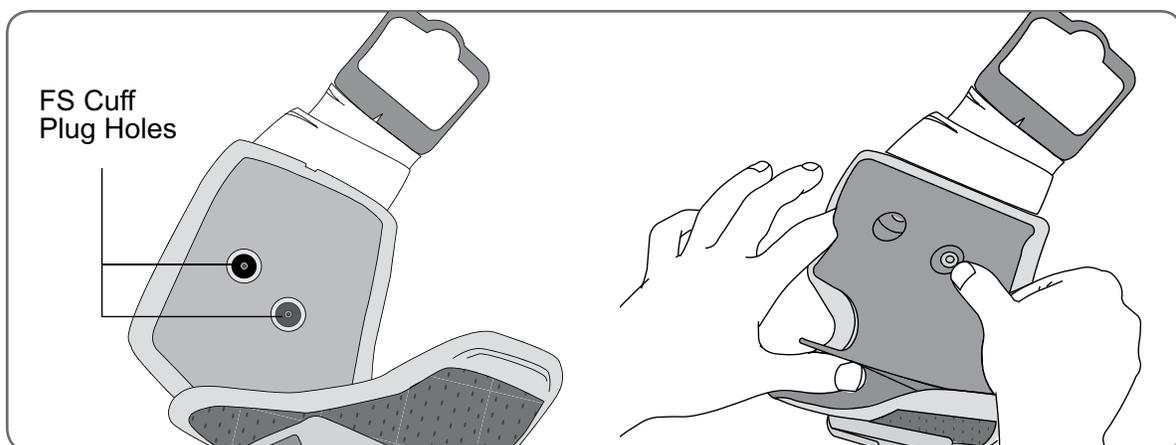


Figure 7-5: Snapping the personal panel buttonholes into the L300 FS Cuff plug holes. (Regular L300 FS Cuff shown).

To attach the personal panel to the L300 FS Cuff for follow-up sessions:

- When the patient returns to the clinic for a follow-up visit, attach the personal panel (with the electrode bases and electrodes attached) onto the L300 FS Cuff inner liner. See Figure 7-6.

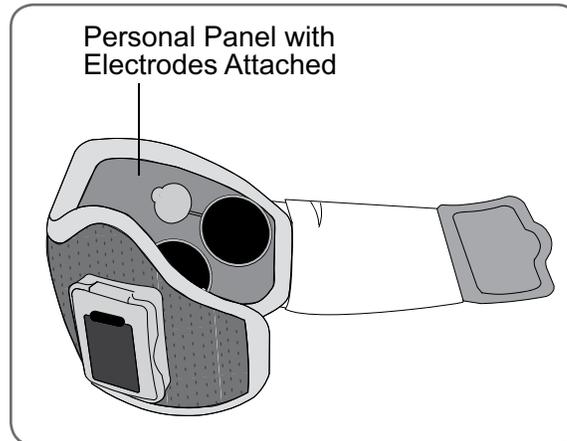


Figure 7-6: Electrode bases and electrodes attached to the personal panel in the L300 FS Cuff. (Regular L300 FS Cuff shown).

When the patient session is finished:

1. Remove the personal panel from the L300 FS Cuff. See Figure 7-7.
2. Write the patient's name and strap size on the personal panel label. If using hydrogel electrodes, re-adhere the electrode covers.
3. Store the personal panel for the patient's next session.

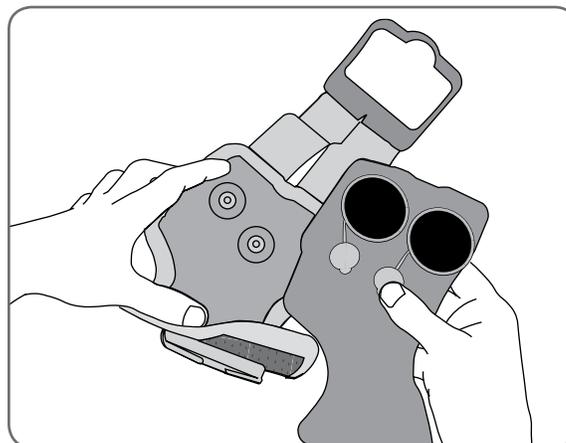


Figure 7-7: Removing the personal panel from the L300 FS Cuff. (Regular L300 FS Cuff shown).

Electrode Bases

The electrode bases are used to:

- Elevate the electrodes from the inner liner of the L300 FS Cuff to optimize electrode contact.
- Ensure accurate positioning of the electrodes with every application.

The electrode bases feature a snap for attachment to the L300 FS Cuff plug holes.

The following electrode bases can be used with the Regular L300 FS Cuff: (See Figure 7-6)

- Regular L300 Cloth Electrode Bases
- Regular L300 Hydrogel Electrode Bases

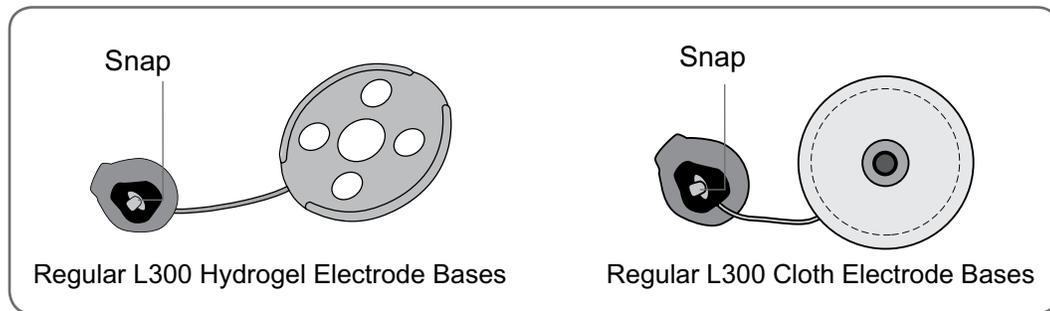


Figure 7-6: Regular L300 FS Cuff electrode base options.

The following electrode base is used with the Small L300 FS Cuff: (See Figure 7-7)

- Small L300 Electrode Bases (used with both the Small Hydrogel Electrodes and the Small Cloth Electrodes).

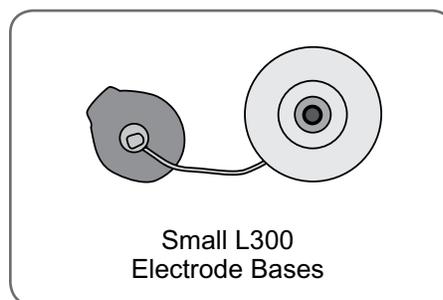


Figure 7-7: Small L300 FS Cuff electrode base option.

Note: When the patient discontinues use of the NESS L300, remove the electrode bases from the personal panel or the L300 FS Cuff and remove the electrodes from the electrode bases. The electrode bases are re-usable. Clean the electrode bases with cool water to remove any hydrogel residue, if applicable. Then disinfect the electrode bases with alcohol or a hard-surface disinfectant.



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

Electrodes

The electrodes transmit the electrical signal from the RF Stim Unit to the target nerve and there are three types of electrodes that can be used with the NESS L300 FS Cuff.

With the Regular L300 FS Cuff the following electrodes can be used: (See Figure 7-8)

- Regular L300 Quick Fit Electrode, left - A or right - A
- Regular L300 Cloth Electrodes
- Regular L300 Hydrogel Electrodes

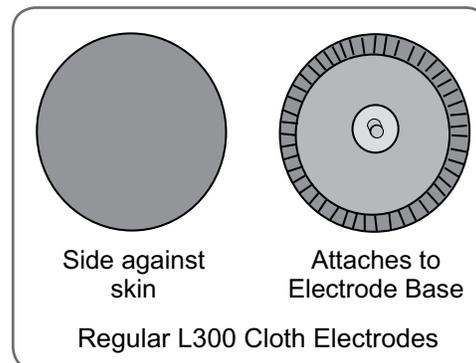
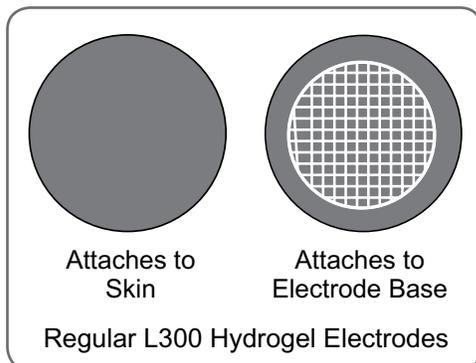
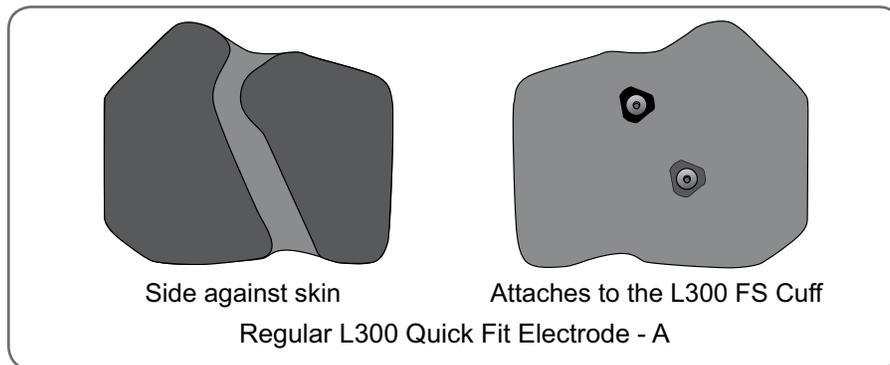


Figure 7-8: Regular L300 FS Cuff electrode options.

With the Small L300 FS Cuff the following electrodes can be used: (See Figure 7-9)

- Small L300 Quick Fit Electrode - A
- Small L300 Quick Fit Electrode - B
- Small L300 Cloth Electrodes
- Small L300 Hydrogel Electrodes (only used for the fitting process)

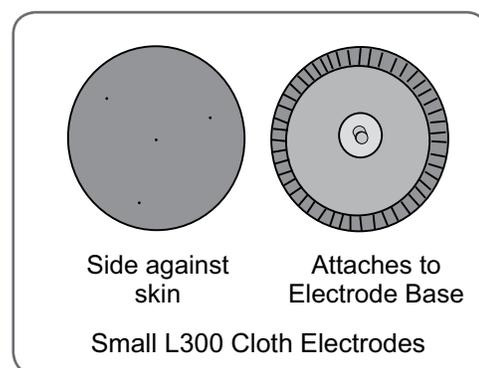
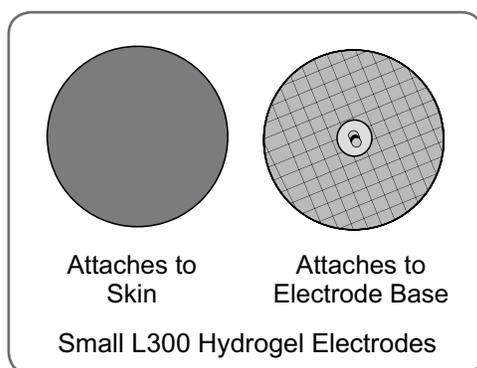
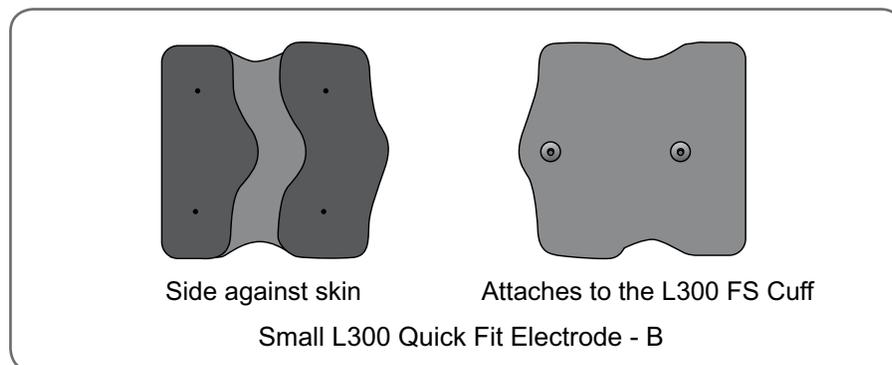
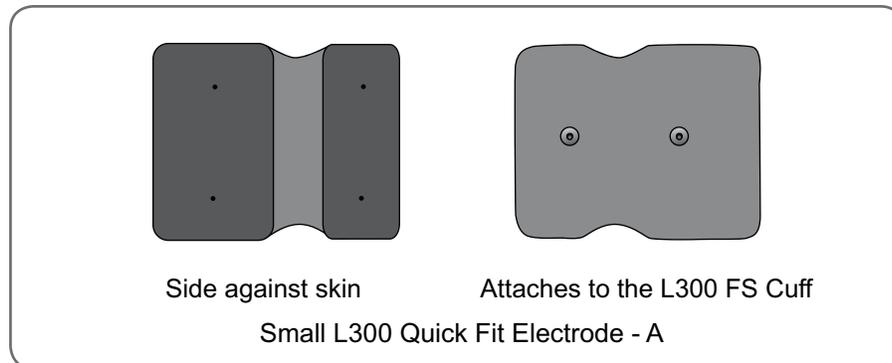


Figure 7-9: Small L300 FS Cuff electrode options.

Wire Concealers

The wire concealers are used to cover the wires and snaps of the electrode bases when attached to the L300 FS Cuff. See Figure 7-10.

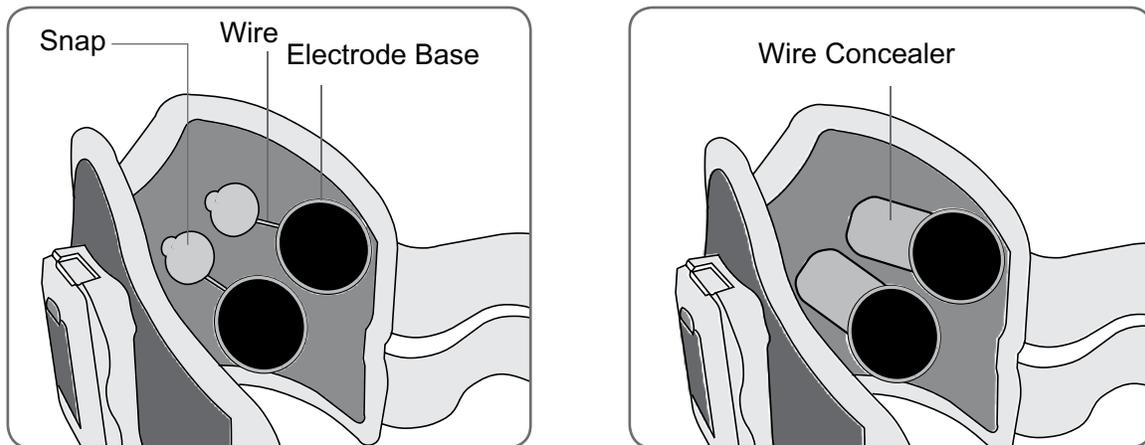


Figure 7-10: L300 FS Cuff without wire concealers (left) and with wire concealers (right). (Regular L300 FS Cuff shown)

Fitting Cable

The fitting cable is used to electrically connect the electrode base snaps to the L300 FS Cuff plug holes during fitting. See Figure 7-11.

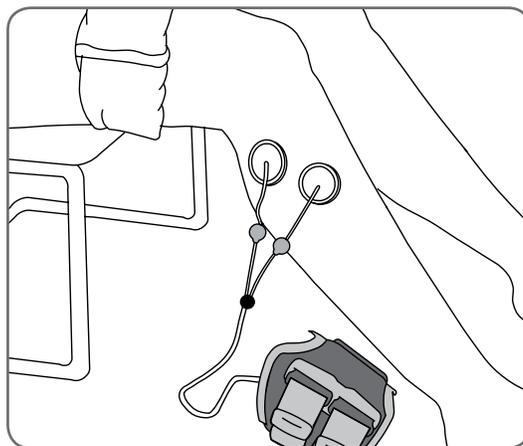


Figure 7-11: Fitting cable connected to the L300 FS Cuff and the electrode bases.

Gait Sensor Pads

The Gait Sensor pad is used to secure the Intelli-Sense Gait Sensor pressure sensor to the inside of the shoe. The Gait Sensor pad is placed under the insole, and the Gait Sensor pressure sensor is placed on top of the Gait Sensor pad. See Figure 7-12.

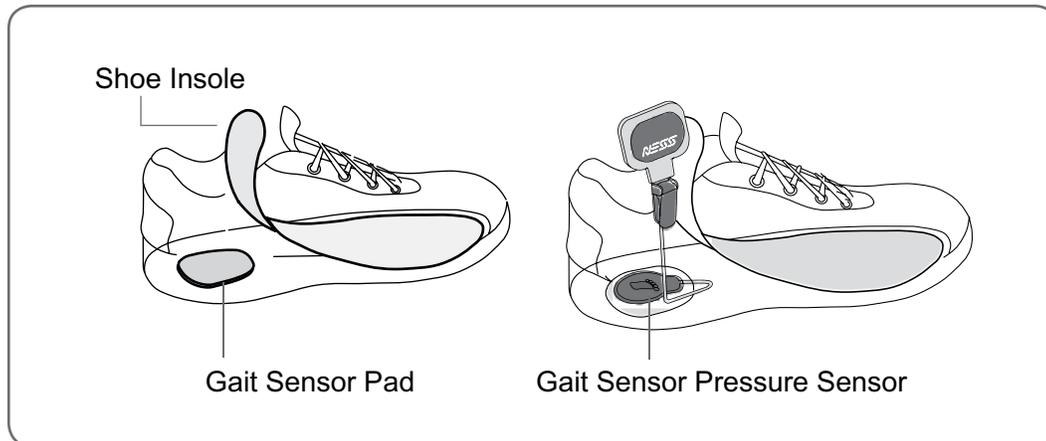


Figure 7-12: Placing the Gait Sensor pad and Gait Sensor pressure sensor in the shoe.

Shoe Spacers

The shoe spacer is used to protect the rim of the shoe from the teeth of the clamp on the Intelli-Sense Gait Sensor. The shoe spacer fits between the teeth of the inner clamp and the outside rim of the shoe.

To fit the shoe spacer:

- Open the clamp, and slide the opening of the shoe spacer over the inner clamp. See Figure 7-13.

