NESS H200®
Hand Rehabilitation System

User’s Guide

Bioness®
Rx Only
User’s Guide

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Service personnel are advised that when changing any part of the NESS H200, care should be taken to dispose of those parts in the correct manner; where applicable, parts should be recycled. When the life cycle of the NESS H200 has been completed, the product should be discarded according to the laws and regulations of the local authority. 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.

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Stroke and other disorders of the central nervous system may lead to long-term disability. For many people, long-term disability may impair muscle control, reduce muscle function, increase muscle spasm, and reduce muscle strength. Other complications may include muscle tightening, swelling, and pain.

The NESS H200 Hand Rehabilitation System is designed to treat the complications associated with upper limb impairment caused by stroke and other disorders of the central nervous system. The NESS H200 Hand Rehabilitation System electronically activates certain muscle groups of the forearm and hand to open and close the hand, helping those who are impaired improve hand function and perform tasks of daily living.

**Clinical Benefits**

- Improve hand active range of motion.
- Improve hand function in hemiplegia and/or tetraplegia due to stroke and C5 spinal cord injury.
- Improve voluntary movement.
- Reduce muscle spasm.
- Re-educate muscles.
- Maintain or increase range of motion, resulting in the prevention of contractures.
- Prevent or retard disuse atrophy.
- Increase local blood circulation.
**System Components**

The NESS H200 Hand Rehabilitation System consists of an ergonomically designed electronic Orthosis for the hand and forearm, and an easy-to-use Control Unit. The Orthosis holds the wrist in a functional angle while stimulating the peripheral nerves. It thereby activates the muscle groups of the forearm and hand.

**System Features**

- The NESS H200 Orthosis features five stimulating electrodes.
- The Orthosis is designed to ensure constant and snug contact of each electrode during limb motion and muscle contraction.
- The NESS H200 Control Unit is portable and rechargeable.
- The Control Unit also features a variety of operating programs for muscle training and function.

This *User's Guide* describes how to use your NESS H200 to achieve maximum benefit. Be sure to read all of this guide and have your clinician explain the information in it. If you have any questions, consult your clinician and the NESS H200 Technical and Clinical Support Department at (800) 211-9136, Option 3.
For Your Health and Safety

Indications for Use
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).

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.
- Do not use the NESS H200 over an area with a regional disorder, such as a fracture or dislocation, that 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 within three feet of shortwave or microwave therapy equipment.

Adverse Reactions
In the unlikely event that any of the following occurs, stop using the NESS H200 immediately and consult your physician and the NESS H200 Technical and Clinical Support Department at (800) 211-9136, Option 3.
- Signs of significant skin irritation or pressure sores where the 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.

**Precautions**

- Inflammation in the region of the NESS H200 Orthosis may be aggravated by motion, muscle activity, or pressure from the Orthosis. Stop using the NESS H200 until the inflammation clears.

- Use caution when treating patients who have suspected or diagnosed epilepsy.

- Before using the NESS H200, patients should be cleared by a doctor if they have been previously diagnosed with abnormal arterial or venous blood flow (such as venous insufficiency or blood clots) or an abnormal blood vessel structure, or if they have a permanent fistula (an access or entry) that is used for getting the blood to a hemodialysis machine.

- Obtain specific physician clearance when a structural deformity (for example, an irregularity of the bone or skin that might irritate the skin beneath the electrode sites) or a metal implant is in the area to be stimulated.

- Obtain specific physician clearance prior to use in patients with an implantable cardiac defibrillator (ICD); patients cleared to use the NESS H200 should be followed closely by their physician to ensure their ICD functions properly.

- The safety of using the NESS H200 during pregnancy has not been established.

- Skin problems where the skin contacts the Orthosis may be aggravated by use of the NESS H200.
• Turn off the NESS H200 before removing or replacing the electrode pads.

• Keep the NESS H200 out of the reach of children.

• The NESS H200 Control Unit is splash proof only. Always protect it from any contact with water, such as from sinks, bathtubs, shower stalls, rain, and snow. Always keep the Control Unit away from any water used to wet the electrode pads.

• Do not store the NESS H200 where temperatures could exceed 60°C (140°F) or fall below -20°C (-4°F ). Temperature extremes could damage the device.

• During the first month of use and after a long period of non-use, gradually increase the duration of daily exercise sessions by five minutes each day to avoid muscle over-fatigue. Your clinician will outline how long and how many times per day you should use the NESS H200.

• To avoid injury, do not use the NESS H200 to grasp knives or other dangerous objects without your clinician’s approval.

• Do not apply stimulation over areas of natural reflexes (for example, carotid sinus, heart, parasympathetic nerves, laryngeal muscles, phrenic nerve).

• Do not apply stimulation over fixed contracture(s).

• If stimulation causes cardiac irregularity, stop the stimulation.

• Do not drive or operate heavy or dangerous machinery while using the NESS H200.

• Any noxious stimulation can trigger autonomic dysreflexia in patients with spinal cord injury at the T6 level and above (acute hypertension and bradycardia).

• Use caution when applying 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 NESS 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 system product manual.

