

Safety Information

L300 Go System

Indications for Use

The L300 Go System is intended to provide ankle dorsiflexion in adult and pediatric individuals with foot drop and/or to assist knee flexion or extension in adult individuals with muscle weakness related to upper motor neuron disease/injury (e.g., stroke, damage to pathways to the spinal cord). The L300 Go System electrically stimulates muscles in the affected leg to provide ankle dorsiflexion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait.

The L300 Go System may also:

- Facilitate muscle re-education
- Prevent/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 implant should not use the L300 Go System.
- The L300 Go System should not be used on a leg where a metallic implant is directly underneath the electrodes.
- The L300 Go System should not be used on a leg where a cancerous lesion is present or suspected.
- The L300 Go 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 lower leg FS Cuff and thigh 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 L300 Go System to the patient and high frequency surgical equipment may result in skin burns where the stimulator electrodes touch and damage to the EPG.
- Do not use the L300 Go System within three feet of short wave or microwave therapy equipment. Such equipment may produce instability in the EPG output.
- The L300 Go System should only be configured by an authorized clinician.
- In case of any inconvenience, turn off stimulation and remove the lower leg FS Cuff and/or thigh FS Cuff. If the stimulation cannot be turned off, remove the FSC to stop stimulation.

Precautions

- Inflammation in the region of the lower leg FS Cuff and thigh FS Cuff may be aggravated by motion, muscle activity, or pressure from the cuff. Stop using the L300 Go 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 lower leg FS Cuff and thigh FS Cuff 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.
 - If you have suspected or diagnosed epilepsy.
- Some patients may experience a skin irritation, an allergic reaction, or hypersensitivity to the electrical stimulation or the electrical conductive medium. Irritation may be avoided by having your clinician change the stimulation parameters, type of electrodes, or electrode placement.
- Do not use the L300 Go System without electrodes.
- After removing the lower leg FS Cuff and/or thigh 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. Alert your clinician and stop using the L300 Go System until any inflammation is gone.
- Stop using the L300 Go System and consult your clinician if stimulation does not start at the correct time during gait.
- Turn off the L300 Go System when at a refueling place. Do not use the L300 Go System near flammable fuel, fumes, or chemicals.
- Only your treating clinician should determine electrode placement and stimulation settings.
- Use only the L300 Go System electrodes supplied by Bioness Inc.
- Turn off the L300 Go System before removing or replacing the electrodes.
- Obtain physician clearance prior to use if you have an alteration in normal arterial or venous flow in the region of the FSC because of local insufficiency, occlusion, arteriovenous fistula for hemodialysis, or a primary disorder of the vasculature.
- Obtain physician clearance before stimulating an area with a structural deformity.
- The safe use of the L300 Go System during pregnancy has not been established.
- Skin problems, on the leg where the lower leg FS Cuff and/or thigh FS Cuff is worn, may be aggravated by the L300 Go System.
- Adult supervision and assistance should be provided for anyone needing help while using the L300 Go System.
- The patient is the intended operator of the L300 Go System.
- The Control Unit neck strap is meant to be worn around the neck and if not used properly could cause bodily harm.
- Protect all electronic components from contact with water, such as from sinks, bathtubs, shower stalls, rain, snow, etc.

- Do not leave the L300 Go 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.
- Do not attempt to repair your L300 Go System. Contact Bioness if you experience a technical problem not covered in this guide.
- The lower leg FS Cuff and thigh 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 L300 Go System before putting on the lower leg FS Cuff and/or thigh FS Cuff. Do not turn on the L300 Go System until the lower leg FS Cuff and/or thigh FS Cuff is fastened in place.
- Shut off the L300 Go System before driving, operating machinery, or performing any activity in which involuntary muscle contractions could injure you.
- Protect the L300 Go System electronic components from condensation. 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.
- Remove the L300 Go System before undergoing any diagnostic or therapeutic medical procedure such as Xray examination, ultrasound, MRI, etc.
- Keep away from pets and pests. While not in use, keep away from children.
- For pediatric use and indications consult the user manual. Care should be taken when removing small parts from the system, which may be accidentally swallowed. If swallowed, consult a doctor immediately.
- Do not modify or alter the system in any way and only use Bioness supplied or approved components and parts.
- While the L300 Go (small lower cuff) is designed to fit and be worn by both pediatric patients and small individuals, the system is intended to be managed and maintained only by adult users, adult caregivers and/or healthcare professionals.