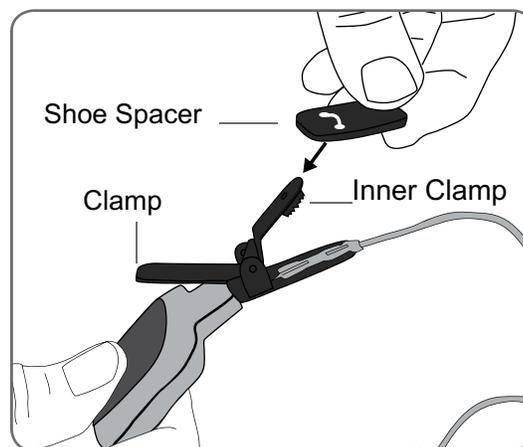


Figure 7-13: Fitting the shoe spacer.

L300 Tester

The L300 Tester provides audio feedback when connected to the NESS L300 and stimulation is applied. The L300 Tester is used to diagnose if there is a disconnection in the L300 FS Cuff or a faulty RF Stim Unit. See figures 7-14 and 7-15, and the Troubleshooting section of this guide. It can also be used for training and demonstrations.

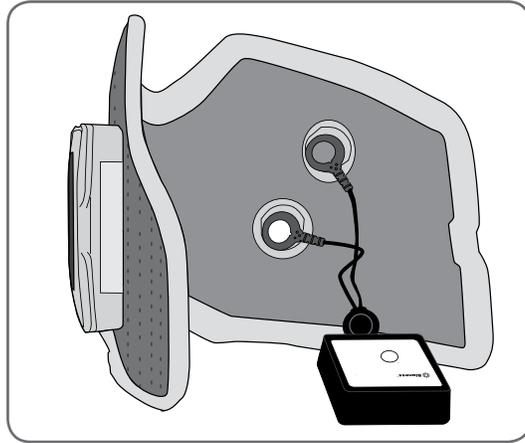


Figure 7-14: L300 Tester connected to the L300 FS Cuff plug holes.

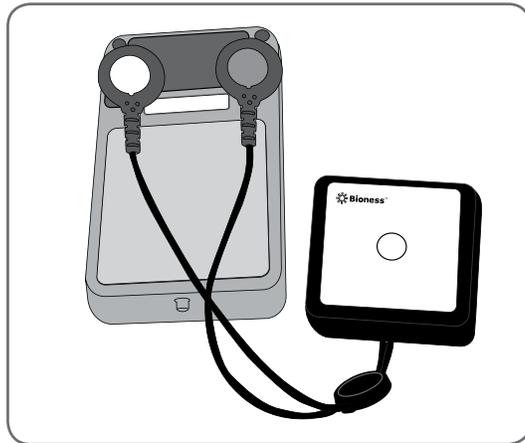


Figure 7-15: L300 Tester connected to the RF Stim Unit.

Set-Up: Clinician's Programmer

Connecting the Clinician's Programmer and Configuration Cradle

To connect the Clinician's Programmer and Configuration Cradle:

1. Orient the Clinician's Programmer in the Configuration Cradle with the touchscreen facing up and the connector port facing left. See Figure 8-1.
2. Plug the communication connector cable with charger adapter (on the Configuration Cradle) into the connector port on the Clinician's Programmer, with the arrows on the adapter facing up.

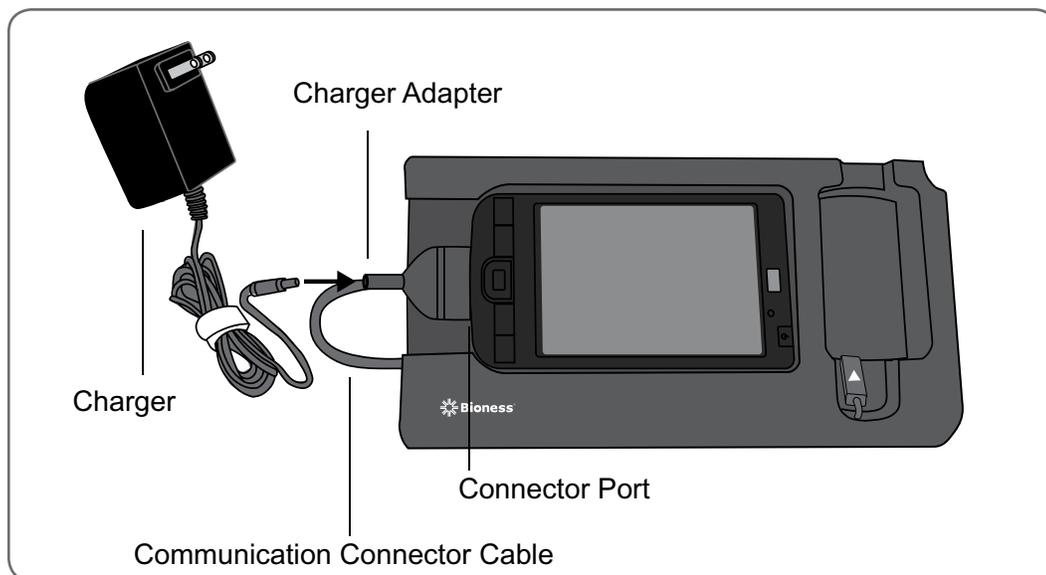


Figure 8-1: Clinician's Programmer set-up and charging configuration.

Charging the Clinician's Programmer

To charge the Clinician's Programmer:

1. Insert the connector on the Clinician's Programmer Charger into the charger adapter on the communication connector cable. See Figure 8-1.

2. Plug the charger into a power socket.
3. Allow the Clinician's Programmer to charge. While charging, the charge indicator light will be AMBER. The Clinician's Programmer can take two to four hours to charge. When the Clinician's Programmer is fully charged, the charge indicator light will be GREEN.

Connecting the Control Unit and Clinician's Programmer



Caution: Turn off the Control Unit or place it in standby mode before connecting it to the Configuration Cradle.

To connect the Control Unit and Clinician's Programmer:

1. Turn off the Control Unit, or place it in standby mode.
2. Plug the communication connector cable of the Configuration Cradle into the connector port of the Control Unit. The white arrow should be facing up.
3. Insert the Control Unit into the Configuration Cradle. See Figure 8-2.

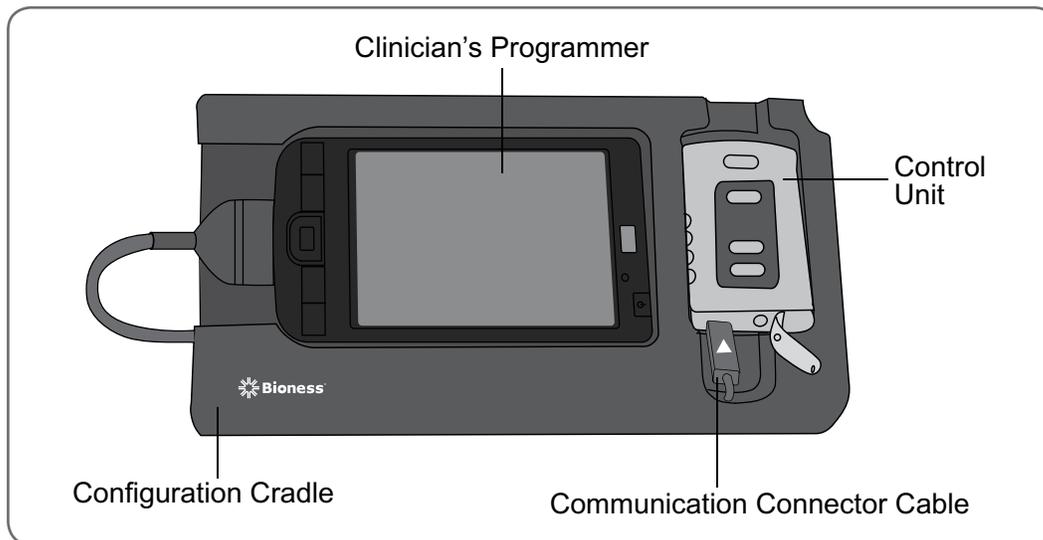


Figure 8-2: Control Unit programming set-up.

Intelli-Gait Software Navigation

User Login

To log into the NESS L300 Intelli-Gait Software:

1. Turn on the Clinician’s Programmer, and launch the NESS L300 Intelli-Gait Software.
2. When the Login Screen window opens, enter a user name and password, and then press **Login**. See Figure 9-1.



Figure 9-1: Login Screen window.

3. The Patients List window will open. See Figure 9-2.



Figure 9-2: Patients List window.

Start-Up Message Screens

New Patient Message

This message appears when a Control Unit with patient data on it is connected to a Clinician's Programmer with no record of the data in the database.

Do one of the following:

- Press **Yes** to add the patient's data to the Clinician's Programmer database.
- Press **No** if you do not want to add the patient's data to the Clinician's Programmer database.

Unassigned Message

This message appears when a new, unassigned Control Unit (one with no patient data on it) is connected to the Clinician's Programmer. See Figure 9-3.

Do one of the following:

- Press **OK** and then **NEW** to create a new patient record.
- Press **OK** and then select a patient record from the Patients List. Press **Open** to copy the parameters stored for that record from the Clinician's Programmer to the Control Unit. (Choose this option for new-patient setup or for a replacement electronic family.)

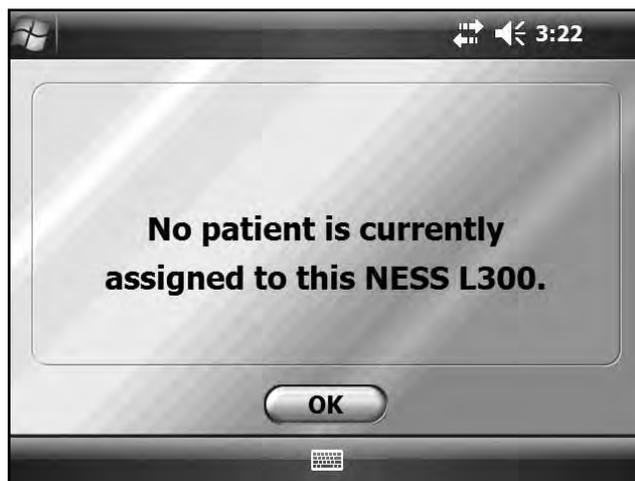


Figure 9-3: Clinician's Programmer unassigned message.

Inconsistency Message

This message appears when the data stored in the Clinician's Programmer database and on the Control Unit differ. See Figure 9-4. A data inconsistency can occur when two different Clinician's Programmers are used to program the Control Unit.

Do one of the following:

- Press **L300 → DB** to overwrite the data in the Clinician's Programmer database with that on the Control Unit.
- Press **DB → L300** to overwrite the data on the Control Unit with that in the Clinician's Programmer database.
- Press **Ignore** to make no changes to either data set.

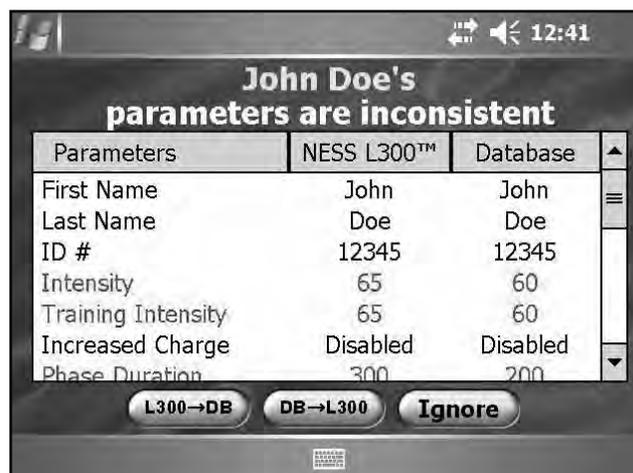


Figure 9-4: Clinician's Programmer inconsistency message.

Patients Menu

Creating a New Patient Record

To create a new patient record:

1. From the Patients List window, press **New**. See Figure 9-5.



Figure 9-5: Patients List window.

2. When the New Patient window opens, enter the patient's first and last name (alpha characters only) **and** assign a patient ID number (numeric characters only). (All fields must be completed.) Then press **OK**. See Figure 9-6.

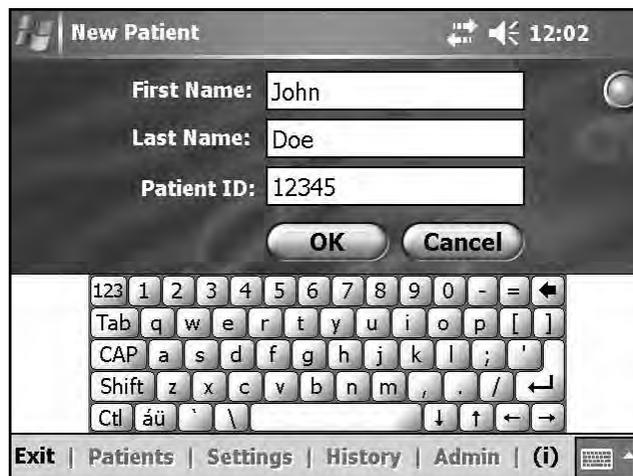


Figure 9-6: New Patient window.

Modifying a Patient Name

To modify a patient's first or last name (patient ID cannot be modified):

1. Select a patient from the Patients List, and then press **Modify**. See Figure 9-5.
2. The Modify Patient window will open. Modify the name and press **OK**. See Figure 9-7.

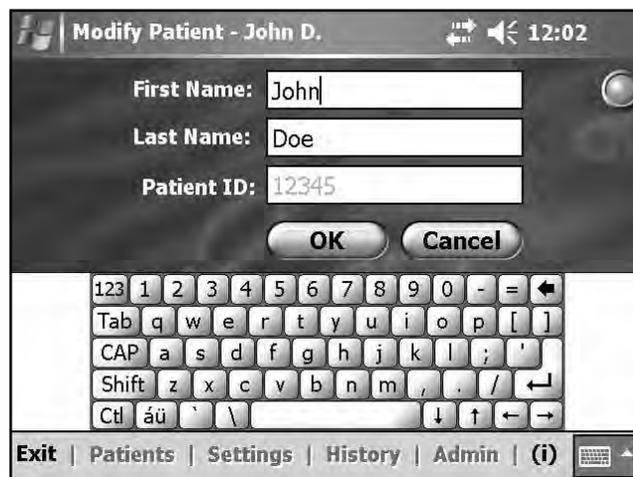


Figure 9-7: Modify Patient window.

Removing a Patient Record

To remove a patient record from the database:

1. Select a patient from the Patients List, and then press **Remove**. See Figure 9-5.
2. Confirm removal. (Press **Yes**.)

Settings Menu

Note: If the Control Unit is disconnected while programming, changes automatically will be saved.

Programming Stimulation Settings

To program stimulation settings:

1. From the Patients List, select a patient and press **Open**. The Stim Settings window will open. See Figure 9-8.
2. Adjust Intensity, Waveform, Phase Duration, and Pulse Rate using the drop-down lists and intensity bar. See Table 9-1.
3. Press **Start** to start stimulation. Stimulation will start with a ramp up time (time it takes for the stimulation to increase from zero to the maximum level set) of 1.5 seconds.
4. Gradually increase stimulation intensity, and then press **Stop** to stop stimulation.

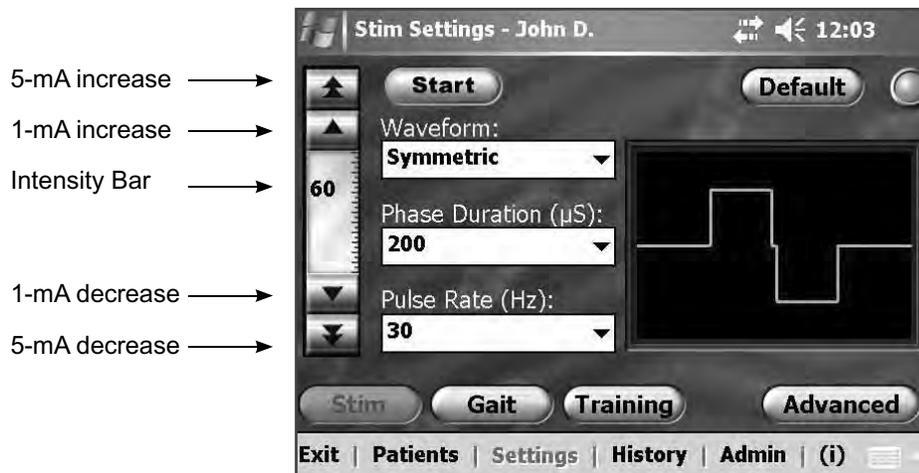


Figure 9-8: Stim Settings window.

Stim Parameter	Definition
Intensity	Strength of Stimulation: 0 mA to 80 mA, in 1mA Steps
Waveform	Type of Stimulation: Symmetric or Asymmetric
Phase Duration	Length of Time of the Pulse: 100, 200, or 300 μ sec
Pulse Rate	Frequency of Stimulation: 20 Hz to 45 Hz, in 5Hz Steps

Table 9-1: Stimulation parameters and definitions.

Programming Advanced Stimulation Settings

Press **Advanced** to open the Advanced Stim Settings window. See Figure 9-9.

Increased Charge

The **Increased Charge** feature optimizes the software algorithm that controls the pulse, to achieve better nerve recruitment in cases of high skin impedance. The **Increased Charge** feature is useful when an increase in intensity fails to produce sufficient dorsiflexion, despite good electrode placement. To select the **Increased Charge** feature, check the box. To return to the Stim Settings window, press **Back**.

Note: The **Increased Charge** feature is only available when using symmetric waveform. Press ? for more information.



Figure 9-9: Advanced Stim Settings window.

Note: When the **Increased Charge** box is checked, the **Advanced** button in the Stim Settings window will be BLUE and intensity will be reset to 0.

Programming Gait Settings

To program gait settings:

1. Press **Gait** to open the Gait Settings window. See Figure 9-10.

Note: The Gait Settings window displays an  audio feedback icon. Press the icon to turn on audio feedback during stimulation. The icon is GREEN when audio feedback is on and GRAY when audio feedback is off.

2. Adjust Ramp Up, Ramp Down, Extended, and Intensity settings. See Table 9-2.
3. Press **Start**. Stimulation will respond to input from the Intelli-Sense Gait Sensor. The Clinician's Programmer will animate heel off and heel contact in gait mode.
4. Press **Stop** to stop stimulation.
5. Fine-tune settings while the patient is walking.