Should a technical problem occur, contact your clinician or the NESS H200 Technical and Clinical Support Department at (800) 211-9136, Option 3. Do not attempt to repair your NESS H200.
Your NESS H200 System Kit

Contents

- Orthosis
- Control Unit
- Control Unit Strap
- Battery Charger
- Electrodes
- Electrode Pads
- Electrode Screw and Washer Set
- Carrying Case
- User's Guide
- User's Instruction Card
Orthosis

The NESS H200 Orthosis is used to maintain the wrist in a functional position while providing electrical stimulation to open and close the hand. The Orthosis features five stimulating electrodes, a main body with a spiral end and wrist bridge, and a wing that opens. See Figure 1. The Orthosis is easy to put on and take off.

The NESS H200 Orthosis is designed to ensure constant and snug contact of each electrode during limb motion and muscle contraction.

Figure 1: Features of the NESS H200 Orthosis.
Figure 2: Details of the Orthosis main body.

Main Body

The Orthosis main body includes a front spiral end that wraps around the wrist (the wrist bridge), a central main body that cradles the forearm, and a cable end. See Figure 2.

The spiral end (See Figure 3) includes an indicator light that flashes when the Control Unit battery charge level is low or when stimulation is on. The spiral end also includes an attachment bar and an attachment ring for attaching the wrist strap. Medium and small orthoses also have a stimulation trigger button on the wrist bridge, used to turn on/off stimulation.

The cable end is where the Orthosis cable is attached. The cable connects the Orthosis to the Control Unit.
Figure 3: Details of the Orthosis spiral end (two views).
**Wing**

The Orthosis wing swivels open and closed so that the Orthosis can be put on and taken off easily. The wing features two electrodes, a wing arm, and a release handle. See Figure 4. The wing arm is used to close the wing. The release handle is used to open the wing. The release handle is located under the wing arm.

![Diagram of the Orthosis wing](image)

**Figure 4:** Details of the Orthosis wing (two views).
Electrodes

The Orthosis features five stimulating electrodes. Two are attached to the wing, one is attached to the spiral end, and two are attached to the central main body. See Figure 5.

Figure 5: The five Orthosis electrodes (numbered 1–5).
Control Unit

The Control Unit is used to select an operating mode, turn on/off stimulation, adjust stimulation intensity level, and adjust thumb flexion. See Figure 6.

The Control Unit has six operating buttons, a thumb lever, a display screen, and a rechargeable battery. The Control Unit also has an enclosed clinical panel for clinician use only.

The Orthosis and battery charger cables connect to the Control Unit by way of the cable connector socket.

Figure 6: Details of the Control Unit.
**Operating Buttons**

The Control Unit has six operating buttons. See Table 1.

<table>
<thead>
<tr>
<th>Display</th>
<th>Description</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ON OFF]</td>
<td>On/Off Button</td>
<td>Turn On/Off the Control Unit</td>
</tr>
<tr>
<td>[MODE]</td>
<td>Mode Button</td>
<td>Select an Operating Mode; Monitor Training Time; Check Battery Status</td>
</tr>
<tr>
<td>[+]</td>
<td>Intensity Adjustment Increase (Plus) Button</td>
<td>Increase Stimulation Intensity Level</td>
</tr>
<tr>
<td>[−]</td>
<td>Intensity Adjustment Decrease (Minus) Button</td>
<td>Decrease Stimulation Intensity Level</td>
</tr>
<tr>
<td>[TRIGGER]</td>
<td>Stimulation Trigger Button</td>
<td>Start/Stop Stimulation</td>
</tr>
<tr>
<td>[CABLE]</td>
<td>Cable Release Button</td>
<td>Release the Orthosis Cable and Battery Charger Cable</td>
</tr>
</tbody>
</table>

Table 1: Control Unit operating buttons.
**Thumb Lever**

The Control Unit thumb lever is used to adjust stimulation for balancing thumb movement. The thumb lever has three positions: up, down, and middle.

- Slide the thumb lever up to flex the mid-joint of the thumb. See Figure 7.
- Slide the thumb lever down to relax the thumb at the mid-joint and flex the thumb at the base. (Your thumb will move toward your palm.) See Figure 8.
- Slide the thumb lever to the middle to balance thumb movement. See Figure 9.

![Thumb Lever](image)

Figure 7: Thumb lever up: flexes the mid-joint of the thumb.

**Note!**

Your clinician will help you adjust thumb movement.
Figure 8: Thumb lever down: relaxes the thumb at the mid-joint and flexes the thumb at the base.

Figure 9: Thumb lever middle: balances thumb movement.
Display Screen

The display screen is used to monitor the battery status, the operating mode, the stimulation activity submode, whether stimulation is on or off, the stimulation speed, the stimulation intensity level, and the training time. See figures 10 and 11.

Figure 10: Sample display screen: battery charging; charge level "0".

Figure 11: Sample display screen: Personal Mode.
Operating Mode
In Figure 11, the displayed operating mode is "\[●●●●\]". To change the operating mode, turn off stimulation and press the \[MODE\] mode button until the desired operating mode appears in the display screen.

Stimulation Activity Submode
When the Control Unit is in Personal Mode, the training program cycles through a series of programmed stimulation activity submodes and then shuts down. In Figure 11, the displayed stimulation activity submode is "EXERCISE".

