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Bioness®
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NESS H200® Wireless

Clinician's Guide

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Patents Pending

Aspects of this device are covered by several patents and patent applications.

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Environmental Policy

Service personnel are advised that when changing any part of the NESS H200 Wireless System, 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 Wireless System 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.

Bioness Client Relations Department: Telephone: (800) 211-9136, Option 3; or (661) 362-4850, Option 3.

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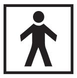
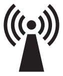
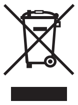
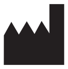
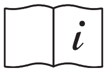
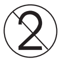
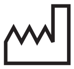
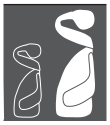
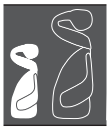
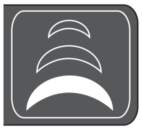
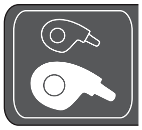
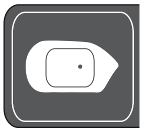
List of Symbols

⚠	Caution or Warning
	Type BF Applied Part(s)
CE 0473	Complies with the European Union Medical Device Directive
⧈	Double Insulated (Equivalent to Class II of IEC 536)
	Non-Ionizing Radiation
	This Product Must Not be Disposed of with Other Household Waste
C ETL US LISTED Intertek 3106069	Complies with United States and Canadian Product Safety Standards
EC REP	European Authorized Representative
	Manufacturer
	Consult Instructions for Use
REF	Re-Order Number
LOT	Lot Number
SN	Serial Number
	Single Patient Use
	Date of Manufacture
Lt	Fits Left Orthosis
Rt	Fits Right Orthosis

	Fits Large Orthosis
	Fits Small and Medium Orthoses
	Thick Wrist Insert
	Large Thenar
	FPL Panel

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Chapter 1

Introduction

Stroke and other disorders of the central nervous system (CNS) may cause long-term disability. For many people, long-term disability may impair muscle control, increase muscle spasm, reduce muscle strength, and reduce functional abilities. When the upper limb is involved, complications may include contractures, edema, pain syndromes of the hand and shoulder, and limb-neglect due to learned non-use.

The NESS H200 Wireless Hand Rehabilitation System delivers electrical stimulation to the nerves of the flexor and extensor muscles that control the hand, to improve hand function and treat upper limb impairments resulting from injury to the central nervous system. The NESS H200 Wireless System is easy to operate independently, and promotes clinical efficacy and patient compliance.

This NESS H200 Wireless *Clinician's Guide* **describes:**

- The NESS H200 Wireless System.
- The NESS H200 Wireless Software.
- How to fit the NESS H200 Wireless System.
- How to program the NESS H200 Wireless System.

This guide also includes important safety instructions. Be sure to review the safety instructions with patients before they use the NESS H200 Wireless System.

If you have any questions, please call the Bioness Client Relations Department at (800) 211-9136, Option 3, or visit the Bioness website: www.bioness.com.

Chapter 2

Device Description and Safety Information

Device Description

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

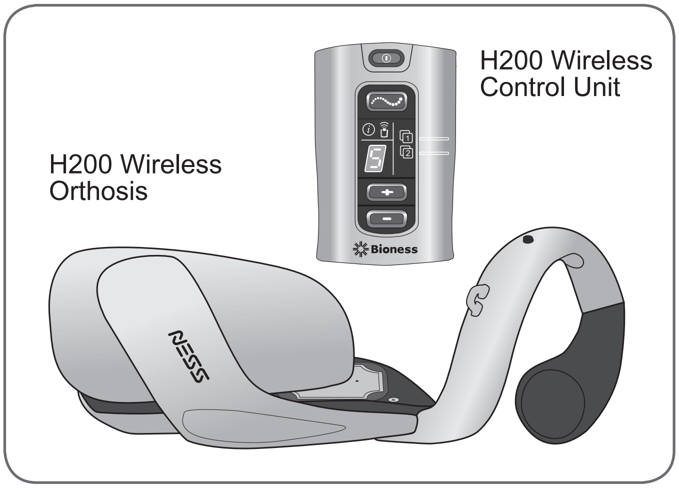


Figure 2-1: H200 Wireless Orthosis and Control Unit.

H200 Wireless Orthosis—stabilizes the wrist at a functional angle and transmits electrical stimulation through five surface electrodes to provide optimal wrist and hand movements.

H200 Wireless Control Unit—used to start and stop stimulation, adjust stimulation intensity, and select stimulation programs. The clinician customizes stimulation programs for each patient using specialized H200 Wireless Software installed on the H200 Wireless Clinician's Programmer.

These components communicate wirelessly to stimulate the nerves of the flexor and extensor muscles that control the hand, to improve hand function and treat upper limb impairments resulting from injury to the central nervous system.

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 on an arm where a cancerous lesion is present or suspected.
- Do not use the NESS H200 Wireless System on patients who 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 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.
- The H200 Wireless Orthosis should not be worn over swollen, infected, or inflamed areas or skin eruptions such as phlebitis, thrombophlebitis, and varicose veins.
- Stimulation should only be applied to normal, intact, clean, healthy skin.
- Advise patients to turn off the NESS H200 Wireless System before driving, operating machinery, or performing any activity in which involuntary muscle contractions may put them at undue risk of injury.
- Advise patients not to use the NESS H200 Wireless System while sleeping.

- The NESS H200 Wireless System should only be configured by an authorized clinician.
- Only trained clinicians should determine electrode placement and stimulation settings.
- The H200 Wireless Clinician's Programmer should only contain the Windows Mobile for Pocket PC operating system and Bioness Inc proprietary software. Third-party software packages are not supported and may interfere with proper operation of the NESS H200 Wireless System, thus voiding the warranty.
- 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, advise patients to stop using the NESS H200 Wireless System immediately and to consult their physician:
    - 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 with patients who have suspected or diagnosed heart problems. Consult with the patient's physician before using the NESS H200 Wireless System. The NESS H200 Wireless System may cause lethal rhythm disturbances to the heart in susceptible individuals.
- 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 with patients who have suspected or diagnosed epilepsy.
- Obtain specific physician clearance before using the NESS H200 Wireless System on patients who have an alteration of normal arterial or venous flow in the region of the H200 Wireless Orthosis because of local insufficiency, occlusion, arteriovenous fistula for the purpose of hemodialysis, or a primary disorder of the vasculature.
- Obtain specific physician clearance before using the NESS H200 Wireless System when patients have a structural deformity in the area to be stimulated.
- The safe use of the NESS H200 Wireless System during pregnancy has not been established.
- Keep the NESS H200 Wireless System out of the reach of children. Advise patients to use the H200 Wireless Orthosis with caution:
  - If the patient has 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.
- Inflammation in the region of the H200 Wireless Orthosis may be aggravated by motion, muscle activity, or pressure from the Orthosis. Advise patients to stop using the NESS H200 Wireless System until any inflammation is gone.
- Always check the skin for redness or a rash when donning and doffing the H200 Wireless Orthosis.
- After doffing 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. Use of the NESS H200 Wireless System should be temporarily halted until any irritation is resolved completely.
- Turn off the NESS H200 Wireless System before donning or doffing the H200 Wireless Orthosis. Do not turn on the NESS H200 Wireless System until the Orthosis is securely in place on the arm and the extensor wing is closed.
- Advise patients to turn off the NESS H200 Wireless System when at a refueling place. They should not use the NESS H200 Wireless System near flammable fuel, fumes, or chemicals.
- Turn off the NESS H200 Wireless System before attaching the electrode bases to the Orthosis.
- 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. However, protect all electronic components from contact with water, such as from sinks, bathtubs, shower stalls, rain, snow, etc. Keep the H200 Wireless Control Unit and Orthosis away from the water used to wet the cloth electrodes.
- 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 NESS H200 Wireless cloth electrodes are 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 donning 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.
- After doffing the H200 Wireless Orthosis, allow the Orthosis to air dry.
- Do not leave the NESS H200 Wireless System stored 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, advise patients to stop using the NESS H200 Wireless System immediately, and to contact their clinician or dermatologist and the **Bioness Client Relations Department: (800) 211-9136, Option 3.** They should resume use only when the skin is completely healed, and then follow a skin conditioning protocol per the recommendation of their health-care specialist.

Chapter 3

Environmental Conditions that Affect Use

Radio Frequency (RF) Communication

Several components of the NESS H200 Wireless 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.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- 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 can affect the NESS H200 Wireless System.

Conformity Certification

The NESS H200 Wireless System complies with Part 15 of the FCC rules. 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: Changes or modifications to this equipment not expressly approved by Bioness Inc could void the user’s authority to operate the equipment.

Travel and Airport Security

The NESS H200 Wireless System charger set with interchangeable blades is compatible with Australian, U.K., European Union, and U.S. voltages: 110/220 V, 50/60 Hz.

Advise patients to turn off the NESS H200 Wireless System before going through airport security. They should wear loose clothing so that they can easily show the security person their NESS H200 Wireless System. The NESS H200 Wireless System will likely set off the security alarm. Patients should be prepared to remove their NESS H200 Wireless System so that security can scan it, or ask for the system to be scanned if they do not want to remove it. Patients may want to carry a copy of their NESS H200 Wireless System prescription. A prescription can be useful when passing through customs as well.

To request a copy of their prescription, patients should call the Bioness Client Relations Department: Telephone: (800) 211-9136, Option 3; or (661) 362-4850, Option 3. A Bioness representative can fax or mail them a copy.

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

Electromagnetic Compatibility

The NESS H200 Wireless System is medical electrical equipment and was tested for electromagnetic compatibility (EMC) in accordance with International Electrotechnical Committee (IEC) 60601-1-2. The tables in the Appendix provide information regarding the EMC testing and guidance for safe use of the system. The NESS H200 Wireless System should be configured and used in accordance with the instructions provided in this guide.

The NESS H200 Wireless System was tested and certified to use the following:

- DC power supply as provided by Bioness Inc, manufactured by FRIWO, Part No. FW7555M/05.
- Y cable (2-way splitter) as provided by Bioness Inc, Model No. L3G-5C00. Manufactured by Tamuz Electronics Ltd.

The plug-in AC/DC adapters for the H200 Wireless Control Unit, Orthosis, and Clinician's Programmer are the only means for disconnecting the devices from the AC power.

Warnings and Cautions

- Use caution when treating patients with implanted intrathecal/intravascular drug delivery systems. During initial trials with the NESS H200 Wireless System, 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 manuals.
- Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.
- Advise patients to remove the NESS H200 Wireless System before undergoing any diagnostic or therapeutic medical procedure such as x-ray examination, ultrasound, Magnetic Resonance Imaging (MRI), etc.
- The use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the NESS H200 Wireless System as replacement parts for internal components, may result in increased emissions or decreased immunity of the NESS H200 Wireless System.
- The use of the accessory, transducer, or cable with equipment and systems other than those specified may result in increased emissions or decreased immunity of the NESS H200 Wireless System.
- The NESS H200 Wireless System may be interfered with by other equipment, even if that other equipment complies with CISPR (International Special Committee on Radio Interference, International Electrotechnical Commission) emission requirements.
- Do not use the NESS H200 Wireless System within three feet of short wave or microwave therapy equipment. Such equipment may produce instability in the stimulation output by the Orthosis.

The NESS H200 Wireless System

H200 Wireless Orthosis

The Orthosis maintains the wrist in a functional position while providing electrical stimulation to elicit hand extension/flexion.

The H200 Wireless Orthosis features: See Figure 4-1.

- Stimulating electrodes. See Table 4-1.
- A flexor support.
- An extensor wing.
- A spiral end.
- Indicator lights (status and stimulation lights).
- Audio alerts.
- A rechargeable battery and charging port.

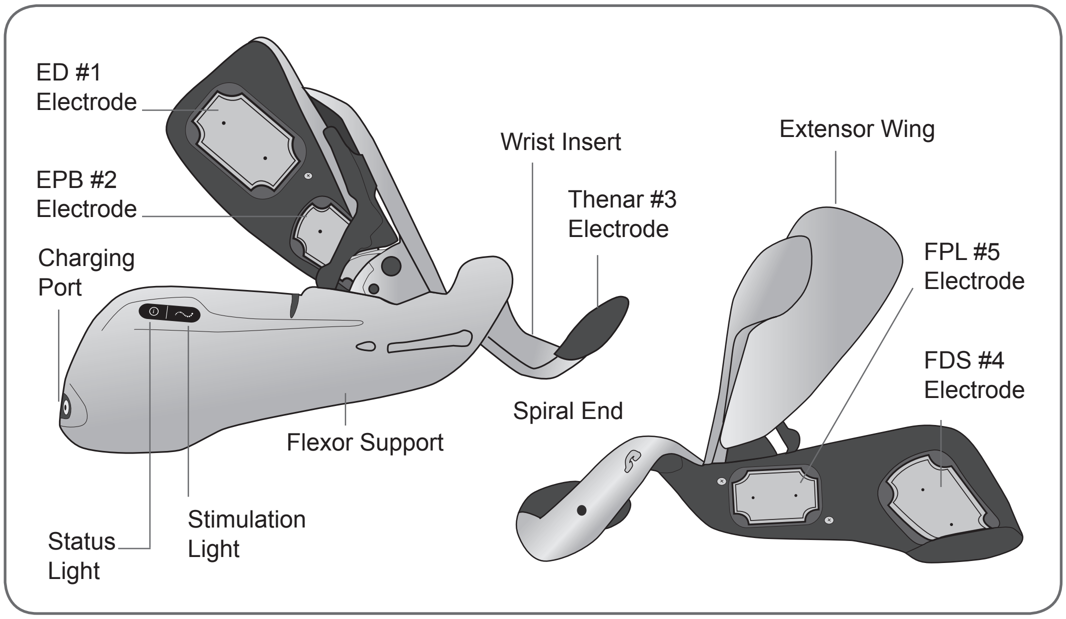

ED #1 Electrode
EPB #2 Electrode
Charging Port
Wrist Insert
Thenar #3 Electrode
Extensor Wing
FPL #5 Electrode
FDS #4 Electrode
Spiral End
Flexor Support
Stimulation Light
Status Light

Figure 4-1: The H200 Wireless Orthosis.

Stimulating Electrodes

The Orthosis transmits electrical stimulation through five surface electrodes custom placed by the clinician to provide optimal wrist and hand movements. See Table 4-1.

- Two electrodes are placed on the ventral aspect of the forearm, to stimulate the flexor muscles.
- One electrode is placed on the thenar eminence to stimulate the thenar muscle group.
- Two electrodes are placed on the dorsal aspect of the forearm, to stimulate the extensor muscles.

Electrode	Target Muscle	Motion
#1	Extensor Digitorum (ED)	Finger Extension
#2	Extensor Pollicis Brevis (EPB) and/or Extensor Pollicis Longus (EPL)	Thumb Extension
#3	Thenar Muscle Group (Thenar)	Thumb Flexion/Opposition
#4	Flexor Digitorum Superficialis (FDS)	Finger Flexion
#5	Flexor Pollicis Longus (FPL)	Thumb Interphalangeal (IP) Joint Flexion

Table 4-1: H200 Wireless electrodes.

Orthosis Flexor Support

The flexor support is designed to support the forearm while stimulating the flexor muscles. See Figure 4-2.

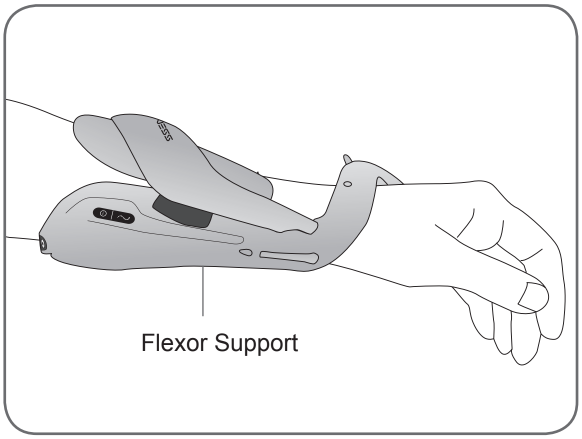

Flexor Support

Figure 4-2: H200 Wireless Orthosis flexor support.

Orthosis Extensor Wing

The extensor wing includes a release handle for opening the wing and a wing arm for closing the wing. See Figure 4-3. It is primarily designed to stimulate the extensor muscles.

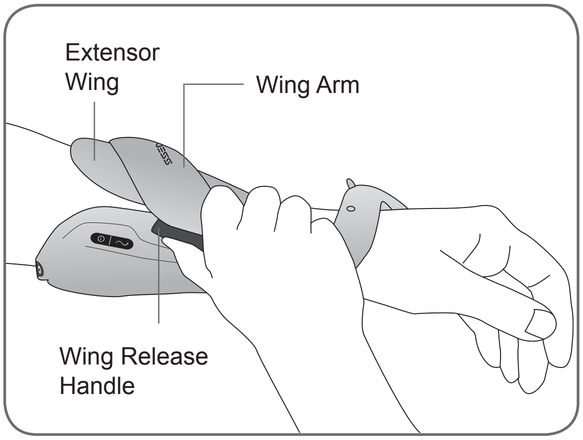

Extensor Wing
Wing Arm
Wing Release Handle

Figure 4-3: H200 Wireless Orthosis extensor wing.

Spiral End of the Orthosis

The spiral end of the Orthosis is designed to support the hand while delivering stimulation to the thenar muscle group.

The spiral end features: See Figure 4-4.

- A removable thenar**—**supports the thenar eminence.
- A wrist bridge**—**used to stabilize the hand in a functional position while in the Orthosis.
- A trigger button**—**used on the wrist bridge for turning on/pausing stimulation.
- A removable wrist insert**—**found on the underside of the wrist bridge and used to cushion the wrist. (Not shown in Figure 4-4.)
- An attachment ring**—**used for the Orthosis wrist strap.
- An attachment bar**—**used for securing the Orthosis wrist strap.

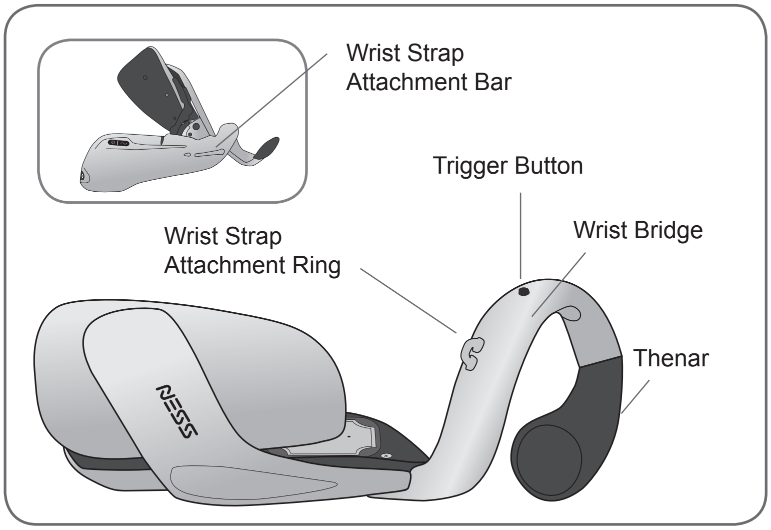

Wrist Strap Attachment Bar
Trigger Button
Wrist Strap Attachment Ring
Wrist Bridge
Thenar
NESS

Figure 4-4: Spiral end of the H200 Wireless Orthosis.

Indicator Lights

The Orthosis status light indicates system status and error messages. The Orthosis stimulation light indicates stimulation on, off, or paused. See Table 4-2.

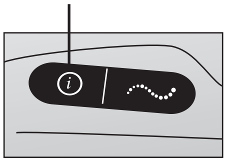
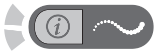
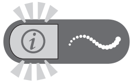
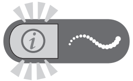
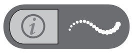
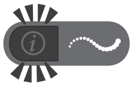
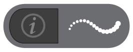
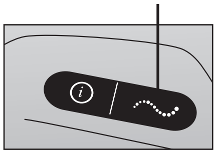
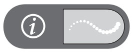
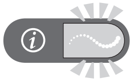
Left Orthosis	Display	Description	Definition
 Status Light		FLASHES GREEN	System On
		FLASHES YELLOW	Low Battery
		ALTERNATELY FLASHES YELLOW and GREEN	Battery Charging
		SOLID GREEN	Battery Fully Charged; Registration Successful
		FLASHES RED	Faulty Electrode Contact
		SOLID RED	Hardware/Software Error; Charging Error
 Stimulation Light		SOLID YELLOW	Stimulation Paused
		FLASHES YELLOW RAPIDLY	Stimulation On

Table 4-2: H200 Wireless Orthosis displays.

Audio Alerts

The Orthosis beeps when:

- A charger is connected.
- Electrode contact is faulty.
- A charging error has occurred.
- The battery charge level is low.
- Stimulation is turned on/off or paused.
- The NESS H200 Wireless System is turned on/off.
- The H200 Wireless Orthosis stimulation unit malfunctions.

Rechargeable Battery and Charging Port

The charging port is located on the distal end of the Orthosis. The Orthosis battery must be charged before initial use and daily thereafter. The NESS H200 Wireless System Kit includes a system charger set for charging the Orthosis and the H200 Wireless Control Unit simultaneously. See Figure 4-5.

Note: While charging please make sure the orthosis is not lying on it's side, causing the trigger button to be pressed continuously. This will cause the system to reset and turn off.

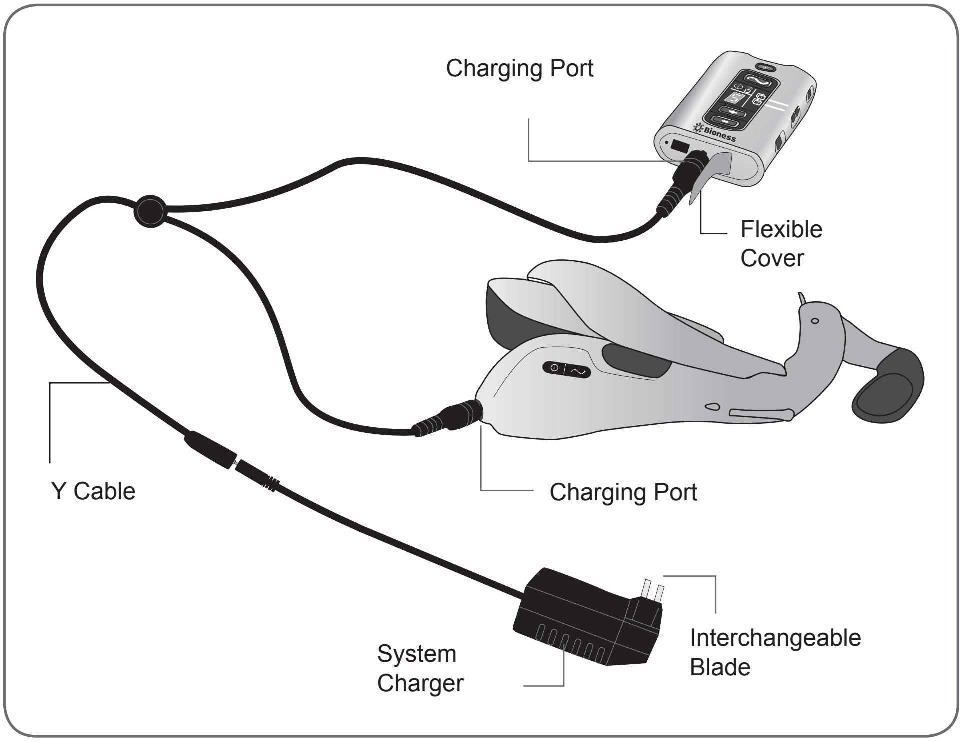

Charging Port
Flexible Cover
Y Cable
Charging Port
System Charger
Interchangeable Blade

Figure 4-5: NESS H200 Wireless System charging setup.