Adverse Reactions

In the unlikely event that any of the following occurs, stop using your L300 Go System

immediately and consult your 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 beneath the electrodes 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 lower leg FS Cuff and thigh FS Cuff. To promote healthy skin with long-term use of the L300 Go System, it is important to 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 lower leg FS Cuff and/or thigh FS Cuff.
- Replace the electrodes at least every two weeks, even if they appear to be in good condition.
- If using cloth based electrodes before use and after every 3-4 hours wet for optimal performance.
- After taking off the lower leg FS Cuff and/or thigh 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 lower leg FS Cuff and/or thigh FS Cuff, make sure the electrodes uniformly contact the skin.
- Ventilate the skin by removing the lower leg FS Cuff and thigh FS Cuff for at least 15 minutes every three to four hours.
- If skin irritation or a skin reaction occurs, stop using your L300 Go System immediately and contact your clinician or dermatologist. You can also contact Bioness Technical Support at 800.211.9136, Option 3. Resume use only when the skin is completely healed, and then follow a skin conditioning protocol per the recommendation of your health-care specialist.

Environmental Conditions that Affect Use

Radio Frequency (RF) Communication Information Several components of the L300 Go 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 may affect the L300 Go System

Conformity Certification

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

- This device may not cause harmful interference.
- 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 L300 Go System charger with interchangeable charging adapters is compatible with Australian, U.K., European Union, and U.S. voltages: 100-240V, 50/60 Hz. Turn off your L300 Go System before going through airport security. Wear loose clothing so that you can easily show the security person your L300 Go System. The L300 Go System will likely set off the security alarm. Be prepared to remove the L300 Go System so that security can scan it, or ask for the system to be scanned if you do not want to remove it. It is recommended that you carry a copy of your L300 Go System prescription. To request a copy of your prescription, contact Bioness or your physician. Note: The L300 Go System contains radio transmitters. The Federal Aviation

Administration rules require that all radio-transmitting devices be turned off during flight.

Safety Information

H200 Wireless System

Indications for Use

The H200 Wireless System is an electrical stimulation device indicated for the following uses:

Functional Electrical Stimulation (FES)

Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury.

NeuroMuscular Electrical Stimulation (NMES)

- Maintenance and/or increase of hand range of motion.
- Prevention and/or retardation of disuse atrophy.
- Increase in local blood circulation.
- Reduction of muscle spasm.
- Re-education of muscles.

Contraindications

- Do not use the H200 Wireless System where a cancerous lesion is present or suspected.
- Do not use the H200 Wireless System if you have a cardiac pacemaker, implanted defibrillator, or implanted metallic device in the forearm or hand intended for the H200 Wireless use. Use of the H200 Wireless System in conjunction with any of the above may cause electric shock, burns, electrical interference, or death.
- Do not use the H200 Wireless System on an arm where a regional disorder, such as a fracture or dislocation, would be adversely affected by motion from the stimulation.

Warnings

- The H200 Wireless Orthosis is to be worn only on the affected forearm and hand of the patient for whom it is fitted. It should not be worn by anyone else or on any other part of the body.
- Do not wear the H200 Wireless Orthosis over swollen, infected, or inflamed areas. Do not wear the Orthosis over skin eruptions, such as phlebitis, thrombophlebitis, and varicose veins.
- Apply stimulation to normal, intact, clean, healthy skin only.
- Turn off the H200 Wireless System before driving or operating machinery.
- Turn off stimulation before performing any activity in which involuntary muscle contractions may injure you.
- Do not use the H200 Wireless System while sleeping.
- Only trained clinicians should fit and program the H200 Wireless System.
- If the H200 Wireless Orthosis overheats, turn off stimulation and remove the Orthosis.
- If stimulation cannot be turned off using the H200 Wireless Control Unit or the trigger button on the H200 Wireless Orthosis, remove the Orthosis to stop stimulation.
- Electrical and wireless medical equipment need special precautions for electromagnetic compatibility and immunity. See Chapter 3 and the Appendix for more information.

Adverse Reactions

In the unlikely event that any of the following occurs, stop using your H200 Wireless System immediately and talk to your doctor or clinician.

- Signs of significant irritation or pressure sores where the H200 Wireless Orthosis contacts the skin.
- 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.

Skin irritations and burns beneath the stimulating electrodes have been reported with the use of powered muscle stimulators.