Stimulation On/Off
When stimulation is on, the stimulation on/off indicator will flash one to three dashes (● ● ●). When stimulation is off, the on/off indicator will not flash.

Fast Speed On/Off and Speed
When Fast Speed is on, "FAST" will appear in the display screen along with the speed of the pulsed movements (for example, "FAST2").

Stimulation Intensity Level
In Figure 11, the displayed stimulation intensity level is "6". To increase or decrease the stimulation intensity level, press the \[+\] plus or \[-\] minus button.

Training Time
In Figure 11, the displayed training time is "00". Training time is the number of minutes you have been training with your NESS H200 in the operational mode that appears on the display screen.
Operating Modes

The NESS H200 has seven operating modes, used for training and functional movement. See Table 2.

The training modes are used to exercise your hand and to improve control of arm and hand function. Many of the training modes can operate at normal or Fast Speed. Fast Speed has a more vigorous effect than normal speed.

Your clinician will specify how long and how many times per day you should exercise with the NESS H200. During the first month of use and after a long period of non-use, you will need to build your exercise program gradually (by five minutes per day) to avoid muscle fatigue.

The functional modes are used to grasp and release objects. Consult your clinician before using the NESS H200 to grasp knives or other dangerous objects.

Personal Mode

Personal Mode activates a programmed sequence of stimulation activities (submodes). These activities are training exercises and functional movements designed to imitate the natural movements of your hand. Personal Mode includes hand opening and closing exercises, rapid hand opening and closing exercises, and sensory stimulation. Exercises are interspersed with short periods of relaxation.

When the Personal Mode activities finish, stimulation shuts down automatically.

Exercise Mode

Exercise Mode consists of repetitive hand opening and closing exercises, with a relaxation pause between exercises.

Fast Exercise Mode consists of pulsed hand opening and closing exercises with a relaxation pause between exercises.
## Table 2: Control Unit operating modes and descriptions.

<table>
<thead>
<tr>
<th>Operating Mode Display</th>
<th>Type</th>
<th>Description</th>
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<tbody>
<tr>
<td>PERSONAL</td>
<td>Training</td>
<td>Personal Mode: A programmable sequence of varying hand exercises.</td>
</tr>
<tr>
<td>●●●●●</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EXERCISE</td>
<td>Training</td>
<td>Exercise Mode: Repeated hand opening and closing exercises; normal speed and fast.</td>
</tr>
<tr>
<td>●○●○○</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OPEN-EXERCISE</td>
<td>Training</td>
<td>Open-Exercise Mode: Repeated hand opening and relaxation exercises; normal speed and fast.</td>
</tr>
<tr>
<td>●●● ○ ○ ○</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GRASP-EXERCISE</td>
<td>Training</td>
<td>Grasp-Exercise Mode: Repeated hand closing and relaxation exercises; normal speed and fast.</td>
</tr>
<tr>
<td>●●●● ○ ○</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OPEN</td>
<td>Functional/Training</td>
<td>Open Mode: Hand opens and remains open; normal speed is used for function and Fast Speed is used for training.</td>
</tr>
<tr>
<td>○●●● ○ ○</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GRASP</td>
<td>Functional</td>
<td>Grasp Mode: Hand opens and then closes and remains closed.</td>
</tr>
<tr>
<td>○○○●● ○</td>
<td></td>
<td></td>
</tr>
<tr>
<td>KEY</td>
<td>Functional</td>
<td>Key Mode: Fingers close as the thumb opens, and then the thumb closes and remains closed.</td>
</tr>
<tr>
<td>○○○○●●</td>
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Open-Exercise Mode
Open-Exercise Mode consists of repetitive hand opening exercises, with a relaxation pause between exercises.

Fast Open-Exercise Mode consists of repetitive pulsed hand opening exercises with a relaxation pause between exercises.

Grasp-Exercise Mode
Grasp-Exercise Mode consists of repetitive hand closing exercises with a relaxation pause between exercises.

Fast Grasp-Exercise Mode consists of repetitive pulsed hand closing exercises with a relaxation pause between exercises.

Open Mode
Open Mode is used to open the hand and keep it open.

Fast Open Mode consists of repetitive pulsed hand opening exercises with no relaxation breaks. Fast Open Mode should only be used for a few minutes at a time.

Grasp Mode
Grasp Mode is used to grasp objects. Grasp Mode opens the hand and then closes it.

Key Mode
Key Mode is used to grip objects between the thumb and the side of the index finger.
Battery Charger
The battery charger is used to charge the Control Unit battery.

Control Unit Strap
The Control Unit Strap is used to carry the Control Unit.

Electrode Pads
The electrode pads are used to cover the electrodes. Each electrode has a corresponding electrode pad designed specifically for the electrode. The number of the electrode pad must match the number of the electrode.

The electrode pads have a white dot on one side. Face the white dot toward the electrode when attaching the electrode pad.

The electrode pads must be thoroughly wet before use.

Never use the NESS H200 without electrode pads.