H200 Wireless Control Unit

The Control Unit communicates wirelessly with the Orthosis to turn on/off and pause stimulation, adjust stimulation intensity, and monitor system status.

The H200 Wireless Control Unit features:

- Operating buttons.
- On/off lights.
- Operating modes.
- Indicators and a digital display.
- Audio alerts.
- A rechargeable battery and charging port.

Operating Buttons

The H200 Wireless Control Unit operating buttons are shown in Figure 4-6.

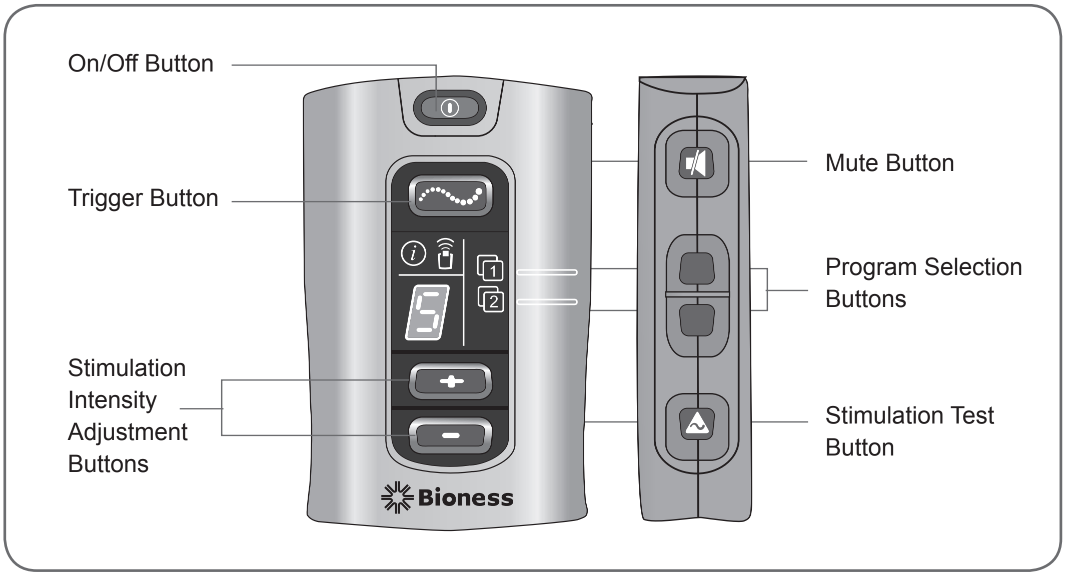

On/Off Button
Trigger Button
Stimulation Intensity Adjustment Buttons
Mute Button
Program Selection Buttons
Stimulation Test Button
1
2
Bioness

Figure 4-6: H200 Wireless Control Unit operating buttons.

The Control Unit operating buttons are used to: See Table 4-3.

- Turn on/off the NESS H200 Wireless System.
- Test stimulation in the H200 Wireless Orthosis.
- Select/change a user program.
- Enter clinical mode to select a clinical program.
- Turn on/off and pause stimulation.
- Adjust the stimulation intensity level.
- Mute system audio alerts.
- Enter deep sleep mode.

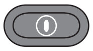
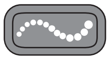
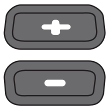
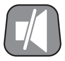
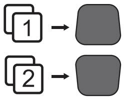
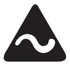
Operating Button	Description	Function
	On/Off Button	Turns On/Off the System Activates deep sleep mode
	Trigger Button	Turns On/Off and Pauses Stimulation
	Intensity Adjustment Buttons	+ Increases Stimulation Intensity − Decreases Stimulation Intensity
	Mute Button	Mutes/Un-Mutes the Control Unit and H200 Wireless Orthosis Audio Alerts
	Program Selection Buttons	**Top:** Selects User Program 1. In clinical mode, advances through Clinical Programs A–G. **Bottom:** Selects User Program 2. In clinical mode, scrolls back though Clinical Programs A–G.
	Stimulation Test Button	Tests Stimulation in the H200 Wireless Orthosis: Alternately tests extensors and flexors.

Table 4-3: H200 Wireless Control Unit operating buttons.

On/Off Lights

The Control Unit on/off lights are described in Table 4-4.

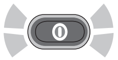
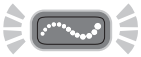
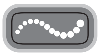
On/Off Lights	Description	Definition
	On/Off Button FLASHES GREEN	System On
	Trigger Button FLASHES YELLOW	Stimulation On
	Trigger Button is SOLID YELLOW	Stimulation Paused

Table 4-4: H200 Wireless Control Unit on/off lights.

Operating Modes

The H200 Wireless System has three operating modes: standby, user, and clinical.

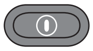
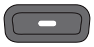
Standby Mode

The NESS H200 Wireless System is on and waiting for commands; stimulation is off.

User Mode

User mode is automatically entered when the Control Unit is turned on. User Programs 1 and 2 can be selected.

Clinical Mode

Clinical mode is entered when the  on/off button and the  minus button are pressed simultaneously. Programs A–G can be accessed directly from the Control Unit.

Indicators and Digital Display

The Control Unit indicators and digital display are illustrated in Figure 4-7.

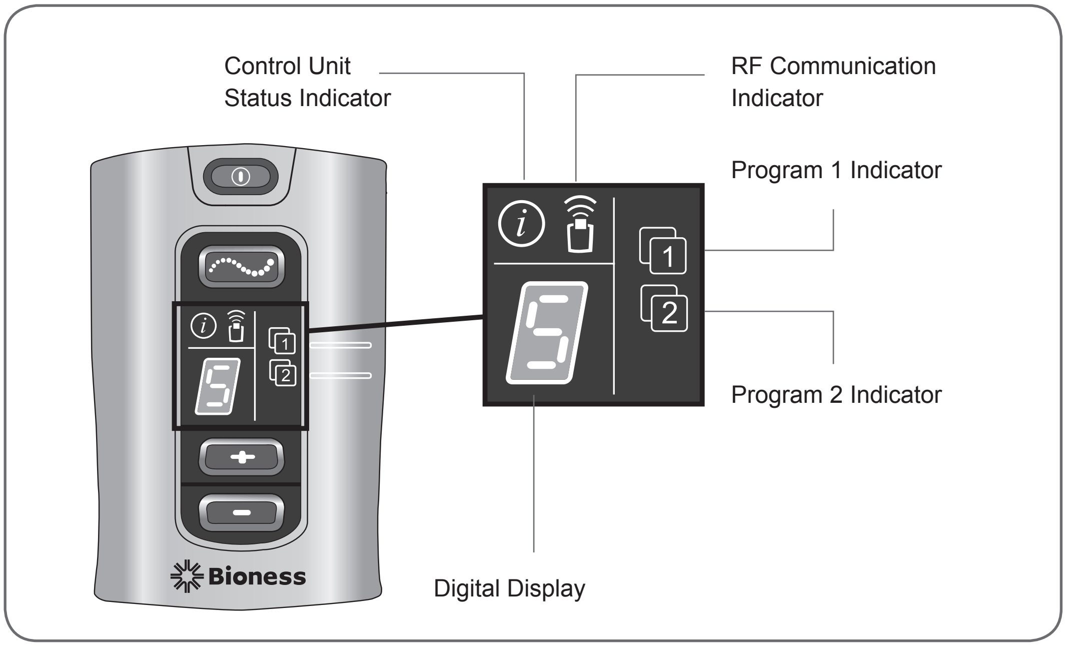

Control Unit Status Indicator
RF Communication Indicator
Program 1 Indicator
Program 2 Indicator
Digital Display
1
2
5
Bioness

Figure 4-7: H200 Wireless Control Unit digital display and indicators.

The Control Unit indicators communicate:

- System status.
- User program selected.
- RF communication status. See Table 4-5.

Indicator	Description	Definition
i	Control Unit Status Indicator FLASHES YELLOW	Low Battery, H200 Wireless Control Unit
i	Control Unit Status Indicator is SOLID RED	Control Unit Charging Error; Electronic Registration Error; Control Unit Hardware/Software Error
1	Program 1 Indicator is GREEN	Program 1 Selected
2	Program 2 Indicator is GREEN	Program 2 Selected
	RF Communication Indicator FLASHES RED	RF Communication Error

Table 4-5: H200 Wireless Control Unit indicator lights.

The Control Unit digital display shows:

- Stimulation intensity level.
- Clinical program selected.
- Electronic registration status.
- Control Unit battery charging status. See Table 4-6.

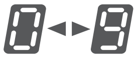
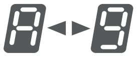
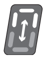
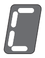
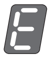
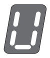
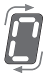
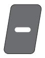
Display	Description	Definition
	0–9	Stimulation Intensity Level; "0" Equals No Stimulation
	A–G	Clinical Program A–G.
	Alternating GREEN Arches	Registration in Process
	Letter "C"	Registration Complete
	Letter "E"	Registration Error
	Letter "U"	H200 Wireless Control Unit Unregistered
	Rotating GREEN Circle	H200 Wireless Control Unit Charging
	Horizontal GREEN Line	H200 Wireless Control Unit Fully Charged

Table 4-6: H200 Wireless Control Unit digital displays.

Audio Alerts

The H200 Wireless Control Unit beeps to indicate:

- A button was pressed.
- RF communication failed.
- A charging error occurred.
- The audio alerts were muted/un-muted.
- A charger was connected or disconnected.
- The NESS H200 Wireless System was turned on/off.
- The H200 Wireless Control Unit battery charge level is low.
- An H200 Wireless Control Unit hardware/software error occurred.
- The electronic registration process was initiated, successful, or unsuccessful.

Rechargeable Battery and Charging Port

The H200 Wireless Control Unit is powered by a single rechargeable NiMH AAA battery that is easily replaced with a Phillips screwdriver. The charging port is located at the bottom of the Control Unit, under the flexible cover. See Figure 4-8.

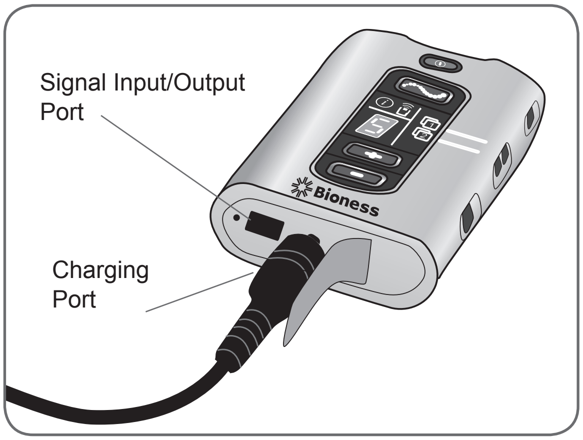


Figure 4-8: H200 Wireless Control Unit charging port.

⚠ **CAUTION: Next to the charging port is a signal input/output port for the configuration cradle communication connector cable. See Figure 4-8. The signal input/output port on the Control Unit is only to be used by the clinician.**

H200 Wireless Clinical Programs

The H200 Wireless System supports:

- Functional Training Programs.
- Neuroprosthesis Programs.
- Motor Neuromodulation Program.
- Personal Preset Programs.
- Custom Personal Programming

Functional Training Programs

There are three functional Training Programs A, B, and C that are designed to exercise the hand. They consist of repetitive motions with a relaxation pause between each motion. They begin when the 〰 trigger button on the Control Unit or Orthosis is pressed. They end when the programmed training time finishes. Training time can range from 5 to 120 minutes.

Program A—Grasp and Release

Activates sequential opening and closing of the hand. Pressing the trigger button starts the stimulation to open the hand. The hand then closes and opens, with a pause between each phase. Stimulation intensity and the duration of the extension and flexion phases can be adjusted, as can total program time.

Program B—Open Hand

Activates the extensor muscles only. When the trigger button is pressed, hand extension is followed by a period of relaxation, and then hand extension repeats. Stimulation intensity and the duration of the extension and relaxation phases can be adjusted, as can total program time.

Program C—Grasp

Activates sequential closing of the hand. When the trigger button is pressed, hand flexion is followed by a period of relaxation, and then hand flexion repeats. Stimulation intensity and the duration of the flexion and relaxation phases can be adjusted, as can the total program time.

Neuroprosthesis Programs

There are three Neuroprosthesis Programs D, E, and F that are designed to help perform a specific task, such as opening a door or grasping an object. They start when the trigger button on the Control Unit or Orthosis is pressed. They continue until the trigger button is pressed again. Neuroprosthesis programs have no set program time. The duration is determined by task/user.

Program D—Open Hand

Activates the hand to open and remain open until the trigger button is pressed again.

Program E—Grasp and Release

Activates the hand to grasp and hold objects using a palmar grasp. When the trigger button is pressed, a half-second pause is followed by a pre-defined duration of hand opening. The hand then closes and remains closed until the trigger button is pressed again to release the grasp. Once the trigger button is pressed the second time, a half second of continued flexor stimulation is followed by an adjustable duration of extensor stimulation to open the hand. The stimulation then shuts off, and the hand relaxes.

Program F—Key Grip

Program F is used to grasp and hold small items in a lateral grasp (or key grip) between the thumb and the lateral side of the index finger. Program F holds the fingers in flexion throughout the operating phases.

When the trigger button is pressed, the thumb opens. The thumb then closes and remains closed until the trigger button is pressed again to release the grip. Once the trigger button is pressed the second time, extensor stimulation opens the thumb. The stimulation then shuts off, and the hand relaxes.

Motor Neuromodulation Program

Program G—Extensors and Flexors, Extensors Only, Flexors Only

There is one Motor Neuromodulation Program G that delivers rapid bursts of stimulation to the flexors and extensors, the flexors only, or the extensors only. The program is started and paused by pressing the trigger button on the Control Unit or Orthosis. Program time can range from 5 to 30 minutes.

Personal Preset Programs

The Personal Preset Programs address patient variances in:

- Voluntary movement of the wrist and fingers.
- Finger response to motor neuromodulation.
- Tone.

The three Personal Preset Program consists of a series of Functional Training and Motor Neuromodulation Program segments that cycle for a total programmed time. Each program may have up to eight exercises with intermittent rest periods. Personal programs begin when the trigger button on the Control Unit or Orthosis is pressed. They end when the program time elapses. Program time can range from 30 to 240 minutes.

- **Personal Preset 1**—For all patients during initial use. Thereafter, for patients with a high level of flexor tone.
- **Personal Preset 2**—For patients with moderate flexor tone.
- **Personal Preset 3**—For patients with mild flexor tone.

Personal Custom Programming

A Personal Custom Program is a clinician-configured program that may include up to eight program segments and 7 rest periods. The clinician customizes the program by adding, deleting, and reordering program segments and adjusting segment duration. Program time can range from 30 to 240 minutes.

Operating the NESS H200 Wireless System

Turning the System On/Off

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

When the system is on:

- The on/off button on the Control Unit will FLASH GREEN.
- The status light on the Orthosis will FLASH GREEN.

Testing Stimulation in the H200 Wireless Orthosis

1. Verify that the system is on. The trigger button should not be lit.
2. Press and hold the stimulation test button to test stimulation of the extensor muscles. Stimulation will turn on and stay on until the button is released. When stimulation is on, the trigger button will FLASH YELLOW RAPIDLY.
3. Release the stimulation test button to turn off stimulation.
4. Repeat to test stimulation of the flexor muscles.

Selecting a User Program

During the clinical/therapy session, the clinician will select the clinical programs that best fit the patient's therapeutic needs, customize the programs, and then, for home users, assign two of the clinical programs to Program Buttons 1 and 2 on the H200 Wireless Control Unit.

To select a User Program turn on the system. User Program 1 is selected automatically. The 1 Program 1 indicator will be GREEN. To select User Program 2, press the 2 Program 2 selection button.

Entering Clinical Mode

With the system off, press and hold the minus button and the on/off button until the H200 Wireless Control Unit beeps and program letter "A" and the stimulation intensity level alternate in the digital display. To exit clinical mode, press the on/off button.

Selecting a Clinical Program

While in clinical mode, press the top or bottom program selection button on the H200 Wireless Control Unit until the desired program letter appears in the digital display.

Turning On Stimulation

Press the ∼ trigger button on the H200 Wireless Control Unit or the trigger button on the Orthosis.

Pausing Stimulation

Press the ∼ trigger button on the H200 Wireless Control Unit or the trigger button on the Orthosis.

Note: Neuroprosthesis Programs cannot be paused. Pressing the trigger button when stimulation is on starts the second phase of a Neuroprosthesis Program.

Turning Off Stimulation

Press the ⏻ on/off button or the ∼ trigger button on the Control Unit, or press the trigger button on the Orthosis.

Note: To stop stimulation immediately press the ⏻ on/off button in a Neuroprosthesis Program.

Adjusting Stimulation Intensity

Press the + plus or − minus button on the Control Unit once to increase/decrease stimulation intensity one level. The Control Unit will beep with each change in level and it will show in the digital display.

Note: An intensity level of "0" equals no stimulation.

Muting/Un-Muting the System Audio Alerts

Press the 🔇 mute button briefly. The mute button is located on the side of the Control Unit.

Entering and Exiting Deep Sleep Mode

With the system off, press and hold the ⏻ on/off button for ten seconds. The Control Unit and Orthosis will beep and the Orthosis lights will flash when entering deep sleep mode. To exit deep sleep mode, press the Orthosis trigger button.

Note: Deep sleep mode is a power saving feature that shuts down the system and displays no indications. The use of deep sleep mode is recommended for extended periods of non-use.

Chapter 5

NESS H200 Wireless Clinician’s Kit

The NESS H200 Wireless Clinician’s Kit is used to fit and program the NESS H200 Wireless System. The small/medium Clinician’s Kit is for fitting small/medium Orthoses. The large Clinician’s Kit is for fitting the large Orthosis.

H200 Wireless Clinician’s Kit (small/medium)

PDA Components

- HP iPAQ Clinician’s Programmer with H200 Wireless® Software
- HP iPAQ Configuration Cradle with Stylus
- HP iPAQ Clinician’s Programmer Charger

Accessories

- Thenars: Left/Right, Regular/Large (small/medium)
- Thenar Screws
- Wrist Inserts: Left/Right, Thick/Medium/Thin (small/medium)
- Wrist Insert Screws (small/medium)
- Wrist Insert Covers (small/medium)
- H200 Wireless FPL Panels: Left/Right (small/medium)
- FPL Panel Screws (small/medium)
- Fitting Panel Sets: Left/Right (small/medium)
- H200 Wireless Cloth Electrodes
- Phillips Screwdriver
- H200 Wireless Clinician’s Reference Card
- HP iPAQ Manufacturer’s Instructions

H200 Wireless Clinician’s Kit (large)

PDA Components

- HP iPAQ Clinician’s Programmer with H200 Wireless® Software
- HP iPAQ Configuration Cradle with Stylus
- HP iPAQ Clinician’s Programmer Charger

Accessories

- Thenars: Left/Right, Large (large)
- Thenar Screws
- Wrist Inserts: Left/Right, Thick/Medium/Thin (large)
- Wrist Insert Screws (large)
- Wrist Insert Covers (large)
- H200 Wireless FPL Panels: Left/Right (large)
- FPL Panel Screws (large)
- Fitting Panel Sets: Left/Right (large)
- H200 Wireless Cloth Electrodes
- Phillips Screwdriver
- H200 Wireless Clinician’s Reference Card
- HP iPAQ Manufacturer’s Instructions

The NESS H200 Wireless Clinician’s Upgrade Kit is to be used with the NESS H200 Clinician's Kit to fit and program the NESS H200 Wireless System.

H200 Wireless Clinician’s Upgrade Kit

PDA Components

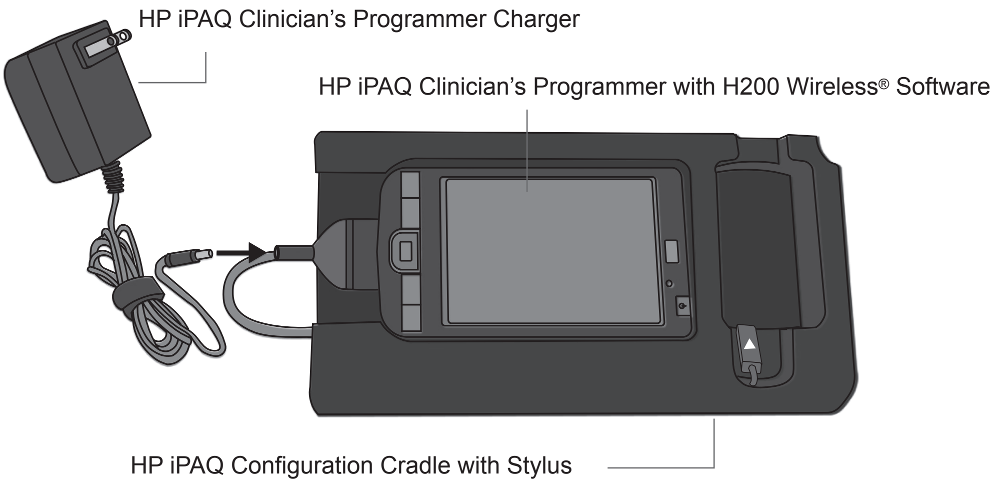
- HP iPAQ Clinician’s Programmer with H200 Wireless® Software
- HP iPAQ Configuration Cradle with Stylus
- HP iPAQ Clinician’s Programmer Charger

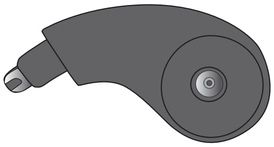
Accessories

- H200 Wireless FPL Panels: Left/Right (small/medium)
- H200 Wireless FPL Panels: Left/Right (large)

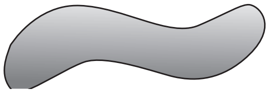
- FPL Panel Screws (small/medium)
- FPL Panel Screws (large)
- Wrist Insert Covers (small/medium)
- Wrist Insert Covers (large)
- H200 Wireless Cloth Electrodes
- H200 Wireless Clinician’s Reference Card
- HP iPAQ Manufacturer’s Instructions

⚠ **CAUTION: Inspect all components for damage prior to use.**

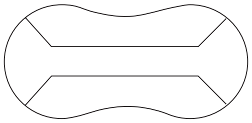

HP iPAQ Clinician’s Programmer Charger
HP iPAQ Clinician’s Programmer with H200 Wireless® Software
HP iPAQ Configuration Cradle with Stylus



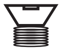
Thenar



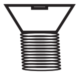
Wrist Insert



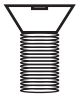
Wrist Insert Cover



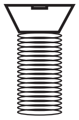
Thenar Screw
2.5 x 4 mm



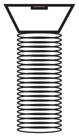
Wrist Insert Screw
(small/medium)
3 x 6 mm



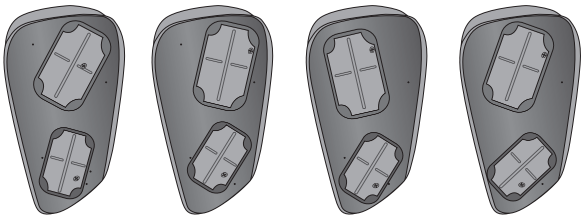
Wrist Insert Screw
(large)
3 x 8 mm



H200 Wireless FPL
Panel Screw
(small/medium)
3 x 12 mm

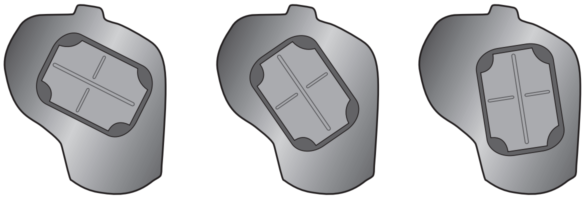


H200 Wireless FPL
Panel Screw
(large)
3 x 14 mm

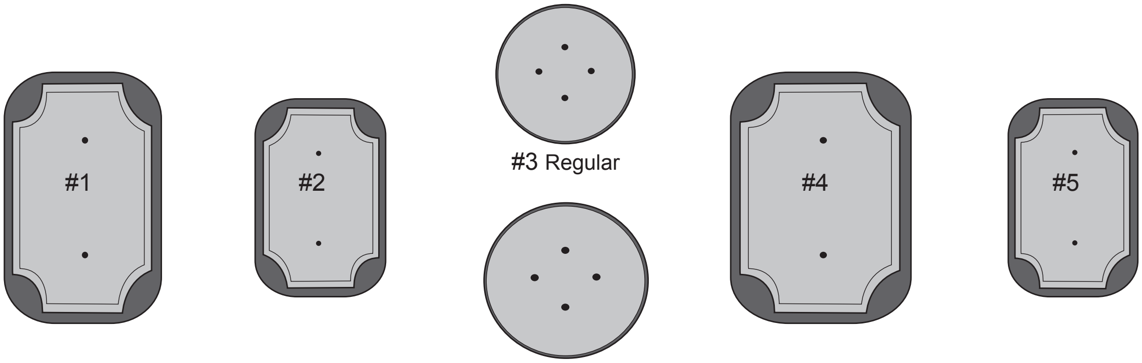


Extensor A, B, C, D

Fitting Panels Set



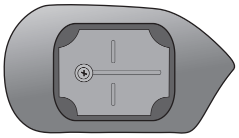
Flexor A, B, C



#3 Regular

#3 Large

H200 Wireless Cloth Electrodes



H200 Wireless FPL Panel

Phillips Screwdriver

PDA Components

HP iPAQ Clinician's Programmer with NESS H200 Wireless Software

The HP iPAQ Clinician's Programmer is a portable personal digital assistant (PDA) used to program the NESS H200 Wireless System. When connected to the HP iPAQ Configuration Cradle and H200 Wireless Control Unit, the Clinician's Programmer can wirelessly communicate with the H200 Wireless Orthosis. See Figure 5-1.

