

Electronic Registration

The NESS L300 Plus System components must be electronically registered to each other to communicate wirelessly. The components in your L300 Plus System Kit are registered.

If you have an L300 Plus System Upgrade Kit, bring your upgrade kit and your L300 Foot Drop System to your first fitting session. Your clinician will register your NESS L300 Plus System at your first fitting session.

This section describes the steps to register a replacement L300 Plus Control Unit, Thigh RF Stim Unit, L300 RF Stim Unit, or Intelli-Sense Gait Sensor. If you have any questions, please call the Bioness Client Relations Department, Option 3.

Note: Components can only be *successfully* registered once. Additional attempts will generate an error indication.

Setup:

1. Place the components you are registering close together on a table but not touching. See Figure 10-1.



Figure 10-1: Registration setup.

2. Make certain no other L300 Plus components are within 30 feet of the components you are registering.
3. Connect the components to the system charger set.

To register a replacement L300 Plus Control Unit or RF Stim Unit:






1. Turn off the L300 Plus System.
2. Simultaneously press and hold for three seconds the  mode and  minus buttons. The L300 Plus Control Unit will beep when registration begins.
3. The L300 Plus Control Unit digital display will show  two alternating GREEN arches while registration is in process. See Figure 10-2.



Figure 10-2: Registration digital displays.

4. When registration is complete,  (“C” for complete) will appear in the digital display and the L300 Plus Control Unit indicator will turn GREEN for a few seconds. See Figure 10-2. The L300 Plus Control Unit will beep.

Note: If  (“E” for error) appears in the digital display, an error has occurred. Repeat steps 2 through 4.

5. After registration is complete, turn on your NESS L300 Plus System. If the replacement component is registered, the L300 and Thigh RF Stim Units will turn on. If you see an RF communication failure indication, then repeat the registration procedure.

6. Locate the System ID Number for the NESS L300 Plus System (for example, A334). The System ID Number can be found on the back label of the existing NESS L300 Plus System components.
7. Write the System ID Number on the blank label on the back of the replacement L300 Plus component. See Figure 10-3.

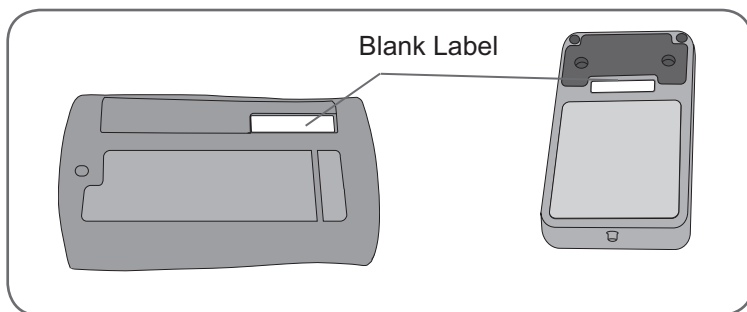






Figure 10-3: L300 Plus Control Unit (left) and RF Stim Unit (right).






CAUTION: Do not turn on the L300 Plus Control Unit if the L300 and Thigh RF Stim Units are not in their cradles.

To register a replacement/additional Intelli-Sense Gait Sensor:

Note: Read steps 1–4 before starting.

1. Turn off the L300 Plus System.
2. Simultaneously press and hold for three seconds the  mode and  minus buttons on the L300 Plus Control Unit. The L300 Plus Control Unit will beep when registration begins.
3. The L300 Plus Control Unit digital display will show  two ALTERNATING GREEN arches while registration is in process.
4. **Within 15 seconds of initiating the registration procedure**, repeatedly press and release the pressure sensor.
5. When registration is complete,  (“C” for complete) will appear in the digital display, the Intelli-Sense Gait Sensor indicator will turn GREEN for a few seconds, and the L300 Plus Control Unit will beep. If registration fails, then repeat the procedure.

Note: If  (“E” for error) appears in the digital display, an error has occurred. Repeat the registration procedure. ( "E" also can mean that the registration procedure was successful on a prior attempt and not noticed.)

6. After registration is complete, turn on the NESS L300 Plus System and select gait mode. Press and release the Intelli-Sense Gait Sensor pressure sensor. If the new Intelli-Sense Gait Sensor is registered, the  mode button will FLASH YELLOW rapidly for four seconds.