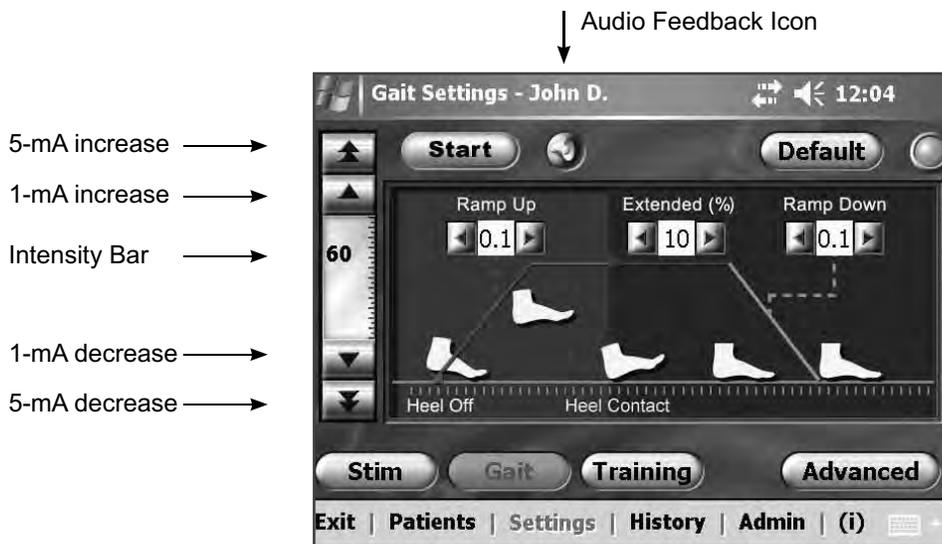


Figure 9-10: Gait Settings window.

Gait Parameter	Definition
Ramp Up	The time, in seconds, that it takes for the stimulation to increase from zero to the maximum level set. A gradual buildup of the current makes the stimulation more comfortable, helps avoid stretch reflexes, and delays the start of muscle contraction. Values are from 0 to 2 seconds in 0.1-second increments.
Ramp Down	The time, in seconds, that it takes for the stimulation to decrease from the maximum level set to zero. The current is reduced slowly to gradually reduce the muscle contraction. Increase this setting to prevent foot slap. Values are from 0 to 2 seconds in 0.1-second increments.
Extended	The percentage of total time from heel on to heel off that the stimulation continues after heel contact with the ground. This parameter determines the length of time before the stimulation starts to ramp down. Increase this setting to prevent foot slap and genu recurvatum (knee hyperextension/knee snapping) or to increase ankle stability during stance.
Intensity	The strength of the electrical stimulation. Values are from 0 to 80 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 in the <i>Training Settings Advanced Settings</i> window.

Table 9-2: Gait parameters and definitions.

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

Programming Advanced Gait Settings

Press **Advanced** to open the Advanced Gait Settings window. See Figure 9-11.

Maximum Duration of Stimulation

To avoid excessive fatigue of the muscles that activate dorsiflexion, the NESS L300 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 NESS L300 is in the air and the system is in gait mode. It limits the duration of stimulation. To adjust the maximum duration of stimulation, use the stylus to move the slider. Press ? for more information.

For fast and stable users:

- This setting can be relatively low (the 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 the involved leg during the swing phase of gait.

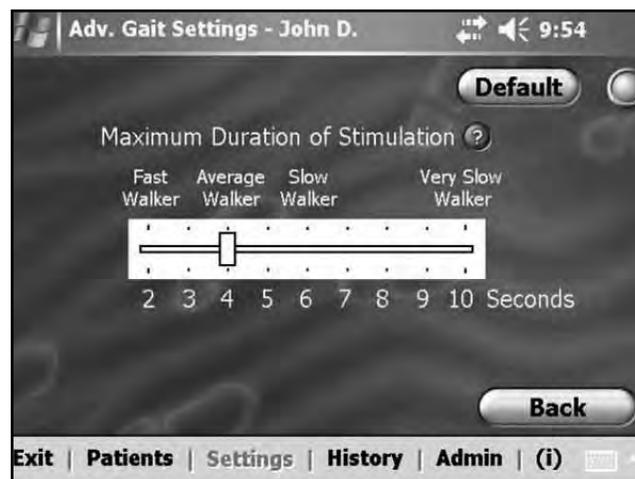


Figure 9-11: Advanced Gait Settings window.

Note: When the slider is moved away from the **Average Walker** position, the **Advanced** button in the Stim Settings window will be BLUE.

Programming Training Settings

To program training settings:

1. Press **Training** to open the Training Settings window. See Figure 9-12.
2. Adjust On Time, Off Time, Ramp Up, Ramp Down, Total Time, and Intensity. See Table 9-3.
3. Press **Start** to turn on stimulation. Press **Stop** to turn off stimulation.

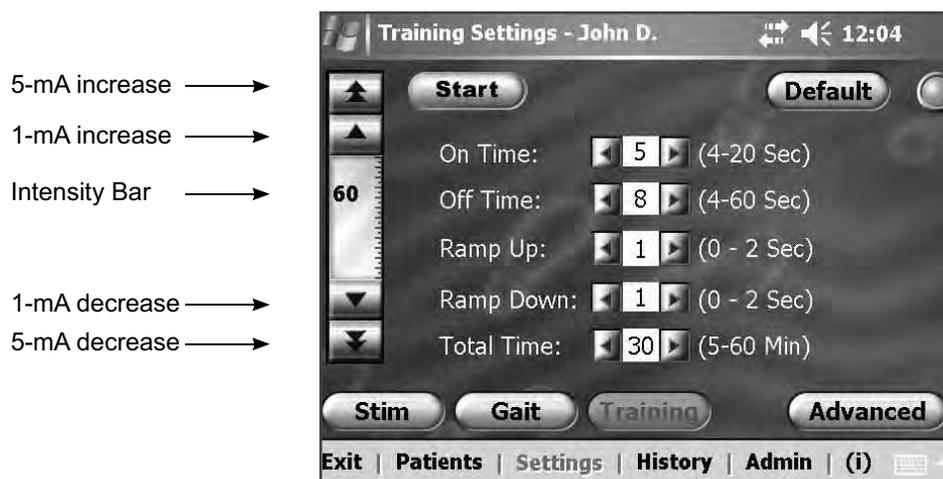


Figure 9-12: Training Settings window.

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 0.1-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. Values are from 0 to 2 seconds in 0.1-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 9-3: Training parameters and definitions.

Programming Advanced Training Settings

Press **Advanced** to open the Advanced Training Settings window. See Figure 9-13.

Enable Specific Intensity Level for Training Mode

Some patients may require a lower or higher intensity level in training mode than in gait mode. Press ? for more information.

To adjust the intensity level in training mode independently of the intensity level set for stimulation and gait settings:

- Check the box next to “Enable specific intensity level for training mode” at the bottom of the Advanced Training Settings window. (The default setting is unchecked.)



Figure 9-13: Advanced Training Settings window.

Note: When the box next to “Enable specific intensity level for training mode” is checked, the **Advanced** button in the Stim Settings window will be BLUE.

History Menu

Viewing a Session History

A patient session begins when a Control Unit is connected to the Clinician's Programmer and the patient's record is opened. A patient session ends when session data are saved and the Control Unit is disconnected from the Clinician's Programmer. If the Control Unit is disconnected and then reconnected within one hour, the most recent session reopens.

To view a patient's Session History:

1. Open the patient's record, and then press **History**.
2. Press **Sessions**. The Sessions List window will open, showing the date, time, and programming clinician for each saved session. See Figure 9-14.
3. Select a session from the Sessions List and press **Open**. The Session Details window will open, showing the parameters saved for that session. See Figure 9-15.
4. Press **Sessions List** to return to the Sessions List window.

Removing a Session

To remove a patient session:

- From the Sessions List window, select a patient session and then press **Remove**. See Figure 9-14.

To remove all of a patient's sessions from the database:

- From the Sessions List window, press **Remove all**. See Figure 9-14.



Figure 9-14: Sessions List window.

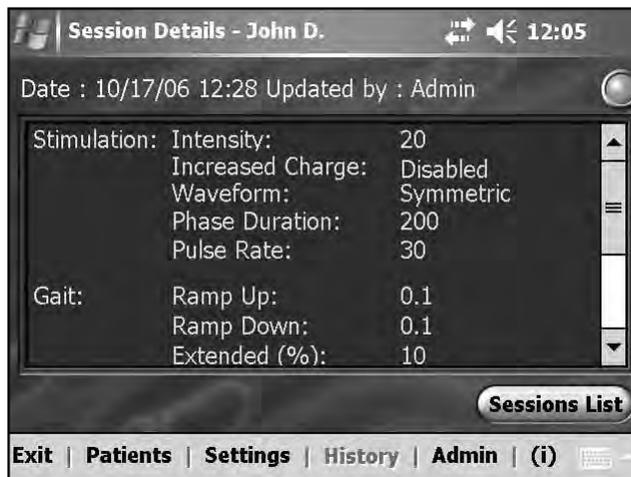


Figure 9-15: Session Details window.

Viewing the Gait Log

The Gait Log is a record of the patient's NESS L300 usage history. See figures 9-16 and 9-17 and Table 9-4. The Gait Log can be filtered by date and time frame, and displayed as a table or graphically.

To view a patient's Gait Log:

1. Open the patient's record, and then press **History**.
2. Press **Gait**. The Gait Log will open in **Tabular View**. See Figure 9-16 and Table 9-4.
3. From the drop-down lists at the top of the screen, enter the filtering dates and time frame.
4. From the drop-down list at the bottom right of the screen, select **Tabular View, # of Steps Graph**, or **Gait Duration Graph**.
 - **Tabular View** displays the date, number of steps recorded for a given date, cumulative number of steps recorded to date, average number of steps recorded to date, total time spent using the NESS L300 for a given date, cumulative time spent using the NESS L300 to date, and average time spent using the NESS L300 to date.
 - The **# of Steps Graph** displays the date and the number of steps at the top of each column. See Figure 44.
 - The **Gait Duration Graph** displays the total time spent using the NESS L300 at the top of each column. Each column represents a day, week, month, or year, per the specified time frame.
5. Press the double arrow to begin the search.
6. Press **Sessions** to return to the Sessions List.

Date	# of Steps	Total	Gait Duration	Total
9/1/06	41	41	00:00:26	00:00:26
9/2/06	102	143	00:01:29	00:01:55
9/3/06	72	215	00:00:45	00:02:40
9/4/06	22	237	00:00:11	00:02:51
9/5/06	78	315	00:00:46	00:03:37
9/6/06	103	418	00:00:51	00:04:28
9/7/06	180	598	00:02:31	00:06:59
Average:	85		00:01:00	

Figure 9-16: Gait Log, Tabular View.

Gait Log Field	Definition
# of Steps	Number of Steps Recorded for a Given Date
Total (# of Steps)	Cumulative Number of Steps Recorded to Date
Average (# of Steps)	Average Number of Steps Recorded to Date
Gait Duration	Total Time Spent Using the NESS L300 for a Given Date
Total (Gait Duration)	Cumulative Time Spent Using the NESS L300 to Date
Average (Gait Duration)	Average Time Spent Using the NESS L300 to Date

Table 9-4: Gait Log data fields and definitions.



Figure 9-17: Gait Log, # of Steps Graph.

Viewing the Training Log

The Training Log is a record of the patient's NESS L300 training history. See figures 9-18 and 9-19 and Table 9-5. The Training Log can be filtered by date and time frame, and displayed as a table or graphically.

To view a patient's Training Log:

1. Open the patient's record, and then press **History**.
2. Press **Training**. The Training Log will open in **Tabular View**. See Figure 9-18 and Table 9-5.
3. From the drop-down lists at the top of the screen, enter the filtering dates and time frame.
4. From the drop-down list at the bottom right of the screen, select **Tabular View** or **Graph View**.
 - **Tabular View** displays the session date, total time in training mode, cumulative time in training mode, and average time in training mode.
 - **Graph View** displays the session date and the amount of session time in training mode at the top of each column. See Figure 9-19.
5. Press the double arrow to begin the search.
6. Press **Sessions** to return to the Sessions List.

Date	Session Duration	Total
2/14/08	00:20:00	00:20:00
2/15/08	00:20:00	00:40:00
2/16/08	00:20:00	01:00:00
2/17/08	00:10:00	01:10:00
2/18/08	00:10:00	01:20:00
2/19/08	00:00:00	01:20:00
2/20/08	00:20:00	01:40:00
Average:		00:14:28

Figure 9-18: Training Log, Tabular View.

Training Log Field	Definition
Session Duration	Total Time in Training Mode
Total	Cumulative Time in Training Mode
Average (Session Duration)	Average Time in Training Mode

Table 9-5: Training Log data fields and definitions.



Figure 9-19: Training Log, Graph View.

Admin Menu

System administrators have access to the **Admin** menu. From the **Admin** menu, administrators can add or remove users, change user passwords, and back up and restore the database. See Figure 9-20.



Figure 9-20: Admin menu, User Administration window.

Adding and Removing Users

To add a new user:

1. From the User Administration window, press **Users** and then **New User**. The Add new user window will open. See Figure 9-21.
2. Enter a user name and password, and confirm the password.
3. From the **Group** drop-down list, select **Administrators** or **Users**, and then press **Add**.

To remove a user:

- From the User Administration window, select a user, and then press **Remove User**. See Figure 9-20.

Note: The last remaining administrator cannot be removed.



Figure 9-21: Add new user window.

Changing User Passwords

To change a user's password:

1. From the User Administration window, select a user, and then press **Change PWD**. See Figure 9-22. The Change Password window will open.
2. Enter and confirm the new password, and then press **OK**.



Figure 9-22: Admin menu, User Administration window.

Backing Up the Database

Administrators can back up the Clinician’s Programmer database to the storage (SD) card automatically or manually at any time.

When a storage card is installed and automatic backup is enabled, the Clinician’s Programmer will automatically back up the database periodically and whenever the Intelli-Gait application is exited. If a storage card is not installed, upon exiting the application a warning will appear.

Note: Users should exit the Intelli-Gait application at the end of each day.

To enable automatic backup:

1. Ensure that a storage card is in the Clinician’s Programmer SD slot.
2. Press **Admin**, and then **Backup**.
3. Check the box next to “Enable automatic database backup”. See Figure 9-23.

To manually back up the database:

1. Ensure that a storage card is in the Clinician’s Programmer SD slot.
2. Press **Admin**, and then **Backup**.
3. Press **Start Backup**. A file will be created on the storage card. The file name will be the date and time the file was created.
4. Monitor the progress bar until the backup is successful, and then press **ok**.



Figure 9-23: Admin menu, Backup window.

Restoring the Database

Administrators can restore the database when the Clinician’s Programmer is replaced or the database is corrupted. Do not enter new patient information before restoring the database.

To restore the database:

1. If a new storage card is in the Clinician’s Programmer, remove it.
2. Make sure the backup storage card lock switch is in the unlocked position, and insert the storage card with the backup files into the Clinician’s Programmer (with the metal contacts inserted first and the label facing up).
3. Open the Intelli-Gait application, and log in using an administrator’s user name and password.
4. Press **Admin** and then **Restore**. The Restore window will open. See Figure 9-24.
5. Select “From the automatic backup” or “From the manual backup”, select a file name from the drop down list, and press **Start Restore**.
6. A message will appear: “Restoring a database will overwrite the current database. Are you sure?” Press **Yes**.
7. Wait until the progress bar shows 100% and a “Restore successful” message appears. Then press **ok**.
8. Press **Patients** to return to the Patients List window, and then verify that the database was restored.

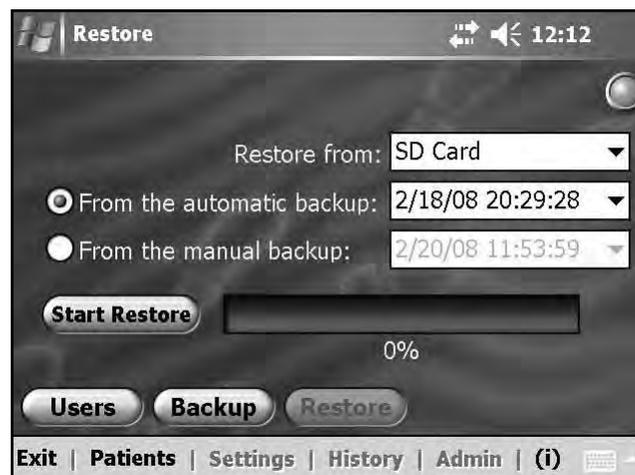


Figure 9-24: Admin menu, Restore window.

Fitting Guidelines

Inspect the Components

To inspect the NESS L300 components:

1. Examine the L300 FS Cuff for signs of wear.
2. Test the Control Unit. Turn on the system, and check that no error indications appear.
3. Test the Intelli-Sense Gait Sensor. Press on it with your thumb while the system is in gait mode, and verify that the RF Stim Unit's  stimulation light flashes YELLOW rapidly. (This test can be done with the FS Cuff either **on** the patient's leg or **off** the patient's leg and attached to the L300 Tester.)
4. Examine the L300 FS Cuff strap, electrode bases, electrodes, and wire concealers for wear and integrity.

Attach the Hydrogel Electrodes and Electrode Bases

Note: For first fittings, always use hydrogel electrodes before fitting cloth electrodes.

To attach the Regular L300 Hydrogel Electrodes to the leg:

1. Clean the skin where the electrodes will adhere with a wet washcloth. If any oils or lotions are on the skin, then clean with soap and water. Rinse well.
2. If necessary, remove excess body hair with an electric shaver or scissors. Excess body hair where the electrodes adhere may reduce electrode contact with the skin. Do not use a razor. A razor can irritate the skin.
3. Separate the two new hydrogel electrodes along the perforation. See Figure 10-1.
4. Split the two-piece covers on each electrode and discard them. See Figure 10-1.

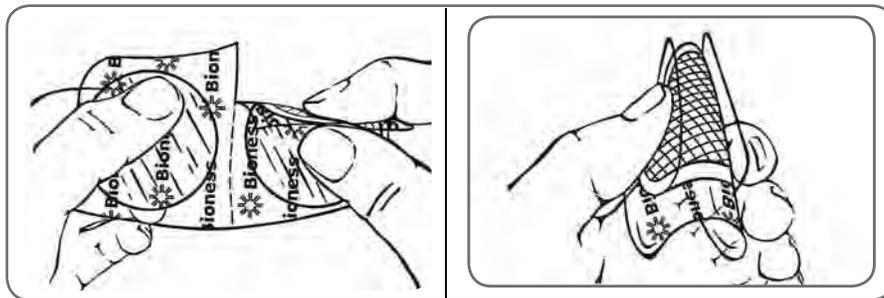


Figure 10-1: Separating the regular hydrogel electrodes and splitting the two-piece covers.

