

# Device Description and Safety Information

## Device Description

The **NESS H200 Wireless System** consists of an Orthosis and a wireless handheld Control Unit. See Figure 2-1.

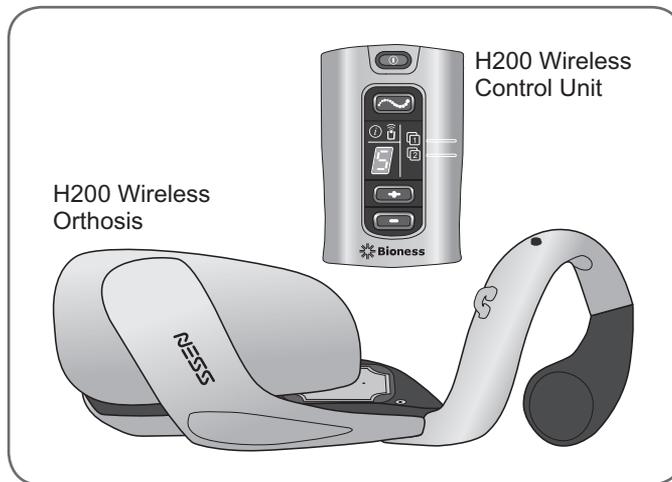


Figure 2-1: H200 Wireless Orthosis and Control Unit.

**H200 Wireless Orthosis**—delivers electrical stimulation to the nerves of the muscles that control hand opening and closing and movement of the thumb. The Orthosis also stabilizes the wrist.

**H200 Wireless Control Unit**—is lightweight and easy to operate. The handheld Control Unit communicates wirelessly with the H200 Wireless Orthosis to:

- Select a stimulation program.
- Adjust stimulation intensity.
- Start, stop, and pause a stimulation program.
- Communicate Control Unit battery status, RF communication errors, and Control Unit hardware/software malfunctions.

## **Indications for Use**

**The NESS 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 NESS H200 Wireless System where a cancerous lesion is present or suspected.
- Do not use the NESS H200 Wireless System if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Use of the NESS H200 Wireless System in conjunction with any of the above may cause electric shock, burns, electrical interference, or death.
- Do not use the NESS 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 or varicose veins.
- Apply stimulation to normal, intact, clean, healthy skin only.
- Turn off the NESS 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 NESS H200 Wireless System while sleeping.
- Only an authorized clinician should fit and program the NESS H200 Wireless System.

- Do not attempt to repair or modify the NESS 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 NESS H200 Wireless System. The NESS 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.
- Use caution if you have suspected or diagnosed epilepsy.
- Talk to your doctor before using the NESS 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 NESS H200 Wireless System during pregnancy has not been established.
- Keep the NESS 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 H200 Wireless Orthosis. Stop using the NESS 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 NESS H200 Wireless System until any irritation is completely gone.
- Turn off the NESS H200 Wireless System before putting on or taking off the Orthosis. Do not turn on the NESS H200 Wireless System until the Orthosis is on the arm and the wing is closed.
- Turn off the NESS H200 Wireless System when at a refueling place. Do not use the NESS H200 Wireless System near flammable fuel, fumes, or chemicals.
- Turn off the NESS H200 Wireless System before removing or replacing the cloth electrodes.
- Remove the H200 Wireless Orthosis before wetting the cloth electrodes.

- The H200 Wireless Control Unit and Orthosis are 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 NESS 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 NESS 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. Contact your clinician or dermatologist, and the **Bioness Client Relations Department: (800) 211-9136, 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.