Precautions

- The long-term effects of chronic electrical stimulation are unknown.
- Use caution if you have suspected or diagnosed heart problems. Talk to your doctor before using the H200 Wireless System. The H200 Wireless System may cause lethal rhythm disturbances to the heart in susceptible individuals.
- Talk to your doctor if you have a spinal cord injury at the T6 level or above. Any harmful stimulation can trigger autonomic dysreflexia in patients with spinal cord injury at the T6 level and above. Symptoms of autonomic dysreflexia include acute hypertension and slow heart rate (bradycardia).
- Use caution if you have suspected or diagnosed epilepsy.
- Talk to your doctor before using the H200 Wireless System if you have any one of the following medical conditions in the affected arm:
 - 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 for the purpose of hemodialysis treatment).
 - Primary disorder of the vasculature (a disease of the arteries, veins, and lymphatics).
 - A bone deformity in the area to be stimulated.
- The safety of using the H200 Wireless System during pregnancy has not been established.
- Keep the H200 Wireless System out of the reach of children.
- Use the H200 Wireless Orthosis 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.
- Motion, muscle activity, and pressure from the H200 Wireless Orthosis may aggravate any inflammation near the Orthosis. Stop using the H200 Wireless System until any inflammation is gone.
- Always check the skin for redness or a rash when putting on and taking off the H200 Wireless Orthosis.

- After removing the H200 Wireless Orthosis, it is normal for the areas under the cloth 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 H200 Wireless System until any irritation is completely gone.
- Turn off the H200 Wireless System before putting on or taking off the Orthosis. Do not turn on the H200 Wireless System until the Orthosis is on the arm and the wing is closed.
- Turn off the H200 Wireless System when at a refueling place. Do not use the H200 Wireless System near flammable fuel, fumes, or chemicals.
- Turn off the H200 Wireless System before removing or replacing the cloth electrodes.
- Remove the H200 Wireless Orthosis before wetting the cloth electrodes.
- The H200 Wireless Orthosis is splash proof. Nevertheless, protect all electronic components from contact with water, such as from sinks, bathtubs, shower stalls, rain, and snow.
- Excess body hair where the H200 Wireless cloth electrodes touch 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.
- Use only H200 Wireless cloth electrodes supplied by Bioness Inc.
- Do not use the H200 Wireless System without the cloth electrodes.
- Be sure the H200 Wireless cloth electrodes are wet and securely attached to the electrode bases before use.
- Wet the H200 Wireless cloth electrodes before use and after every three to four hours of use.
- Replace the H200 Wireless cloth electrodes at least every two weeks, even if they appear to be in good condition.
- Always store the H200 Wireless cloth electrodes where they can air dry.
- When putting on the H200 Wireless Orthosis, make sure the cloth electrodes uniformly contact the skin.
- Ventilate the skin by removing the H200 Wireless Orthosis for at least 15 minutes every 3 to 4 hours.
- Store the H200 Wireless Orthosis where it can air dry.
- Do not store the H200 Wireless System where temperatures may exceed the recommended storage temperature range: -25°C (-13°F) to +70°C (+158°F). Temperature extremes can damage the components.

If skin irritation or a skin reaction occurs, stop using your H200 Wireless System immediately and contact your clinician or dermatologist. Also contact the Bioness Client Relations Department: 800.211.9136, Option 3 (in the United States) or your local distributor (outside the United States). Resume use only when the skin is completely healed. Then follow a skin conditioning protocol, per the recommendation of your health-care specialist.

Radio Frequency (RF) Communication

Several components of the H200 Wireless System communicate via radio communication. They have been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 (RF Devices) of the Federal Communications Commission (FCC) 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. If not installed and used according to the instructions, it may cause harmful interference with 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, try one or more of the following corrective measures:

- Reorient or move the receiving antenna.
- Increase the separation distance between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or technician for assistance.
- The antenna for each transmitter must not be near to or operating in conjunction with any other antenna or transmitter.
- Portable and mobile RF communications equipment can affect the H200 Wireless System.

Conformity Certification

The H200 Wireless System complies with Part 15 of the FCC regulations. 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.

Note: FCC regulations provide that changes or modifications not expressly approved by Bioness Inc. could void authority to operate.

Travel and Airport Security

The H200 Wireless System charger is compatible with Australian, U.K., European Union, and U.S. voltages: 100-240 VAC, 50/60 Hz. Turn off your H200 Wireless System before going through airport security. Wear loose clothing so that you can easily show the security person your H200 Wireless System. The H200 Wireless System will likely set off the security alarm. Be prepared to remove the H200 Wireless 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 H200 Wireless 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 3; or your local distributor. A Bioness representative can fax or mail you a copy.

Note: The H200 Wireless System contains radio transmitters. The Federal Aviation Administration rules require that all radio-transmitting devices be turned off during flight.