5. Attach the grid side of the electrodes to the Regular L300 Hydrogel Electrode Bases and then press firmly.
6. Remove the larger covers (with the Bioness logo) from the electrodes and save them. (Always cover the hydrogel electrodes between uses. Make sure the Bioness logo on the cover faces up.)
7. Have the patient sit and extend the leg to between 15 and 20 degrees of flexion. (The patient should maintain this position throughout the fitting process.) The heel should be elevated, if possible.
8. Position one electrode (the nerve electrode) over the common peroneal nerve, distal and slightly posterior to the fibular head. See Figure 10-2.
9. Position the other electrode (the muscle electrode) approximately 5 cm (2 in.) distal and anterior to the nerve electrode, over the belly of the tibialis anterior muscle.

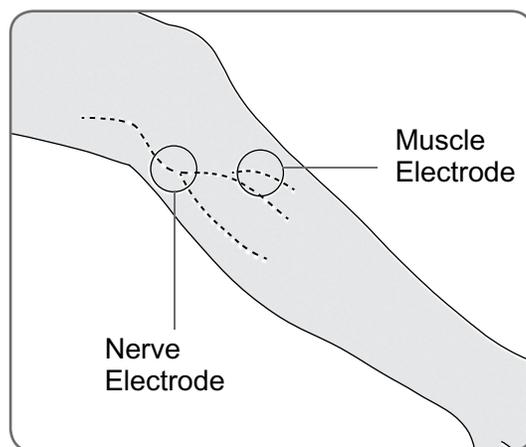


Figure 10-2: Positioning the electrodes on the leg.

To attach the Small L300 Hydrogel Electrodes to the leg:

1. Clean the skin where the electrodes will adhere with a wet washcloth. If any oils or lotions are on the skin, then clean with soap and water. Rinse well.
2. If necessary, remove excess body hair with an electric shaver or scissors. Excess body hair where the electrodes adhere may reduce electrode contact with the skin. Do not use a razor. A razor can irritate the skin.
3. Separate the two new hydrogel electrodes along the perforation. See Figure 10-3.
4. Snap the snap side of the electrodes into the Small L300 Electrode Bases
5. Peel the covers off each electrode and discard them.

6. Have the patient sit and extend the leg to between 15 and 20 degrees of flexion. (The patient should maintain this position throughout the fitting process.) The heel should be elevated, if possible.
7. Position one electrode (the nerve electrode) over the common peroneal nerve, distal and slightly posterior to the fibular head. See Figure 10-2.
8. Position the other electrode (the muscle electrode) approximately 5 cm (2 in.) distal and anterior to the nerve electrode, over the belly of the tibialis anterior muscle.

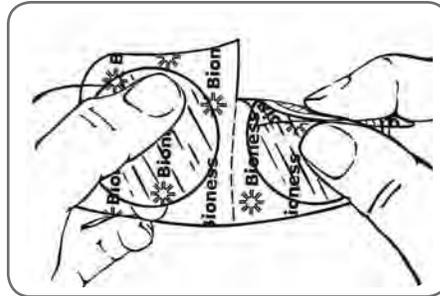


Figure 10-3: Separating the small hydrogel electrodes.

Note: The Small L300 Hydrogel Electrodes are for fitting purposes only and not for patient home use. The electrodes are a single patient/ single use item.

Connect the Fitting Cable

To connect the fitting cable:

1. Make sure the RF Stim Unit is connected to the cradle on the L300 FS Cuff.
2. Connect the fitting cable to the electrode bases and to the L300 FS Cuff plug holes.
 - Connect the ORANGE ends of the fitting cable to the muscle electrode base and the ORANGE FS Cuff plug hole.
 - Connect the BLUE ends of the fitting cable to the nerve electrode base and the BLUE FS Cuff plug hole.
3. Place the L300 FS Cuff next to the patient's foot. See Figure 10-4.

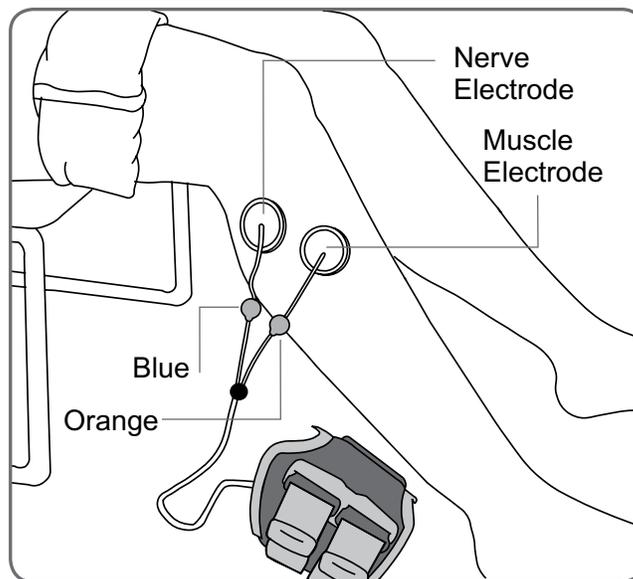


Figure 10-4: Fitting cable connected.

Adjust the Position of the Electrodes While Stimulating: Patient Seated

To check the position of the electrodes:

1. Connect the patient's Control Unit to the Clinician's Programmer.
2. Log into the Intelli-Gait Software, and open the Stim Settings window.
3. Adjust waveform and phase duration, if necessary.
4. Set stimulation intensity to "0", and press **Start** to apply stimulation.

5. When applying stimulation, observe the patient's foot for proper dorsiflexion.
6. Gradually increase stimulation intensity to achieve dorsiflexion with a small amount of eversion.

If inversion is excessive:

- Move the nerve electrode posterolaterally to increase eversion.

If eversion is excessive:

- Move the nerve electrode slightly anteriorly to decrease eversion.

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

Test the Effect of a Positional Change

To test the effect of a positional change:

- With stimulation on, gently move the electrode and skin as a unit over the common peroneal nerve area. (Do not leave stimulation on for long. Fatigue may result.)

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

Adjust the Position of the Electrodes While Stimulating: Patient Standing

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

Transfer the Electrodes to the L300 FS Cuff

To transfer the electrodes to the L300 FS Cuff:

1. Stop stimulation.
2. Using a marker, make four small, evenly spaced marks on the patient's leg around the electrode bases for reference.

3. Disconnect the fitting cable from the electrode bases and L300 FS Cuff, making sure not to move the electrodes.
4. For in-patient use, attach an FS Cuff personal strap cover and personal panel to the L300 FS Cuff.
5. Grasp the L300 FS Cuff on each side to flare the Orthosis slightly open. Then tilt the bottom of the L300 FS Cuff away from the leg about 30 degrees.
6. Position the locator of the L300 FS Cuff below the patella, over the tibial plateau. See Figure 10-5. Make sure the L300 FS Cuff does not touch the electrode bases. The locator should fit snugly but comfortably under the inferior pole of the patella.

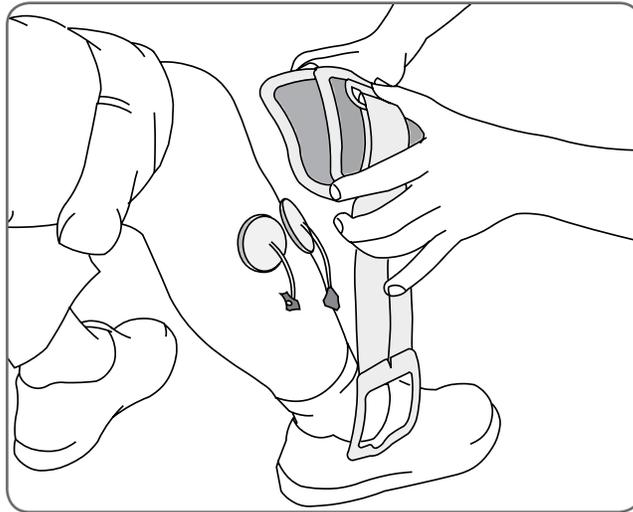


Figure 10-5: Positioning the locator below the patella.

7. Keeping the L300 FS Cuff open, lower the bottom of the L300 FS Cuff, allowing only the front of the FS Cuff to contact the anterior surface of the tibia. Then wrap the ends of the L300 FS Cuff around the leg to “capture” the electrode bases. See Figure 10-6.

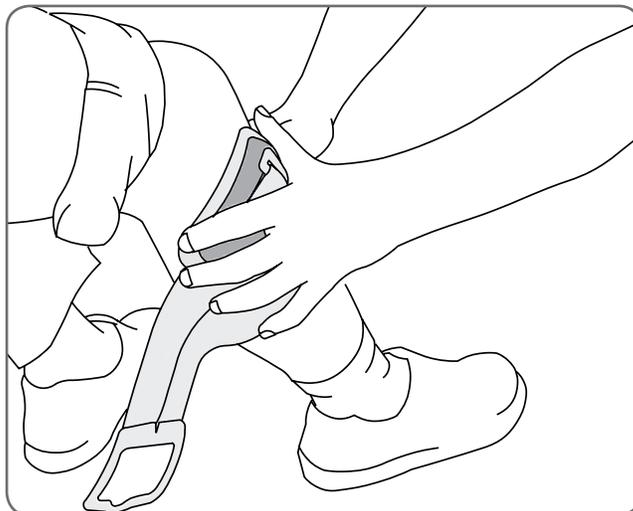


Figure 10-6: Capturing the electrode bases.

8. Gently remove the L300 FS Cuff from the leg. See Figure 10-7.

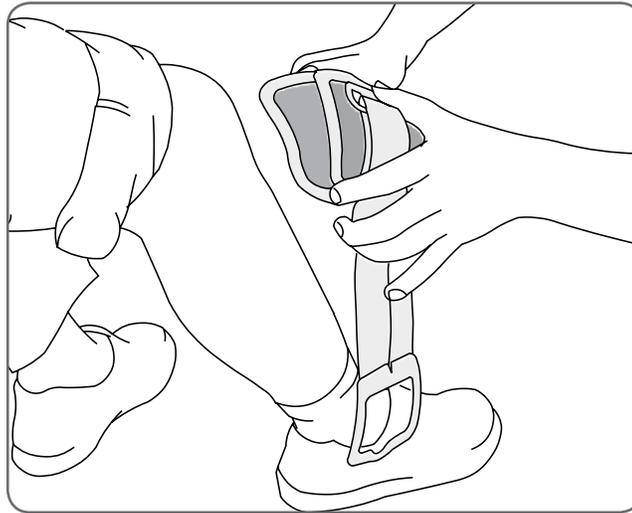


Figure 10-7: Removing the L300 FS Cuff with the captured electrode bases.

9. Press firmly on the electrode bases to secure them to the L300 FS Cuff. Plug the electrode base snaps into the L300 FS Cuff plug holes.

Don the L300 FS Cuff

To don the L300 FS Cuff:

1. Wipe the leg with lukewarm water.
2. Have the patient sit and extend the knee so that the patella is clearly defined. Use a footrest if needed.
3. Tilt the top of the L300 FS Cuff toward the leg. Gently slide the locator up to the base of the patella. Lower the bottom of the L300 FS Cuff until it is flush with the leg. The L300 FS Cuff should gently grip the leg.
4. Pull the strap handle around the leg and the L300 FS Cuff cradle to fasten it.
5. Make sure the fastened L300 FS Cuff fits comfortably, with the locator below the patella and the strap handle around the cradle, as shown in Figure 10-8.

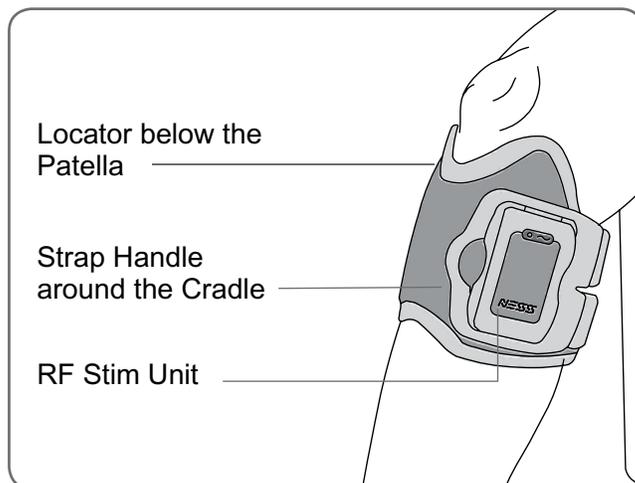


Figure 10-8: Regular L300 FS Cuff on the right leg.

Retest Electrode Placement: Patient Sitting and Standing

To retest electrode placement:

1. Press **Start** on the Clinician's Programmer to turn on stimulation.
2. Press **Stop** to turn off stimulation.
3. If patient response is not accurate or is inconsistent with the original response, reposition the L300 FS Cuff and assess the response to stimulation.

Fitting the Small L300 Cloth Electrodes

Note: The Small L300 Hydrogel Electrodes are used for the initial fitting process only. After the position of the electrodes have been determined, the small hydrogel electrodes will need to be removed and replaced with the Small L300 Cloth Electrodes.

To fit the Small L300 Cloth Electrodes: (See Figure 10-9)

1. Remove the Small L300 FS Cuff from patient's leg.
2. Carefully detach the Small L300 Hydrogel Electrodes from the Small L300 Electrode Bases. Be careful not to detach the electrode bases from the Small FS Cuff.
3. Remove the Small L300 Cloth Electrodes from package.
4. Wet the new Small L300 Cloth Electrodes with water until they are saturated.
5. With a soft cloth, gently wipe or blot excess water off the back (side with the snap) of the electrodes.
6. Snap the Small L300 Cloth Electrodes into the Small L300 Electrode Bases.
7. Verify the desired dorsiflexion response is elicited. If necessary, adjust the stimulation setting or position of the cloth electrodes.

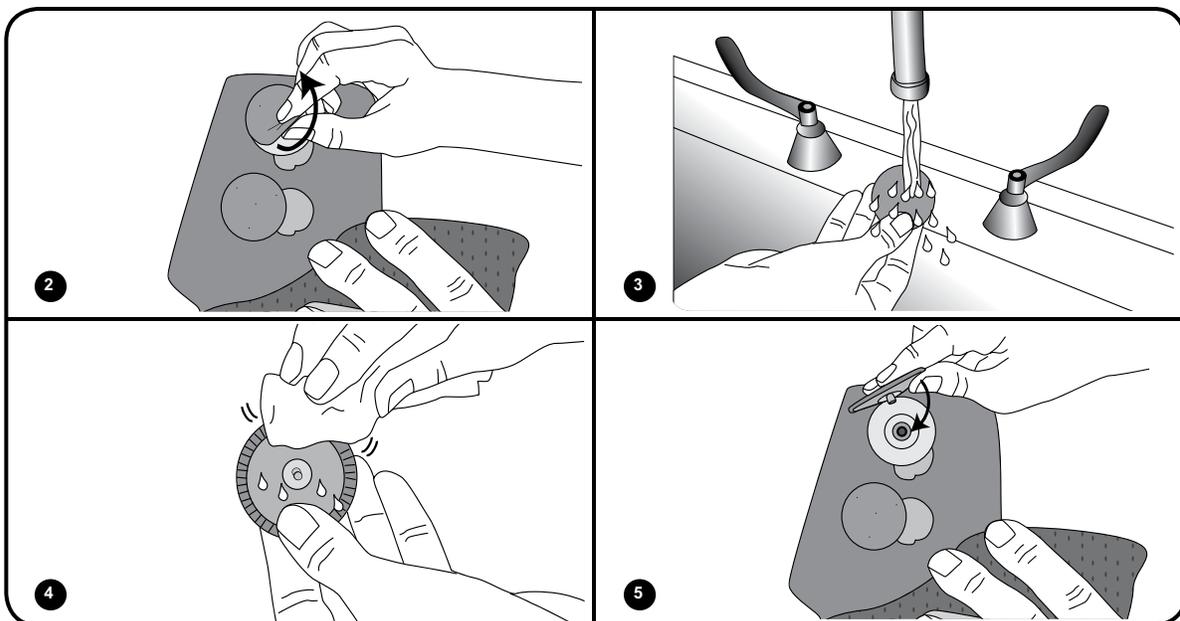


Figure 10-9: Fitting the Small L300 Cloth Electrodes.

Fitting the Regular L300 Cloth Electrodes

To fit the Regular L300 Cloth Electrode Bases: (See Figure 10-10)

1. Remove the Regular L300 FS Cuff from patient's leg.
2. Mark the position of the Regular L300 Hydrogel Electrode Bases on the FS Cuff liner.
3. Disconnect the snap on the hydrogel electrode bases from the L300 FS Cuff plug holes.
4. Remove the hydrogel electrode bases.
5. Attach the cloth electrode bases where the hydrogel electrode bases were attached.

Note: The cloth electrode base is 2 mm smaller than the hydrogel electrode base.