Electrodes, and Electrode Screw and Washer Set
The electrodes and electrode screw and washer set are for clinician use only. Your clinician will attach the electrodes to your Orthosis.
Charging the Control Unit Battery

*To charge the Control Unit battery:*

1. If the Orthosis is connected to the Control Unit, then press the cable release button (See Figure 12) on the Control Unit to disconnect the Orthosis cable.

2. Connect the battery charger cable to the Control Unit cable connector socket, with "TOP" facing up. The cable connector should **click** into the socket. See Figure 12.

![Figure 12: Connecting the battery charger to the Control Unit.](image-url)
3. Connect the battery charger to a power supply.

4. The Control Unit will begin to charge. Charging can take up to nine hours.

5. The Control Unit display screen will show "CHARGING" when the battery is charging and "CHARGING FULL" when the battery is fully charged. See figures 13 and 14. The display screen will also show the battery charge level (0–9).

![Display screen: battery charging, charge level "0".](image1)

**Figure 13:** Display screen: battery charging, charge level "0".

![Display screen: battery fully charged, charge level "9".](image2)

**Figure 14:** Display screen: battery fully charged, charge level "9".

6. When the display screen shows "CHARGING", "FULL" and "9", disconnect the battery charger from the Control Unit.

7. Reconnect the Orthosis cable to the Control Unit.
Preparing Your Skin

To prepare your skin:

1. Remove any jewelry from your hand, wrist, and forearm.

2. Clean the skin where the Orthosis will be worn with a wet washcloth. If any oils or lotions are on the skin, then clean with soap and water. Rinse well.

⚠️ CAUTION: Your NESS H200 Control Unit is splash proof only. Always protect it from contact with water and cleaning agents.
Preparing the Orthosis

Your clinician will attach the electrodes and electrode pads to your Orthosis. Afterward, you will need to prepare the Orthosis each time you use it.

To prepare the Orthosis:

1. Set the Orthosis, Control Unit, and a cushion or pillow to support your arm (optional) on a table. Make sure the Control Unit and Orthosis are close to you.

2. Open the Orthosis. Pinch the wing release handle and arm together, and lift the wing. See Figure 15.

Figure 15: Pinch the wing arm and release handle together to open the Orthosis.
3. Remove and wet the electrode pads. Place them under running water or dip them into a cup of water.

4. Make certain the entire surface of each pad is saturated. (Gently blot dry if overwet.)

5. Reattach the electrode pads to the electrodes. Make sure each electrode pad is attached to the appropriate electrode. See Figure 16. (The white dot on the electrode pad faces the electrode.)

Figure 16: Electrodes (numbered 1–5).
Putting on the Orthosis

Before you put on the Orthosis, make sure you are sitting upright and centered (not leaning to one side). Make sure your arm is comfortable, and that your shoulder is relaxed.

To put on the Orthosis:

1. Place the spiral end of the Orthosis around your hand. See figures 17 and 18.

   - Hold the Orthosis with your unaffected hand, and place the spiral end around your affected hand, or
   - Position the Orthosis on the table, and place your hand in the spiral end. See Figure 18.

Figure 17: Placing the spiral end of the Orthosis around your hand.
Figure 18: Using a tabletop to put on the Orthosis.
2. Make certain that the #3 electrode is over the muscle at the base of your thumb. See Figure 19.

![Figure 19: Positioning the #3 electrode.](image)

3. Make certain that the wrist bridge lies comfortably on your wrist. See Figure 20.

![Figure 20: Positioning the wrist bridge.](image)
4. Make certain that the cable is hanging freely. See Figure 21.

Figure 21: Positioning the cable.

5. Position the main body of the Orthosis around your forearm. See Figure 22.

Figure 22: Positioning the main body.
6. Push the wing arm down to close the wing. See figures 23 and 24. Do not pinch the release handle while closing the wing.

**Figure 23:** Pushing the wing arm down.

**Figure 24:** The wing closed.

⚠️ **CAUTION:** Do not pinch the release handle while closing the wing.
Connecting the Orthosis Cable to the Control Unit

To connect the Orthosis Cable to the Control Unit:

1. Orient the Orthosis cable connector with "TOP" facing up.

2. Insert the cable connector into the cable connector socket on the Control Unit. See Figure 25.

Figure 25: Connecting the Orthosis cable to the Control Unit.
Attaching the Wrist Strap

The wrist strap is used to support your hand in the Orthosis. (Your clinician will determine if you should use the wrist strap.) The wrist strap clips to the attachment ring on the wrist bridge. See Figure 26.

To attach the wrist strap:

1. Attach the wrist strap hook to the attachment ring, making certain that the sponge pad faces the arm.

2. Put on the Orthosis.

3. Bring the wrist strap under the wrist and into the wrist strap attachment bar, pull up on the wrist strap, and then bring the wrist strap down to fasten. Do not pull down on the wrist strap. Pulling down on the wrist strap can break the wrist strap attachment bar.

CAUTION: Do not tighten the wrist strap so much that it interferes with blood flow to the hand.
Turning On the Control Unit

To turn on the Control Unit:

1. Press the on/off button on the Control Unit.

2. The NESS logo will appear on the display screen for a few seconds. Then, the display screen will show the operating mode, training time, and stimulation intensity level. See Figure 27.