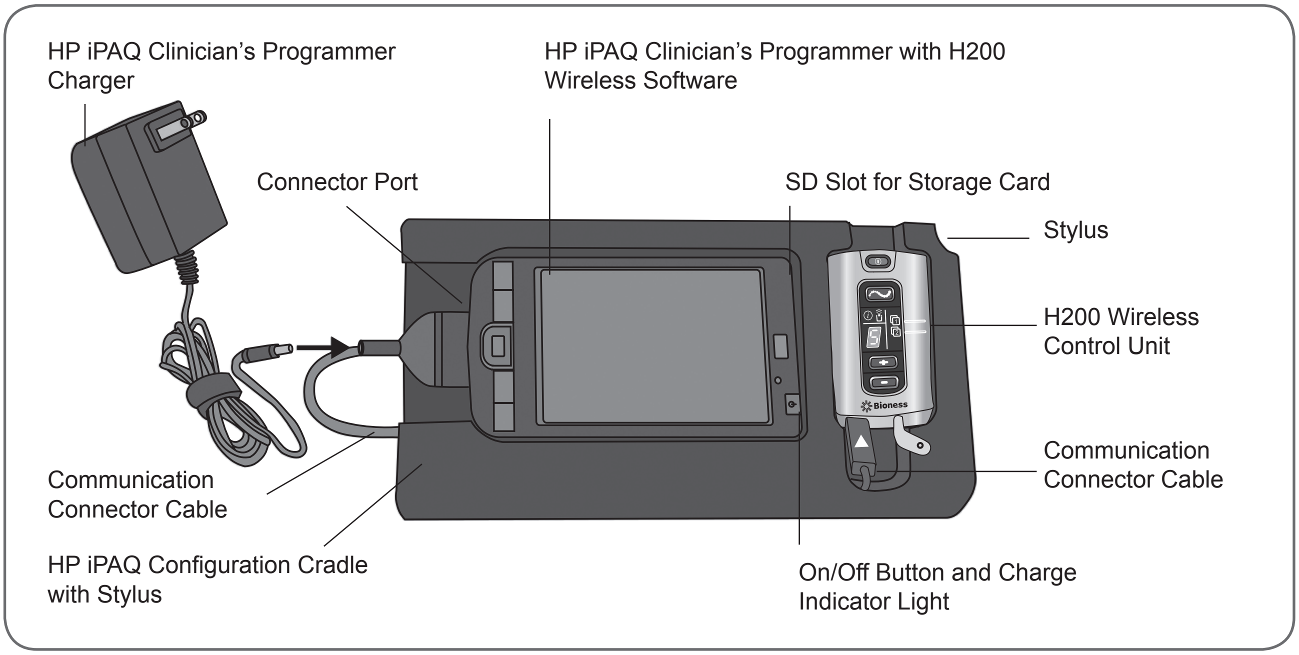

HP iPAQ Clinician's Programmer Charger
HP iPAQ Clinician's Programmer with H200 Wireless Software
Connector Port
SD Slot for Storage Card
Stylus
H200 Wireless Control Unit
Communication Connector Cable
Communication Connector Cable
HP iPAQ Configuration Cradle with Stylus
On/Off Button and Charge Indicator Light
Bioness

Figure 5-1: PDA components, H200 Wireless Control Unit connected.

WARNING: The Clinician's Programmer should only contain the Windows Mobile® operating system and Bioness Inc proprietary software. Third-party software packages are not supported and may interfere with proper operation of the NESS H200 Wireless System, thus voiding the warranty.

On/Off Button

Used to turn on/off the Clinician’s Programmer.

Charge Indicator Light

The charge indicator light is YELLOW when the Clinician’s Programmer is charging and GREEN when the Clinician’s Programmer battery charge is complete.

SD (Secure Digital) Slot

The SD slot is for the SD card, used to back up and restore the Clinician's Programmer database.

Connector Port

Used to connect the Clinician’s Programmer to the communication connector cable on the HP iPAQ Configuration Cradle.

HP iPAQ Configuration Cradle with Stylus

The HP iPAQ Configuration Cradle connects the Clinician’s Programmer to the H200 Wireless Control Unit and to the Clinician’s Programmer Charger. The stylus is for software navigation.

HP iPAQ Clinician’s Programmer Charger

Used to charge the Clinician’s Programmer battery. Use only the Clinician’s Programmer Charger included in the H200 Wireless Clinician’s Kit.

Accessories

Thenar

The thenar is a removable unit that attaches to the spiral end of the Orthosis. See Figure 5-2. It is used to stimulate the thenar muscle group. The thenar is available in right (Rt) and left (Lt) configurations, in regular and large sizes.

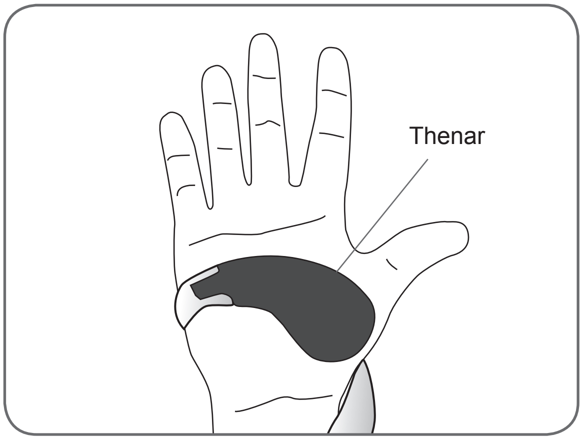


Figure 5-2: Thenar.

Thenar Screws

One thenar screw is needed to attach the thenar to the spiral end of the H200 Wireless Orthosis. See Figure 5-3.

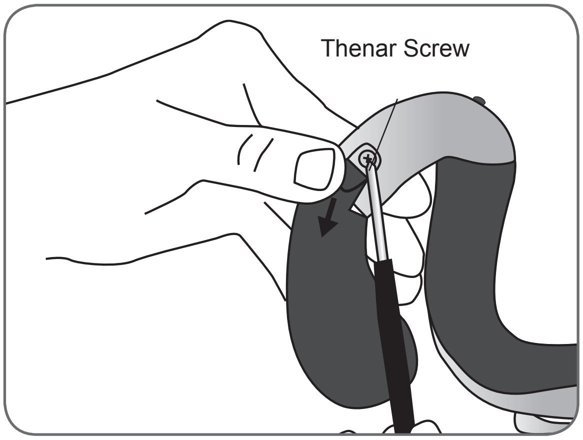


Figure 5-3: Thenar screw.

Wrist Insert

The wrist insert is a removable unit that attaches to the underside of the wrist bridge of the Orthosis. See Figure 5-4. It is used to cushion the back of the hand, maintain contact pressure between the Orthosis and the hand in order to stabilize the hand, and optimize hand posture during stimulation. The wrist insert is available in right (Rt) and left (Lt) configurations, and in three sizes (thick, medium, and thin).

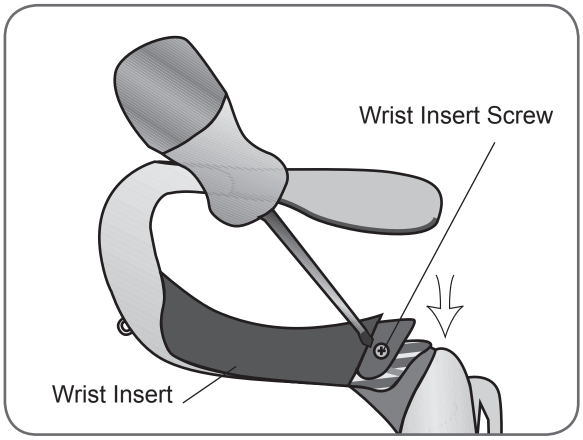


Figure 5-4: Wrist insert and wrist insert screw.

Wrist Insert Screws

One wrist insert screw is needed to attach the wrist insert to the wrist bridge of the H200 Wireless Orthosis. See Figure 5-4.

Wrist Insert Covers

The wrist insert cover adheres to the wrist insert and is used as an hygienic cover when the Orthosis is used by multiple patients. Two sizes are available: small/medium and large. The wrist insert cover is single use only. See Figure 5-5.

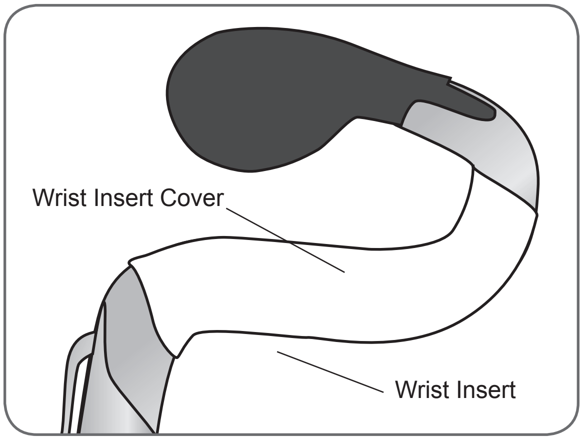

Wrist Insert Cover
Wrist Insert

Figure 5-5: Wrist insert cover adhered to wrist insert.

H200 Wireless FPL Panel

The Wireless FPL panel fits over the #5 electrode base on the Orthosis. See Figure 5-6. The FPL panel is for patients who have small wrists, to improve limb contact with the FPL electrode. The FPL panel is available in right (Rt) and left (Lt) configurations.

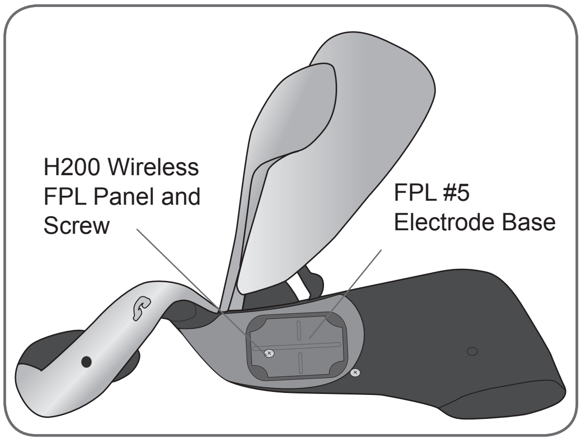

H200 Wireless FPL Panel and Screw
FPL #5 Electrode Base

Figure 5-6: FPL panel and FPL panel screw.

H200 Wireless FPL Panel Screws

One H200 Wireless FPL panel screw is needed to attach the H200 Wireless FPL panel to the Orthosis. See Figure 5-6.

Fitting Panels

The fitting panels feature an array of electrode base configurations used to stimulate opening and closing of the hand and fingers. The extensor fitting panels attach to the Orthosis extensor wing. The flexor fitting panels attach to the Orthosis flexor support. The fitting panels are used in the clinic setting and to customize the electrode bases to the Orthosis for home users. See Figure 5-7.

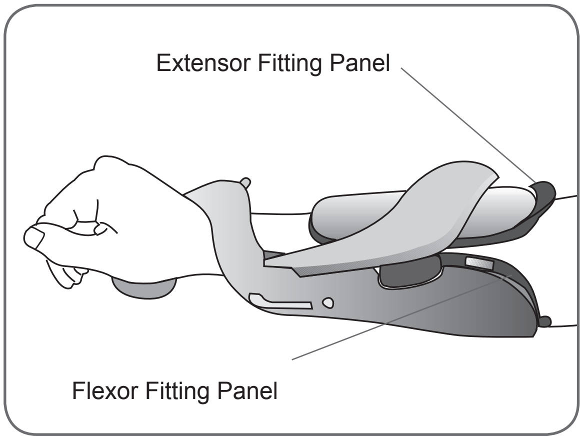


Figure 5-7: Fitting panels in place on the Orthosis.

Extensor Fitting Panels

The extensor fitting panels are available in right (Rt) and left (Lt) configurations, and in four electrode base configurations: A, B, C, and D. See Figure 5-8.

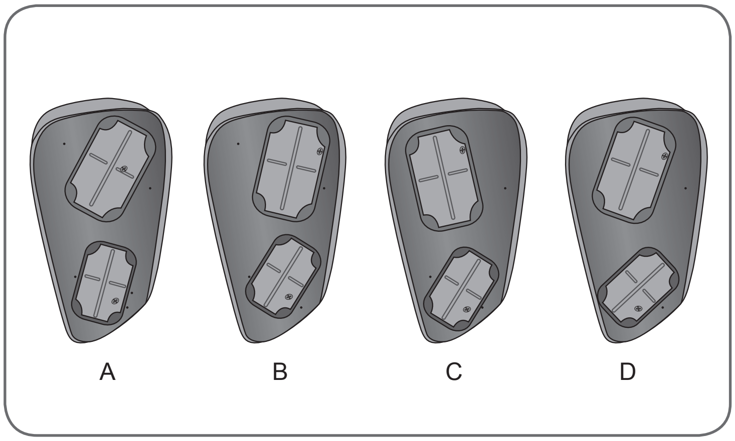


Figure 5-8: Extensor fitting panels A, B, C, and D: right (Rt) configuration.

⚠ **CAUTION: Disinfect the fitting panels between uses.**

Each extensor fitting panel has two electrode bases (Extensor Digitorum (ED) #1 and Extensor Pollicis Brevis (EPB) #2) on one side and two conducting springs on the other side. See Figure 5-9. The conducting springs make electrical contact with the #1 and #2 electrode base sockets on the Orthosis.

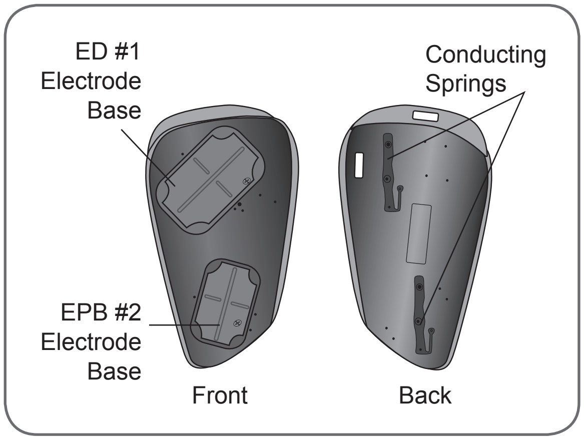


Figure 5-9: Right (Rt) extensor fitting panel, front and back.

Flexor Fitting Panels

The flexor fitting panels are available in right (Rt) and left (Lt) configurations, in three electrode base configurations: A, B, and C. See Figure 5-10.

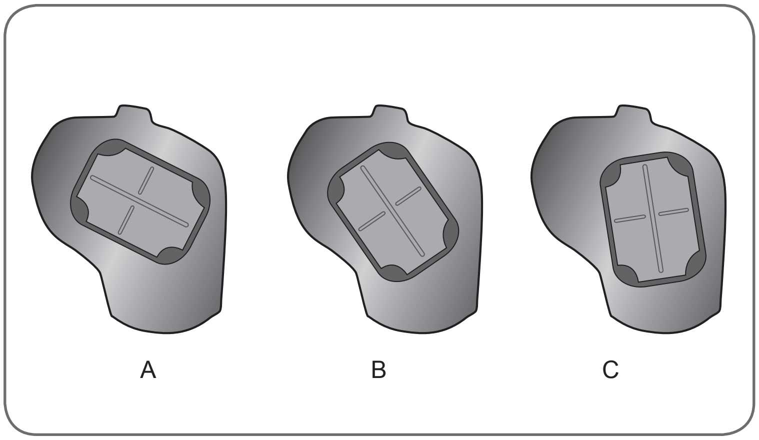


Figure 5-10: Flexor fitting panels A, B, and C: right (Rt) configuration.

The flexor fitting panels have one electrode base (Flexor Digitorum Superficialis (FDS) #4) and one conducting spring each. The conducting spring is on the back of the fitting panel and makes contact with the #4 electrode base socket on the Orthosis.

Electrode Base Set

The electrode base set is used to customize the electrode positions for home-use Orthoses.

Electrode Base Screw and Washer Set

The electrode base screw and washer set is used to attach electrode bases #1, #2, and #4 to home-use H200 Wireless Orthoses. Use one screw and one washer for each electrode base.

H200 Wireless Cloth Electrodes

The H200 Wireless Orthosis uses five cloth electrodes. The electrodes insert to the electrode bases. The cloth electrodes are made from a non-woven cotton/polymer fabric designed to retain moisture while the H200 Wireless Orthosis is on the arm. The cloth electrodes must be wet before use and after every three to four hours of use.

The thenar cloth electrode is available in regular and large sizes.

⚠ **CAUTION: Do not use the NESS H200 Wireless System without the cloth electrodes.**

⚠ **CAUTION: The H200 Wireless cloth electrodes must be wet before use and wet again after every four hours of use.**

⚠ **CAUTION: The H200 Wireless cloth electrodes are for single patient use.**

⚠ **CAUTION: The H200 Wireless cloth electrodes must be replaced every two weeks, or sooner if they become damaged.**

Fitting the H200 Wireless Orthosis

Before fitting the H200 Wireless Orthosis:

- Wash the patient's hand and forearm with soap and water and remove any lotions or oils.
- Have the patient remove any jewelry from the hand, wrist, and forearm.

Measuring for Orthosis Size

The Orthosis is available in three sizes: small, medium, and large. The wrist circumference measurements for the small and medium Orthoses are the same, but the small Orthosis will fit a thinner or smaller forearm.

Using a measuring tape, measure the patient's wrist circumference, forearm circumference, and forearm length, and refer to Table 6-1.

Orthosis Size	Wrist Circumference (Distal to Ulnar Styloid Process)	Forearm Circumference (8 cm (3 in.) Distal to Lateral Epicondyle)	Forearm Length (From Distal Wrist Crease to Elbow Crease)
Small	~ 14.5 to 20 cm (5.75 to 7.75 in.)	~ 17 to 20 cm (6.75 to 8 in.)	~ 24 cm (9.5 in.) or less
Medium	~ 14.5 to 20 cm (5.75 to 7.75 in.)	> 20 cm (8 in.)	~ 24 cm (9.5 in.) or less
Large	~ 17 to 25 cm (6.75 to 9.75 in.)	> 20 cm (8 in.)	~ 24 cm (9.5 in.) or more

Table 6-1: H200 Wireless Orthosis fitting chart.

Fitting the Thenar

The thenar #3 electrode should rest on the thenar eminence. See Figure 6-1.

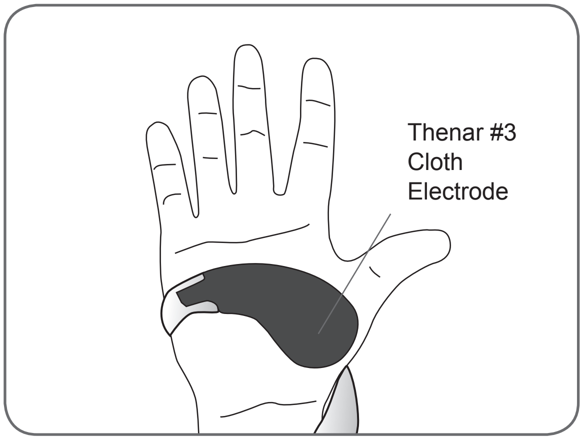


Figure 6-1: Placement of the thenar on the thenar eminence.

To fit the thenar:

1. Choose a thenar of appropriate size and configuration.
2. Pull back the flexible cover on the thenar to expose the metal. See Figure 6-2.

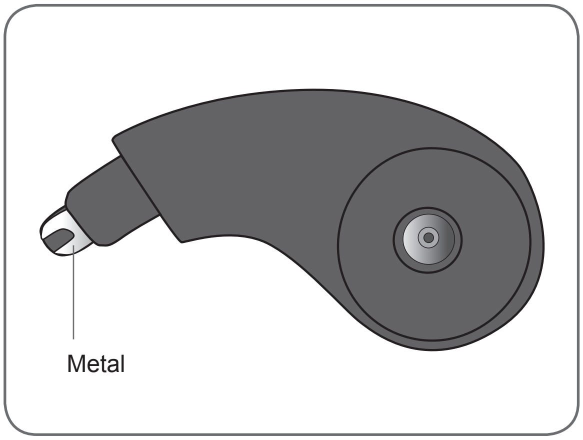


Figure 6-2: Thenar.

3. Slide the metal end of the thenar into the slot on the spiral end of the Orthosis.
4. Tighten the thenar screw. The screw secures the thenar in place and makes the electrical contact between the thenar and the Orthosis. See Figure 6-3.

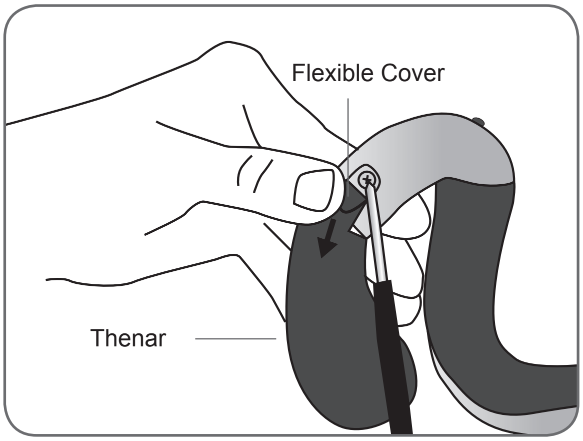


Figure 6-3: Attaching the thenar to the Orthosis spiral end.