6. Connect the snaps on the cloth electrode bases to the plug holes on the L300 FS Cuff.

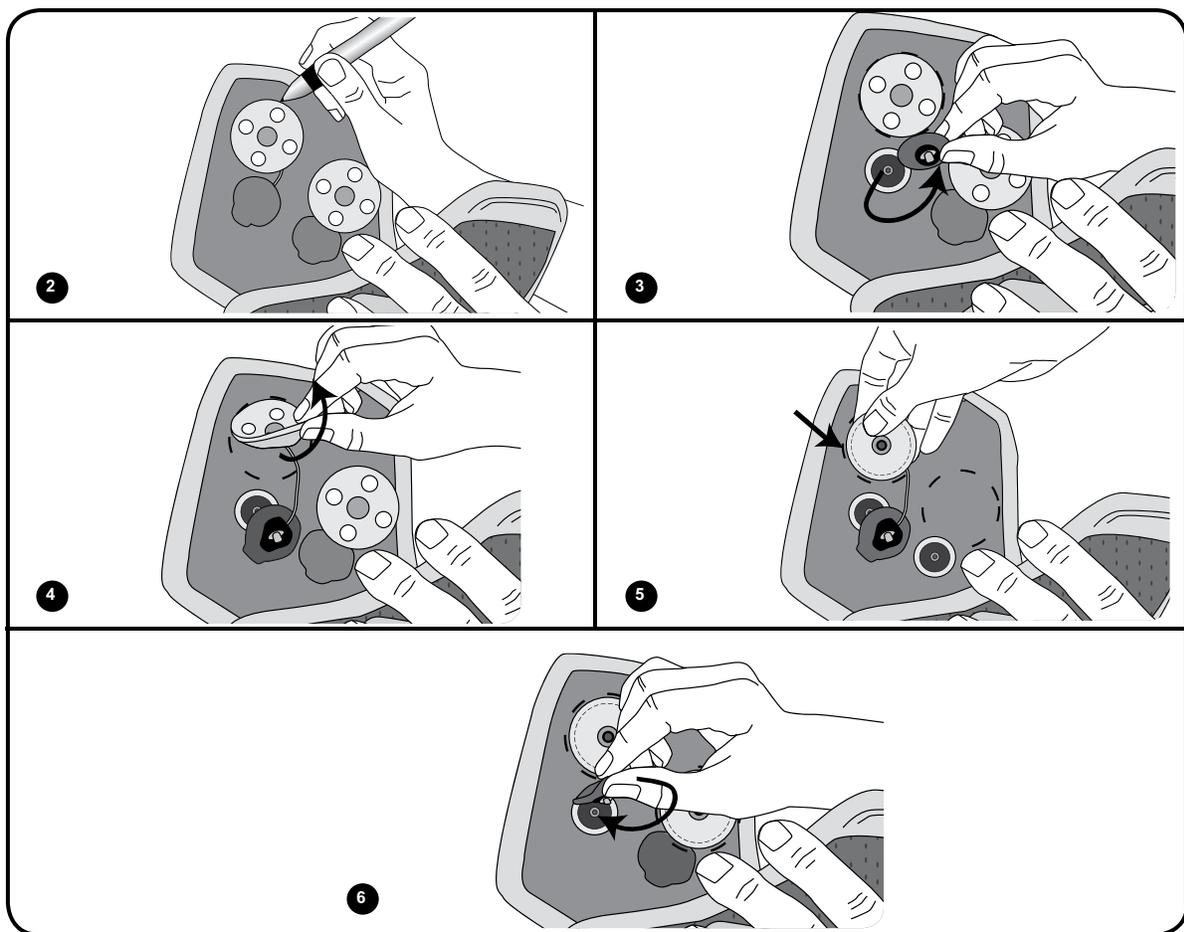


Figure 10-10: Fitting the Regular L300 Cloth Electrode Bases.

To fit the Regular L300 Cloth Electrodes: (See Figure 10-11)

1. Wet the new Regular L300 Cloth Electrodes with water until saturated.
2. With a soft cloth, gently wipe or blot excess water from the back (side with the snap) of the cloth electrodes.
3. Attach the cloth electrodes to the cloth electrode bases in the Regular L300 FS Cuff.
4. Verify that the desired dorsiflexion response is elicited. If needed, optimize the stimulation settings and the position of the cloth electrodes.

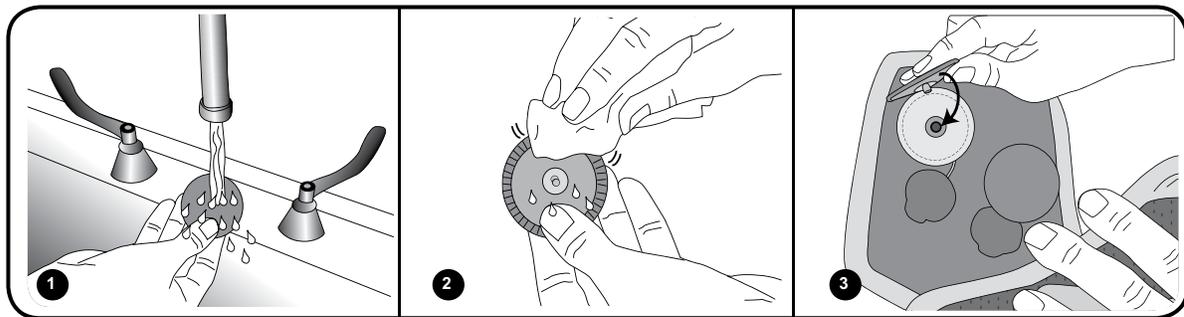


Figure 10-11: Fitting the Regular L300 Cloth Electrodes.

Fitting the L300 Quick Fit Electrodes

The Regular L300 FS Cuff can use one type of Quick Fit Electrode, the Regular L300 Quick Fit Electrode - A, which is available in left and right configurations. The Small L300 FS Cuff can use two types of Quick Fit Electrodes, the Small L300 Quick Fit Electrode - A or the Small L300 Quick Fit Electrode - B.

To select a Small L300 Quick Fit Electrode:

- Measure the circumference of the patient's leg at its broadest point (the gastrocnemius muscle belly) and refer to Table 10-1.

Small L300 Quick Fit Electrode	Calf Circumference
Small L300 Quick Fit Electrode - A	24-31 cm
Small L300 Quick Fit Electrode - B	22-25 cm

Table 10-1: Small L300 Quick Fit Electrode fitting chart.

Note: Patients with middle range calf circumference (24-25cm) may fit both types of the Small L300 Quick Fit Electrodes.

To fit the L300 Quick Fit Electrode: (See Figure 10-12)

1. Wet the entire new L300 Quick Fit Electrode with water.
2. Remove excess water from the L300 Quick Fit Electrode with a cloth.
3. Align the orange and blue snaps on the L300 Quick Fit Electrode with the orange and blue plug holes on the L300 FS Cuff.
4. Press firmly to snap the L300 Quick Fit Electrode into the L300 FS Cuff.
5. Don the L300 FS Cuff.
6. Adjust the stimulation settings in order to achieve the desired dorsiflexion response.

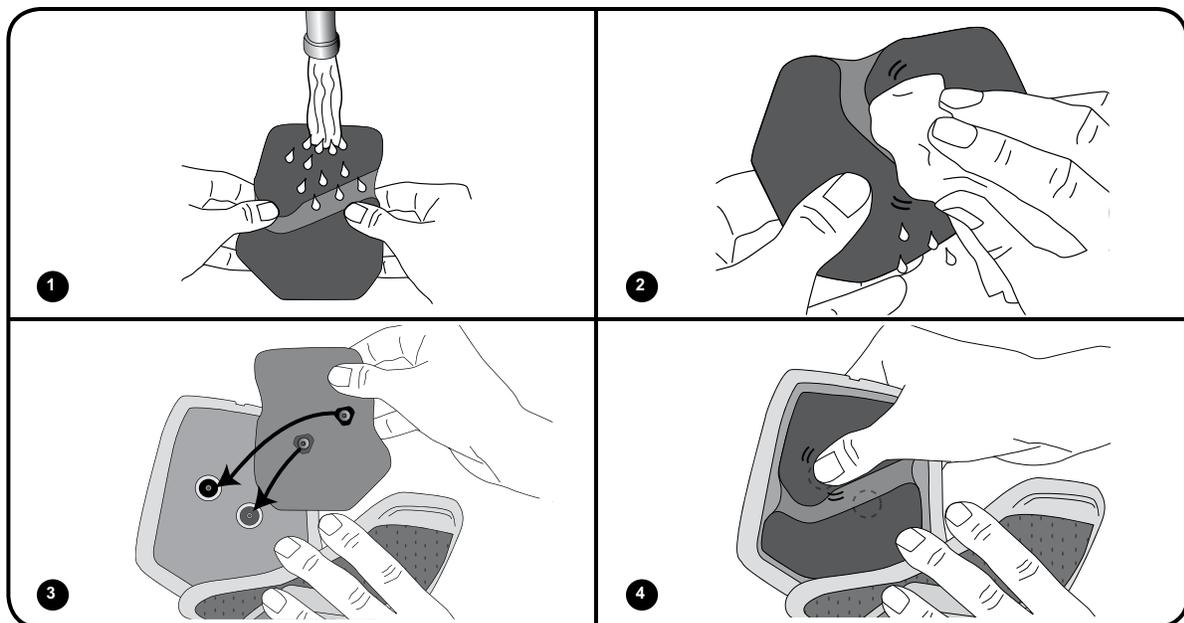


Figure 10-12: Fitting the L300 Quick Fit Electrode.
(Regular L300 Quick Fit Electrode and Regular L300 FS Cuff shown.)

Place the Intelli-Sense Gait Sensor in the Shoe



Caution: The Intelli-Sense Gait Sensor has not been validated for use by individuals weighing more than 136 kilograms (300 pounds).



Caution: Do not use the Intelli-Sense Gait Sensor with a rigid insole such as a custom rigid orthosis or an ankle foot orthosis.

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

Note: The Gait Sensor pad and Intelli-Sense Gait Sensor pressure sensor should be placed under the insole of the shoe. If the shoe does not have a detachable insole, place the Gait Sensor pad and pressure sensor on top of the insole. Then, place a soft, thin (one layer versus two) generic insole over them. Generic insoles can be purchased from drugstores, shoe stores, or Bioness Inc.

To place the Intelli-Sense Gait Sensor in the shoe:

1. First determine the appropriate placement (heel position or forefoot position) of the Gait Sensor based on patient presentation.
2. Lift the shoe insole, and attach a Gait Sensor pad to the heel or forefoot of the shoe.
3. For **heel position** placement point the wire of the Intelli-Sense Gait Sensor toward the toe of the shoe. For **forefoot position** placement point the wire of the Intelli-Sense Gait Sensor toward the heel of the shoe. Attach the pressure sensor to the Gait Sensor pad. See Figure 10-13.

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

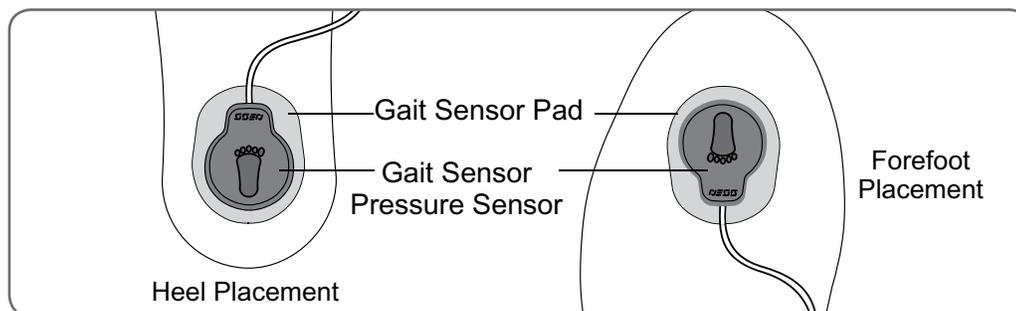


Figure 10-13: Positioning the Gait Sensor in the shoe.

4. Clamp the Intelli-Sense Gait Sensor transmitter to the inner rim of the shoe. Face the NESS logo on the transmitter away from the ankle. See Figure 10-14.

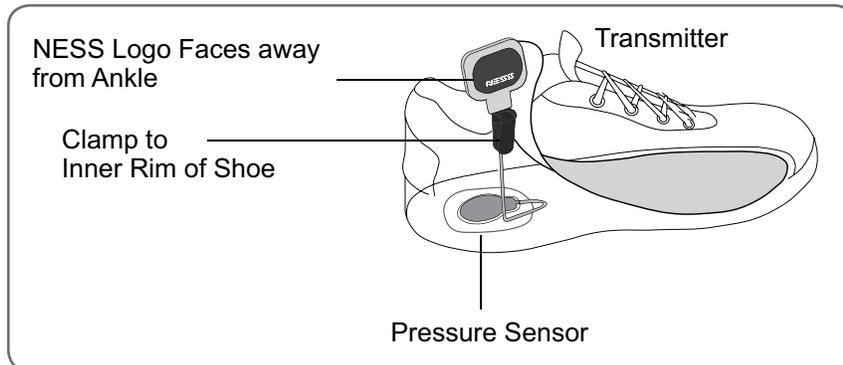


Figure 10-14: Clamping the transmitter to the inner rim of the shoe.
(Gait sensor in the heel position in a left shoe shown.)

5. Lower the insole over the pressure sensor, tucking any excess wire under the insole. See Figure 10-15.

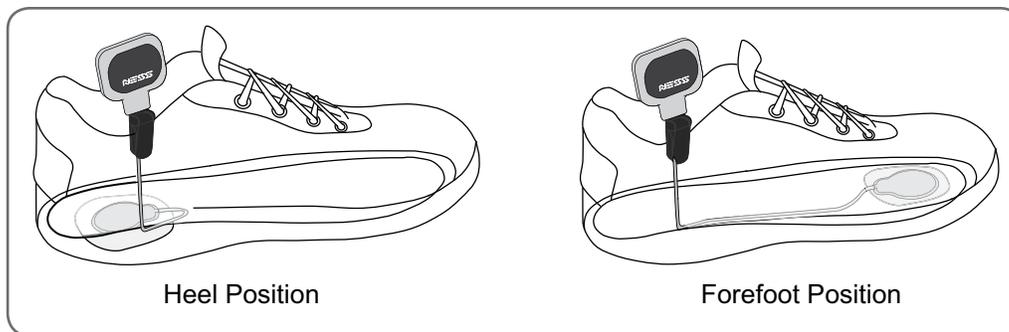


Figure 10-15: Insole covering the pressure sensor and wire. (Left shoe shown.)

Program Gait, Training, and Advanced Settings

Note: The clinician will need to assess the patient walking and make gait setting adjustments as needed. Training settings should be adjusted with the patient seated.

To program gait, training, and advanced settings:

- Refer to the Intelli-Gait Software Navigation section of this guide.

Doff the L300 FS Cuff

To doff the L300 FS Cuff:

1. Turn off the stimulation prior to doffing the L300 FS Cuff.
2. With a marker, mark the location of the L300 FS Cuff locator on the leg for reference.
3. Unhook the L300 FS Cuff strap handle from the L300 FS Cuff cradle, and slowly lift the L300 FS Cuff away from the skin.

Note: For the Regular L300 FS Cuff using hydrogel electrodes, gently peel the electrodes from the skin, and reapply the electrode covers to the electrodes.

4. With a marker, make small, evenly spaced marks around the electrode bases on the liner of the L300 FS Cuff (or on the personal panel) for reference.
5. If appropriate, cover the electrode base wires and snaps with the wire concealers. See Figure 10-16. Make sure the wires are tucked under the wire concealers.

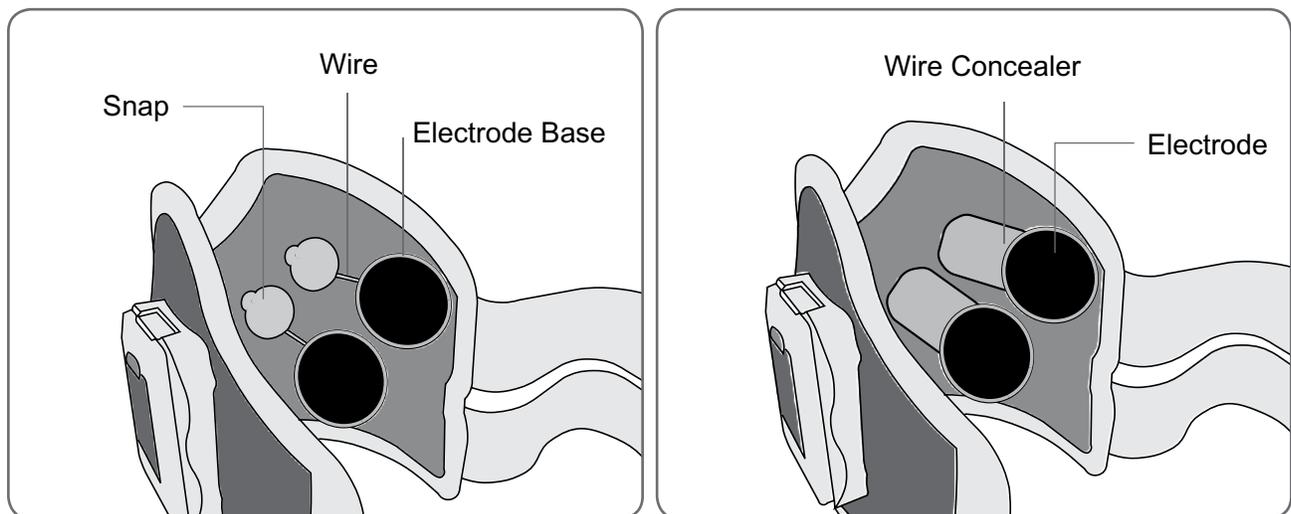


Figure 10-16: Regular L300 FS Cuff without (left) and with (right) wire concealers.

Note: Make sure to instruct patients who will be using the NESS L300 at home to remove the L300 FS Cuff several times daily to allow the skin below the FS Cuff to breathe.

General Conditioning and Training Guidelines

Acute/Subacute Patients

Gait Mode

Use gait mode anytime an appropriate patient is walking under clinical supervision in the acute (less than three months post stroke) in-patient or out-patient setting.

Training Mode

Use training mode to gradually increase strength, improve endurance, and avoid over-fatigue. The recommended training time is 20 minutes twice a day on Day 1. Separate sessions by more than four hours to allow for recovery. Gradually increase training time five minutes each day until the patient can tolerate two 60-minute sessions per day. As ambulatory time increases, training time should decrease.

Home Program Training

When the NESS L300 is introduced in the out-patient setting for home program training for patients who are more than three months post stroke, muscle strength and endurance should be built up gradually to avoid over-fatigue. Separate gait and training sessions with rest periods of up to four hours during Week 1 and Week 2 to allow for recovery.

Recommended gait and training times for a home program are shown in Table 11-1. **Times may vary depending on patient medical status, level of independence, daily routine, muscle endurance, motivation, etc.**

Standard Conditioning Protocol for NESS L300 Home Use

Patient Name: _____						
First week: From ____ / ____ / ____ To ____ / ____ / ____						
Day	Walking with the NESS L300*	Mark (✓) when completed	Training mode**	Mark (✓) when completed		During the first week, the L300 FS Cuff should only be worn for ~1–2 hours at a time . It is best to divide the time that you wear the L300 FS Cuff between the morning and afternoon or evening.
1	15 min		15 min			
2	20 min		15 min			
3	25 min		15 min			
4	30 min		15 min			
5	40 min		15 min			
6	50 min		15 min			
7	60 min		15 min			
Twice a day if gait is limited						
Second week: From ____ / ____ / ____ To ____ / ____ / ____						
Day	Walking with the NESS L300*	Mark (✓) when completed	Training mode**	Mark (✓) when completed		The L300 FS Cuff should only be worn for ~ 2–4 hours at a time during the second week. It is best to take the L300 FS Cuff off for >1 hour to let the skin breathe.
1	1.0 hr		20 min			
2	1.5 hr		20 min			
3	2.0 hr		20 min			
4	2.5 hr		20 min			
5	3.0 hr		20 min			
6	3.5 hr		20 min			
7	4.0 hr		20 min			
Twice a day if gait is limited						
Third week: From ____ / ____ / ____ To ____ / ____ / ____ (◇During the third week, the time noted in the walking column refers to the total time that the device can be worn with gait mode turned on. The user is NOT expected to walk the entire time indicated. The goal is to extend wear time throughout the day as appropriate for the user.)						
Day	◇Walking with the NESS L300*	Mark (✓) when completed	Training mode**	Mark (✓) when completed		It is best to take the L300 FS Cuff off every 4 hours for >15 minutes to let the skin breathe.
1	4 hr		20 min			
2	5 hr		20 min			
3	6 hr		20 min			
4	7 hr		20 min			
5	8 hr		20 min			
6	9 hr		20 min			
7	Use the system all day long		20 min			
Twice a day if gait is limited						
Cover the NESS L300 hydrogel electrodes when not in use. * Always use your recommended assistive device unless otherwise directed by your therapist. You should wear the NESS L300 for the time listed and put the L300 in gait mode whenever you are standing. Your prescribed AFO or other recommended brace should be worn when the NESS L300 is not in use. **The amount in training mode will vary with walking ability and time in gait mode. Please do not exceed the total time.						