7. Locate the System ID Number for the NESS L300 Plus System (for example, A334). The System ID Number can be found on the back label of the existing NESS L300 Plus System components. The System ID Number identifies which NESS L300 Plus System the replacement/additional Intelli-Sense Gait Sensor is registered to. The System ID Number on each component of a NESS L300 Plus System must match.
8. Write the number on the small label on the back of the new Intelli-Sense Gait Sensor. See Figure 10-4.

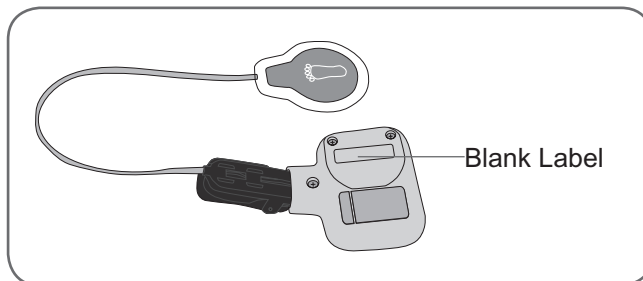


Figure 10-4: Intelli-Sense Gait Sensor.

Technical Specifications

L300 Plus 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	<ul style="list-style-type: none"> • On/Off illuminated button • Mode illuminated button to change operating modes • Intensity +/- buttons to fine-tune intensity level • Mute button to mute audio and visual alerts • RF Stim Unit selection buttons • Stimulation test button
Indications	<ul style="list-style-type: none"> • Seven status LEDs: L300 Plus Control Unit, L300 RF Stim Unit, Thigh RF Stim Unit, Intelli-Sense Gait Sensor, L300 RF Stim Unit and Thigh RF Stim Unit Arrow Indicators, and RF Communication • Numerical display designates relative stimulation intensity • Illuminated buttons designate system operating mode • “Beeps” for audio alerts
Carrying Options	In pocket, neck strap, wrist strap, or belt pouch
Dimensions	Length: 73 mm (2.9 in.); Width: 46 mm (1.8 in.); Height: 18 mm (0.7 in.)
Weight	45 grams (1.5 oz.)
Environmental Ranges	<ul style="list-style-type: none"> • Transport and storage temperature: -25°C to +55°C (-13°F to +131°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: 700 hPa to 1060 hPa

L300 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, 750 mAh
Indications	<ul style="list-style-type: none"> • Status (fault, battery, charging) and Stimulation LEDs • “Beeps” for audio alerts
Dimensions	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Transport and storage temperature: -25°C to +55°C (-13°F to +131°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: 700 hPa to 1060 hPa
Pulse Parameters	
Pulse	Balanced Biphasic
Waveform	Symmetric or Asymmetric
Intensity (Peak)	0–80 mA, 1-mA resolution (positive phase)
Maximum Intensity (rms)	13.2 mA (rms)
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 (%)	0–100% of stance time, 10% resolution					
Max. Duration of Stimulation	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	1–60 minutes					

Thigh 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, 750 mAh
Indications	<ul style="list-style-type: none"> • Status (fault, battery, charging) and Stimulation LEDs • “Beeps” for audio alerts
Dimensions	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Transport and storage temperature: -25°C to +55°C (-13°F to +131°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: 700 hPa to 1060 hPa
Pulse Parameters	
Pulse	Balanced Biphasic
Waveform	Symmetric or Asymmetric
Intensity (Peak)	0–100 mA, 1-mA resolution (positive phase)
Maximum Intensity (rms)	16.5 mA (rms)
Max Voltage	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						
Swing Control Delay (%)	0–100% of phase* time, 5% resolution					
Swing Control End (%)	0–100% of phase* time, 5% resolution					
Stance Control Delay (%)	0–100% of phase* time, 5% resolution					
Stance Control End (%)	0–100% of phase* time, 5% resolution					
Ramp Up	0–2 seconds, 0.1-second resolution					
Ramp Down	0–2 seconds, 0.1-second resolution					
Extend (%)	0–100% of stance time, 10% resolution					
Max. Duration of Stimulation	2–10 seconds, 1-second resolution					
* Stimulation burst can start either on swing or stance phase.						