5. Close the flexible cover over the screw.

To remove the thenar:

1. Carefully lift the flexible cover overlying the thenar screw and loosen the screw. Do not remove the screw. Be careful not to tear the flexible cover.
2. Slide the thenar away from the Orthosis.

Note: Using an incorrect screw can damage the H200 Wireless Orthosis.

⚠ **CAUTION: Do not use the NESS H200 Wireless System without wetting and attaching the thenar cloth electrode.**

Fitting the Wrist Insert

The wrist insert fits under the wrist bridge of the Orthosis. See Figure 6-4.

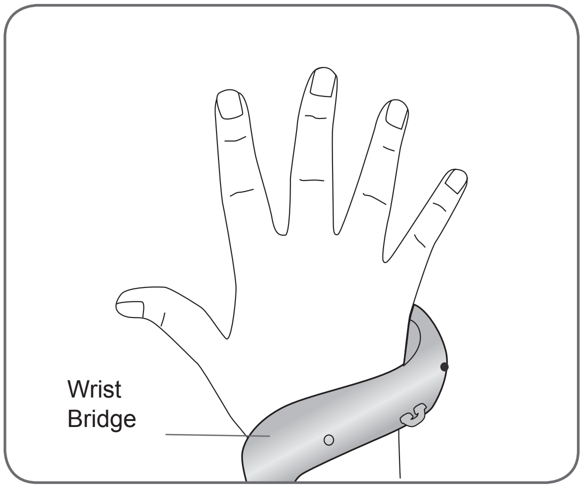


Figure 6-4: Wrist bridge, with wrist insert underneath.

To fit the wrist insert:

1. Select a wrist insert of appropriate size, side, and thickness. When choosing a thickness, follow these guidelines:
   - **Hand/Arm Posture:** The patient's hand/arm will determine which wrist insert to use. The optimum angle of the wrist should be between 0 and 20 degrees of extension when the Orthosis is donned. Selecting a thin wrist insert, will provide a greater freedom of movement of the hand than selecting a thick wrist insert.
   - **Orthosis Stability and Contact:** The Orthosis should fit snugly on the hand/arm. Size of the wrist insert and functional position of the hand are elements that affect the fit of the orthosis.
2. Select an appropriate wrist insert screw.
3. Align the wrist insert over the wrist bridge. The prong(s) on the wrist insert should be distal and the screw hole proximal. See Figure 6-5.
4. Insert the wrist insert prong(s) into the wrist bridge. See Figure 6-6. Do not damage the electronic circuitry in the wrist bridge.
5. Align the screw hole of the wrist insert with the screw hole of the wrist bridge.
6. Insert the wrist insert screw into the screw holes, and tighten the screw. See Figure 6-7.

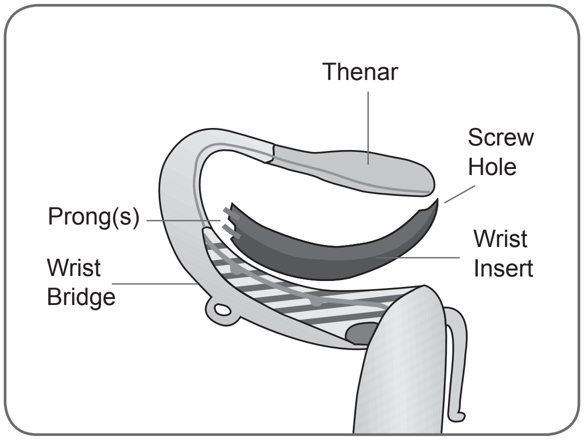

Thenar
Screw Hole
Prong(s)
Wrist Insert
Wrist Bridge

Figure 6-5: Aligning the wrist insert.

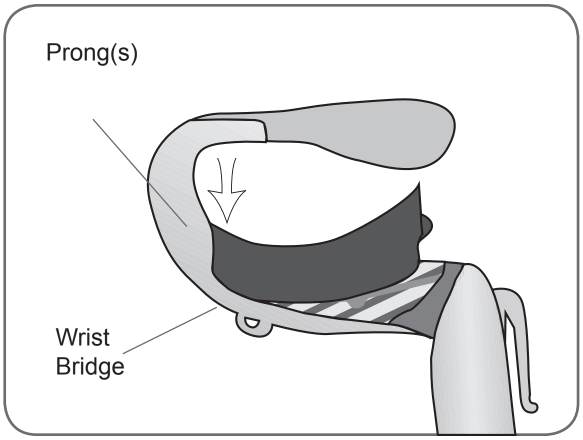

Prong(s)
Wrist Bridge

Figure 6-6: Inserting the wrist insert into the wrist bridge.

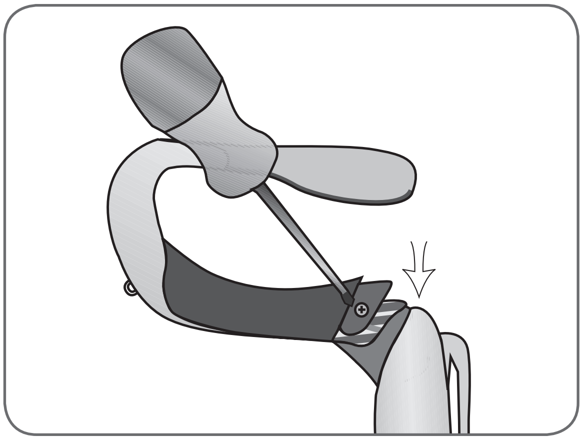


Figure 6-7: Tightening the wrist insert screw.

To remove the wrist insert:

1. Carefully lift the corner padding overlying the wrist insert screw. Do not tear the padding.
2. Remove the screw.
3. Lift the wrist insert (screw hole end first) away from the wrist bridge. Do not damage the electronic circuitry in the wrist bridge.

Note: Using an incorrect screw can damage the H200 Wireless Orthosis.

To apply the wrist insert cover:

1. Select the appropriate wrist insert cover size. Use a small/medium wrist insert cover with the small/medium Orthosis and a large wrist insert cover with the large Orthosis.
2. Peel the middle liner off.
3. Attach the wrist insert cover to the wrist bridge covering the wrist insert (blue area).
4. Peel the side liners off and tighten over the wirst bridge. Do not place the wrist insert cover over the Orthosis trigger button or wrist strap attachment ring.
5. Make sure the entire wrist insert is covered. See Figure 6-8.

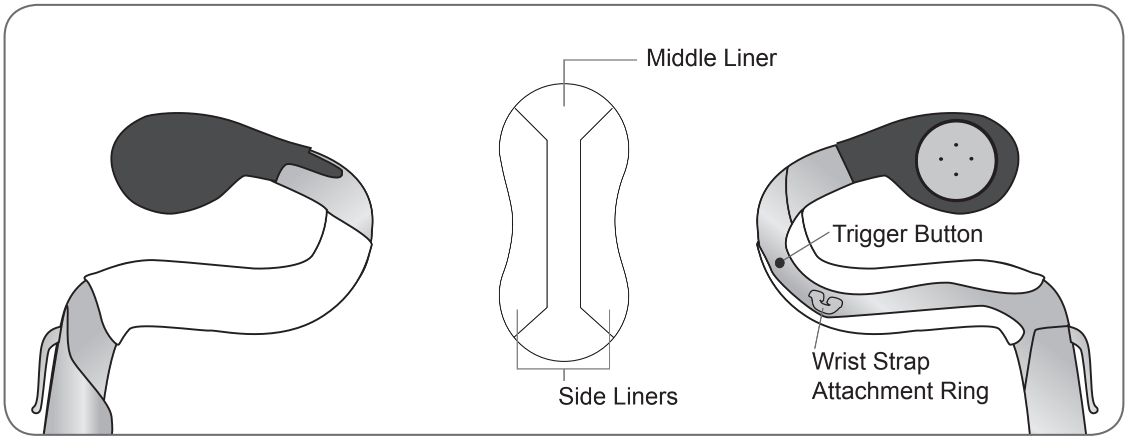


Figure 6-8: Wrist insert cover adhered to wrist insert.

To remove the wrist insert cover:

1. Grab the edge of the wrist insert cover and carefully peel off from the wrist insert

Note: Remove and dispose of the wrist insert cover after each use.

Fitting the Wrist Strap and FPL Panel

1. With the extensor wing open, position the spiral end of the Orthosis proximally on the hand.
2. Bring the Orthosis around the forearm, and position the flexor support on the forearm. See Figure 6-9.

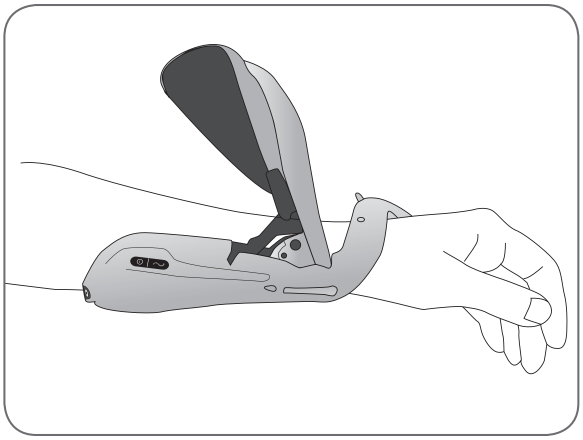


Figure 6-9: Positioning the flexor support.

3. Recheck the position of the spiral end. Make certain there is no excess pressure on the arm/hand, especially in the wrist area. Make certain the thenar is positioned at the center of the thenar eminence.
4. If the Orthosis is positioned too distally, then remove the Orthosis and start again. Do not slide the Orthosis proximally on the arm.

5. If the Orthosis is positioned correctly, close the extensor wing. Place your hand on top of the wing arm and grasp under the Orthosis extensor wing with your fingers. Pull the extensor wing out while pushing down on the wing arm. Push until no more clicking can be heard. See Figure 6-10.

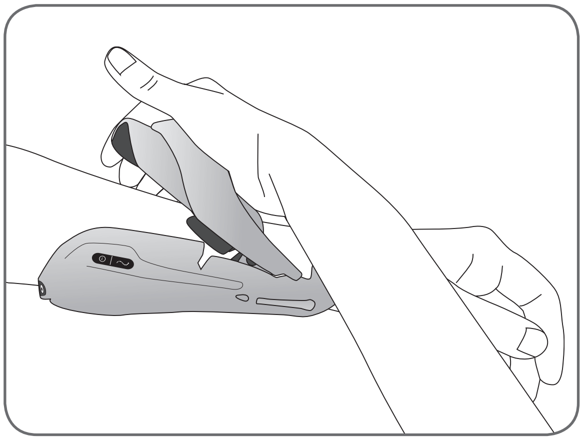


Figure 6-10: Closing the extensor wing.

6. Check to see if the FPL #5 electrode is in contact with the radial side of the wrist. There should be no visible gap between the forearm and the extensor wing. If there is a gap, attach and tighten the wrist strap.

Note: Do not pinch the wing release handle while closing the wing.

Note: Position the Orthosis properly to avoid poor or unbalanced hand activation and pressure marks around the wrist.

Attaching the Wrist Strap

1. Attach the hook on the wrist strap to the attachment ring on the Orthosis wrist bridge. See Figure 6-11.

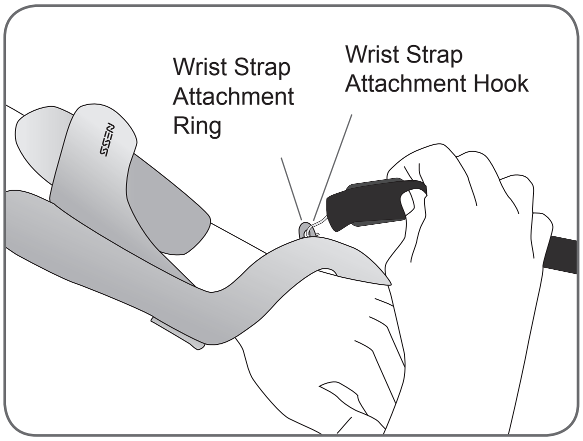

Wrist Strap Attachment Ring
Wrist Strap Attachment Hook
NESS

Figure 6-11: Attaching the wrist strap.

2. Bring the wrist strap under the wrist and up through the wrist strap attachment bar. See Figure 6-12.

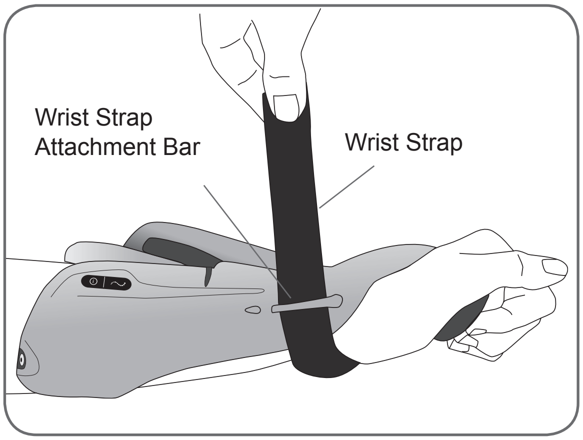

Wrist Strap Attachment Bar
Wrist Strap

Figure 6-12: Securing the wrist strap.

3. Pull up on the wrist strap.
4. Bring the wrist strap down onto itself to fasten.
5. Check to see if the FPL #5 electrode is in contact with the radial side of the wrist. If there is a gap, tighten the wrist strap. If there is still a gap, attach the FPL panel.

Note: If the patient is feeling excessive pressure under the wrist strap or over the radial side of the wrist, loosen the wrist strap.

⚠ **CAUTION: 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.**

Attaching the FPL Panel

The FPL panel fits over the FPL #5 electrode base. See Figure 6-13.

Note: The FPL panel is for patients who have small wrists, to improve limb contact with the FPL electrode.

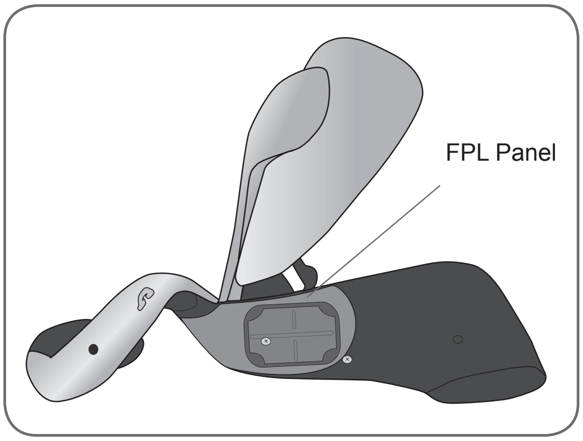


Figure 6-13: The FPL panel placed over the #5 electrode base.

To attach the FPL panel:

1. Select the appropriate FPL panel.
2. Open the Orthosis extensor wing.
3. Remove the screw from the Orthosis FPL #5 electrode base. Do not remove the electrode base. See Figure 6-14.

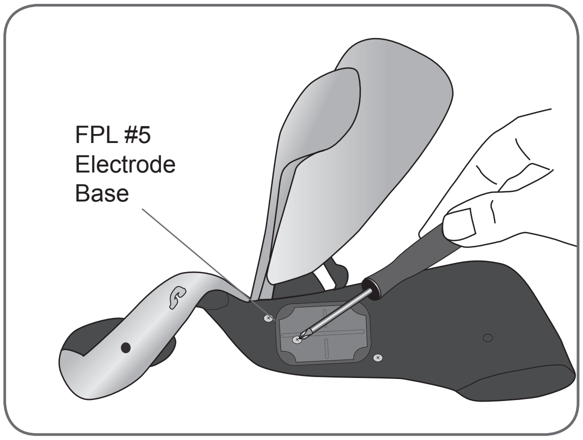


Figure 6-14: Removing the screw from the FPL #5 electrode base.

4. Place the FPL panel on top of the Orthosis FPL #5 electrode base.
5. Insert the FPL panel screw through the FPL panel electrode base and into the Orthosis FPL #5 electrode base and socket.
6. Tighten the screw.

CAUTION: Do not use the NESS H200 Wireless System without wetting and attaching the FPL #5 cloth electrode.

Determining the Optimal Electrode Configuration

The fitting panels are used to determine the optimal electrode configuration for the extensors and flexors. The fitting panels easily snap in and out of the Orthosis and can be changed to elicit the desired hand movement.

Extensor Fitting Panels

1. Select an extensor fitting panel that will elicit the desired hand movement. See Figure 6-15.

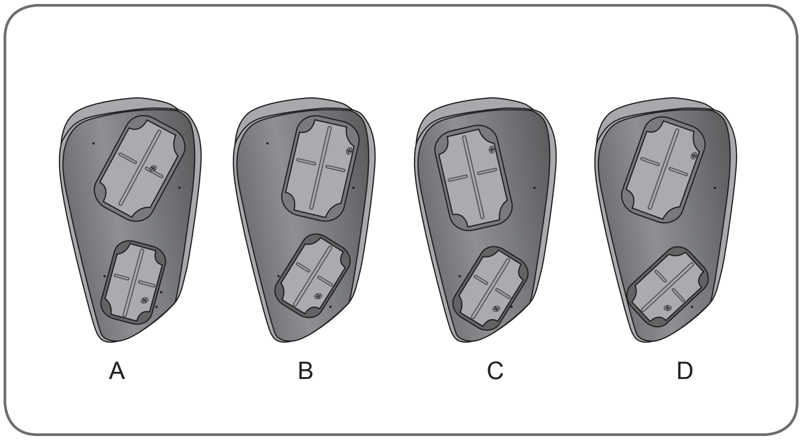


Figure 6-15: Extensor fitting panels.

- Always start with fitting panel A.
- For increased wrist ulnar stimulation and extension of digits 4 and 5, use extensor fitting panel B.
- For increased wrist radial stimulation and extension of digits 1 and 2, use extensor fitting panel C or D. See Figure 6-16.

Ulnar electrode placement B - A - C - D Radial electrode placement

Figure 6-16: Extensor fitting panel, selection guide.

2. With the Orthosis wing opened, align the narrow end of the extensor fitting panel with the narrow end of the extensor wing. See Figure 6-17. Make sure the lip of the fitting panel rests outside of the wing.

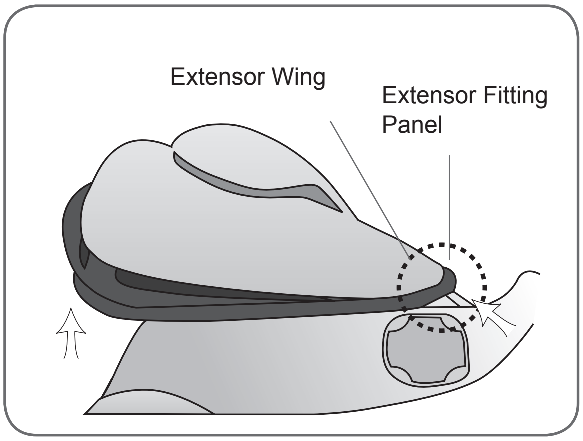


Figure 6-17: Placement of the extensor fitting panel.

3. Grasp the extensor fitting panel and the extensor wing and gently press on the fitting panel until it clicks into place.

⚠ **CAUTION: Do not use the fitting panels without first wetting and attaching the cloth electrodes.**

⚠ **CAUTION: Disinfect the fitting panels and Orthosis after each use. See the maintenance and cleaning section of this guide.**

Flexor Fitting Panels

1. Select a flexor fitting panel that will elicit the desired hand movement. See Figure 6-18.

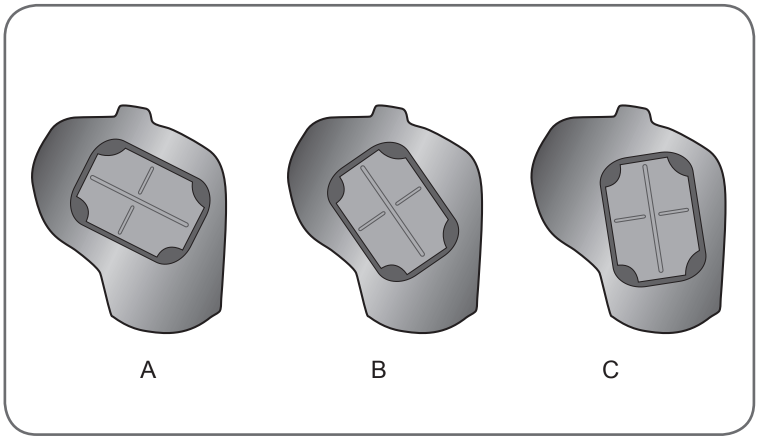


Figure 6-18: Flexor fitting panels.

- Always start with fitting panel A.
- Use the B or C flexor fitting panel for additional radial stimulation and for better index finger and/or thumb flexion. See Figure 6-19.

Ulnar electrode placement A - B - C Radial electrode placement

Figure 6-19: Flexors fitting panel, selection guide.

2. With the Orthosis wing open, fit the flexor fitting panel to the Orthosis flexor support. See Figure 6-20.

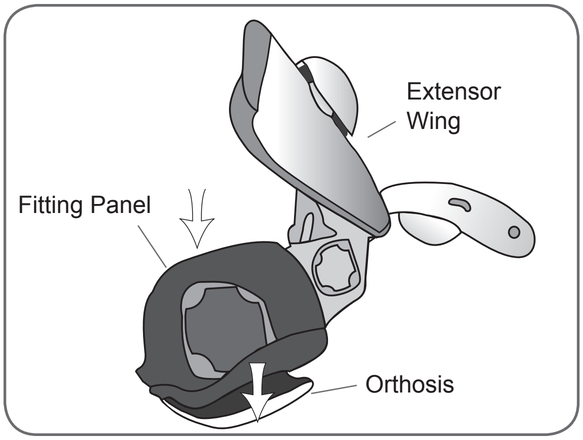


Figure 6-20: Placement of the flexor fitting panel.

3. Make sure the lip of the fitting panel rests beyond the edge of the Orthosis.
4. Grasp the ulnar edge of the flexor fitting panel and the ulnar edge of the H200 Wireless Orthosis.
5. Gently press together until the fitting panel clicks into place.

⚠ **CAUTION: Do not use the fitting panels without first wetting and attaching the cloth electrodes.**

⚠ **CAUTION: Disinfect the fitting panels and Orthosis after each patient use. See the maintenance and cleaning section of this guide.**

Wetting/Attaching the H200 Wireless Cloth Electrodes

To wet the cloth electrodes:

1. Remove the cloth electrodes from the H200 Wireless Orthosis.
2. Wet the cloth electrodes thoroughly and uniformly. See Figure 6-21.

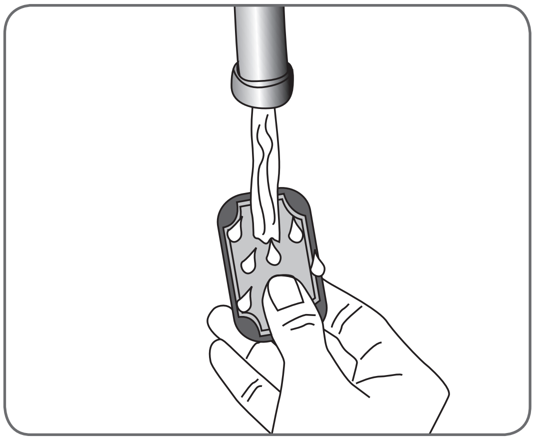


Figure 6-21: Wetting the cloth electrodes.