Table 11-1: Recommended gait and training mode times for conditioning to the NESS L300.

Patient Training and Follow-Up

Patient Training

Clinicians and patients should know the limitations, warnings, and precautions associated with the NESS L300 Foot Drop System. Clinicians should review the safety information with patients, and train patients on component set-up, operation, and maintenance. Patients should understand the system displays and indicators, troubleshooting solutions, and whom to contact for technical support. A training program should cover the following topics, which are described in this manual and in the NESS L300 User's Guide:

- General safety information.
- Overview of the NESS L300 Foot Drop System and System Kit contents.
- Donning and doffing the L300 FS Cuff.
- Snapping the RF Stim Unit in and out of the cradle.
- Replacing electrodes and electrode bases.
- Placing an Intelli-Sense Gait Sensor in the shoe.
- Transferring the Intelli-Sense Gait Sensor to a different shoe.
- Using multiple Gait Sensors, for different shoes.
- Operating the Control Unit.
- The system component buttons, displays, and audio alerts: their definitions and functions.
- Using gait and training modes.
- Maintenance of the system components, including charging and battery replacement.
- Review of basic troubleshooting.
- Practice with the system.
- Review of the Skin Care Guidelines.
- Contact for Technical Support.
- The NESS L300 User's Guide

Patient Follow-Up

The NESS L300 program should be followed and supervised by a qualified clinician to monitor clinical progress, maximize clinical effectiveness and safety, and provide clinical and technical support.

A suggested follow-up agenda would include:

- Component check-out: wear and function.
- Programming adjustments: stimulation, gait, and training parameters.
- Gait training, including advanced training as appropriate (for example, stair negotiation).
- Review of training topics as necessary:
 - General safety information.
 - Overview of the NESS L300 Foot Drop System and System Kit contents.
 - Donning and doffing the L300 FS Cuff.
 - Snapping the RF Stim Unit in and out of the cradle.
 - Replacing electrodes and electrode bases.
 - Placing an Intelli-Sense Gait Sensor in the shoe.
 - Transferring the Intelli-Sense Gait Sensor to a different shoe.
 - Using multiple Intelli-Sense Gait Sensors, for different shoes.
 - Operating the Control Unit.
 - The system component buttons, displays, and audio alerts: their definitions and functions.
 - Using gait and training modes.
 - Maintenance of the system components, including charging and battery replacement.
 - Review of basic troubleshooting.
 - Practice with the system.
 - Review of the Skin Care Guidelines.
 - Contact for Technical Support.
 - The NESS L300 User's Guide
- Skin evaluation (under the L300 FS Cuff and around the Intelli-Sense Gait Sensor).
- Troubleshooting.

Care and Maintenance

Replacing the Intelli-Sense Gait Sensor Battery

The Clinician's Kit includes a replacement battery for the Intelli-Sense Gait Sensor. The Gait Sensor battery is not rechargeable. A Gait Sensor battery will need to be replaced approximately **every six months**. The Gait Sensor indicator on the Control Unit will flash YELLOW when the battery has about two weeks of charge left.

To replace the Gait Sensor battery (Lithium coin cell, CR2430):

1. On an open, clean surface, remove the screws from the battery cover. See Figure 14-1.
2. Slide the cover out.
3. Note the "+" orientation of the old battery.
4. Remove the old battery and dispose of it according to your local environmental regulations.
5. Insert the new battery with the "+" facing outward.
6. Slide the cover back into place, and replace the screws.
7. Press the Intelli-Sense Gait Sensor pressure sensor to activate the Gait Sensor.

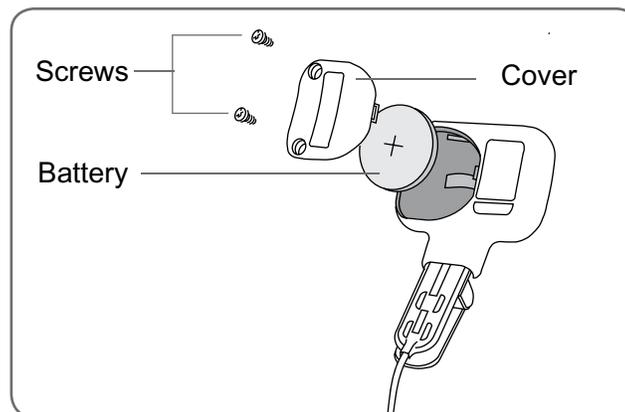


Figure 14-1: Replacing the Intelli-Sense Gait Sensor battery.



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

Replacing the Clinician's Programmer Battery

During extended periods of nonuse, remove the battery from the Clinician's Programmer. Refer to the PDA manufacturer's instructions for information on battery removal and replacement.

Replacing the RF Stim Unit Battery

The RF Stim Unit rechargeable battery should be replaced approximately every two years by a Bioness Inc certified technician. Contact Bioness Inc for assistance.

Replacing the Control Unit Battery

The Control Unit rechargeable battery should be replaced approximately every two years. Refer to the NESS L300 User's Guide for battery replacement instructions.

Replacing the L300 Quick Fit Electrode

The L300 Quick Fit Electrode will need to be replaced at least every two weeks.



Caution: Use only NESS L300 electrodes supplied by Bioness.

Caution: Do not use the NESS L300 without electrodes.

Caution: Do not fold or twist the L300 Quick Fit Electrode.

To replace the L300 Quick Fit Electrode: (See Figure 14-2)

1. Turn off the Control Unit and remove the L300 FS Cuff.
2. Gently remove the used L300 Quick Fit Electrode from the L300 FS Cuff.
3. Wet the entire new L300 Quick Fit Electrode with water.
4. Remove excess water from the L300 Quick Fit Electrode with a cloth.
5. Align the orange and blue snaps on the L300 Quick Fit Electrode with the orange and blue plug holes on the L300 FS Cuff.
6. Press firmly to snap the L300 Quick Fit Electrode into the L300 FS Cuff.

Note: Instruct patients to remove and re-wet the entire L300 Quick Fit Electrode every time they remove the L300 FS Cuff from the leg for more than one hour, and after every three to four hours of use. When wetting the L300 Quick Fit Electrode, always remove it from the L300 FS Cuff.

Note: Store the L300 Quick Fit Electrode where it can air dry, when not in use.

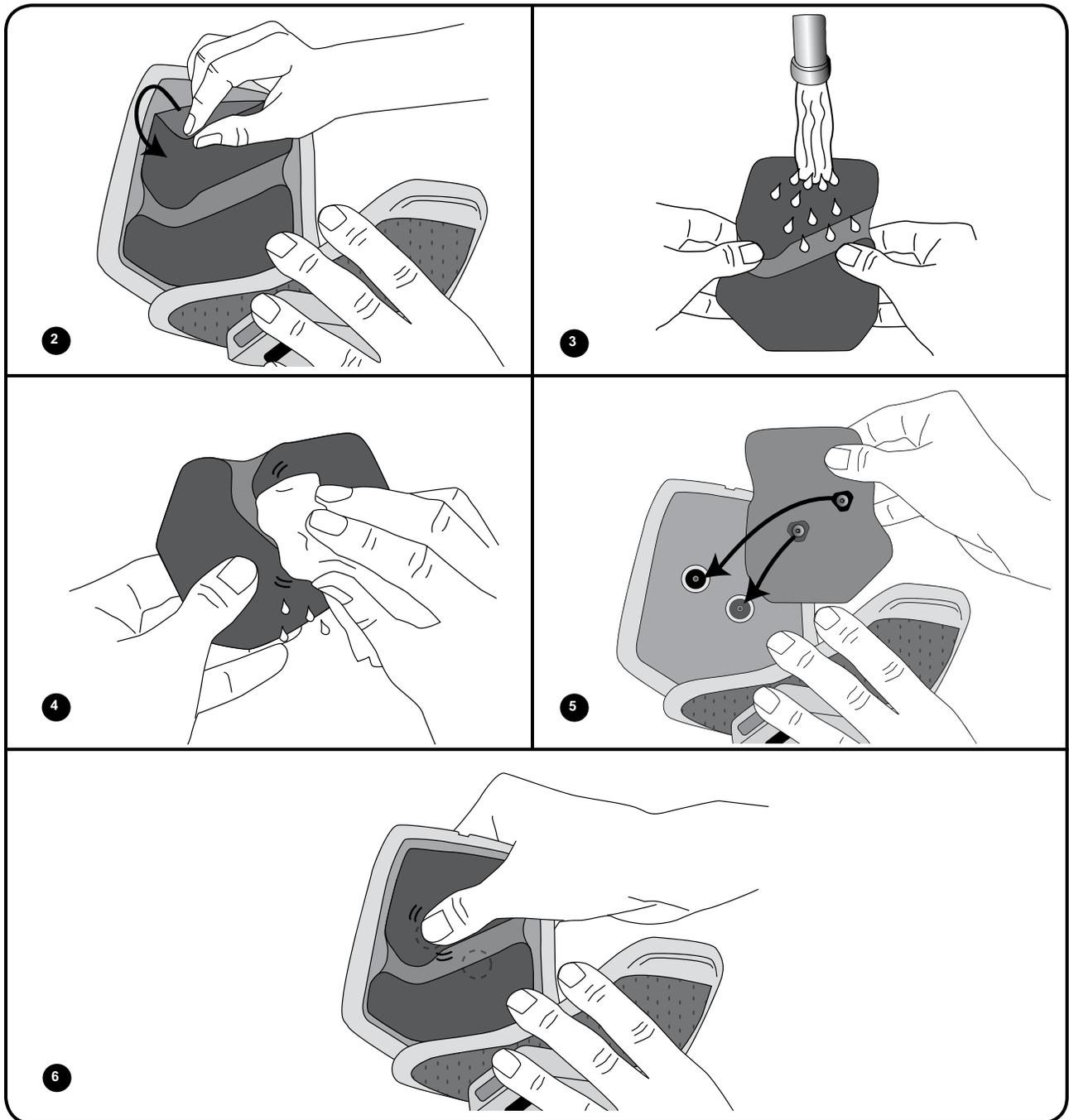


Figure 14-2: Replacing the L300 Quick Fit Electrode.
(Regular L300 Quick Fit Electrode and Regular L300 FS Cuff shown.)

Replacing the L300 Cloth Electrodes

Cloth electrodes will need to be replaced at least every two weeks.



Caution: Use only NESS L300 Cloth Electrodes supplied by Bioness.

Caution: Do not use the NESS L300 without electrodes.

To replace the L300 Cloth Electrodes: (See Figure 14-3)

1. Turn off the Control Unit and remove the L300 FS Cuff..
2. Gently pull the used L300 Cloth Electrodes from the electrode bases. Be careful not to detach the electrode bases from the L300 FS Cuff.
3. If necessary, clean the electrode bases with a damp cloth. Do not use a chemical-based cleaning substance.
4. Wet the new L300 Cloth Electrodes with water until they are saturated.
5. With a soft cloth, gently wipe or blot excess water off the back (side with the snap) of the cloth electrodes.
6. Attach the L300 Cloth Electrodes to the electrode bases.

Note: Instruct patients to remove and re-wet the L300 Cloth Electrodes every time they remove the L300 FS Cuff from the leg for more than one hour, and after every four hours of use. When wetting the cloth electrodes, always remove them from the L300 FS Cuff. If the cloth electrodes dry out, the response to the stimulation may change. If patients need to adjust stimulation intensity more often than usual, they should try re-wetting the cloth electrodes following the steps listed above.

Note: Store the L300 Cloth Electrodes, when not in use, in a location where they can air dry.

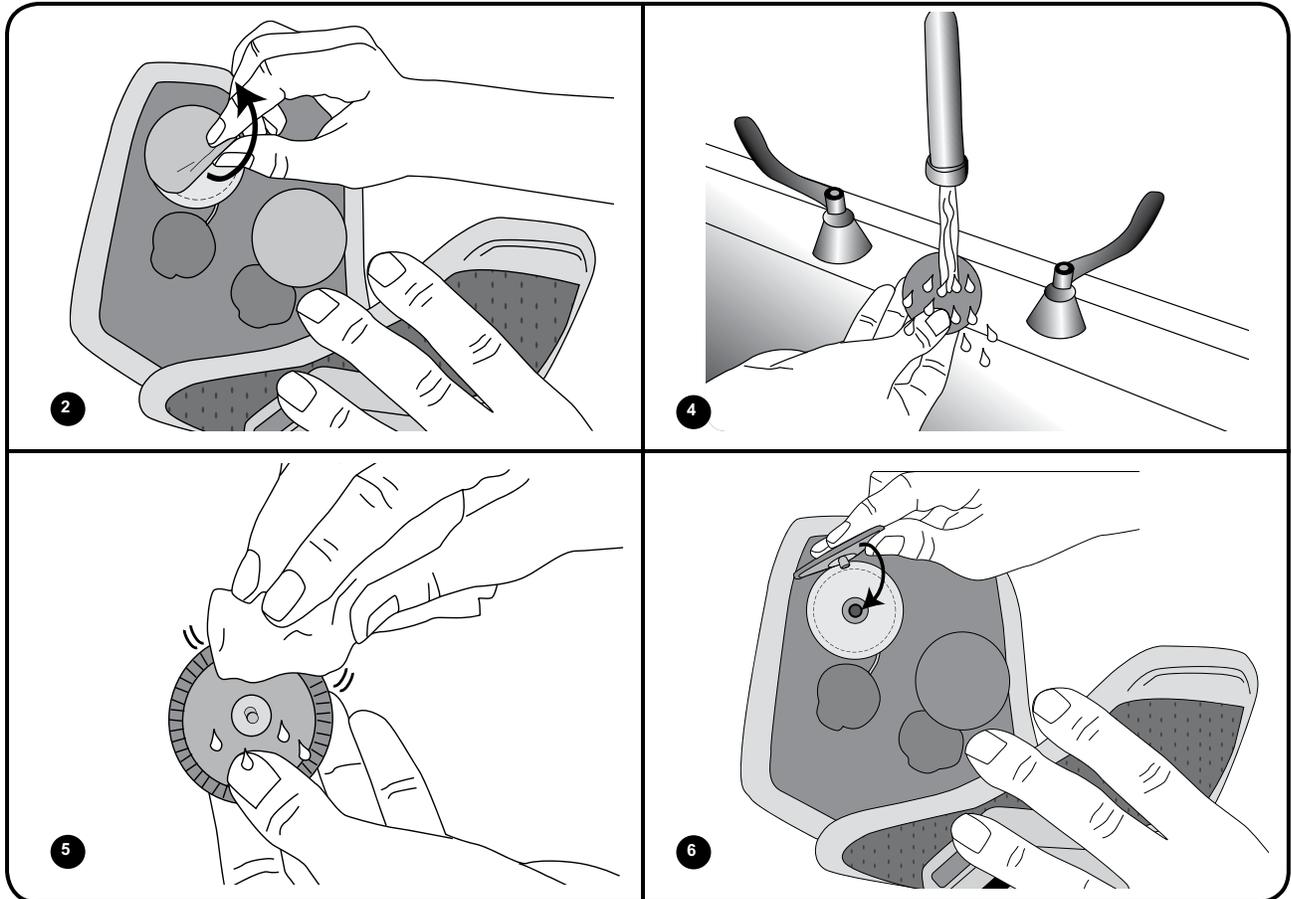


Figure 14-3: Replacing the L300 Cloth Electrodes. (Regular L300 Cloth Electrodes and Regular L300 FS Cuff shown.)

Replacing the Regular L300 Hydrogel Electrodes

The Regular L300 Hydrogel Electrodes will need to be replaced every two weeks for optimal stimulation.



Caution: Use only NESS L300 Hydrogel Electrodes supplied by Bioness.

Caution: Do not use the NESS L300 without electrodes.

To replace the Regular L300 Hydrogel Electrodes: (See Figure 14-4)

1. Turn off the Control Unit and remove the L300 FS Cuff.
2. Gently pull the used hydrogel electrodes from the hydrogel electrode bases. Be careful not to detach the hydrogel electrode bases from the L300 FS Cuff.
3. If necessary, clean the electrode bases with a damp cloth. Do not use a chemical-based cleaning substance.
4. Separate the two new electrodes along the perforation.
5. Split the two-piece covers on each new electrode and discard them.
6. Attach the grid side of the electrodes to the electrode bases, and then press firmly.
7. Remove the covers from the electrodes.

Note: Save the covers. Always reapply the covers between uses. When reapplying the covers, make sure the Bioness logo faces up.

Note: If the electrode gel becomes dry, rehydrate it with one to two drops of water.

