



## **NESS H200<sup>®</sup> Hand Rehabilitation System**

### **Indications, Benefits, Contraindications, Adverse Reactions and Precautions**

#### **Indications for Use of the NESS H200<sup>®</sup> Hand Rehabilitation System**

The NESS H200 Hand Rehabilitation System is intended for patients with injuries to the central nervous system resulting in a motor deficit of the upper limb(s).

#### **Clinical Benefits**

- Improving Hand Active Range of Motion and Hand Function\*
- Improving Voluntary Movement
- Re-Educating Muscles
- Maintaining or Increasing Range of Motion, Resulting in the Prevention of Contractures
- Preventing or Retarding Disuse Atrophy
- Increasing Local Blood Circulation
- Reducing Muscle Spasm

\* In hemiplegia due to stroke and/or tetraplegia due to C5 spinal cord injury

#### **Contraindications**

- Patients with a demand-type cardiac pacemaker should not use the NESS H200.
- Stimulation should not be applied directly over the area of a malignant tumor.
- The NESS H200 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.

- Do not use the NESS H200 simultaneously with high-frequency surgical equipment.
- Do not use the NESS H200 in proximity (less than 1 meter) to short wave or microwave therapy equipment.

### **Adverse Reactions**

In the unlikely event of any of the following occurrences, instruct your patient to stop using the NESS H200 immediately and consult his or her personal physician.

- Signs of significant skin irritation or pressure sores on the limb in areas of contact with the Orthosis
- A significant increase in muscle spasticity
- A feeling of heart-related stress during stimulation
- Swelling of the hand, wrist or forearm
- Any other unanticipated reaction

### **Precautions**

- Inflammation in the region of the NESS H200 may be aggravated by motion, muscle activity or pressure from the Orthosis. Use of the device should be temporarily halted until the inflammation clears.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Specific physician clearance should be obtained prior to use in patients with alteration of normal arterial or venous flow due to local insufficiency, occlusion, arterio-venous fistula for the purpose of hemodialysis, or primary disorder of the vasculature.
- Specific physician clearance should be obtained when there is a structural deformity or placement of metal implant in the area to be stimulated.
- Specific physician clearance should be obtained prior to use in patients with implantable cardiac defibrillators (ICDs); those patients cleared to use the

NESS H200 should be followed closely by the relevant physician to ensure continued proper functioning of their ICD devices.

- The safety of the NESS H200 during pregnancy has not been established.
- Skin problems in areas of contact with the Orthosis may be aggravated by use of the NESS H200.
- The NESS H200 should be turned OFF before removing or replacing electrode pads.
- The NESS H200 should be kept out of the reach of children.
- The NESS H200 control unit is splash proof. However, it should be protected from any contact with water, such as dampness from sinks, bathtubs and shower stalls, from weather such as rain and snow, or from any other source of water. Always keep the control unit at a safe distance while wetting the electrode pads.
- Do not leave the NESS H200 stored in a car in hot weather where the temperature may exceed the recommended storage temperature and could cause damage to the device.
- Stimulation should not be applied over areas of “natural reflexes” (e.g. carotid sinus, heart, parasympathetic nerves, laryngeal muscles, phrenic nerve).
- Stimulation should not be applied over fixed contracture(s).
- If stimulation causes cardiac irregularity, stop stimulation.
- Patients should not drive or operate heavy or dangerous machinery while using the device.
- Any noxious stimulation can trigger autonomic dysreflexia in patients with spinal cord injury at the T6 level and above (acute hypertension and bradycardia).
- Caution should be taken when using very strong electrical stimulation over superficial bony prominences.
- Caution should be used for patients with implanted intrathecal/intravascular drug delivery systems. During initial trials with the H200, clinicians should monitor carefully patients on intraspinal/intravascular therapy for any new

neurological or other medical signs or symptoms. Those clinicians should be advised to inform patients of the signs and symptoms of drug underdose or overdose. Clinicians and patients also should be advised to follow programming guidelines and precautions provided in the relevant drug delivery systems' product manuals.

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 H200<sup>®</sup>. Should any clinical problem occur, patients should contact their clinician and the clinician should then contact Bioness Inc.



## **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.