3. Blot excess water from the cloth electrodes. See Figure 6-22.

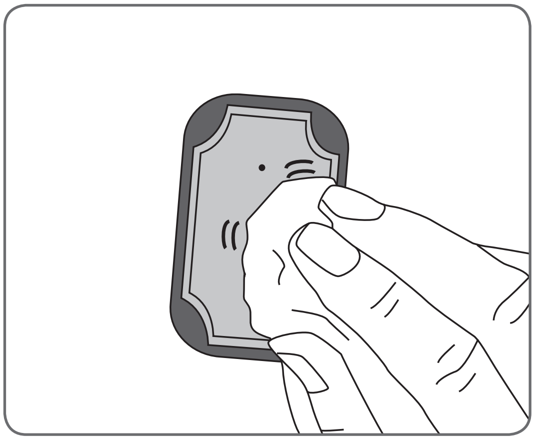


Figure 6-22: Blotting the cloth electrodes.

⚠ **CAUTION: Do not use the H200 Wireless Orthosis without first wetting and attaching the cloth electrodes.**

4. Snap cloth electrode #3 to the thenar.
5. For cloth electrodes #1, 2, 4, and 5, face the white dot on the cloth electrode toward the electrode base. Insert the corners of the cloth electrode into the electrode base. See Figure 6-23.

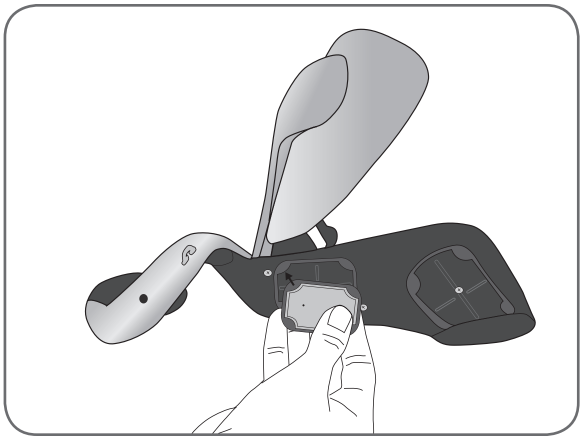


Figure 6-23: Inserting the #5 cloth electrode into the #5 electrode base.

Chapter 7

PDA Setup

Connecting the Clinician’s Programmer to the Cradle

1. Orient the Clinician’s Programmer in the Configuration Cradle with the touchscreen facing up and the connector port facing left. See Figure 7-1.

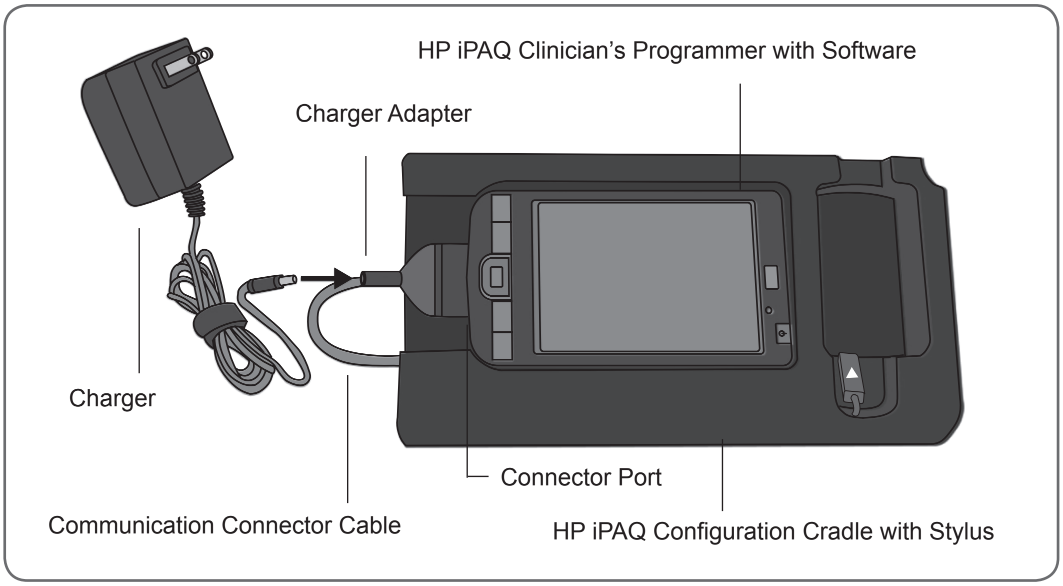

HP iPAQ Clinician’s Programmer with Software
Charger Adapter
Charger
Connector Port
Communication Connector Cable
HP iPAQ Configuration Cradle with Stylus

Figure 7-1: PDA setup and charging configuration.

2. Plug the communication connector cable with charger adapter into the connector port of the Clinician’s Programmer.

Charging the Clinician’s Programmer

1. Connect the Clinician’s Programmer Charger to the charger adapter on the communication connector cable. See Figure 7-1.
2. Plug the charger into an electrical outlet.
3. Allow the Clinician’s Programmer to charge. While charging, the charge indicator light will be AMBER. The Clinician’s Programmer can take two to four hours to charge. When the Clinician’s Programmer is fully charged, the charge indicator light will be GREEN.

Connecting the H200 Wireless Control Unit

1. Turn off the Control Unit, or make sure it is in standby mode. Stimulation should not be on or paused.
2. Plug the communication connector cable of the Configuration Cradle into the signal input/output port of the Control Unit. The white arrow should be facing up. See Figure 7-2.
3. Insert the Control Unit into the Configuration Cradle.

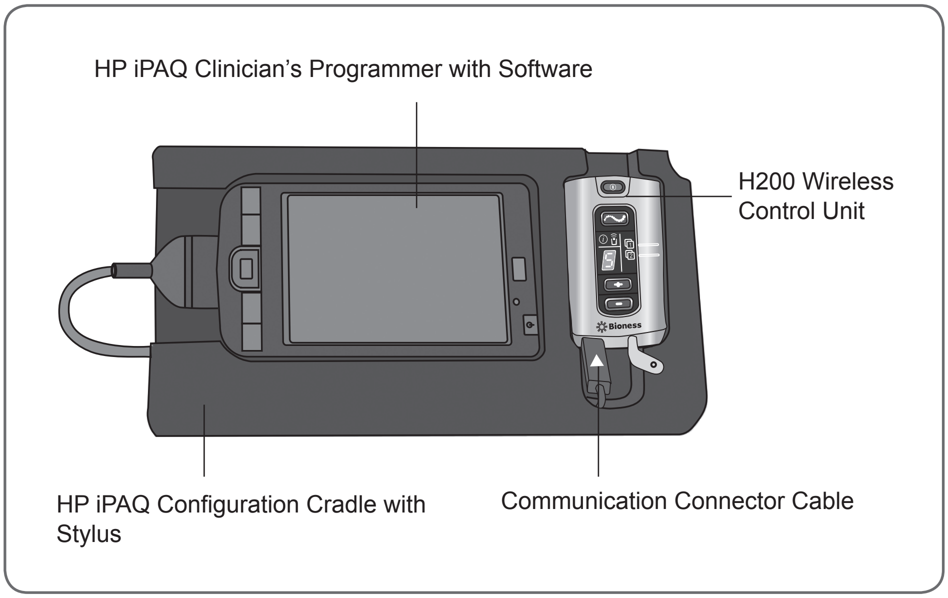

HP iPAQ Clinician’s Programmer with Software
H200 Wireless Control Unit
Bioness
HP iPAQ Configuration Cradle with Stylus
Communication Connector Cable

Figure 7-2: H200 Wireless Control Unit connected to the HP iPAQ Clinician’s Programmer.

⚠ **CAUTION: Turn off the H200 Wireless Control Unit or place it in standby mode before connecting it to the Configuration Cradle.**

⚠ **WARNING: Do not simultaneously charge the H200 Wireless Control Unit, Orthosis, and Clinician’s Programmer while the Control Unit is connected to the Configuration Cradle.**

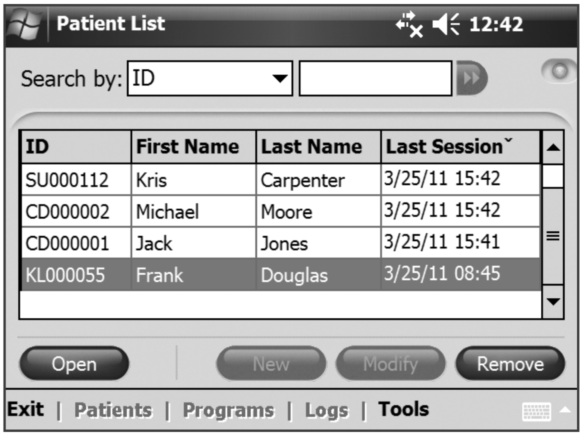
NESS H200 Wireless Software

The H200 Wireless Software is used to program the NESS H200 Wireless System.

Navigation Tools

Information Icon

The information icon is positioned in the top right corner of the software screens. The information icon indicates system status and, when pressed, opens error messages and troubleshooting screens. See Figure 8-1 and Table 8-1.



Search by: ID

ID	First Name	Last Name	Last Session
SU000112	Kris	Carpenter	3/25/11 15:42
CD000002	Michael	Moore	3/25/11 15:42
CD000001	Jack	Jones	3/25/11 15:41
KL000055	Frank	Douglas	3/25/11 08:45

Information Icon

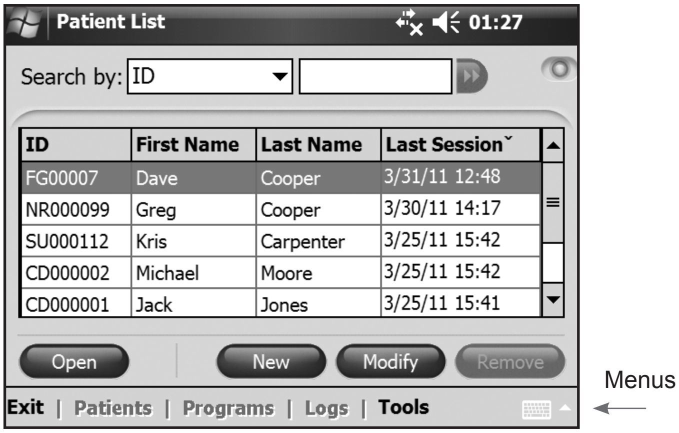
Figure 8-1: Information icon.

Information Icon	Display	Definition
●	SOLID GREEN	H200 Wireless Control Unit connected.
	SOLID GRAY	H200 Wireless Control Unit disconnected.
	FLASHING YELLOW	Low battery in the H200 Wireless Control Unit and/or Orthosis.
	FLASHING RED	Error: RF communication failure, faulty electrode contact.
	SOLID RED	Error: Software or hardware malfunction in the H200 Wireless Control Unit and/or Orthosis.

Table 8-1: Information icon displays.

Menus

The H200 Wireless Software has five menus at the bottom of each screen: **Exit, Patients, Programs, Logs,** and **Tools**. See Figure 8-2 and Table 8-2.



Search by: ID

ID	First Name	Last Name	Last Session
FG00007	Dave	Cooper	3/31/11 12:48
NR000099	Greg	Cooper	3/30/11 14:17
SU000112	Kris	Carpenter	3/25/11 15:42
CD000002	Michael	Moore	3/25/11 15:42
CD000001	Jack	Jones	3/25/11 15:41

Menus

Figure 8-2: Menus.

Menu	Function
Exit	Exit or log off the H200 Wireless Software.
Patients	Open the Patient List window to open, create, modify, or remove a patient record.

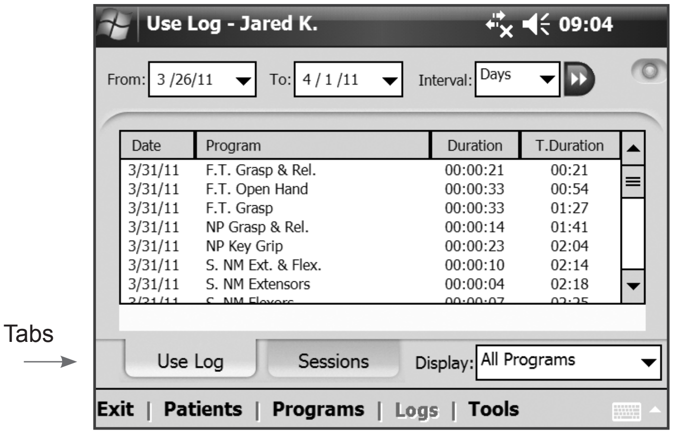
Programs	• Open the Stimulation Parameters window to:
	  • Adjust and test stimulation intensity, phase duration, and pulse rate.
	  • Deactivate/activate the remote trigger button on the Orthosis.
	• Open the Program Settings window to view/program stimulation intensity and time settings for Clinical Programs A–G.
	• Assign programs to the H200 Wireless Control Unit User Program 1 and 2 buttons.
	• Customize a Personal Program.

Logs	View a patient’s use log and session details.
Tools	View the System Information window. For administrators only: manage users and backup and restore the database.

Table 8-2: Menu functions.

Tabs

The **Logs menu** has two tabs: **Use Log** and **Sessions**. See Figure 8-3.


Use Log - Jared K.
09:04
Tabs
Use Log
Sessions
Exit | Patients | Programs | Logs | Tools

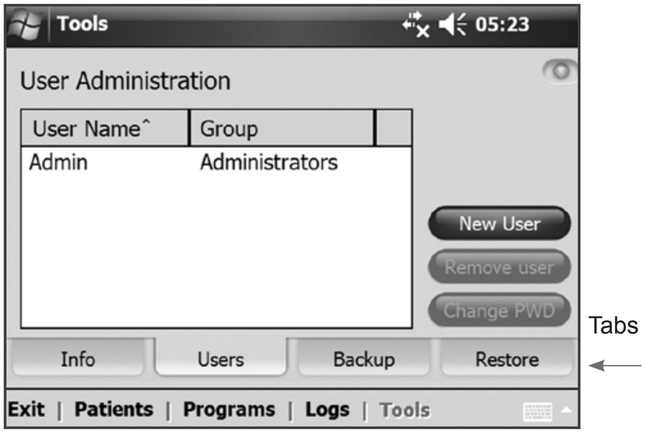
From: 3 /26/11 To: 4 / 1 /11 Interval: Days

Date	Program	Duration	T.Duration
3/31/11	F.T. Grasp & Rel.	00:00:21	00:21
3/31/11	F.T. Open Hand	00:00:33	00:54
3/31/11	F.T. Grasp	00:00:33	01:27
3/31/11	NP Grasp & Rel.	00:00:14	01:41
3/31/11	NP Key Grip	00:00:23	02:04
3/31/11	S. NM Ext. & Flex.	00:00:10	02:14
3/31/11	S. NM Extensors	00:00:04	02:18

Display: All Programs

Figure 8-3: Tabs, **Logs menu**.

The **Tools menu** has four tabs: **Info, Users, Backup, and Restore**. Only Administrators have access to the Users, Backup, and Restore tabs. See Figure 8-4.


Tools
05:23
New User
Remove user
Change PWD
Tabs
Info
Users
Backup
Restore
Exit | Patients | Programs | Logs | Tools

User Administration

User Name˄	Group
Admin	Administrators

Figure 8-4: Tabs, **Tools menu**.

Buttons

The buttons, when pressed, open a new screen or execute a command. See Figure 8-5. Frequently used buttons are described in Table 8-3.

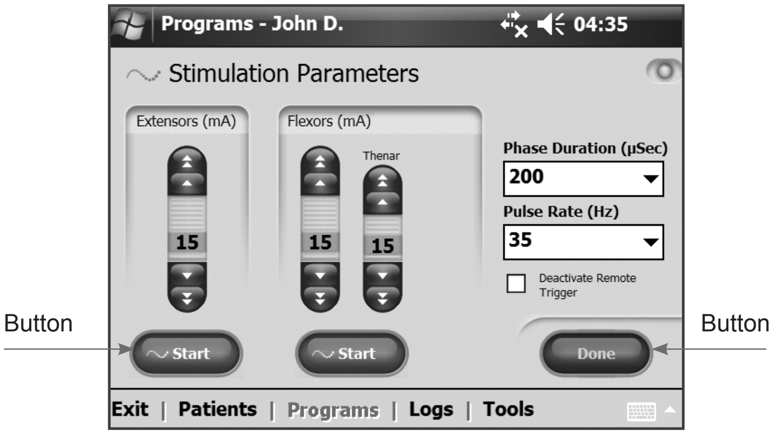
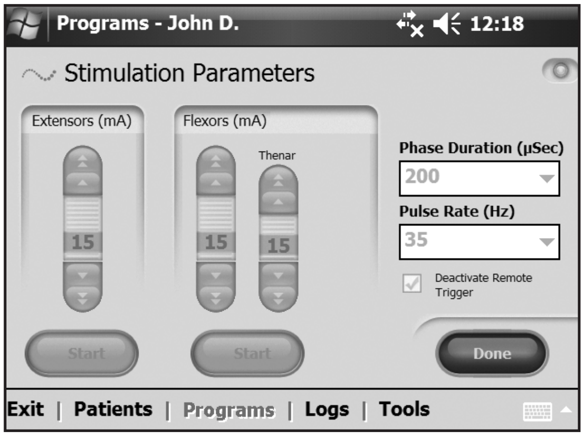

Programs - John D.
04:35
Stimulation Parameters
Extensors (mA)
Flexors (mA)
Thenar
15
15
15
Phase Duration (µSec)
200
Pulse Rate (Hz)
35
☐ Deactivate Remote Trigger
Button
Start
Start
Done
Button
Exit | Patients | Programs | Logs | Tools

Figure 8-5: Buttons.

Button	Function
Start	Starts stimulation.
Stop	Stops stimulation.
Trigger	Starts a stimulation phase in a trigger-controlled exercise.
Modify	Opens a window to change various data.
View	Press to view the assigned program for Program Button 1 or Program Button 2: enabled when an H200 Wireless Control Unit is not connected.
Edit	Opens a program window to change a program setting: enabled when an H200 Wireless Control Unit is connected.
Next Seq.	Advances to the next program segment of a Custom Personal Program.
Add	Adds a program segment.
Delete	Deletes a program segment.
Done	Goes back to the prior screen.
New	Creates a new patient record.
Remove	Removes a patient record.
Stim. Parameters	Opens the window for adjusting stimulation.
Program Settings	Opens the window for selecting the appropriate program.

Table 8-3: Frequently used buttons.

Note: An H200 Wireless Control Unit must be connected to the Clinician's Programmer to enable changes to a patient record. When a Control Unit is not connected, many of the navigation tools may be disabled. See Figure 8-6.



Programs - John D.

Stimulation Parameters

Phase Duration (µSec): 200

Pulse Rate (Hz): 35

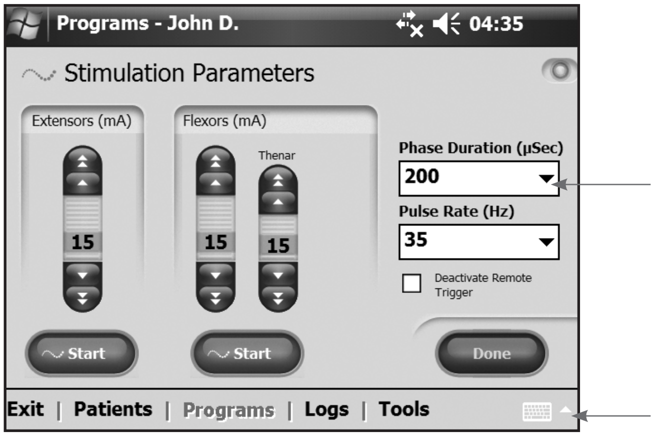
☑ Deactivate Remote Trigger

12:18
Extensors (mA)
Flexors (mA)
Thenar
15
15
15
Start
Start
Done
Exit | Patients | Programs | Logs | Tools

Figure 8-6: Disabled buttons, intensity bars, and drop-down lists.

Keyboard

Use the on-screen keyboard to enter characters in a field that requires alphanumeric input. The keyboard appears collapsed at the bottom right of most screens. To enlarge or reduce the keyboard, touch the keyboard with the stylus. To enter data, select each character using the stylus. See Figure 8-7.



Programs - John D.

Stimulation Parameters

Phase Duration (µSec): 200

Pulse Rate (Hz): 35

☐ Deactivate Remote Trigger

04:35
Extensors (mA)
Flexors (mA)
Thenar
15
15
15
Start
Start
Done
Exit | Patients | Programs | Logs | Tools

Drop-Down List

Keyboard

Figure 8-7: On-screen keyboard and drop-down lists.

Drop-Down Lists

Press the down arrow to display the values in a drop-down list. Use the stylus to select a value. See Figure 8-7.

Scroll Bars

Press an arrow on a scroll bar to move through the selectable data set. See Figure 8-8.

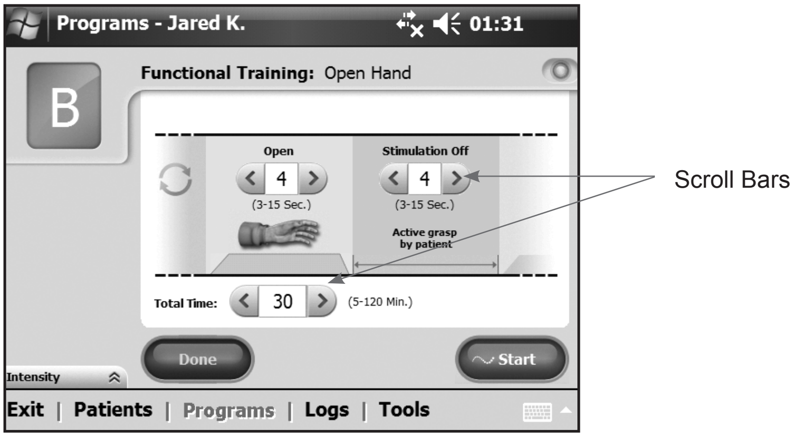

Programs - Jared K.
01:31
B
Functional Training: Open Hand
Open
4
(3-15 Sec.)
Stimulation Off
4
(3-15 Sec.)
Active grasp by patient
Total Time:
30
(5-120 Min.)
Intensity
Done
Start
Exit | Patients | Programs | Logs | Tools
Scroll Bars

Figure 8-8: Scroll bars.

Stimulation Intensity Bar

Press on the stimulation intensity bar to open or collapse the bar. See Figure 8-9. Press on the arrows to increase/decrease stimulation intensity.