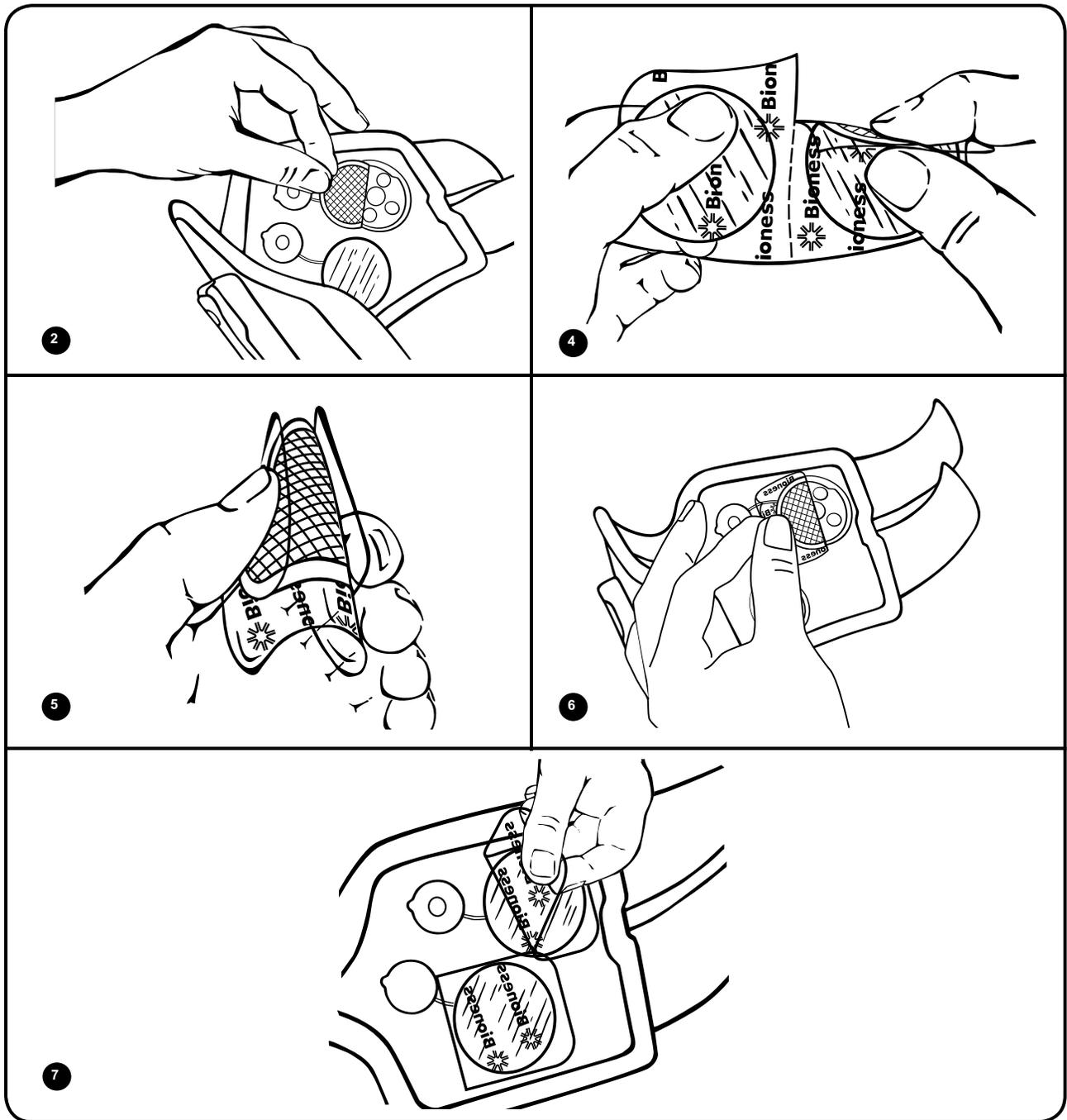


Figure 14-4: Replacing the Regular L300 Hydrogel Electrodes.

Replacing the Electrode Bases

If the electrode bases become worn, they may need to be replaced.

To replace the electrode bases: (See Figure 14-5)

1. Remove any electrode base wire concealers.
2. Mark the position of the used electrode bases on the L300 FS Cuff liner with a permanent marker.
3. Disconnect the electrode base snaps from the plug holes.
4. Remove the used electrode bases from the L300 FS Cuff.
5. Attach the new electrode bases where the previous bases were attached.
6. Connect the electrode base snaps to the plug holes.
7. Recover the wires and snaps with the wire concealers, if desired.

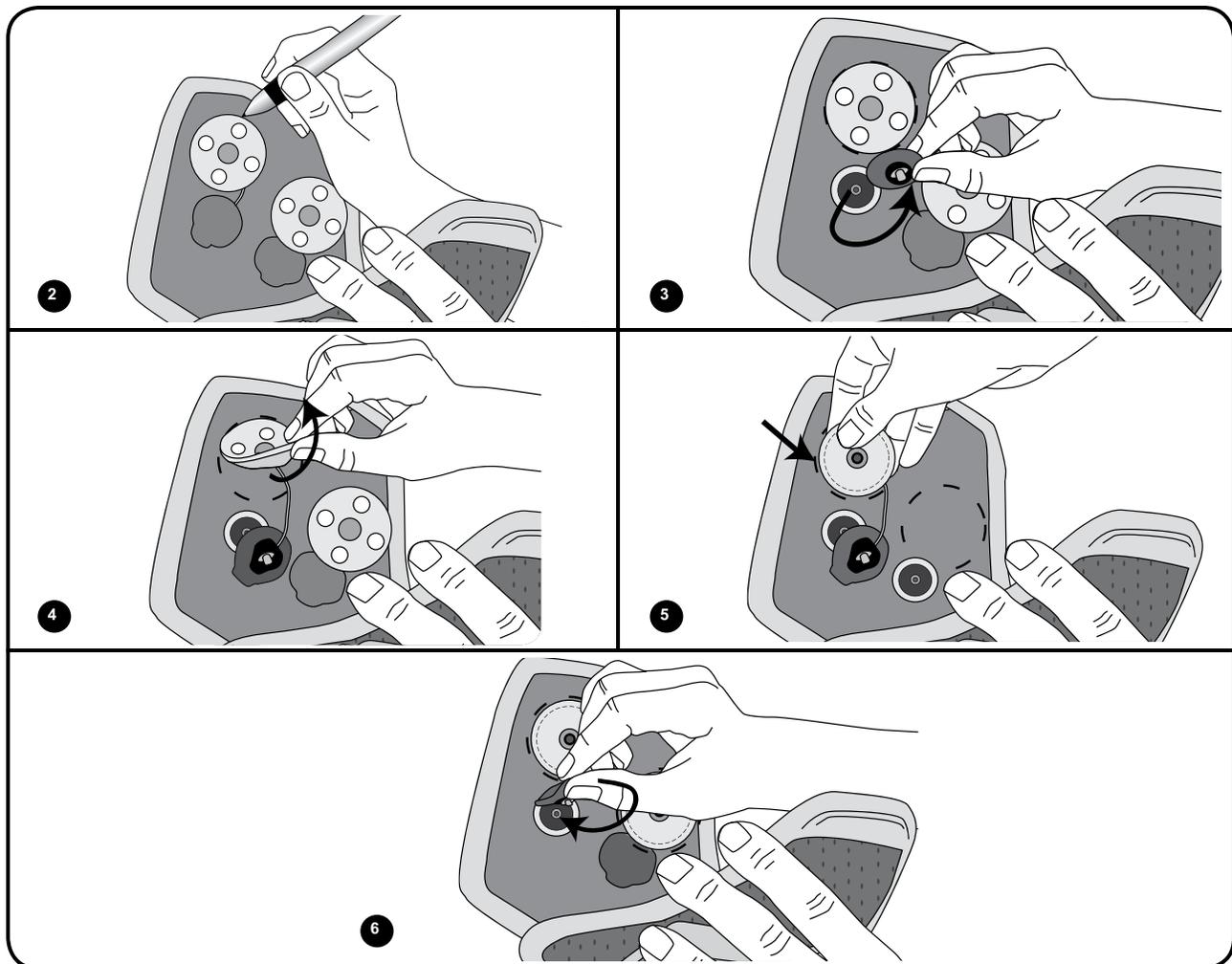


Figure 14-5: Replacing the L300 Electrode Bases. (Regular L300 FS Cuff shown.)

Replacing the L300 FS Cuff

To replace the L300 FS Cuff for a patient using the NESS L300 at home:

1. Place the old L300 FS Cuff on the leg.
2. Use a permanent pen to mark the position of the locator on the leg. Mark a few small dots.
3. Remove the L300 FS Cuff from the leg. (The leg should show dimples where the electrodes were attached.)
4. Detach the RF Stim Unit from the L300 FS Cuff.
5. Remove the electrodes and electrode bases from the L300 FS Cuff.
6. Place the L300 hydrogel electrodes and electrode bases on the leg, using the dimples left by the electrodes for reference.
7. Transfer the electrodes from the leg to the new L300 FS Cuff.
8. Attach the RF Stim Unit to the new L300 FS Cuff.
9. Connect the electrode base snaps to the L300 FS Cuff plug holes.
10. Cover the electrode base wires and snaps with the wire concealers, if desired.
11. Place the new L300 FS Cuff on the patient and check for fit and functionality.
12. Record the serial number of the new L300 FS Cuff on the patient's System Kit ID Card, found under the handle of the System Kit carrying case.

Electronically Registering New Components

When a NESS L300 Control Unit, RF Stim Unit, or Intelli-Sense Gait Sensor is replaced, the new component must be electronically registered to the other NESS L300 components for the system to communicate wirelessly.

Refer to the NESS L300 **User's Guide** for instructions on how to electronically register new components.

Troubleshooting

Frequently Asked Questions

If you have any questions or concerns, please contact the NESS L300 Technical and Clinical Support Department at (800) 211-9136, Option 3.

Our clinic owns multiple NESS L300 systems. How can we identify which components belong to which system?

- Each NESS L300 system has an alphanumeric System Identification (ID) Number (for example, A123) printed on the back of the Control Unit, RF Stim Unit, and Gait Sensor. The System ID Numbers on all three components must match for the system to work. Check the ID numbers before use to see if they match.

The buttons in the Intelli-Gait Software used to create a new patient record or adjust the settings for a current patient are grayed out and nonfunctional.

- The Clinician's Programmer and the Control Unit are not communicating. Both must be connected to the Configuration Cradle communication connector cable to communicate. Turn off the Control Unit or place it in standby mode. Then reconnect the Configuration Cradle communication connector cable to the Control Unit and the Clinician's Programmer.

I connected the Control Unit to the Configuration Cradle and a message appeared on the Clinician's Programmer. The message says that the date and time in the Control Unit differ from those in the Clinician's Programmer.

- The clocks on the Control Unit and Clinician's Programmer must be synchronized for the Gait Log and Training Log to record accurately.
 - » If the date and time settings of the Clinician's Programmer are correct, update the L300 clock.
 - » If the date and time settings of the Clinician's Programmer are not correct, press **Exit** to close the Intelli-Gait Software and open the PDA settings screen. (See the PDA manufacturer's instructions.) Use the stylus to adjust the Clinician's Programmer time zone, clock, and date. Press **Ok** to save the settings. Log back into the Intelli-Gait Software, reconnect the Control Unit, and update the L300 clock to match the Clinician's Programmer clock.

I connected the Control Unit to the Configuration Cradle, and a message appeared on the Clinician's Programmer. The message says that a new patient was found and asks if I would like to add this record to the database.

- Select **Yes**, if you want to review or make changes to the patient's settings. If not, select **No** to return to the Patients List. Then, with the Control Unit still connected to the Configuration Cradle, you can open another patient record or set up a new patient record for use with the Control Unit.

When I connected the Control Unit to the Configuration Cradle, a message appeared on the Clinician's Programmer saying that the parameters are inconsistent.

- A different Clinician's Programmer was last used to update the patient's system.
 - » Press **L300** → **DB** to overwrite the data on the Clinician's Programmer with the data on the Control Unit (preferred when patients have been using the Control Unit settings and are returning for a follow-up evaluation).
 - » Press **DB** → **L300** to overwrite the parameters on the Control Unit with the parameters on the Clinician's Programmer.
 - » Press **Ignore** to leave the parameters on the Clinician's Programmer and the Control Unit unchanged.

When charging the L300, how will I know when the batteries are fully charged?

- When the Control Unit is fully charged, a  horizontal GREEN line will appear in the Control Unit digital display.
- When the RF Stim Unit is fully charged, the  status light on the RF Stim Unit will be solid GREEN.
- Charging takes approximately three hours. Once the components are fully charged, you may keep the components connected to the system charger set.

After I fully charged the Control Unit and RF Stim Unit, I disconnected the system charger set and then immediately reconnected it. The charging icons displayed again on the Control Unit and RF Stim Unit. Do I need to repeat the charging process?

- If you just charged your system and the fully charged icons were displayed, your system is still fully charged. You do not have to repeat the charging process.

If I charge the L300 every day, will I harm the batteries?

- No. Daily charging will not affect the lifespan or functionality of the batteries. Daily charging is recommended.

While charging the Control Unit and RF Stim Unit,  "E" appears in the digital display.

- An error occurred while charging. Reconnect the system charger set. If the problem persists, contact Bioness.

The Control Unit (or RF Stim Unit) does not light up when turned on.

- The battery needs to be charged. Charge the battery. If the problem persists, contact Bioness.

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

- A Gait Sensor battery will last for approximately six months, and then it will need to be replaced. When the Gait Sensor battery charge level is low, the Gait Sensor indicator on the Control Unit will flash YELLOW and the Control Unit will emit an audio alert. The audio alert will become more persistent as the battery weakens.



Stimulation works in training mode but not in gait mode. When I turn on gait mode I hear a beep, the RF Stim Unit and Gait Sensor indicators on the Control Unit alternately flash RED, and "E" flashes in the digital display.

- The Gait Sensor and RF Stim Unit are not communicating. The Gait Sensor is probably hibernating. Apply pressure to the Gait Sensor pressure sensor. If pressure does not resolve the problem, the battery may be depleted or the Gait Sensor may be faulty. If no wire issues are apparent, replace the Gait Sensor battery and try again.



When I turn on the Control Unit, it beeps, the Control Unit and RF Stim Unit indicators alternately flash RED, and "E" flashes in the digital display. The RF Stim Unit indicators are not lit.

- The RF Stim Unit battery is likely discharged, preventing the Control Unit and RF Stim Unit from communicating. Turn off the Control Unit, and charge the Control Unit and RF Stim Unit fully. Then, disconnect the system charger set and turn on the Control Unit. The Control Unit  on/off button and the  status light on the RF Stim Unit should flash GREEN. Communication should be restored.



I hear a beep, the RF Stim Unit indicator on the Control Unit flashes RED, and the stimulation intensity level flashes in the Control Unit digital display.

If the patient feels stimulation but the intensity level seems weaker than usual and ankle movement is unsatisfactory, electrode contact may be compromised.

- Turn off the Control Unit and remove the FS Cuff.
- Thoroughly cleanse the skin, removing dead cells and oils.
- If using hydrogel electrodes, remove and replace the worn electrodes. Press firmly on the new electrodes until they are securely attached to the electrode bases. Then, remove the covers.
- If using cloth electrodes, remove the cloth electrodes and wet them with water until saturated. Blot the snap side of the electrodes before re-adhering them to the electrode bases.
- Replace hydrogel and cloth electrodes every two weeks.

If the patient does not feel stimulation:

- Turn off the Control Unit and remove the FS Cuff.
- For hydrogel electrodes, confirm that the covers have been removed.
- For cloth electrodes, remove and wet the cloth electrodes, if they are dry.
- Make sure the RF Stim Unit is properly snapped into the cradle on the FS Cuff. Press firmly near the upper edges of the RF Stim Unit until it is flush with the cradle.
- Make sure the electrode bases are snapped into the plug holes of the FS Cuff, especially if using a fitting panel.
- If using a fitting cable, check that the cable is correctly connected to both plug holes of the FS Cuff and to both electrode bases.
- Use the L300 Tester to test the electrical flow.

The electrodes or electrode bases are frayed, peeling, damaged, or falling off the FS Cuff.

- Replace any worn or damaged electrodes or electrode bases.



One of the component indicators is solid RED, an "E" appears in the digital display, and the Control Unit beeps.

- The component is malfunctioning. Turn off the Control Unit and turn it back on. If the problem persists, then stop using the NESS L300 and contact Bioness.



One of the component indicators is flashing YELLOW.

- The component battery charge level is low. Charge or replace the battery.

The patient's ankle is not moving (or the foot does not lift satisfactorily), and the system is not indicating any errors.

- Turn off the Control Unit and reposition the FS Cuff. Make sure the FS Cuff strap is snug and the FS Cuff is secure.

Stimulation is inconsistent when the patient is walking, but the system is not indicating any errors.

- Have the patient stop walking and shift weight from side to side. If the problem persists, check for proper placement of the pressure sensor, reposition the pressure sensor slightly forward in the shoe, or loosen the shoelace, if it is tight. Also, check the Gait Sensor wires for wear or fraying, and check the transmitter and pressure sensor for damage.

The skin is irritated or has a skin reaction where the electrodes or FS Cuff adheres.

- Stop using the NESS L300 immediately and contact Bioness. Resume use only when the skin is completely healed. Give patients the NESS L300 Skin Care Guidelines and a skin conditioning protocol.

I received a replacement component and was told I need to "register" it. Why is registration important, and how do I register a component?

- A replacement Control Unit, RF Stim Unit, or Gait Sensor needs to be electronically registered to the other components in the system to communicate wirelessly. To register a component, see the L300 *User's Guide*.

I tried the registration procedure and saw a  "C" immediately, but I never saw the alternating GREEN arches in the digital display. The replacement component is not working.

- Clinician mode (for use by clinicians only) may have been started instead of the registration process. Clinician mode is started by pressing the minus  and  on/off buttons on the Control Unit. Registration is started with the Control Unit off, and then by pressing the minus  and mode  buttons on the Control Unit. Turn off the Control Unit, and press the  minus and  mode buttons to restart the registration process.

How can I verify that current is flowing through the L300?

Connect the L300 Tester to the RF Stim Unit, the FS Cuff plug holes, or the ends of the fitting cable, depending on the setup. The L300 Tester will buzz when stimulation intensity is at least 10 mA.

What else can I use the L300 Tester for?

- The L300 Tester can be used as an educational tool, to demonstrate when stimulation is on in the various stimulation modes.

Using the L300 Tester

The L300 Tester provides audio feedback when connected to the NESS L300 and stimulation is applied.

Testing in Training Mode

1. Connect the L300 Tester to the FS Cuff. See Figure 15-1.
2. Press the Control Unit  on/off button to turn on the system.
3. Press and hold the  mode button until the Control Unit beeps, the  mode button starts flashing YELLOW SLOWLY (indicating that stimulation is off), and  ("t" for training) alternates with the intensity level in the digital display. When stimulation is on, the  mode button will flash YELLOW RAPIDLY.
4. You should hear a buzzing when stimulation is on and no buzzing when stimulation is off.

Testing in Gait Mode

1. Connect the L300 Tester to the FS Cuff.
2. Press the Control Unit  on/off button to turn on the system.
3. Press the  mode button briefly to enter gait mode. The Control Unit will beep and the  mode button will flash YELLOW SLOWLY (indicating that stimulation is off).
4. Press and release the pressure sensor on the Gait Sensor. You should hear a buzzing when you release the pressure from the pressure sensor and no buzzing when you press on the pressure sensor.