Figure 27: Display screen showing operating mode ("PERSONAL"), training time ("00"), and stimulation intensity level ("6").
Selecting an Operating Mode

To select an operating mode:

1. Make certain stimulation is off. Then press the \[MODE\] mode button until the desired operating mode is displayed in the display screen.

\[NOTE!\]
The operating mode cannot be changed while stimulation is on.

Changing the Stimulation Intensity Level

Stimulation intensity has 10 levels, ranging from 0 to 9.

To change the stimulation intensity level:

- Press the \[+\] plus button to increase the stimulation intensity level.
- Press the \[-\] minus button to decrease the stimulation intensity level.

\[CAUTION: Consult your clinician before increasing the stimulation intensity level.\]
Using a Training Mode

The training modes are used for exercising.

*To use a training mode:*

1. Turn on the Control Unit and select an operating mode used for training.
2. Press the stimulation trigger button to start stimulation.
3. The letter “t” will appear briefly in the display screen and then stimulation will begin.
4. Your hand will start moving per the selected mode.
   - To pause the stimulation, press the stimulation trigger button.
   - To increase or decrease the stimulation intensity level, press the plus or minus button.
   - To check battery charge level status, press and hold the mode button.

⚠️ **CAUTION:** Do not exceed the stimulation intensity level set by your clinician.

👉 **NOTE!**
To stop stimulation at any time, press the on/off button.
Using a Functional Mode

The functional modes are used for grasping, holding, manipulating, and releasing objects.

Using Open Mode

Open Mode is used to open the hand. In Open Mode, your hand stays open until you press the stimulation trigger button again.

Open Mode should not be used for more than 30 seconds at a time, to avoid muscle fatigue.

Consult your clinician to see if Open Mode is appropriate for you.

To use Open Mode:

1. Turn on the Control Unit.
2. Press the mode button until "OPEN" appears in the display screen
3. Press the stimulation trigger button. The letter “t” will appear briefly in the display screen, and then stimulation will begin.
4. Your hand will open.

NOTE!
Consult with your clinician before using the functional modes. Make sure they are appropriate for you.
5. If necessary, adjust the stimulation intensity level. Press the + plus button to increase the intensity level or the - minus button to decrease the intensity level.

6. To stop stimulation, press the TRIGGER stimulation trigger button.

**Using Grasp Mode**

Grasp Mode is used to grasp and hold large objects. Grasp Mode opens your hand and then closes it.

Consult your clinician to see if Grasp Mode is appropriate for you.

**To use Grasp Mode:**

1. Turn on the Control Unit.
2. Press the MODE mode button until "GRASP" appears in the display screen.
3. Press the TRIGGER stimulation trigger button. The letter “t” will appear in the display screen, and then stimulation will begin.
4. Your hand will open for several seconds.
5. Position your hand next to the object you want to grasp.
6. The stimulation will pause for two seconds, allowing your hand to relax.

⚠️ **CAUTION: Do not exceed the stimulation intensity level set by your clinician.**
7. Stimulation will start again and your hand will close, allowing you to grasp the object.
   - If necessary, adjust the stimulation intensity level by pressing the + plus or - minus button until the grasp is firm but not too strong.
   - If necessary, adjust your thumb position using the thumb lever to improve your grasp.

8. Two seconds before you are ready to release the object, press the stimulation trigger button again. In two seconds your hand will open and remain open for several seconds, allowing you to release the object from your grasp.

9. After several seconds, stimulation will stop entirely. Your hand will relax.

NOTE!
To stop stimulation at any time, press the on/off button. If you are grasping an object when stimulation turns off, the object will fall from your grasp.
Using Key Mode

Key Mode is used to pick up and hold small objects between the thumb and the side of the index finger.

Consult your clinician to see if Key Mode is appropriate for you.

To use Key Mode:

1. Turn on the Control Unit.
2. Press the mode button until "KEY" appears in the display screen.
3. Press the stimulation trigger button to start stimulation.
4. The letter “t” will appear briefly in the display screen. Then stimulation will begin.
5. Your fingers will close and your thumb will open, opening a gap between your thumb and the side of your index finger.
6. Your fingers and thumb will remain in this position for several seconds.
7. While your fingers and thumb are in this position, place the object you want to grip into the gap.
8. Stimulation will then pause for a few seconds, allowing your fingers and thumb to relax around the object.
9. Stimulation will start again, closing your fingers and thumb around the object. If necessary:

- Adjust the stimulation intensity level. Press the + plus or - minus button until the grip is firm but not too strong.
- Adjust the thumb lever to improve the grip.

10. Position the object where you want to release it. Then press the stimulation trigger button. After two seconds, your fingers will open.

11. After several seconds, stimulation will stop. Your hand will relax.

⚠️ **CAUTION: Do not exceed the stimulation intensity level set by your clinician.**
Using Fast Speed

Your clinician will set a Fast Speed on your NESS H200, if appropriate, and explain how and when to use Fast Speed. Consult your clinician to see if Fast Speed is appropriate for you.

*To use Fast Speed:*

1. Press the *mode* button to select one of the following operating modes: Exercise, Open-Exercise, Grasp-Exercise, or Open.