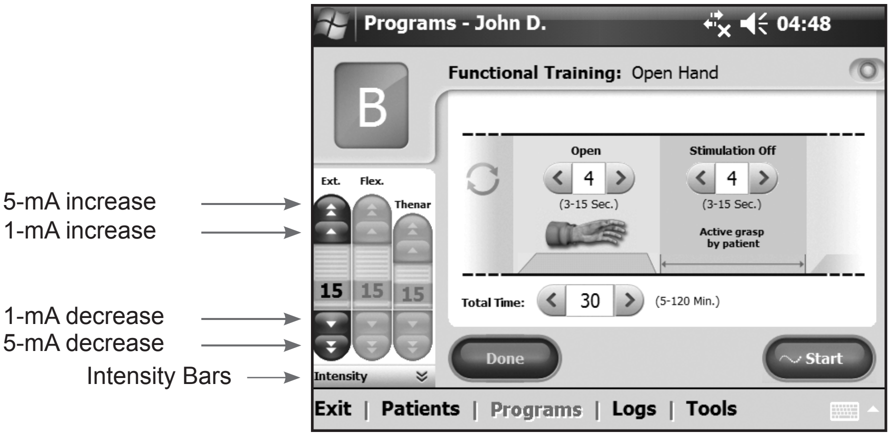
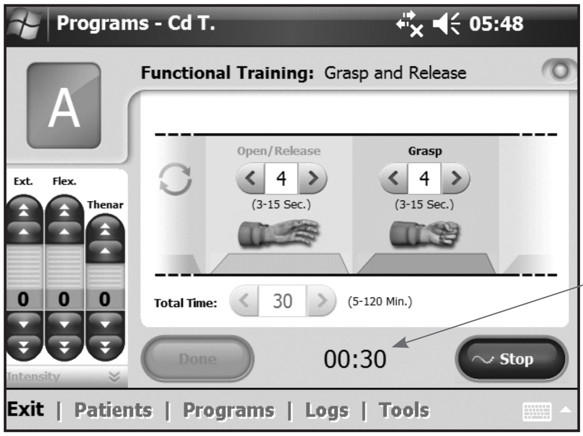

Programs - John D.
04:48
B
Functional Training: Open Hand
Ext.
Flex.
Thenar
15
15
15
Open
4
(3-15 Sec.)
Stimulation Off
4
(3-15 Sec.)
Active grasp by patient
Total Time:
30
(5-120 Min.)
Intensity
Done
Start
Exit | Patients | Programs | Logs | Tools
5-mA increase
1-mA increase
1-mA decrease
5-mA decrease
Intensity Bars

Figure 8-9: Stimulation intensity bar.

Note: Stimulation intensity can be adjusted from A-G programs.

Program Countdown Clock

The program countdown clock displays the remaining time in a program (HH:MM). The countdown clock appears when **Start** is pressed. See Figure 8-10.


Programs - Cd T.
05:48
A
Ext.
Flex.
Thenar
0
0
0
Intensity
Done
Stop
Exit | Patients | Programs | Logs | Tools

Functional Training: Grasp and Release

Open/Release: 4 (3-15 Sec.)

Grasp: 4 (3-15 Sec.)

Total Time: 30 (5-120 Min.)

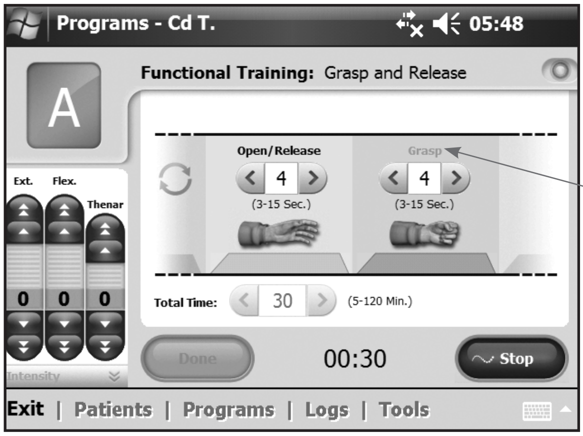
00:30

Countdown
Clock

Figure 8-10: Countdown clock.

Program Active Phase Color Display

During a multi-phase program, the active phase will display in ORANGE. See Figure 8-11.


Programs - Cd T.
05:48
A
Ext.
Flex.
Thenar
0
0
0
Intensity
Done
Stop
Exit | Patients | Programs | Logs | Tools

Functional Training: Grasp and Release

Open/Release: 4 (3-15 Sec.)

Grasp: 4 (3-15 Sec.)

Total Time: 30 (5-120 Min.)

00:30

Active Phase in
ORANGE

Figure 8-11: Program active phase color display.

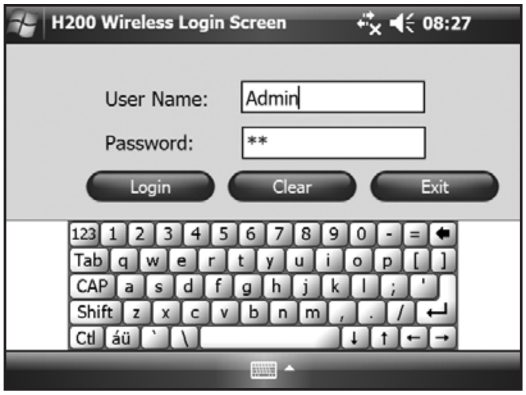
Programming the NESS H200 Wireless System

Before programming the H200 Wireless System:

- Make sure the cloth electrodes are wet and attached to the Orthosis electrode bases.
- Make sure there is good contact between the cloth electrodes and the forearm.
- Make sure there are no signs of pressure or skin irritation around the wrist or palm, or where the cloth electrodes contact the skin.
- Check the position of the wrist bridge and thenar. The wrist bridge should lie across the wrist and the thenar should sit on the thenar eminence.

Logging In

1. Turn on the Clinician’s Programmer and launch the H200 Wireless Software.
2. From the Login screen, enter a user name and password, and then press **Login**. See Figure 8-12.
3. If the login is successful, the Patient List window will open. See Figure 8-13.

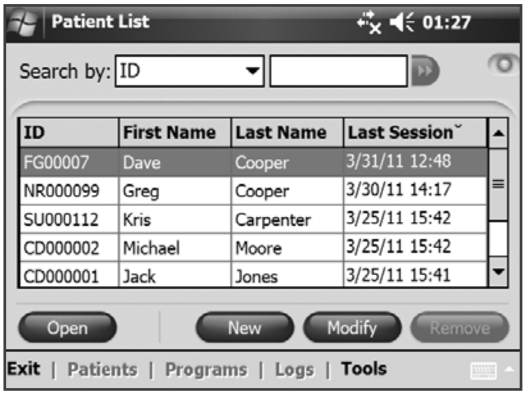

H200 Wireless Login Screen

User Name: Admin

Password: **

08:27
Login
Clear
Exit
123 1 2 3 4 5 6 7 8 9 0 - =
Tab q w e r t y u i o p [ ]
CAP a s d f g h j k l ; '
Shift z x c v b n m , . /
Ctl áü ` \ ↓ ↑ ← →

Figure 8-12: Login screen.



Search by: ID

ID	First Name	Last Name	Last Session
FG00007	Dave	Cooper	3/31/11 12:48
NR000099	Greg	Cooper	3/30/11 14:17
SU000112	Kris	Carpenter	3/25/11 15:42
CD000002	Michael	Moore	3/25/11 15:42
CD000001	Jack	Jones	3/25/11 15:41

Figure 8-13: Patient List window.

Start-Up Messages

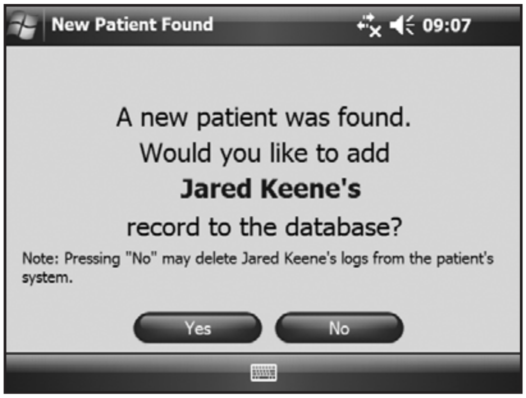
When an Control Unit is connected to the Clinician's Programmer, one of the following start-up messages may appear.

New Patient Detected

Message appears when an Control Unit with patient data on it is connected to a Clinician's Programmer with no record of the data in the database. See Figure 8-14. Do one of the following:

- Press **Yes** to add the patient's data to the Clinician's Programmer database.
- Press **No** and open an existing patient record.

Note: If you press **No** and open an existing patient record, the opened record will permanently overwrite all existing data on the NESS H200 Wireless System.



A new patient was found.
Would you like to add
Jared Keene's
record to the database?

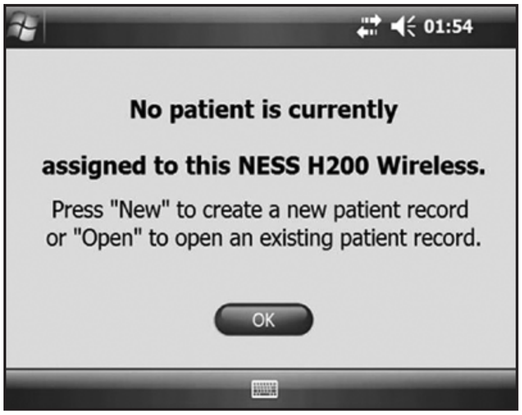
Note: Pressing "No" may delete Jared Keene's logs from the patient's system.

Figure 8-14: New patient message.

Control Unit Unassigned

Message appears when a new, unassigned Control Unit (one with no patient data on it) is connected to the Clinician's Programmer. See Figure 8-15. Do one of the following:

- Press **OK** and then **NEW** to create a new patient record.
- Press **OK** and then select a patient record from the Patient List. Press **Open** to copy the parameters stored for that record from the Clinician's Programmer to the NESS H200 Wireless System. (Choose this option for new-patient setup or for a replacement NESS H200 Wireless System.)



No patient is currently

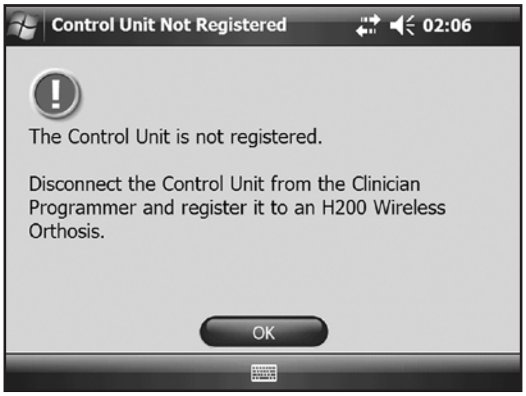
assigned to this NESS H200 Wireless.

Press "New" to create a new patient record
or "Open" to open an existing patient record.

Figure 8-15: Control unit unassigned message.

H200 Wireless Control Unit Not Registered

Message appears when the connected Control Unit is not registered to an Orthosis. See Figure 8-16. This may occur, for example, when a patient brings in a replacement Control Unit that has not been electronically registered. Disconnect the unregistered Control Unit and register it to the existing Orthosis. Refer to the H200 Wireless *User's Guide* for instructions on electronic registration of replacement parts.



The Control Unit is not registered.

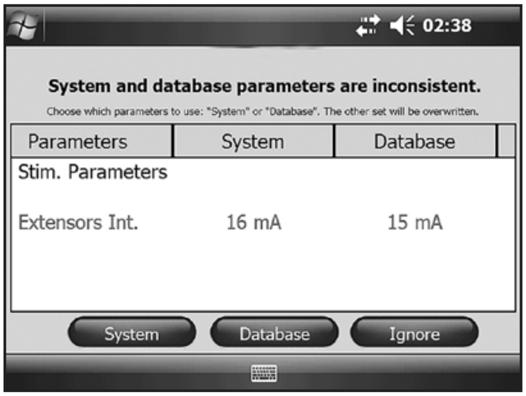
Disconnect the Control Unit from the Clinician Programmer and register it to an H200 Wireless Orthosis.

Figure 8-16: Control unit not registered message.

Data Inconsistency

Message appears when the data stored in the Clinician's Programmer database and on the NESS H200 Wireless System differ. See Figure 8-17. A data inconsistency can occur when two Clinician's Programmers are used to program the system. Do one of the following:

- Press **System** to overwrite the data in the Clinician's Programmer database with that on the NESS H200 Wireless System.
- Press **Database** to overwrite the data on the NESS H200 Wireless System with that in the Clinician's Programmer database.
- Press **Ignore** to make no changes to either data set.



System and database parameters are inconsistent.

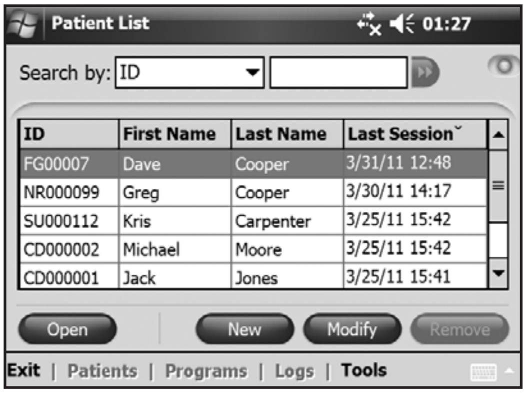
Choose which parameters to use: "System" or "Database". The other set will be overwritten.

Parameters	System	Database
Stim. Parameters		
Extensors Int.	16 mA	15 mA

Figure 8-17: Data inconsistency message.

Opening/Creating a Patient Record

1. Select a patient record from the patient list and press **Open**, or press **New** to create a new patient record. See Figure 8-18.

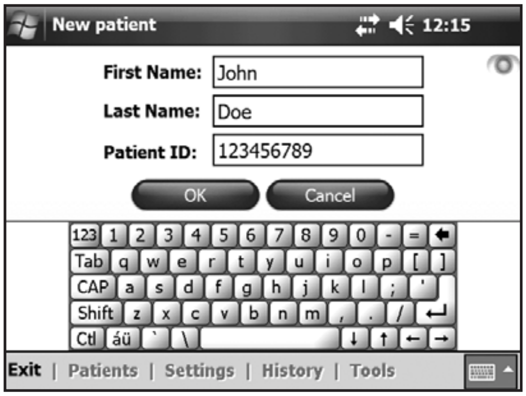

Patient List
01:27
Open
New
Modify
Remove
Exit | Patients | Programs | Logs | Tools

Search by: ID

ID	First Name	Last Name	Last Session
FG00007	Dave	Cooper	3/31/11 12:48
NR000099	Greg	Cooper	3/30/11 14:17
SU000112	Kris	Carpenter	3/25/11 15:42
CD000002	Michael	Moore	3/25/11 15:42
CD000001	Jack	Jones	3/25/11 15:41

Figure 8-18: Patient List window.

2. For new patients, enter the patient's first and last name (alpha characters only) in the New Patient window, and assign a patient ID (1–14 characters). All fields must be completed. Then press **OK**. See Figure 8-19.

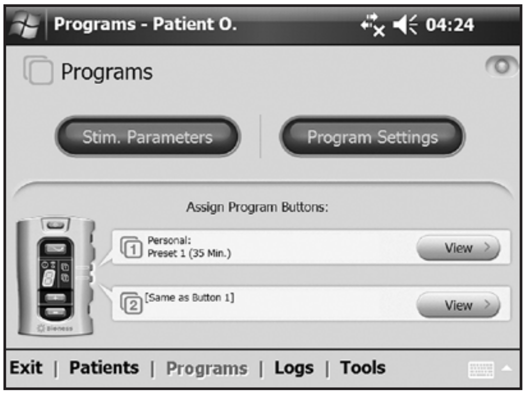

New patient
12:15
OK
Cancel
123 1 2 3 4 5 6 7 8 9 0 - =
Tab q w e r t y u i o p [ ]
CAP a s d f g h j k l ; '
Shift z x c v b n m , . /
Ctl áü ` \ ↓ ↑ ← →
Exit | Patients | Settings | History | Tools

First Name: John
Last Name: Doe
Patient ID: 123456789

Figure 8-19: New Patient window.

Configuring Stimulation Parameters

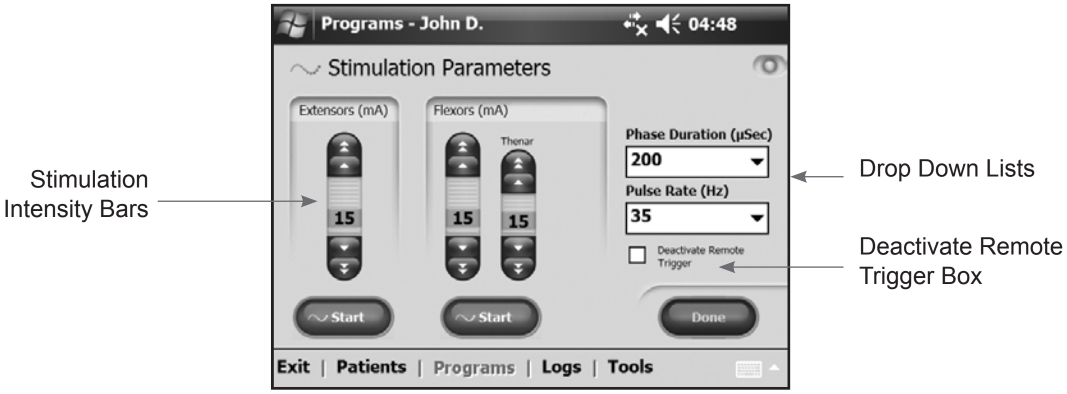
1. Open the patient record.
2. From the **Programs menu** (See Figure 8-20), press **Stim. Parameters** to open the Stimulation Parameters window. If the patient record is new, the Stim Parameters window will open automatically. See Figure 8-21.


Programs - Patient O.
04:24
Programs
Stim. Parameters
Program Settings
Assign Program Buttons:
View
View
Exit | Patients | Programs | Logs | Tools

1 Personal: Preset 1 (35 Min.)

2 [Same as Button 1]

Figure 8-20: Program menu window.


Programs - John D.
04:48
Stimulation Parameters
Extensors (mA)
Flexors (mA)
Thenar
15
15
15
Start
Start
Done
Exit | Patients | Programs | Logs | Tools
Stimulation Intensity Bars
Drop Down Lists
Deactivate Remote Trigger Box

Phase Duration (µSec): 200

Pulse Rate (Hz): 35

☐ Deactivate Remote Trigger

Figure 8-21: Stimulation Parameters window.

3. Adjust Phase Duration and Pulse Rate using the drop-down lists.
4. Adjust stimulation intensity for the extensors and flexors.
    - Press **Start** to turn on stimulation.
    - Press **Stop** to turn off stimulation.
5. Deactivate/activate the remote trigger button on the Orthosis, if desired, by checking/unchecking the "Deactivate Remote Trigger" box.

6. Press **Done** to return to the Programs window.

Note: “0” intensity equals no stimulation.

Note: Adjustments to stimulation intensity affect all programs except Program F—Key Open.

Configuring Clinical Programs A–G

1. From the **Programs menu**, press **Program Settings** to open the Program Settings window. See Figure 8-22.

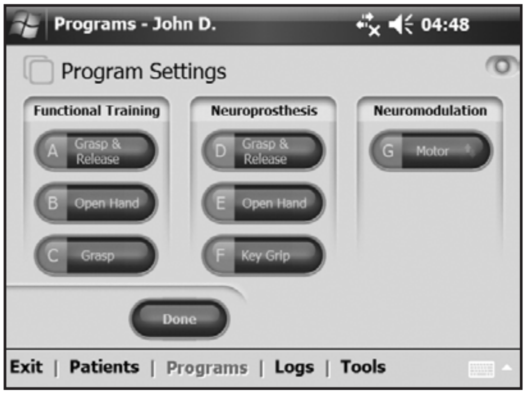

Programs - John D.
04:48
Program Settings
Functional Training
A Grasp & Release
B Open Hand
C Grasp
Neuroprosthesis
D Grasp & Release
E Open Hand
F Key Grip
Neuromodulation
G Motor
Done
Exit | Patients | Programs | Logs | Tools

Figure 8-22: Program Settings window.

Program A—Grasp & Release

Program A activates sequential opening and closing of the hand. Pressing **Start** starts the program. Hand opening begins after a half-second pause. Then, the hand closes and opens cyclically, with a pause between each cycle. The program shuts down automatically after the total time has elapsed (range: 5–120 minutes). Stimulation intensity, the duration of extension and flexion, and total time are adjustable. See Figure 8-23.

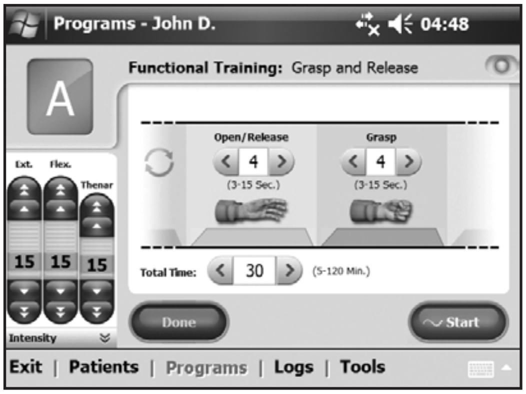

Programs - John D.
Functional Training: Grasp and Release
Open/Release: 4 (3-15 Sec.)
Grasp: 4 (3-15 Sec.)
Total Time: 30 (5-120 Min.)
Ext.: 15
Flex.: 15
Thenar: 15

Figure 8-23: Program A window.

To configure Program A:

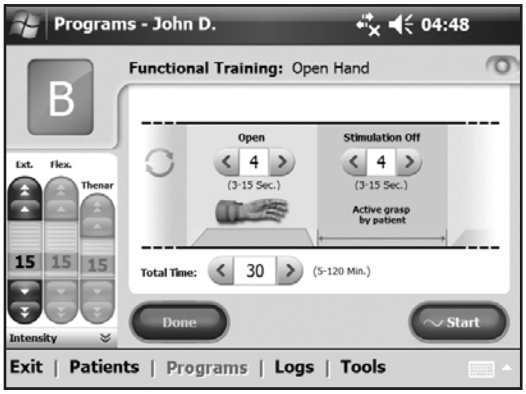
1. Select Program A.
2. Adjust open/release time, grasp time, and total time.
3. Press **Start**. The program countdown clock will appear at the bottom of the screen.
4. If needed, adjust stimulation intensity.
5. Allow the program to continue for the total time or press **Stop**.
6. Press **Done** to return to the Program Settings window.

Note: The active program phase will be highlighted in ORANGE.

Note: Adjustments to stimulation intensity affect all programs except Key Open.

Program B—Open Hand

Program B activates the extensor muscles only. Pressing **Start** starts the program. Cyclical hand extension is followed by a period of relaxation, and then hand extension repeats. The program shuts down automatically after the total time has elapsed (range: 5–120 minutes). Stimulation intensity, the duration of extension and relaxation, and total time are adjustable. See Figure 8-24.



Programs - John D.

Functional Training: Open Hand

Open: 4 (3-15 Sec.)

Stimulation Off: 4 (3-15 Sec.)

Active grasp by patient

Total Time: 30 (5-120 Min.)

Intensity: Ext. 15, Flex. 15, Thenar 15

Figure 8-24: Program B window.

To configure Program B:

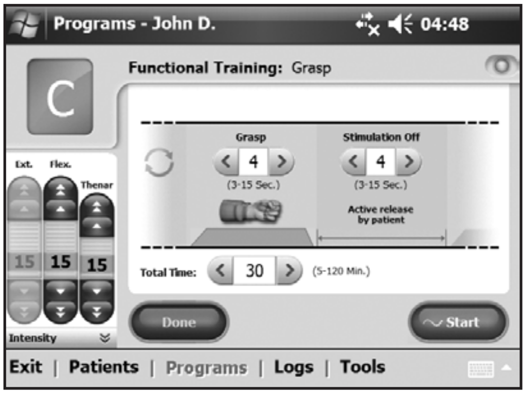
1. Select Program B.
2. Adjust open time, stimulation off time, and total time.
3. Press **Start**. The program countdown clock will appear at the bottom of the screen.
4. If needed, adjust stimulation intensity.
5. Allow the program to continue for the total time or press **Stop**.
6. Press **Done** to return to the Program Settings window.

Note: The active program phase will be highlighted in ORANGE.

Note: Adjustments to stimulation intensity affect all programs except Key Open.

Program C—Grasp

Program C activates the flexor muscles only. Pressing **Start** starts the program. Cyclical hand flexion is followed by a period of relaxation, and then hand flexion repeats. The program shuts down automatically after the total program time has elapsed (range: 5–120 minutes). Stimulation intensity, the duration of flexion and relaxation, and total time are adjustable. See Figure 8-25.