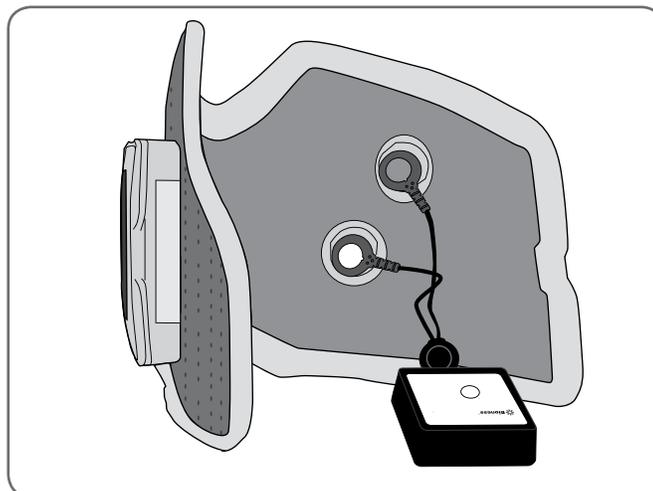


Figure 15-1: L300 Tester connected to the Regular L300 FS Cuff.

If either of the above steps elicits an error indication, test using the advanced testing procedures.

Advanced Testing

Note: If stimulation is not delivered to the patient's leg, a "faulty electrode contact" error may appear. After you have rechecked that the electrode base snaps are secured to the plug holes of the FS Cuff and that the RF Stim Unit is fully snapped into the FS Cuff cradle, use the L300 Tester to differentiate among problems in the RF Stim Unit, FS Cuff, and electrode bases using a process of elimination. Follow the steps below to determine which component may be faulty.

Step 1: Test the FS Cuff:

1. Connect the L300 Tester to the FS Cuff. See Figure 15-2.

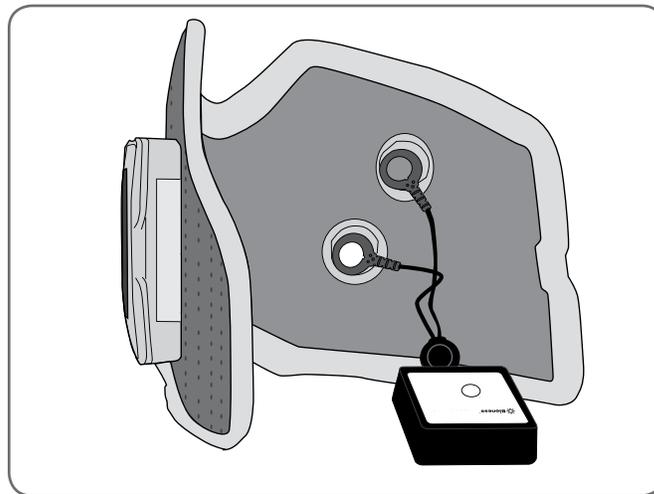


Figure 15-2: L300 Tester connected to the Regular L300 FS Cuff.

2. Apply stimulation using the Control Unit in clinician mode or by using the Clinician's Programmer. The minimum intensity required to produce a sound is 10 mA.
3. If the circuit is intact in the FS Cuff and the RF Stim Unit is working properly, the L300 Tester will buzz. If the patient was not feeling stimulation while the FS Cuff was donned, the problem may be in the electrode bases. If this is the case, replace the electrode bases and electrodes.
4. If the L300 Tester does not buzz, then you need to determine whether the fault is in the FS Cuff or the RF Stim Unit. This can be verified by connecting the L300 Tester directly to the RF Stim Unit.

Step 2: Test the RF Stim Unit:

1. Remove the RF Stim Unit from the FS Cuff cradle. See Figure 15-3.

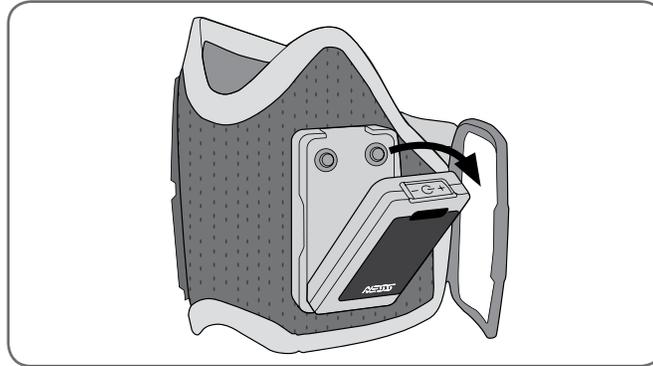


Figure 15-3: Removing the RF Stim Unit.

2. Connect the L300 Tester to the electrical sockets on the back of the RF Stim Unit. See Figure 15-4.
3. Apply stimulation using the Control Unit in clinician mode or by using the Clinician's Programmer. The minimum intensity required to produce a sound is 10 mA.
4. If the RF Stim Unit is working, the L300 Tester will buzz, indicating that the problem may be in the FS Cuff. Replace the FS Cuff.
5. After replacing the FS Cuff, connect the RF Stim Unit to the new FS Cuff, repeat the test sequence from "Step 1: Test the FS Cuff".
6. If the L300 Tester does not buzz, the RF Stim Unit may be faulty. Replace the RF Stim Unit or contact Bioness Inc.

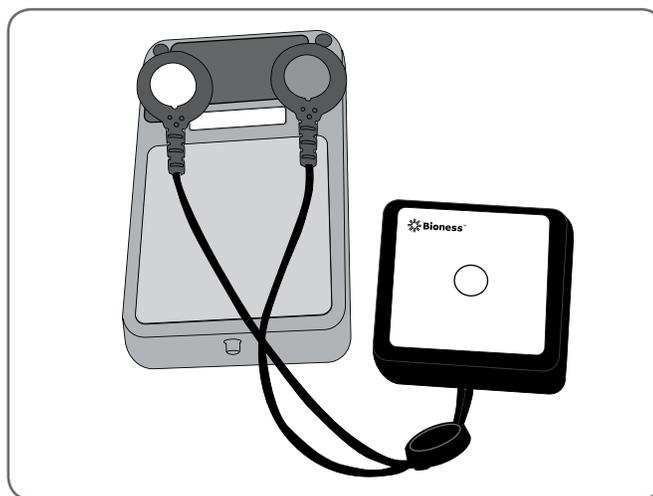


Figure 15-4: L300 Tester connected to the RF Stim Unit.

Troubleshooting Quick Reference Table

Control Unit	Solution
Will not turn on	Charge the Control Unit
	Change the battery and charge the Control Unit
	Replace the Control Unit and register it
Component malfunction	Replace the Control Unit and register it
RF Stim Unit	Solution
Will not turn on	Charge the RF Stim Unit
	Charge the RF Stim Unit or contact Bioness Inc to replace the battery
	Replace the RF Stim Unit and register it
Component malfunction	Replace the RF Stim Unit and register it
Intelli-Sense Gait Sensor	Solution
Communication error	Press and release the pressure sensor while in gait mode to activate the Gait Sensor
	Change the battery, and press the pressure sensor to activate the Gait Sensor
	Replace the Gait Sensor and register it
Will not function	Change the battery, and press the pressure sensor to activate the Gait Sensor
	Replace the Intelli-Sense Gait Sensor and register it
Functioning but not reliably	Relocate the pressure sensor to the correct placement under the heel or forefoot, and replace the Gait Sensor pad, if it appears worn
	Replace the Gait Sensor and register it

FS Cuff	Solution
The Control Unit is displaying a faulty electrode connection	Ensure good contact of the electrode to the skin and base, and ensure that the FS Cuff connections are intact
An electrode is damaged or peeling off	Replace the electrode
An electrode base is damaged	Replace the electrode base
The FS Cuff strap is frayed or damaged	Replace the FS Cuff strap
The FS Cuff is damaged.	Replace the FS Cuff
Clinician's Programmer	Solution
Will not turn on	Charge the Clinician's Programmer
	Change the battery and charge the Clinician's Programmer
	Press the Clinician's Programmer reset button
	Replace the Clinician's Programmer
Lost the Intelli-Gait application/ data	Contact Bioness Inc
Will not communicate with the Control Unit	Reconnect the communication connector cable of the Configuration Cradle to the Clinician's Programmer and Control Unit
	Contact Bioness Inc

Technical Specifications

Control Unit Specifications	
Classification	Internally powered, continuous operation
Operation Modes	Gait, Training, Clinician, and Standby
Battery Type	Rechargeable AAA NiMH 1.2 V, 900–1100 mAh
Controls	<p>On/Off illuminated button</p> <p>Mode illuminated button for changing operation modes</p> <p>Intensity +/- buttons to fine-tune intensity level</p> <p>Volume adjustment buttons for audio alerts</p>
Indications	<p>Three status LEDs: Control Unit, RF Stim Unit, and Intelli-Sense Gait Sensor</p> <p>Digital display designates relative stimulation intensity</p> <p>Illuminated buttons designate system operation mode</p> <p>“Beeps” for audio alerts</p>
Carrying Options	In pocket, neck strap, wrist strap, or belt pouch
Dimensions	<p>Length: 73 mm (2.9 in.)</p> <p>Width: 46 mm (1.8 in.)</p> <p>Height: 18 mm (0.7 in.)</p>
Weight	45 grams (1.5 oz.)
Environmental Ranges	<p>Transport and storage temperature: -20°C to +60°C (-4°F to +140°F)</p> <p>Operating conditions temperature: 5°C to 40°C (41°F to 104°F)</p> <p>Charging temperature: 5°C to 40°C (41°F to 104°F)</p> <p>Relative humidity: 25% to 85%</p> <p>Atmospheric pressure: 900 hPa to 1060 hPa</p>

RF Stim Unit Specifications	
Classification	Internally powered, continuous operation with type BF applied parts
Operating Voltage	3.7 V
Battery Type	Proprietary rechargeable Li-Ion (Lithium Ion) 3.7 V, 700 mAh
Indications	Status (fault, battery, charging) and Stimulation LEDs "Beeps" for audio alerts
Dimensions	Length: 74 mm (2.9 in.) Width: 43 mm (1.7 in.) Height: 15 mm (0.6 in.)
Weight	50 grams (1.6 oz.)
Environmental Ranges	Transport and storage temperature: -20°C to +60°C (-4°F to +140°F) Operating conditions temperature: 5°C to 40°C (41°F to 104°F) Charging temperature: 5°C to 40°C (41°F to 104°F) Relative humidity: 25% to 85% Atmospheric pressure: 900 hPa to 1060 hPa

Pulse Parameters						
Pulse	Balanced Biphasic					
Waveform	Symmetric or Asymmetric					
Intensity	0–80 mA, 1mA resolution (positive phase)					
Max Voltage	120 V					
	Symmetric			Asymmetric		
Positive Pulse Duration (µsec)	100	200	300	100	200	300
Negative Pulse Duration (µsec)	100	200	300	400	800	1200
Inter-Phase Interval (µsec)	50			0		
Total Pulse Duration (µsec)	250	450	650	500	1000	1500
Max Load	5000 ohm (Subject to max voltage limitation)					
Pulse Repetition Rate	20–45 Hz (5-Hz resolution)					

Gait Parameters	
Ramp Up	0–2 seconds, 0.1 second resolution
Ramp Down	0–2 seconds, 0.1 second resolution
Extend (Delay)	0–100% of stance time, 10% resolution
Max Duration	2–10 seconds, 1 second resolution
Training Parameters	
On Time	4–20 seconds, 1 second resolution
Off Time	4–60 seconds, 1 second resolution
Ramp Up	0–2 seconds, 1 second resolution
Ramp Down	0–2 seconds, 1 second resolution
Total Time	5–60 minutes

FS Cuff Specifications		
	<i>Regular L300 FS Cuff</i>	<i>Small L300 FS Cuff</i>
Material	Fabric-Polymer	Fabric-Polymer
Fits Limb Circumference	29–51 cm (11–20 in.)	22–31 cm (8-12.2 in.)
Dimensions	Height: 160 mm (6.3 in.) Width: 100 mm (3.9 in.) Depth: 125 mm (4.9 in.)	Height: 110.5 mm (4.5 in.) Width: 80 mm (3 in.) Depth: 100 mm (4 in.)
Weight	Approximately 150 grams (4.8 oz)	Approximately 104 grams (3.6 oz.)

Electrode and Electrode Base Specifications - Regular L300 System	
Regular L300 Hydrogel Electrodes	Two, 45 mm (1.77 in.) diameter, surface area 15.8 cm ² hydrogel electrodes Note: Use only electrodes provided by Bioness Inc
Regular L300 Hydrogel Electrode Bases	Two relocatable polymer electrode bases for individual fitting
Regular L300 Cloth Electrodes	Two, 45 mm (1.77 in.) diameter, surface area 15.8 cm ² non-woven polymer fabric (80% viscose, 20% polypropylene); conductive layer, stainless steel Male snap connector Low Density Polyethylene (LDPE) 10% + Ethylene Vinyl acetate (EVA)
Regular L300 Cloth Electrode Bases	Two, 45 mm (1.77 in.) diameter, relocatable Thermoplastic elastomer (TPE) electrode bases
Regular L300 Quick Fit Electrode (Right - A and Left - A)	Non-woven polymer fabric (80% viscose, 20% polypropylene); conductive layer, stainless steel Male snap connector Low Density Polyethylene (LDPE) 10% + Ethylene Vinyl acetate (EVA) Surface area: 43.2 cm ² \ 55.3 cm ²

Electrode and Electrode Base Specifications - Small L300 System	
Small L300 Hydrogel Electrodes	Two, 36 mm (1.41 in.) diameter, surface area 10.1 cm ² hydrogel electrodes Use only for fitting process Note: Use only electrodes provided by Bioness Inc
Small L300 Electrode Bases	Two, 36 mm (1.41 in.) diameter, relocatable Thermoplastic elastomer (TPE) electrode bases
Small L300 Cloth Electrodes	Two, 36 mm (1.41 in.) diameter, surface area 10.1cm ² non-woven polymer fabric (80% viscose, 20% polypropylene); conductive layer, stainless steel Male snap connector Low Density Polyethylene (LDPE) 10% + Ethylene Vinyl acetate (EVA)
Small L300 Quick Fit Electrode - A	Non-woven polymer fabric (80% viscose, 20% polypropylene); conductive layer, stainless steel Male snap connector Low Density Polyethylene (LDPE) 10% + Ethylene Vinyl acetate (EVA) Surface area: 31.1 cm ² \ 20.6 cm ²
Small L300 Quick Fit Electrode - B	Non-woven polymer fabric (80% viscose, 20% polypropylene); conductive layer, stainless steel Male snap connector Low Density Polyethylene (LDPE) 10% + Ethylene Vinyl acetate (EVA) Surface area: 19.9 cm ² \ 18.2 cm ²

Intelli-Sense Gait Sensor Specifications	
Classification	Internally powered, continuous operation with type BF applied part(s)
Battery Type	Lithium coin cell, CR2430, 280 mAh
Dimensions of the Transmitter	Length: 80 mm (3.2 in.) Width: 50 mm (2.0 in.) Height: 10 mm (0.4 in.)
Weight	35 grams (1.1 oz.)
Environmental Ranges	Transport and storage temperature: -20°C to +60°C (-4°F to 140°F) Operating conditions temperature: 5°C to 40°C (41°F to +104°F) Relative humidity: 25% to 85% Atmospheric pressure: 900 hPa to 1060 hPa

Power Supply Specifications	
Use medical Class II safety approved power supply provided/approved by Bioness Inc with the following ratings:	
Input	
Voltage	100–240 V AC
Current	400 mA
Frequency	50–60 Hz
Output	
Voltage	5 V \pm 5%
Current	2400 mA

Note: Do not use the Control Unit or RF Stim Unit while charging.

Wireless Link Specifications	
Frequency Band	2.4 GHz, ISM band
Transmission Power	Complies with FCC 15.247 (for US)/ETSI EN 300-440 (for Europe) regulations

Appendix - EMI Tables

System Characteristics	
Transmitters	
Operating Frequency Band	2401–2482 MHz
Type of Modulation	FSK
Type of Modulating Signal	Binary data message
Data Rate [=Frequency of Modulating Signal]	250 Kbps
Effective Radiated Power	<10 dBm
Receivers	
Operating Frequency Band	2401–2482 MHz
Receiver Bandwidth	812 kHz around a selected frequency

Guidance and Manufacturer’s Declaration—Electromagnetic Emissions		
The NESS L300 System is intended for use in the electromagnetic environment specified below. The customer or the user of the NESS L300 System should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment –Guidance
RF emissions CISPR 11	Group 1	The NESS L300 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. The NESS L300 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.
RF emissions CISPR 11	Class B	
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 NESS L300 System is intended for use in the electromagnetic environment specified below. The customer or the user of the NESS L300 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	6 kV contact 8 kV air	6 kV contact 8 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 (Class II without any grounded interconnections)	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% 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 NESS L300 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	3 A/m	3 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 NESS L300 System is intended for use in the electromagnetic environment specified below. The customer or the user of the NESS L300 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 NESS L300 System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	$[E_1] = 10 \text{ V/m}$ in 26 MHz to 1 GHz $[E_1] = 3 \text{ V/m}$ in 1 GHz to 2.5 GHz	Recommended separation distance: $d = 0.4\sqrt{P}$, 80–800 MHz range $d = 0.7\sqrt{P}$, 800–1000 MHz range $d = 2.3\sqrt{P}$, 1000–2500 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 NESS L300 System is used exceeds the applicable RF compliance level above, the NESS L300 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 NESS L300 System.

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

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the NESS L300 System

The NESS L300 System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NESS L300 System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NESS L300 System as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter			
	150 kHz to 80 MHz Outside ISM Bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 0.4\sqrt{P}$	800 MHz to 1000 MHz $d = 0.7\sqrt{P}$	1000 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	4.7 in. (0.12 m)	1.6 in. (0.04 m)	2.8 in. (0.07 m)	9.1 in. (0.23 m)
0.1	15 in. (0.38 m)	5.2 in. (0.13 m)	8.7 in. (0.22 m)	2 ft 5 in. (0.73 m)
1	3 ft 11 in. (1.2 m)	15 ft 7 in. (0.4 m)	2 ft 4 in. (0.7 m)	7 ft 7 in. (2.3 m)
10	12 ft 6 in. (3.8 m)	4 ft 2 in. (1.3 m)	7 ft 3 in. (2.2 m)	24 ft 11 in. (7.3 m)
100	39 ft 4 in. (12 m)	13 ft 1 in. (4 m)	23 ft (7 m)	75 ft 6 in. (23 m)

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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

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

