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Rx Only

602-00382-001 Rev. B

Bioness®
LiveOn®

NESS
L300®Plus

User's Guide

NESS
L300®Plus

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Bioness®

Rx Only

Environmental Policy

Service personnel are advised that when changing any part of the NESS L300 Plus System, care should be taken to dispose of those parts in the correct manner; where applicable, parts should be recycled. For more detailed information regarding these recommended procedures, please contact Bioness Inc. Bioness Inc is committed to continuously seeking and implementing the best possible manufacturing procedures and servicing routines.

Bioness Client Relations Department: Telephone: (800) 211-9136, Option 2; or (661) 362-4850, Option 2.

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Contents

List of Symbols

	Caution or Warning
	Double Insulated (Equivalent to Class II of IEC 536)
	Type BF Applied Part(s)
	Non-Ionizing Radiation
	Date of Manufacture
	Manufacturer
	This Product Must not be Disposed of with Other Household Waste
	Consult Instructions for Use
SN	Serial Number
REF	Re-Order Number
LOT	Lot Number
Intertek 3106069	Complies with United States and Canadian Product Safety Standards
CE 0473	Complies with the European Union Medical Device Directive
	Single Patient Use

1

Introduction

Central nervous system (CNS) injuries and diseases often cause a gait disorder called foot drop. People who have foot drop are unable to raise their foot while walking. They often drag their foot, resulting in instability and increased effort during gait. Many people with CNS injuries/diseases also suffer from thigh muscle weakness. Weak thigh muscles can cause considerable difficulties with flexing or extending the knee during ambulation.

The NESS L300 Plus System is intended to provide ankle dorsiflexion and knee flexion or extension in individuals with foot drop and thigh muscle weakness following an upper motor neuron injury or disease.

This NESS L300 Plus *User's Guide* describes:

- Important safety information about the NESS L300 Plus System.
- The components of the NESS L300 Plus System.
- How to set up, operate, and maintain the NESS L300 Plus System.
- Troubleshooting information.

Be sure to review this guide with your clinician before using the NESS L300 Plus System.

If you have clinical or technical questions, consult your clinician or the Bioness Client Relations Department at (800) 211-9136, Option 3, or visit the Bioness website: www.bioness.com.

CAUTION: Do not put on or operate the NESS L300 Plus System before being properly fitted and trained by a certified clinician.

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Device Description and Safety Information

Device Description

The NESS L300 Plus System consists of four main components:

- **L300 Functional Stimulation (FS) Cuff with L300 Radio Frequency (RF) Stim Unit**—used to stimulate the nerves that control the muscles of the lower leg.
- **Thigh FS Cuff with Thigh RF Stim Unit**—used to stimulate the nerves that control the muscles of the thigh.
- **Intelli-Sense Gait Sensor**—used to sense and wirelessly transmit heel events in the affected leg.
- **L300 Plus Control Unit**—used to wirelessly control and monitor the NESS L300 Plus System.

These components communicate wirelessly to provide synchronized ankle dorsiflexion and knee flexion or extension.

Indications for Use

The NESS L300 Plus System is intended to provide ankle dorsiflexion and knee flexion or extension in individuals with foot drop and thigh muscle weakness following an upper motor neuron injury or disease.

During gait, the NESS L300 Plus System electrically stimulates muscles in the affected leg to provide dorsiflexion of the foot and knee flexion or extension; thus, it may improve the individual's gait.

The NESS L300 Plus System may also:

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

Contraindications

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

Warnings

- The long-term effects of chronic electrical stimulation are unknown.
- The L300 and Thigh FS Cuffs 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 Plus System to the patient and high-frequency surgical equipment may result in skin burns where the stimulator electrodes touch and damage to the L300 and Thigh RF Stim Units.
- The NESS L300 Plus System should only be configured by an authorized clinician.

Precautions

- Inflammation in the region of the L300 and Thigh FS Cuffs may be aggravated by motion, muscle activity, or pressure from the FS Cuffs. Stop using the NESS L300 Plus System until any inflammation is gone.
- Use caution if you have a suspected or diagnosed heart problem.
- Use caution if you have suspected or diagnosed epilepsy.
- Use the L300 and Thigh FS Cuffs with caution:
    - If you have a tendency to bleed heavily following acute trauma or fracture.
    - Following recent surgical procedures when muscle contraction may disrupt the healing process.
    - Over areas of the skin that lack normal sensation.

- Obtain physician clearance prior to use if you have an alteration in normal arterial or venous flow in the region of the L300 and/or Thigh FS Cuffs because of local insufficiency (insufficient blood flow), occlusion (a blood flow blockage), arteriovenous fistula for the purpose of hemodialysis (an abnormal connection between an artery and vein), or a primary disorder of the vasculature (a disease of the blood vessels: arteries, veins, and lymphatics).
- Obtain physician clearance before stimulating an area with a structural deformity.
- The safe use of the NESS L300 Plus System during pregnancy has not been established.
- Keep the NESS L300 Plus System out of the reach of children.
- The L300 and Thigh FS Cuffs are to be worn only on the leg of the patient for whom they have been fitted. They should not be worn by anyone else or on any other part of the body.
- Skin problems where the L300 and Thigh FS Cuffs are worn may be aggravated by the NESS L300 Plus System.
- Some patients may experience a skin irritation, an allergic reaction, or hypersensitivity to the electrical stimulation or the electrical conductive medium. In some cases, irritation may be avoided by having your clinician change the stimulation parameters, type of electrodes used, or electrode placement.
- After removing the L300 and Thigh FS Cuffs, 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. Stop using the NESS L300 Plus System until any irritation is gone.