L300 FS Cuff Specifications	
Material	Fabric-Polymer
Fits Limb Circumference	29–51 cm (11–20 in.)
Dimensions	<ul style="list-style-type: none"> • Height: 160 mm (6.3 in.) • Width: 100 mm (3.9 in.) • Depth: 125 mm (4.9 in.)
Weight	Approximately 150 grams (4.8 oz.)

Thigh FS Cuff Specifications	
Material	Skeleton–TPU; Panel Assemblies and Buckles–Silicone
Fits Limb Circumference	<ul style="list-style-type: none"> • Upper thigh circumference: 53 cm–85 cm (20.9 in.–33.5 in.) • Knee circumference: 33 cm–50 cm (13 in.–19.7 in.) • Thigh length: 24 cm–35 cm (9.4 in.–13.8 in.)
Dimensions	<ul style="list-style-type: none"> • Length: 17 cm–26 cm (6.7 in. – 10.24 in.) • Circumference (minimal): <ul style="list-style-type: none"> • Proximal panel: 42 cm (16.5 in.) • Distal panel, regular: 45 cm (17.7 in.) • Distal panel, large: 51 cm (20.1 in.)
Weight	Approximately 420 grams (14.8 oz.)

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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Transport and storage temperature: -25°C to +55°C (-13°F to +131°F) • Operating conditions temperature: 5°C to 40°C (41°F to 104°F) • Relative humidity: 25% to 85% • Atmospheric pressure: 700 hPa to 1060 hPa

Charger Specifications

Use medical Class II safety approved power supply provided/approved by Bioness 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 NESS L300 Plus System while charging. Do not wear the L300 or Thigh FS Cuffs while charging.

Wireless Link Specifications

Frequency Band	2.4 GHz, ISM band
Transmission Power	Complies with FCC 15.247 (for U.S.) regulations

L300 Electrode and L300 Electrode Base Specifications	
Hydrogel Electrodes	Two 45-mm (1.77-in.) diameter hydrogel electrodes Note: Use only electrodes provided by Bioness Inc.
Hydrogel Electrode Bases	Two relocatable polymer electrode bases
Cloth Electrodes	Two 45-mm (1.77-in.) diameter non-woven fabric/cloth electrodes Note: Use only electrodes provided by Bioness Inc.
Cloth Electrode Bases	Two relocatable polymer electrode bases
Thigh FS Cuff Cloth Electrode Specifications	
Material	Non-woven cloth Note: Use only electrodes provided by Bioness Inc
Dimensions	Proximal: Oval, 130 mm x 75 mm (5.1 in. X 3 in.); Distal: Oval, 120 mm x 63 mm (4.7 in. X 2.5 in.)

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		
<p>The NESS L300 Plus System is intended for use in the electromagnetic environment specified below. The customer or the user of the NESS L300 Plus System should assure that it is used in such an environment.</p>		
Emissions Test	Compliance	Electromagnetic Environment — Guidance
RF emissions CISPR 11	Group 1	The NESS L300 Plus System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The NESS L300 Plus System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

**Guidance and Manufacturer's Declaration—
Electromagnetic Immunity for All Equipment and Systems**

The NESS L300 Plus System is intended for use in the electromagnetic environment specified below. The customer or the user of the NESS L300 Plus 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
<p>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</p>	<p><5% U_T (>95% dip in U_T) for 0.5 cycle</p> <p>40% U_T (60% dip in U_T) for 5 cycles</p> <p>70% U_T (30% dip in U_T) for 25 cycles</p> <p><5% U_T (>95% dip in U_T) for 5 sec</p>	<p><5% U_T (>95% dip in U_T) for 0.5 cycle</p> <p>40% U_T (60% dip in U_T) for 5 cycles</p> <p>70% U_T (30% dip in U_T) for 25 cycles</p> <p><5% U_T (>95% dip in U_T) for 5 sec</p>	<p>Mains power quality should be that of a typical commercial or hospital environment. If the user of the NESS L300 Plus System requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.</p>
<p>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</p>	<p>3 A/m</p>	<p>3 A/m</p>	<p>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</p>

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 Plus System is intended for use in the electromagnetic environment specified below. The customer or the user of the NESS L300 Plus 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 Plus 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 V/m in 26 MHz to 1 GHz [E ₁] = 3 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 Plus System is used exceeds the applicable RF compliance level above, the NESS L300 Plus 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 Plus 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 Plus System

The NESS L300 Plus 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 Plus System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NESS L300 Plus 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.