Programs - John D.
04:48
C
Ext.
Flex.
Thenar
15
15
15
Intensity
Active release by patient
Done
Start
Exit | Patients | Programs | Logs | Tools

Functional Training: Grasp

Grasp: 4 (3-15 Sec.)

Stimulation Off: 4 (3-15 Sec.)

Total Time: 30 (5-120 Min.)

Figure 8-25: Program C window.

To configure Program C:

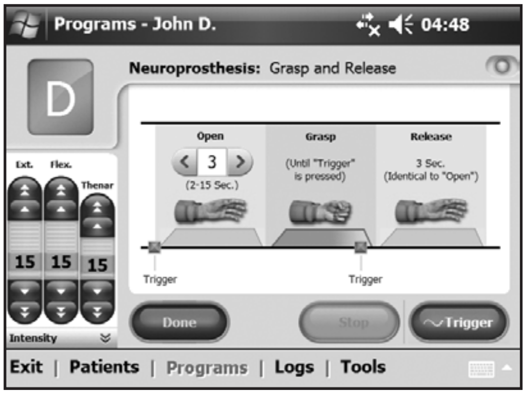
1. Select Program C.
2. Adjust grasp time, stimulation off time, and total time.
3. Press **Start**. The program countdown clock will appear at the bottom of the screen.
4. If needed, adjust stimulation intensity.
5. Allow the program to continue for the total time or press **Stop**.
6. Press **Done** to return to the Program Settings window.

Note: The active program phase will be highlighted in ORANGE.

Note: Adjustments to stimulation intensity affect all programs except Key Open.

Program D—Grasp & Release

Program D is used to grasp and hold objects using a palmar grasp. Pressing **Trigger** starts the program. A half-second pause is followed by several seconds of the hand opening. The hand then closes and remains closed until the trigger button is pressed again to release the grasp. Once the trigger button is pressed the second time, a half second of continued flexor stimulation is followed by a pre-determined duration of extensor stimulation. The stimulation then shuts off, and the hand relaxes. Stimulation intensity and the duration of extension and release are adjustable. See Figure 8-26.



Programs - John D. 04:48

Neuroprosthesis: Grasp and Release

Open: 3 (2-15 Sec.)

Grasp: (Until "Trigger" is pressed)

Release: 3 Sec. (Identical to "Open")

Ext. 15

Flex. 15

Thenar 15

Figure 8-26: Program D window.

To configure Program D:

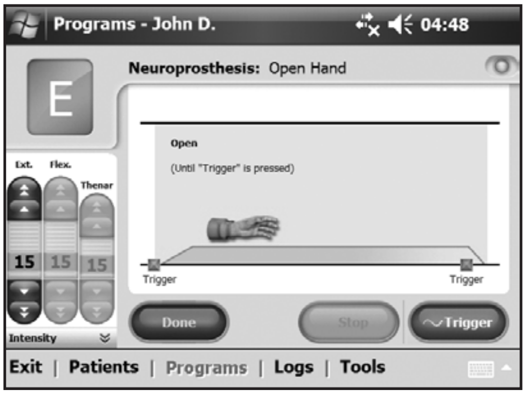
1. Select Program D.
2. Adjust open time (which will also adjust release time).
3. Press **Trigger** to start the open phase. The grasp phase follows automatically.
4. If needed, adjust stimulation intensity.
5. Press **Trigger** to stop the grasp phase and start the release phase, or press **Stop** to end the program.
6. Press **Done** to return to the Program Settings window.

Note: The active program phase will be highlighted in ORANGE.

Note: Adjustments to stimulation intensity affect all programs except Key Open.

Program E—Open Hand

Program E causes the hand to open and remain open. Pressing **Trigger** starts the program. Pressing **Trigger** ends the program. See Figure 8-27.



Programs - John D.

04:48

Neuroprosthesis: Open Hand

Open

(Until "Trigger" is pressed)

E
Ext.
Flex.
Thenar
15
15
15
Intensity
Trigger
Trigger
Done
Stop
Trigger
Exit | Patients | Programs | Logs | Tools

Figure 8-27: Program E window.

To configure Program E:

1. Select Program E.
2. Press **Trigger** to start the program.
3. If needed, adjust stimulation intensity.
4. Press **Trigger** to stop the program, or press **Stop** to stop the program immediately.
5. Press **Done** to return to the Program Settings window.

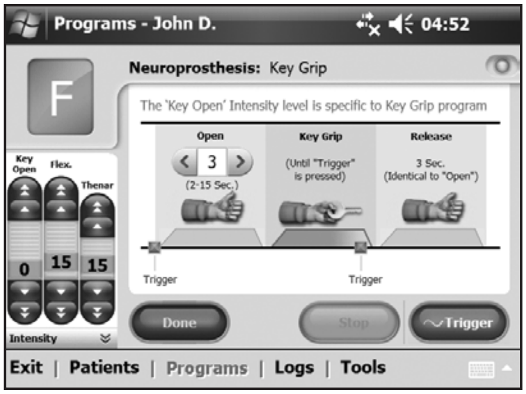
Note: Adjustments to stimulation intensity affect all programs except Key Open.

Note: Extended use (more that 30 seconds of uninterrupted use) of this mode is not recommended due to potential fatigue in the extensor muscles.

Program F—Key Grip

Program F is used to grasp and hold small items in a lateral grasp (or key grip) between the thumb and the lateral side of the index finger. Pressing **Trigger** starts the program. A half-second pause is followed by several seconds of thumb opening. The thumb then closes against the lateral side of the index finger and remains closed until **Trigger** is pressed again to release the grip. Once **Trigger** is pressed the second time, a half second of flexor stimulation is followed by a pre-determined duration of extensor stimulation to open the thumb. The stimulation then shuts off, and the hand relaxes. Stimulation intensity and the duration of extension and release are adjustable. See Figure 8-28.

Note: The extensor stimulation bar in this program is referred to as Key Open. It stimulates the thumb and finger extensors and finger flexors simultaneously to produce an open thumb.



Programs - John D.

Neuroprosthesis: Key Grip

The 'Key Open' Intensity level is specific to Key Grip program

Open: 3 (2-15 Sec.)

Key Grip: (Until "Trigger" is pressed)

Release: 3 Sec. (Identical to "Open")

Key Open: 0

Flex.: 15

Thenar: 15

Figure 8-28: Program F window.

To configure Program F:

1. Select Program F.
2. Adjust open time (which will also adjust release time).
3. Press **Trigger** to start the open phase. The key grip phase will follow automatically.
4. Adjust stimulation intensity for the Key Open intensity. Adjust time.
5. If needed, adjust the flexor and thenar intensity.
6. Press **Trigger** to stop the key grip phase and start the release phase, or press **Stop** to end the program.
7. Press **Done** to return to the Program Settings window.

Note: The active program phase will be highlighted in ORANGE.

Program G—Motor Neuromodulation

Program G delivers pulsed stimulation above the motor threshold for an adjustable program time (5–30 minutes). Pressing **Start** starts the program. See Figure 8-29.

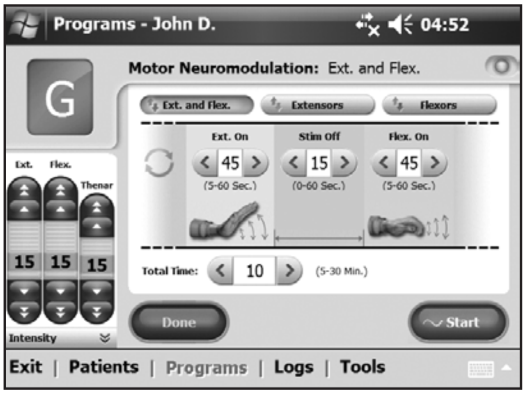

Programs - John D.
04:52
G
Motor Neuromodulation: Ext. and Flex.
Ext. and Flex.
Extensors
Flexors
Ext. On
45
(5-60 Sec.)
Stim Off
15
(0-60 Sec.)
Flex. On
45
(5-60 Sec.)
Ext.
Flex.
Thenar
15
15
15
Intensity
Total Time:
10
(5-30 Min.)
Done
Start
Exit | Patients | Programs | Logs | Tools

Figure 8-29: Program G, extensors and flexors window.

To configure Program G:

1. Select Program G.
2. Select **Ext. and Flex**., **Extensors**, or **Flexors**.

Ext. and Flex. (Extensors and Flexors)

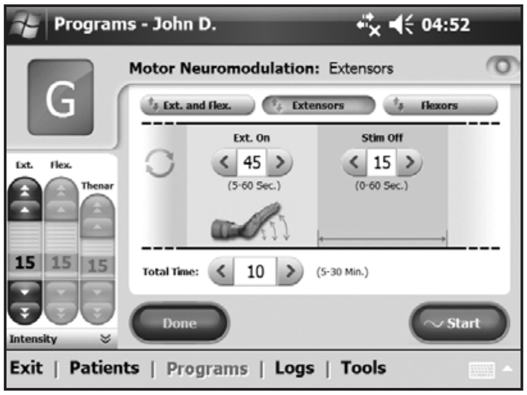
1. Adjust extensors on time, stimulation off time, flexors on time, and total time. See Figure 8-29.
2. Press **Start**. The program countdown clock will appear at the bottom of the screen.
3. If needed, adjust stimulation intensity.
4. Allow the program to continue for the total time, or press **Stop**.
5. Press **Done** to return to the Program Settings window.

Note: The active program phase will be highlighted in ORANGE.

Note: Adjustments to stimulation intensity affect all programs except Key Open.

Extensors

1. Adjust extensors on time, stimulation off time, and total time. See Figure 8-30.


G
Ext. and Flex.
Extensors
Flexors
Ext.
Flex.
Thenar
Intensity
Done
Start
Exit | Patients | Programs | Logs | Tools

Programs - John D. 04:52

Motor Neuromodulation: Extensors

Ext. On 45 (5-60 Sec.)

Stim Off 15 (0-60 Sec.)

Total Time: 10 (5-30 Min.)

Ext. 15 Flex. 15 Thenar 15

Figure 8-30: Program G, extensors window.

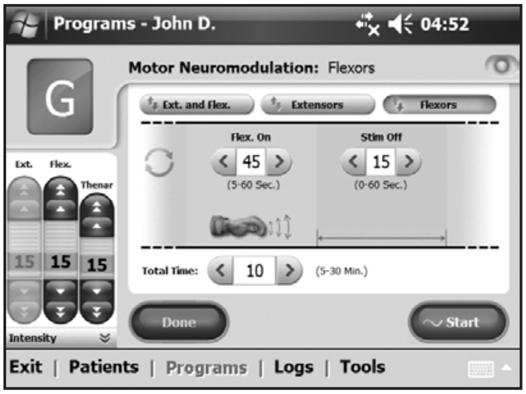
2. Press **Start**. The program countdown clock will appear at the bottom of the screen.
3. If needed, adjust stimulation intensity.
4. Allow the program to continue for the total time, or press **Stop**.
5. Press **Done** to return to the Program Settings window.

Note: The active program phase will be highlighted in ORANGE.

Note: Adjustments to stimulation intensity affect all programs except Key Open.

Flexors

1. Adjust flexors on time, stimulation off time, and total time. See Figure 8-31.


Programs - John D.
04:52
G
Ext. and Flex.
Extensors
Flexors
Intensity
Done
Start
Exit
Patients
Programs
Logs
Tools

Motor Neuromodulation: Flexors

Flex. On: 45 (5-60 Sec.)

Stim Off: 15 (0-60 Sec.)

Total Time: 10 (5-30 Min.)

Ext. 15

Flex. 15

Thenar 15

Figure 8-31: Program G, flexors window.

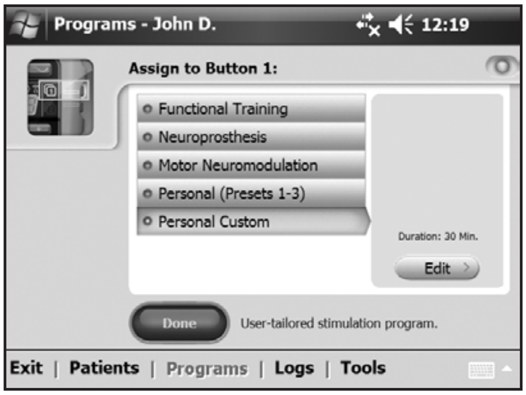
2. Press **Start**. The program countdown clock will appear at the bottom of the screen.
3. If needed, adjust stimulation intensity.
4. Allow the program to continue for the total time, or press **Stop**.
5. Press **Done** to return to the Program Settings window.

Note: The active program phase will be highlighted in ORANGE.

Note: Adjustments to stimulation intensity affect all programs except Key Open.

Configuring a Personal Custom Program

1. From the Assign to Button 1 or Assign to Button 2 window, select **Personal Custom** and press **Edit**. See Figure 8-32.

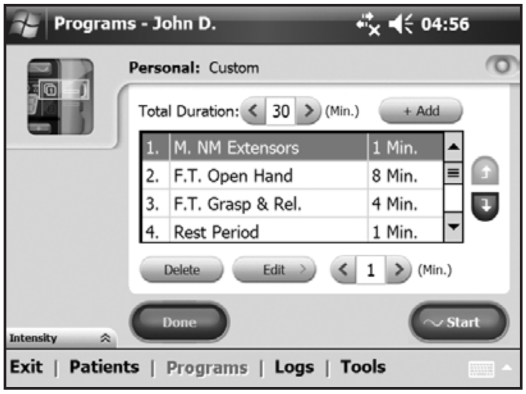

Programs - John D.
12:19
Assign to Button 1:
Functional Training
Neuroprosthesis
Motor Neuromodulation
Personal (Presets 1-3)
Personal Custom
Edit
Done
Exit | Patients | Programs | Logs | Tools

Duration: 30 Min.

User-tailored stimulation program.

Figure 8-32: Assign to Button 1 window.

2. The Personal Custom window will open, displaying the program segment list. See Figure 8-33. Adjust the total duration using the arrows at the top of the screen. To adjust the duration of an individual segment, highlight the segment and adjust the duration using the arrows at the bottom of the screen.


Programs - John D.
04:56
+ Add
Delete
Edit
Done
Start
Intensity
Exit | Patients | Programs | Logs | Tools

Personal: Custom

Total Duration: 30 (Min.)

1.	M. NM Extensors	1 Min.
2.	F.T. Open Hand	8 Min.
3.	F.T. Grasp & Rel.	4 Min.
4.	Rest Period	1 Min.

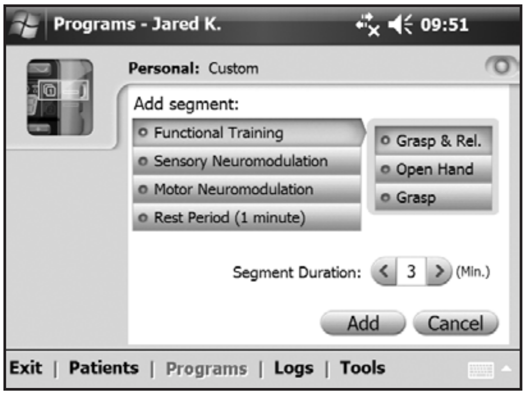
1 (Min.)

Figure 8-33: Personal Custom Program segment list.

3. To reorder a segment, highlight the segment and press the up/down arrows.

4. To edit a segment, highlight the segment and press **Edit**. The selected program settings window will open. Adjust the program settings and press **Done** to return to the Personal Custom window.

5. To delete a segment, highlight the segment and press **Delete**.
6. To add a segment, press **Add** to open the Add Segment window. See Figure 8-34. Select the desired segment, adjust the segment duration, and press **Add**. The added segment will appear at the bottom of the segment list.


Programs - Jared K.
09:51
Add segment:
Functional Training
Sensory Neuromodulation
Motor Neuromodulation
Rest Period (1 minute)
Grasp & Rel.
Open Hand
Grasp
Add
Cancel
Exit | Patients | Programs | Logs | Tools

Personal: Custom

Segment Duration: 3 (Min.)

Figure 8-34: Personal Custom Program Add Segment window.

7. Press **Start** and adjust stimulation intensity.
8. Press **Next Seg.** to advance to the next program segment, or press **Stop**.
9. Press **Done** to return to the Assign to Button window.

Note: The maximum number of program segments is eight. The maximum number of rest periods is 15.

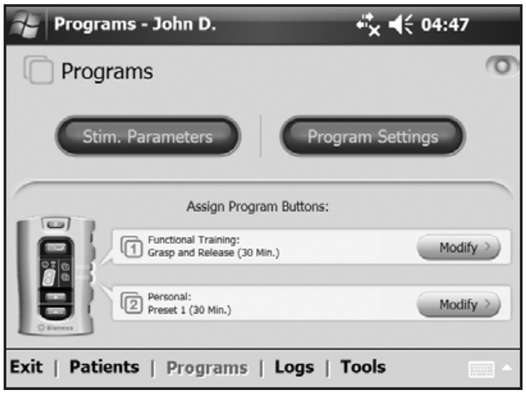
Note: Adjustments to stimulation intensity affect all programs except Key Grip.

Assigning User Program Buttons 1 and 2

The clinician may assign up to two programs to the H200 Wireless Control Unit for patient use at home. The assigned User Programs are patient accessible by pressing the Program 1 and Program 2 buttons on the H200 Wireless Control Unit.

To assign User Program Button 1 :

1. From the **Programs menu**, press 1 **Modify**. See Figure 8-35.

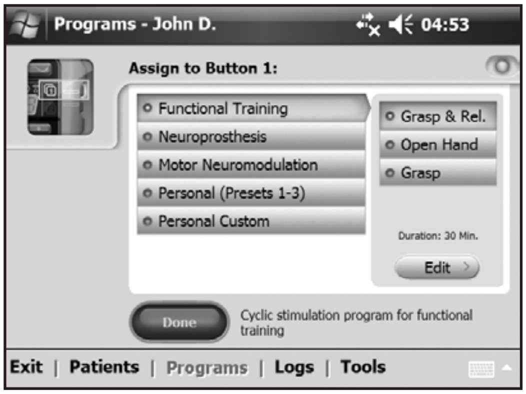

Programs - John D.
04:47
Programs
Stim. Parameters
Program Settings
Assign Program Buttons:
1
Modify
2
Modify
Exit | Patients | Programs | Logs | Tools

Functional Training:
Grasp and Release (30 Min.)

Personal:
Preset 1 (30 Min.)

Figure 8-35: Programs window.

2. The Assign to Button 1 window will open. See Figure 8-36.


Programs - John D.
04:53
Assign to Button 1:
Functional Training
Neuroprosthesis
Motor Neuromodulation
Personal (Presets 1-3)
Personal Custom
Grasp & Rel.
Open Hand
Grasp
Edit
Done
Exit | Patients | Programs | Logs | Tools

Duration: 30 Min.

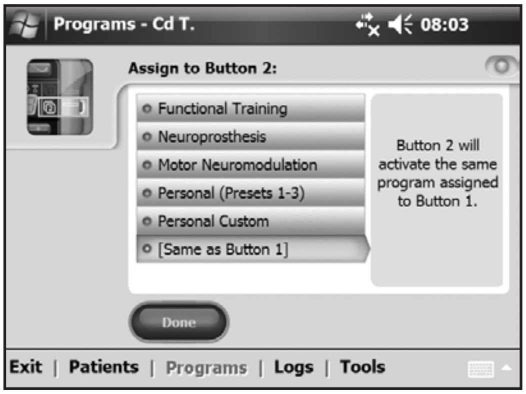
Cyclic stimulation program for functional training

Figure 8-36: Assign to Button 1 window.

3. Select a program.
4. Press **Done** to return to the **Programs menu**, or press **Edit** to open the program and change the program settings.

To assign User Program Button 2:

1. From the **Programs menu**, press 2 **Modify.**
2. The Assign to Button 2 window will open. See Figure 8-37.


Programs - Cd T.
08:03
Assign to Button 2:
Functional Training
Neuroprosthesis
Motor Neuromodulation
Personal (Presets 1-3)
Personal Custom
[Same as Button 1]
Done
Exit | Patients | Programs | Logs | Tools

Button 2 will activate the same program assigned to Button 1.

Figure 8-37: Assign to Button 2 window.

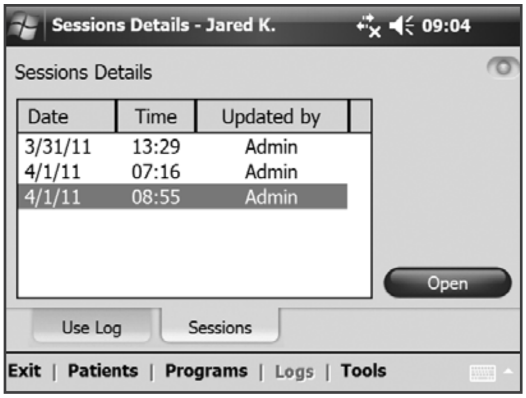
3. Select a program or press "Same as Button 1."
4. Press **Done** to return to the **Programs menu**, or press **Edit** to open the program and change the program settings.

Viewing a Patient’s Session Log

A patient session begins when an H200 Wireless Control Unit is connected to the Clinician’s Programmer and the patient’s record is opened. A patient session ends when session data are saved and the H200 Wireless Control Unit is disconnected from the Clinician’s Programmer. If the H200 Wireless Control Unit is disconnected and then reconnected within one hour, the most recent session reopens.

To view a patient’s Session Log:

1. Open the patient’s record, and then press the **Logs menu**.
2. Press the **Sessions tab**. The Sessions List window will open, showing the date, time, and system user for each saved session. See Figure 8-38.



Sessions Details - Jared K.

Sessions Details

Date	Time	Updated by
3/31/11	13:29	Admin
4/1/11	07:16	Admin
4/1/11	08:55	Admin

Figure 8-38: Sessions List window.

3. Select a session from the Sessions List and press **Open**.
4. The Session Details window will open, showing the details saved for the session. See Figure 8-39.

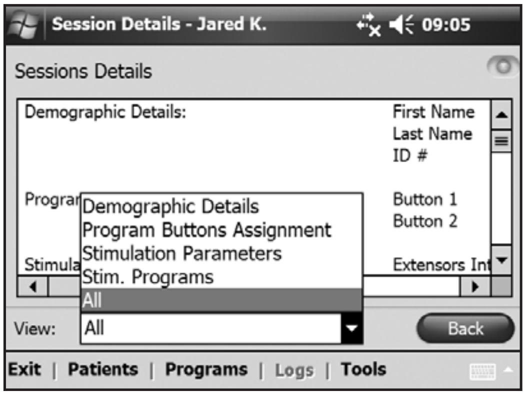

Session Details - Jared K.
09:05
Sessions Details
Demographic Details:
First Name
Last Name
ID #
Prograr
Button 1
Button 2
Stimula
Extensors Int
Demographic Details
Program Buttons Assignment
Stimulation Parameters
Stim. Programs
All
View:
All
Back
Exit | Patients | Programs | Logs | Tools

Figure 8-39: Session Details window.

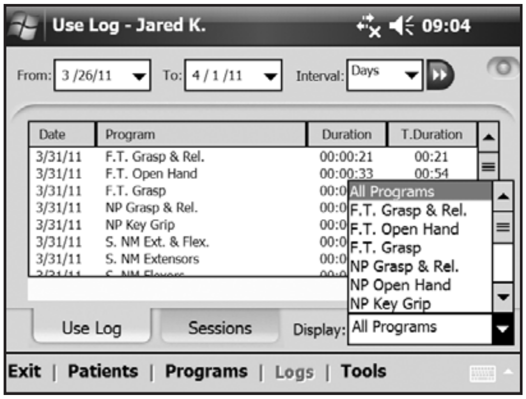
5. From the View drop-down list, select "All" to view all the session details, or narrow the search by selecting one of the following:
   - Demographic Details
   - Program Buttons Assignment
   - Stimulation Parameters
   - Stimulation Programs
6. Press **Back** to return to the Sessions List window.