- Do not use the NESS L300 Plus System without electrodes.
- Use only electrodes supplied by Bioness Inc.
- Change the electrodes at least every two weeks.
- Only the treating clinician should determine electrode placement and stimulation settings.
- Turn off the NESS L300 Plus System before removing, replacing, and wetting the electrodes.
- Turn off the NESS L300 Plus System before putting on the L300 and Thigh FS Cuffs. Do not turn on the NESS L300 Plus System until the FS Cuffs are fastened in place.
- Turn off the NESS L300 Plus System before driving, operating machinery, or performing any activity in which involuntary muscle contractions could injure you.
- Turn off the NESS L300 Plus System when at a refueling place. Do not use the NESS L300 Plus System near flammable fuel, fumes, or chemicals.
- Stop using the NESS L300 Plus System and consult your clinician if stimulation does not start at the correct time during gait.
- Protect all electronic components from contact with water, such as from sinks, bathtubs, shower stalls, rain, snow, etc.
- Do not leave the NESS L300 Plus System stored where temperatures may exceed the acceptable environmental range: -25°C to +55°C (-13°F to +131°F). Temperature extremes can damage the components.
- The NESS L300 Plus 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. See Chapter 3 and the Appendix.

- Do not attempt to repair your NESS L300 Plus System. Changes or modifications to the NESS L300 Plus System components not expressly approved by Bioness Inc could void the user's authority to operate the equipment.

Contact the Bioness Client Relations Department, Option 3, if you experience a clinical or technical problem not covered in this guide.

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

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

Adverse Reactions

In the unlikely event that any of the following occurs, stop using your NESS L300 Plus System immediately and consult your physician:

- Signs of significant irritation or pressure sores where the L300 and/or Thigh FS Cuffs contact 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 NESS L300 Plus System electrodes or the L300 and/or Thigh FS Cuffs.

To promote healthy skin with long-term use of the NESS L300 Plus System, it is important to follow a daily skin-care routine:

- Clean the skin where the electrodes touch 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 L300 and Thigh FS Cuffs.
- Wet the cloth electrodes before use and after every three to four hours of use.

- Replace the electrodes at least every two weeks, even if they appear to be in good condition.
- Store the L300 hydrogel electrodes with the protective plastic covers attached. Do not allow the hydrogel electrodes to dry.
- Store the cloth electrodes where they can air dry.
- Excess body hair where the L300 hydrogel 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 L300 and Thigh FS Cuffs, make sure the electrodes uniformly contact the skin.
- Ventilate the skin by removing the L300 and Thigh FS Cuffs for at least 15 minutes every 3 to 4 hours.

If skin irritation or a skin reaction occurs, stop using your NESS L300 Plus System immediately. Contact your clinician or dermatologist, and the Bioness Client Relations Department, Option 3. Resume use only when the skin is completely healed. Then follow a skin conditioning protocol per the recommendation of your health-care specialist.

If you have any questions or concerns, please call the Bioness Client Relations Department at (800) 211-9136, Option 3.

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Environmental Conditions that Affect Use

Radio Frequency (RF) Communication Information

Several components of the NESS L300 Plus System communicate via radio communication and have been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 (RF Devices) of the FCC (Federal Communications Commission) Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate RF energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

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

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

Conformity Certification

The NESS L300 Plus System complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:

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

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

Travel and Airport Security

The NESS L300 Plus system charger is compatible with Australian, U.K., European Union, and U.S. voltages: 110/220 V, 50/60 Hz.

Turn off your NESS L300 Plus System before going through airport security. Wear loose clothing so that you can easily show the security person your NESS L300 Plus System. The NESS L300 Plus System will likely set off the security alarm. Be prepared to remove the NESS L300 Plus System so that security can scan it, or ask for the system to be scanned if you do not want to remove it. You may want to carry a copy of your NESS L300 Plus System prescription. A prescription can be useful when passing through customs as well.

To request a copy of your prescription, call the Bioness Client Relations Department: 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 Plus System contains radio transmitters. The Federal Aviation Administration rules require that all radio-transmitting devices be turned off during flight.

Electromagnetic Emissions

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

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

- DC power supply as provided by Bioness Inc, manufactured by FRIWO, Part No. FW7555M/05.
- W cable (3-way splitter) as provided by Bioness Inc, Model No. L3P-5A00. Manufactured by Tamuz Electronics Ltd.

Warnings

- Do not use the NESS L300 Plus System within three feet of shortwave or microwave therapy equipment. Such equipment may produce instability in the output of the L300 and Thigh RF Stim Units.
- Remove the NESS L300 Plus System before undergoing any diagnostic or therapeutic medical procedure such as x-ray examination, ultrasound, Magnetic Resonance Imaging (MRI), etc.
- The NESS L300 Plus System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.
- The use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the NESS L300 Plus System as replacement parts for internal components, may result in increased emissions or decreased immunity of the NESS L300 Plus System.

- 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 Plus System.
- The NESS L300 Plus System may be interfered with by other equipment, even if that other equipment complies with CISPR (International Special Committee on Radio Interference, International Electrotechnical Commission) emission requirements.