2. Press and hold the *stimulation trigger* button for several seconds until the Control Unit beeps twice.

3. When Fast Speed is on, the display screen will show "FAST" and the stimulation speed: for example, "FAST2".

Emergency Stop Stimulation

To stop the stimulation at any time, press the *on/off* button.

NOTE!

If you are grasping an object when stimulation turns off, the object will fall from your grasp.
Automatic Shutdown

**Stimulation Shutdown**

Stimulation will shut down automatically:

- At the end of the stimulation session in Personal Mode.
- After 90 minutes in Exercise, Open-Exercise, and Grasp-Exercise modes.
- After 45 minutes in Grasp, Key, and Open modes.
- When the battery charge level becomes very low.

The Control Unit will beep to warn that stimulation is going to shut down automatically:

- First warning: three beeps.
- Second warning (30 seconds after the first warning): three beeps.
- Final warning (30 seconds after the second warning): three beeps repeated five times, and then stimulation shuts down.
After Stimulation Shutdown in Personal Mode

When stimulation shuts down because Personal Mode has finished, press the on/off button to turn off the Control Unit.

After Stimulation Shutdown in All Other Modes

When stimulation shuts down in any of the other modes, do one of the following:

- Press the stimulation trigger button to continue stimulation.
- Or, press the on/off button to turn off the Control Unit.

When a low battery charge level shuts down stimulation, recharge the Control Unit battery.

Control Unit Shutdown

The Control Unit will shut down automatically when:

- The battery charge level becomes very low.
- The Control Unit malfunctions.

When a low battery charge level shuts down the Control Unit, recharge the Control Unit battery.
Removing the Orthosis

*To remove the Orthosis:*

1. Turn off the Control Unit.

2. Press and hold the cable release button on the Control Unit. Then disconnect the Orthosis cable from the cable connector socket.

3. Pinch the Orthosis wing release handle and wing arm together. Then open the wing. See Figure 28.

4. Rotate the cable end of the Orthosis away from your forearm.

5. Remove the spiral end of the Orthosis from your hand.

**NOTE!**

After use, leave the Orthosis open to dry the electrode pads.
Maintenance and Cleaning

Have your NESS H200 checked out every one to two years by an authorized Bioness technician. Contact the NESS H200 Technical and Clinical Support Department at (800) 211-9136, Option 3, for details, or visit the Bioness website: www.bioness.com.

Replacing the Control Unit Battery

The Control Unit battery should last for approximately two years before needing to be replaced. Contact Bioness or your local distributor for battery replacement instructions.

⚠ CAUTION: Only Bioness should change the Control Unit battery.

Low Battery Warning

The Control Unit will emit audio and visual warnings when the battery charge level is low. Depending on the age of the battery, the warnings will start 2 to 10 minutes before the battery is completely discharged. The display screen will show a flashing “L” (low) and the Control Unit will beep, slowly at first and then faster.
Checking the Battery Charge Level

To check the battery charge level:

1. Press and hold the mode button.

2. A battery status indicator and a number will appear on the left side of the display screen. The number (0–9) represents the battery charge level. See Figure 29.

![Figure 29: Battery charge level indicators.](image)

NOTE!
As a battery ages, the battery status indicator may become less reliable. It may indicate that the battery is partially charged when it is almost discharged.
Charging the Battery

The Control Unit contains a rechargeable battery. The battery will need to be recharged after approximately 15 hours of use. As the Control Unit battery ages it will hold less charge. It will require charging after fewer hours of use.

To charge the Control Unit battery:

1. Press the cable release button on the Control Unit to release the Orthosis cable connector.

2. Insert the battery charger cable connector into the cable connector socket until it clicks. See Figure 30.

Figure 30: Connecting the battery charger to the Control Unit.

⚠️ CAUTION: The Control Unit battery cannot be charged when the charge level is "9".
3. Insert the battery charger power supply cable into an electrical socket.

4. Monitor the display screen as the battery charges. The display screen will show a rotating circle and a number (the battery charge level) while the battery charges. See Figure 31.

![CHARGING 0](image)

**Figure 31**: Battery charging display: charge level "0".

5. It takes approximately nine hours for the battery to fully charge. When charging is complete, "FULL" and "9" will appear in the display screen. See Figure 32.

![CHARGING FULL 9](image)

**Figure 32**: Full battery display while charging: charge level "9".
Charging the Battery After Two Weeks of Non-Use

When the NESS H200 is not used for two weeks or more, the Control Unit battery will need to be fully charged, discharged, and fully re-charged before use.

To fully charge the battery:

1. Insert the battery charger cable connector into the cable connector socket until it clicks. See Figure 33.

2. Insert the battery charger power supply cable into an electrical socket.

Figure 33: Connecting the battery charger to the Control Unit.
3. Monitor the display screen as the battery charges. The display screen will show a rotating circle while the battery charges. The battery charge level will appear next to the circle. See Figure 34.

![Figure 34: Battery charging display: charge level "0".](image)

4. It takes approximately nine hours for the battery to become fully charged. When charging is complete, "FULL" and "9" will appear on the screen. See Figure 35.

