



NESS L300™ Foot Drop System

Indications, Contraindications, Warnings, Precautions and Adverse Reactions

Indications for Use of the NESS L300™ Foot Drop System

The NESS L300 Foot Drop System is intended for patients with injuries to the central nervous system resulting in a motor deficit of the lower limb(s).

Contraindications

- Patients with a demand-type pacemaker, defibrillator or any electrical or metallic implant should not use the NESS L300™ Foot Drop System.
- The NESS L300 should not be used on the leg if a cancerous lesion is present or suspected.
- The NESS L300 should not be used over areas of regional disorders, such as a fracture or dislocation, which would be adversely affected by motion from the stimulation.

Warnings

- The long-term effects of chronic electrical stimulation are unknown.
- The Functional Stimulation Cuff (Orthosis) should not be applied over swollen, infected, or inflamed areas or skin eruptions, such as phlebitis, thrombophlebitis, varicose veins, and so on.
- Simultaneous connection of the NESS L300 to the patient and to high-frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the RF Stim Unit of the Functional Stimulation Cuff (Orthosis).

- Do not use the NESS L300 in close proximity (less than three feet) to short wave or microwave therapy equipment as it may produce instability in the RF Stim Unit output.
- System configuration should only be performed by an authorized clinician.
- The Clinician's Programmer [Personal Digital Assistant (PDA)] used for programming the NESS L300 Control Unit should only contain the Windows Mobile 5 for Pocket PC operating system and the NESS proprietary software. Third-party software packages are not supported and may interfere with proper operation of the NESS L300™ Foot Drop System, thus voiding the warranty.

Precautions

- Inflammation in the region of the NESS L300 may be aggravated by motion, muscle activity, or pressure from the Functional Stimulation Cuff (Orthosis). Use of the device should be temporarily halted until the inflammation is resolved completely.
- Caution should be used in patients with suspected or diagnosed heart problems.
- Caution should be used in the presence of the following conditions in the area of the Functional Stimulation Cuff (Orthosis):
 - When there is 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.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by changing the stimulation parameters or alternate electrode placement (performed by the treating clinician).
- Electrode placement and stimulation setting should be determined by the treating clinician.

- The NESS L300 should be used only with electrodes supplied by Bioness Neuromodulation Ltd. or Bioness Inc.
- Specific physician clearance should be obtained prior to use in patients with alteration of normal arterial or venous flow in the region of the Functional Stimulation Cuff (Orthosis) due to local insufficiency, occlusion, arterio-venous fistula for the purpose of hemodialysis, or a primary disorder of the vasculature.
- Specific physician clearance should be obtained when there is a structural deformity in the area to be stimulated.
- The safety of the NESS L300's use during pregnancy has not been established.
- Skin problems in areas of contact with Functional Stimulation Cuff (Orthosis) may be aggravated by use of the NESS L300.
- The NESS L300 should be turned off before removing or replacing the electrodes.
- The NESS L300 should be kept out of the reach of children.
- The NESS L300 Control Unit is splash proof. However, it should be protected from any contact with water, such as water from sinks, bathtubs, and shower stalls, from weather such as rain or snow, or any other source of water.
- Do not leave the NESS L300 stored in a car in hot or cold weather where the temperature may exceed the recommended storage temperatures of -20 to 60°C (-4 to 140°F) and could cause damage to the device.
- Should any technical problem occur that is not covered in the Troubleshooting section of the NESS L300 User's Guide, contact Bioness Inc. Do not attempt to repair the NESS L300.
- The Functional Stimulation Cuff (Orthosis) is meant to be worn only on the leg of the patient for whom it is fitted. It should not be applied to anyone else or any other part of the body.
- Put on the Functional Stimulation Cuff (Orthosis) only when the NESS L300 is turned off. Do not activate it until it is fastened in place.
- The system should be shut off while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the patient at undue risk of injury.

- Medical electrical equipment needs special precautions regarding Electromagnetic Compatibility (EMC).
- In order to avoid condensation problems, when moving the NESS L300 between hot and cold temperatures, place the NESS L300 in an airtight plastic bag and let it slowly adjust to the temperature changes (at least 2 hours) before using the system.

Adverse Reactions

In the unlikely event of any of the following occurrences, the patient should stop using the NESS L300 immediately and consult his/her personal physician:

- Signs of significant skin irritation or pressure sores on the limb in areas of contact with the Functional Stimulation Cuff (Orthosis).
- 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.

Should any technical problem occur, patients should contact their clinician or Bioness Inc. No attempt should be made by a patient to repair the NESS L300™. Should any clinical problem occur, patients should contact their clinician and the clinician should then contact Bioness Inc.

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