![Figure 35: Full battery charging display: charge level "9".](image)
NOTE!
The discharge process can be started only when the battery is fully charged and the display screen shows "9".

To fully discharge the battery:

1. When "FULL" appears in the display screen, press and hold the \( - \) minus button on the Control Unit until "0" flashes in the display screen.
2. Release the \( - \) minus button on the Control Unit.
3. The battery will begin to discharge. Discharging will take approximately three to four hours. While the battery is discharging, "0" will continue to flash in the display screen.

To fully recharge the battery:

1. Once the battery fully discharges, the battery will recharge automatically. The battery will take approximately nine hours to fully recharge. When recharging is complete, "FULL" and "9" will appear on the screen. See Figure 36.

Figure 36: Full battery charging display: charge level "9".
Changing the Electrode Pads

The five Orthosis electrode pads should be changed every two weeks.

To change the Orthosis electrode pads:

1. Turn off the Control Unit

2. Disconnect the Orthosis from the Control Unit.

3. Remove the pads for electrodes #1, 2, 4, and 5. See Figure 37.

4. Unsnap and remove the pad for electrode #3. See Figure 37.

5. Clean the underlying electrodes, if necessary. Use a soft damp cloth and a mild liquid hand soap.

6. Snap a new pad for electrode #3 (round pad) into place.

7. Select the appropriate new pad for electrodes #1, 2, 4, and 5.

8. Hold each electrode pad with the white sticker facing the electrode. Then insert the corners of the pad under the corners of the electrode plastic frame.

⚠️ **CAUTION:** Do not remove the electrodes.

**CAUTION:** Do not remove the electrode plastic frames.

**CAUTION:** Do not use the NESS H200 without electrode pads.
**Figure 37**: Location of the five Orthosis electrodes.
Cleaning the Orthosis

You should clean the Orthosis regularly.

_To clean the Orthosis:_

1. Disconnect the Orthosis cable from the Control Unit.

2. Wipe the inner and outer surfaces of the Orthosis using a soft damp cloth and mild liquid hand soap. Do not wipe the cable connector.

3. Wipe the Orthosis dry with a soft cloth.

⚠️ **CAUTION:** Do not clean the Orthosis with any cleaning agents other than mild liquid hand soap.

**CAUTION:** Do not over-wet the Orthosis.

**NOTE!**
After each use, leave the Orthosis open so that the electrode pads can dry.
Your NESS H200 Control Unit is splash proof only. Always protect it from contact with water and cleaning agents.
Troubleshooting

If you have any questions, please contact your clinician or the NESS H200 Technical and Clinical Support Department at (800) 211-9136, Option 3, or visit the Bioness website: www.bioness.com.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>A component (Orthosis, cable, connector, Control Unit, etc.) is broken, damaged, or detached.</td>
<td>Contact Bioness Inc.</td>
</tr>
<tr>
<td>Nothing appears in the display screen when the Control Unit is turned on.</td>
<td>Charge the Control Unit battery. If the problem persists, contact Bioness Inc.</td>
</tr>
<tr>
<td>The NESS logo does not disappear from the display screen after the Control Unit is turned on.</td>
<td>Contact Bioness Inc.</td>
</tr>
<tr>
<td>&quot;ERROR SHUTDOWN&quot; appears in the display screen.</td>
<td>Contact Bioness Inc.</td>
</tr>
<tr>
<td>During charging, &quot;CHARGING FAIL&quot; appears in the display screen.</td>
<td>Contact Bioness Inc.</td>
</tr>
<tr>
<td>Problem</td>
<td>Solution</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>The operating buttons on the Control Unit and Orthosis are not functioning as described in this guide.</td>
<td>Contact Bioness Inc.</td>
</tr>
<tr>
<td>The electrode pads are dirty, damaged, or falling off the Orthosis.</td>
<td>• Wipe the skin prior to use.</td>
</tr>
<tr>
<td></td>
<td>• Replace the electrode pads.</td>
</tr>
<tr>
<td>After charging the Control Unit battery, the battery charge level is still low.</td>
<td>• Make sure the charger cable is clicked into the Control Unit.</td>
</tr>
<tr>
<td></td>
<td>• Discharge and recharge the Control Unit. (See Charging the Battery after Two Weeks of Non-Use.)</td>
</tr>
<tr>
<td></td>
<td>• Contact Bioness Inc.</td>
</tr>
<tr>
<td>Shortly after charging the Control Unit battery, “L” appears in the display screen.</td>
<td>Fully charge the Control Unit battery, fully discharge the battery, and then fully recharge the battery. (See Charging the Battery after Two Weeks of Non-Use.) If the problem persists, contact Bioness Inc.</td>
</tr>
</tbody>
</table>
## No Finger Movement

| The Control Unit is on, the stimulation trigger button has been pressed, the stimulation active symbol (■■■■) is flashing, but there is no finger movement. | Wait 30 seconds. If after 30 seconds your fingers still are not moving:
1. Turn off the Control Unit.
2. Make sure the electrode pads are wet.
3. Make sure the Orthosis is properly positioned on your hand and arm.
4. Press down on the center of the wing arm.
5. Turn on the Control Unit.
6. Press the stimulation trigger button.

If the problem persists:
1. Turn off the Control Unit.
2. Disconnect the cable from the Control Unit, and then reconnect it, making sure it clicks in.
3. Turn on the Control Unit, and then press the stimulation trigger button.

If the problem persists:
1. Turn off the Control Unit.
2. Take off the Orthosis.
3. Wet the electrode pads thoroughly.
5. Turn on the Control Unit.
6. Press the stimulation trigger button.

If the problem persists: Wait 30 seconds.

If the problem persists: Contact Bioness Inc.
<table>
<thead>
<tr>
<th>Finger Movement is Unsatisfactory</th>
<th>Solution</th>
</tr>
</thead>
</table>
| If finger movement is unsatisfactory: | 1. Make sure that the Orthosis is snug against your forearm and that the pads are in close contact with your skin.  
2. Make sure you are in the desired mode. |
| If the problem persists: | Relax your shoulder and hand for 30 seconds. |
| If the problem persists: | 1. Turn off the Control Unit.  
2. Remove the Orthosis.  
3. Replace the electrode pads, if they have been used for more than two weeks.  
4. Make sure the electrode pads are saturated with water.  
5. Put the Orthosis back on.  
6. Make sure the Orthosis is positioned correctly.  
7. If the problem persists, contact Bioness Inc. |
### Chapter 9

#### Technical Specifications

<table>
<thead>
<tr>
<th><strong>Type of Electrical Stimulation</strong></th>
<th>Constant voltage, biphasic symmetrical pulse</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Microprocessor-Controlled Automatic Operation</strong></td>
<td>Single current source multiplexed among five surface electrodes on the Orthosis</td>
</tr>
</tbody>
</table>
| **Dimensions and Weight** | **Control Unit (including battery)** 9.1 x 4.0 x 17.2 cm; 377 g (3.6 x 1.6 x 6.8 in.; 0.83 lb)  
**Orthosis Medium** 8.9 x 7.7 x 27.5 cm, 325 g (3.5 x 3.0 x 10.8 in.; 0.72 lb)  
**Orthosis Large** 10.7 x 9.5 x 30.5 cm; 396 g (4.2 x 3.7 x 12.0 in.; 0.87 lb) |
| **Battery** | 9.6-V Rechargeable Nickel-Metal-Hydride Holds 280-mAh charge, giving 15 hours of continuous operation at typical power |
| **Charger** | AC Adapter, Class 2 Transformer  
Input: 100-240 V AC, 50–60 Hz |
| **Battery Indicator** | Charge Indicator  
Battery low visual display and audio beep warning |
<p>| <strong>10 Selectable Stimulation Intensity Levels</strong> | Push-button adjustment of pulse intensity Ramp up and ramp down in all modes |
| <strong>7 Selectable Operating Modes</strong> | Personal (pre-set program or personalized), Exercise⁹, Open-Exercise⁹, Grasp-Exercise⁹, Open⁹, Grasp, and Key |
| F = Fast Speed available | |
| <strong>Carrier Wave</strong> | Wave form: Sinusoidal, balanced, no DC component Frequency: 11 kHz |
| <strong>Stimulation Pulse Burst</strong> | <strong>Personal, Exercise, Open-Exercise, Grasp-Exercise, and Open modes:</strong> Duration: 10 levels from 0.01 mSec to 0.35 mSec Frequency: 36 Hz <strong>Grasp and Key modes:</strong> Duration: 10 levels from 0.01 mSec to 0.5 mSec Frequency: 18 Hz or 36 Hz <strong>Pulse Voltage and Current (all modes):</strong> 115 V rms; 58 mA rms, at 2K Ω load 75 V rms; 150 mA rms, at 500 Ω load |
| <strong>Average Parameters</strong> | <strong>Maximum Voltage:</strong> 1.46 V rms at 2K Ω load (Exercise Mode) <strong>Maximum Current:</strong> 1.9 mA rms at 500 Ω load (Exercise Mode) |</p>
<table>
<thead>
<tr>
<th><strong>Maximum Power</strong></th>
<th>0.13 W at 500 Ω load (Exercise Mode)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Automatic Shutdown</strong></td>
<td>Exercise, Open-Exercise, and Grasp-Exercise modes: 90 min</td>
</tr>
<tr>
<td></td>
<td>Open, Grasp, and Key modes: 45 min</td>
</tr>
<tr>
<td></td>
<td>Personal Mode: programmable up to 99 min</td>
</tr>
<tr>
<td><strong>Classification</strong></td>
<td>Internally powered, Type BF, continuous operation</td>
</tr>
<tr>
<td><strong>Transport and Storage Environmental Ranges</strong></td>
<td>-20°C to +60°C (-4°F to +140°F) ambient temperature</td>
</tr>
<tr>
<td></td>
<td>10% to 85% relative humidity</td>
</tr>
<tr>
<td></td>
<td>500 hPa to 1060 hPa atmospheric pressure</td>
</tr>
<tr>
<td><strong>Operating Environmental Ranges</strong></td>
<td>5°C to 40°C (40°F to 105°F) ambient temperature</td>
</tr>
<tr>
<td></td>
<td>10% to 85% relative humidity</td>
</tr>
</tbody>
</table>