Viewing a Patient's Use Log

The Use Log is a record of the patient’s NESS H200 Wireless System usage history. The Use Log can be filtered by date and interval.

To view a patient’s Use Log:

1. Open the patient’s record, and then press the **Logs menu**.
2. Press the **Use Log tab**. The Use Log will open. See Figure 8-40.
3. From the Display drop-down list at the bottom right of the screen, select "All" to view the Use Log for all programs, or narrow the search by selecting a specific program.


Use Log - Jared K.
09:04
Use Log
Sessions
All Programs
F.T. Grasp & Rel.
F.T. Open Hand
F.T. Grasp
NP Grasp & Rel.
NP Open Hand
NP Key Grip
Exit | Patients | Programs | Logs | Tools

From: 3 /26/11 To: 4 / 1 /11 Interval: Days

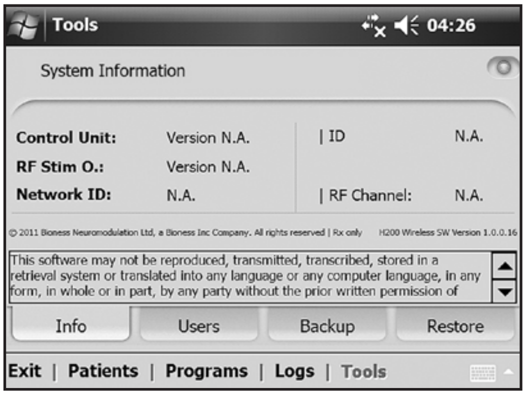
Date	Program	Duration	T.Duration
3/31/11	F.T. Grasp & Rel.	00:00:21	00:21
3/31/11	F.T. Open Hand	00:00:33	00:54
3/31/11	F.T. Grasp	00:0	
3/31/11	NP Grasp & Rel.	00:0	
3/31/11	NP Key Grip	00:0	
3/31/11	S. NM Ext. & Flex.	00:0	
3/31/11	S. NM Extensors	00:0	

Display: All Programs

Figure 8-40: Use Log, all programs.

Viewing the System Information

1. Connect an H200 Wireless Control Unit to the Clinician’s Programmer.
2. From the **Tools menu**, press the **Info tab**. See Figure 8-41.



System Information

Control Unit: Version N.A. | ID N.A.
RF Stim O.: Version N.A.
Network ID: N.A. | RF Channel: N.A.

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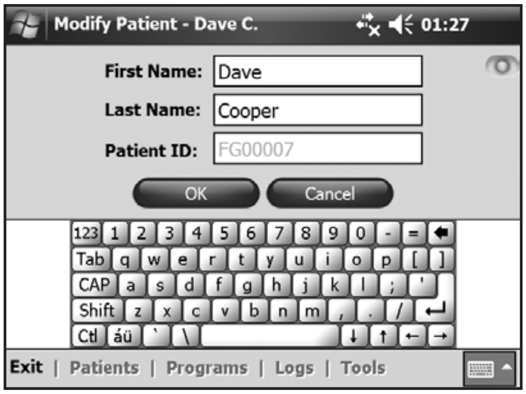
Figure 8-41: System Information window.

Managing Patient Records

Modifying a Patient Name

1. Select a patient from the Patient List, and then press **Modify**.
2. The Modify Patient window will open. See Figure 8-42.
3. Modify the name, and press **OK.**

Note: Patient ID cannot be modified.

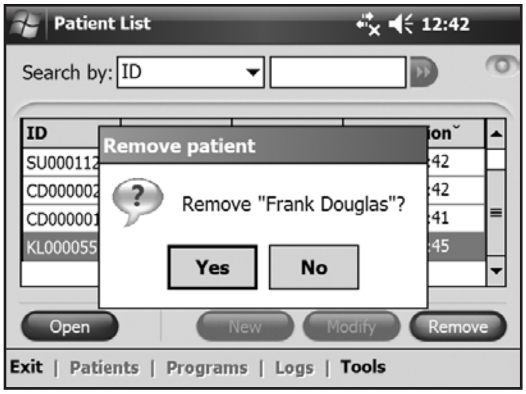

Modify Patient - Dave C.
01:27
OK
Cancel
Exit | Patients | Programs | Logs | Tools

First Name: Dave
Last Name: Cooper
Patient ID: FG00007

Figure 8-42: Modify Patient window.

Removing a Patient Record

1. Disconnect the Control Unit from the PDA.
2. Select a patient from the Patient List.
3. Press **Remove**.
4. The Remove Patient confirmation window will open. See Figure 8-43. Press **Yes.**


Patient List
12:42
ID
SU00011
CD00000
CD00000
KL000055
Open
New
Modify
Remove
Exit | Patients | Programs | Logs | Tools
Yes
No

Search by: ID

Remove patient

Remove "Frank Douglas"?

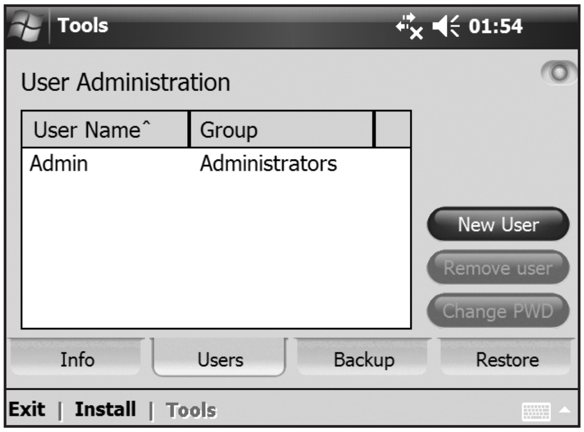
Figure 8-43: Remove Patient confirmation window.

Managing Users

From the **Tools menu**, system administrators can add or remove users, change user passwords, and back up and restore the database.

Adding a User

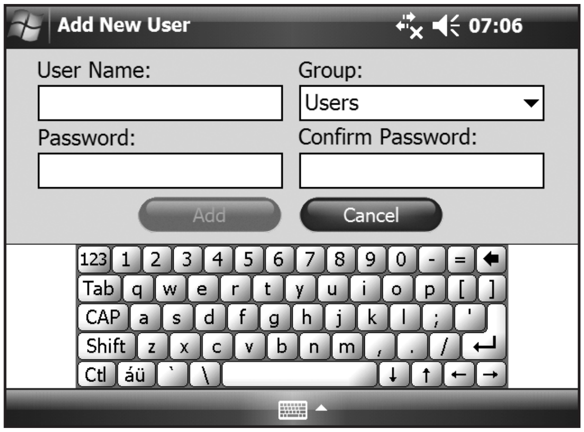
1. Press the **Users tab** to view the User Administration window. See Figure 8-44.


Tools
01:54
User Administration
New User
Remove user
Change PWD
Info
Users
Backup
Restore
Exit | Install | Tools

User Nameˆ	Group
Admin	Administrators

Figure 8-44: User Administration window.

2. Press **New User**. The Add New User window will open. See Figure 8-45.


Add New User
07:06
User Name:
Password:
Confirm Password:
Add
Cancel
123 1 2 3 4 5 6 7 8 9 0 - =
Tab q w e r t y u i o p [ ]
CAP a s d f g h j k l ; '
Shift z x c v b n m , . /
Ctl áü ` \ ↓ ↑ ← →

Group: Users

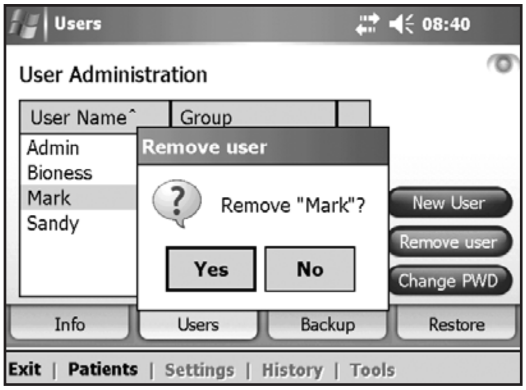
Figure 8-45: Add New User window.

3. Enter a user name and password, and confirm the password.
4. From the "Group" drop-down list, select "Administrators" or "Users**,"** and then press **Add**.

Removing a User

1. From the User Administration window, select a user.
2. Press **Remove User.**
3. A confirmation message will appear. See Figure 8-46. Press **Yes**.

Note: The last remaining administrator cannot be removed.

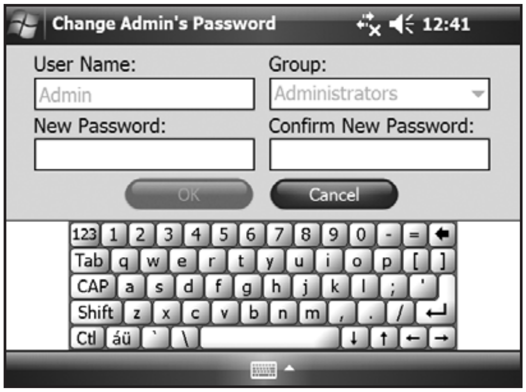

Users
08:40
User Administration
User Name
Group
Admin
Bioness
Mark
Sandy
Remove user
Yes
No
New User
Remove user
Change PWD
Info
Users
Backup
Restore
Exit
Patients
Settings
History
Tools

Remove "Mark"?

Figure 8-46: Remove User confirmation window.

Changing a User's Password

1. From the User Administration window, select a user.
2. Press **Change PWD.** The Change User's Password window will open. See Figure 8-47.
3. Enter and confirm the new password. Press **OK**.


Change Admin's Password
12:41
OK
Cancel
123 1 2 3 4 5 6 7 8 9 0 - =
Tab q w e r t y u i o p [ ]
CAP a s d f g h j k l ; '
Shift z x c v b n m , . /
Ctl áü ` \

User Name: Admin

Group: Administrators

New Password:

Confirm New Password:

Figure 8-47: Change User's Password window.

Backing Up and Restoring the Database

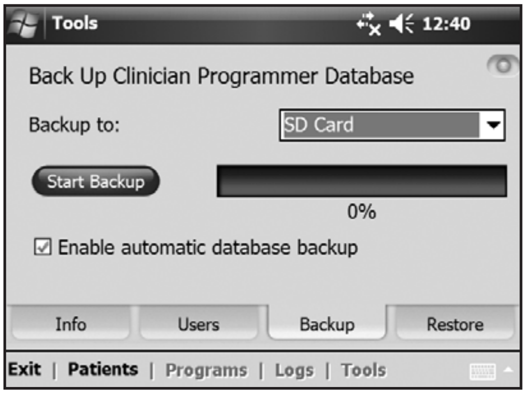
Automatic Backup

The H200 Wireless Software will automatically back up the database whenever the application is exited. If a storage card is not in the SD slot, upon exiting the application a warning will appear.

Note: Users should exit the H200 Wireless Software at the end of each day.

To disable automatic database backup:

1. Press the **Tools menu** and then the **Backup tab**.
2. Uncheck the box next to “Enable automatic database backup.” See Figure 8-48.



Back Up Clinician Programmer Database

Backup to: SD Card

0%

☑ Enable automatic database backup

Figure 8-48: Backup window.

Manual Backup

Administrators can manually back up the Clinician's Programmer database to the storage (SD) card at any time.

To manually back up the database:

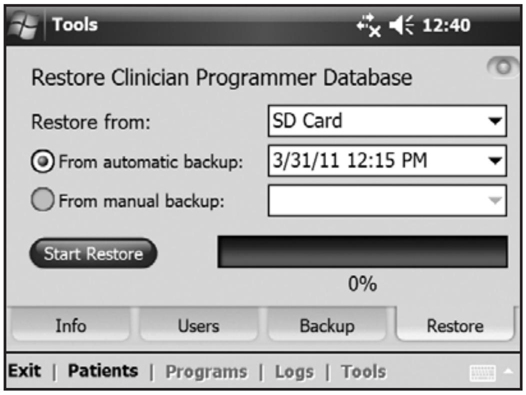
1. Ensure that a storage card is in the Clinician’s Programmer SD slot.
2. Press the **Tools menu** and then the **Backup tab**.
3. Press **Start Backup**. A file will be created on the storage card. The file name will be the date and time the file was created.
4. Monitor the progress bar until the backup is successful, and then press **ok**.

Restore

Administrators can restore the database when the Clinician's Programmer is replaced or the database is corrupted. Do not enter new patient information before restoring the database.

To restore the database:

1. If a new storage card is in the Clinician's Programmer, remove it.
2. Make sure the backup storage card lock switch is in the unlocked position, and then insert the storage card with the backup files into the Clinician's Programmer.
3. Open the H200 Wireless Software, and log in using an administrator's user name and password.
4. Press the **Tools menu** and then the **Restore tab**. The Restore window will open. See Figure 8-49.
5. Select "From automatic backup" or "From manual backup," select a file name from the drop down list, and press **Start Restore**.



Restore Clinician Programmer Database

Restore from: SD Card

◉ From automatic backup: 3/31/11 12:15 PM

○ From manual backup:

0%

Figure 8-49: Restore window.

6. A message will appear: "Restoring a database will overwrite the current database. Are you sure?" Press **Yes**.
7. Wait until the progress bar shows 100% and a "Restore successful" message appears. Then press **ok**.
8. Press the **Patients menu** to return to the Patient List window, and then verify that the database was restored.

Chapter 9

Patient Training and Follow-Up

Patient Training

Clinicians should train patients on the setup, operation, and maintenance of their NESS H200 Wireless System. Patients should be able to follow their H200 Wireless training program, identify problems, and know whom to contact for assistance.

Patient training should include the following topics:

- Review of the H200 Wireless User Reference Card and *User's Guide.*
- How to don and doff the Orthosis.
- How to operate the NESS H200 Wireless System.
- System maintenance and cleaning Instructions.
- Basic troubleshooting.
- Review of the patient's personal training program.
- Practice with the NESS H200 Wireless System.

Many of the above topics are covered in the H200 Wireless *User's Guide*. This section discusses some additional points to consider.

Donning/Doffing the H200 Wireless Orthosis

Remind patients to:

- Remove any lotions or oils from their hand and forearm with soap and water.
- Make sure the cloth electrodes are wet and have no dry patches. Dry patches reduce the stimulation current reaching the arm/hand.
- Manually extend their fingers, wrist, elbow, and shoulder, if necessary, to make it easier to don the Orthosis.
- Put the spiral end of the Orthosis on first.
- Check the position of the wrist bridge and thenar before bringing the flexor support under the forearm. The wrist bridge should lie across the wrist and the thenar should sit on the thenar eminence. Make sure patients can identify the correct position of the Orthosis on the arm/hand. Poor positioning may result in poor or unbalanced activation of the hand, and pressure marks on the skin around the wrist.
- Remove and reposition the Orthosis if it is positioned too distally on the hand. Remind patients not to slide the Orthosis on the forearm.
- Close the wing arm firmly, and check for gaps between the arm and the Orthosis. There should be no visible gaps.
- Check the position of the Orthosis using the ▲ stimulation test button on the Control Unit. Press once to check the extensors. Press again to check the flexors.

Operating the NESS H200 Wireless System

Review with patients how to:

- Turn on the system.
- Test stimulation in the Orthosis using the ▲ stimulation test button.
- Select User Program 1 and 2.
- Turn on/off and pause stimulation using the Control Unit and Orthosis trigger button.
- Increase/decrease stimulation intensity.
- Mute/un-mute the audio alerts for the Orthosis and Control Unit.
- Electronically register a replacement Control Unit or Orthosis.

Maintaining and Cleaning the NESS H200 Wireless System

Review with patients how to:

- Charge the Orthosis and Control Unit batteries.
- Wet the cloth electrodes and when to replace them.
- Clean and disinfect the NESS H200 Wireless System components and NESS H200 Wireless System Kit carrying case.
- Clean the electrode bases.

Troubleshooting

Instruct patients to contact you or the Bioness Client Relations Department if they have any questions or problems. **Bioness Client Relations Department: (800) 211-9136, Option 3.**

Practicing with the NESS H200 Wireless System

Have patients set up and operate the NESS H200 Wireless System, following their training program.

Patient Follow-Up and Clinical Support

A patient follow-up and clinical support program should:

- Evaluate the benefits of continuing with the chosen selected programs.
- Monitor clinical progress.
- Maximize clinical effectiveness.
- Provide clinical and technical support.

Suggested Follow-up Agenda

1. Check the Orthosis and Control Unit.
2. Check the patient's Use Log.
3. Perform a clinical evaluation.
4. If necessary, adjust the stimulation parameters.
5. If necessary, update the patient's training program.
6. If appropriate, train the patient on additional exercises (for example, passive range of motion exercises and functional training).
7. If appropriate, assign different programs to the Control Unit Program 1 and Program 2 buttons.
8. Set a date for the next follow-up visit.

Maintenance and Cleaning

Charging

The H200 Wireless Clinician's Programmer should be charged at least four hours before use, daily, and when a low battery indicator is displayed.

Batteries

HP iPAQ Clinician's Programmer

During extended periods of nonuse, remove the battery from the HP iPAQ Clinician's Programmer. Refer to the PDA manufacturer's instructions for information on battery removal and replacement.

H200 Wireless Orthosis

The Orthosis rechargeable batteries may need to be replaced approximately every two years. The batteries should only be replaced by a Bioness Inc certified technician. Contact the **Bioness Client Relations Department at (800) 211-9136, Option 3**, for assistance.

H200 Wireless Control Unit

Refer to the H200 Wireless *User's Guide* for battery replacement instructions.

⚠ **CAUTION: Use only a battery provided by Bioness Inc.**

⚠ **WARNING: Do not simultaneously charge the H200 Wireless Control Unit, Orthosis, and Clinician's Programmer while the Control Unit is connected to the Configuration Cradle.**

⚠ **WARNING: The H200 Wireless Orthosis can be worn while the Orthosis and Control Unit are charging, as long as the Control Unit is NOT connected to the Clinician's Programmer while the Clinician's Programmer is charging.**

H200 Wireless Cloth Electrodes

The H200 Wireless Cloth Electrodes should be replaced every two weeks, or sooner if they become damaged.

The H200 Wireless Cloth Electrodes should be wet before use and after three to four hours of use. Remove the cloth electrodes from the Orthosis before wetting them.

Electrode Bases

To replace the electrode bases, unscrew and remove them from the Orthosis. Then follow the fitting procedure for attaching the electrode bases.

Electronic Registration

A replacement H200 Wireless Control Unit will need to be electronically registered to the existing H200 Wireless Orthosis for the components to communicate wirelessly. See the H200 Wireless *User's Guide* for instructions on electronically registering a replacement H200 Wireless Control Unit.

A replacement H200 Wireless Orthosis will need to be electronically registered to the existing H200 Wireless Control Unit for the components to communicate wirelessly. See the H200 Wireless *User's Guide* for instructions on electronically registering a replacement Orthosis.

Maintenance Summary

Table 10-1 provides a short list of maintenance responsibilities for users.

Responsibility	Task
Patient	• Monitor the H200 Wireless Orthosis and Control Unit battery charge status. • Charge the H200 Wireless Orthosis and Control Unit batteries. • Identify a defective/aged H200 Wireless Control Unit or Orthosis battery. • Replace the H200 Wireless Control Unit battery. • Wet the H200 Wireless cloth electrodes before using the Orthosis and after every three to four hours of use. • Replace the H200 Wireless cloth electrodes every two weeks or sooner, if they are damaged. • Clean/disinfect the H200 Wireless Orthosis, electrode bases, Control Unit and accessories. • Electronically register a replacement H200 Wireless Orthosis or Control Unit.
Clinician	• All of the above "Patient" responsibilities for clinic system kits. • Monitor the Clinician's Programmer battery charge status. • Charge the Clinician's Programmer. • Identify and report to Bioness any component fault or damage. • Replace removable components and electrode bases as required. • Check for mechanical faults in the H200 Wireless Orthosis and Control Unit. • Clean the H200 Wireless Clinician's Kit contents and carrying case. • Disinfect the H200 Wireless Orthosis and fitting panels after clinic use, to prevent patient cross-contamination.
Service Technician	• Periodic component checkup and maintenance. • Fault diagnosis, and repair, and/or replacement of components.

Table 10-1: Maintenance summary.

Cleaning the H200 Wireless Components

All H200 Wireless components may be cleaned as needed or weekly by carefully wiping them with a damp cloth. The electrical components are not waterproof. **Do not immerse them in water.**

Disinfecting the H200 Wireless Components

Electronic Components

The H200 Wireless Control Unit may be cleaned and low-level disinfected using CaviWipes™ (Metrex, Orange, CA), or wipes or cloths saturated (but not dripping) with 70% isopropyl alcohol (IPA) per the instructions below:

1. Use one saturated disinfectant wipe or cloth to thoroughly wet the component surface.
2. Use a second saturated disinfectant wipe or cloth to remove any surface contaminants. Soil, etc., will impede the disinfectant's effectiveness, if not removed.
3. As needed, use additional saturated disinfectant wipes or cloths to keep the component surface wet for 3 minutes.

Note: Be sure to follow the Bioness instructions for the specified contact time to ensure an effective bacteria kill.

The H200 Wireless Orthosis (except for the wrist insert) may be cleaned and low-level disinfected using wipes or cloths saturated with 70% isopropyl alcohol (IPA) per the instructions below:

1. Use one saturated disinfectant wipe or cloth to thoroughly wet the component surface.
2. Use a second saturated disinfectant wipe or cloth to remove any surface contaminants. Soil, etc., will impede the disinfectant's effectiveness, if not removed.
3. As needed, use additional saturated disinfectant wipes or cloths to keep the components surface wet for 3 minutes.

Note: Be sure to follow the Bioness instructions for the specified contact time to ensure an effective bacteria kill.

⚠ **WARNING: Disinfect the fitting panels and Orthosis between uses to prevent patient cross contamination.**

Wrist Insert

The wrist insert cannot be disinfected. The wrist insert can only be cleaned with soap and water. Do not use 70% IPA on the wrist insert. Use the single-use wrist insert covers to prevent patient cross-contamination.

Clinician Kit Carrying Case

The H200 Wireless Clinician Kit carrying case may be cleaned and low-level disinfected using CaviCide® (Metrex, Orange, CA) or 70% isopropyl alcohol (IPA) per the following instructions:

CaviCide:

1. Spray the entire surface of the Clinician Kit carrying case with CaviCide.
2. Use a clean towel to remove any surface contaminants. Soil, etc., will impede the disinfectant's effectiveness, if not removed.
3. Spray the entire surface of the Clinician Kit carrying case again with CaviCide.
4. Keep spraying the entire carrying case surface as needed to keep it wet for 10 minutes.

70% IPA:

1. Wipe the entire surface of the Clinician Kit carrying case with a cloth or wipe saturated with 70% IPA.
2. Use a new cloth or wipe saturated with 70% IPA to remove any surface contaminants. Soil, etc., will impede the disinfectant's effectiveness, if not removed.
3. Wipe the entire surface of the Clinician Kit carrying case again with a new cloth or wipe saturated with 70% IPA.
4. Use additional new cloths or wipes saturated with 70% IPA as needed to keep the entire surface of the carrying case wet for 10 minutes.

Note: Be sure to follow the Bioness instructions for the specified contact time to ensure an effective bacteria kill.

Note: Do not use other cleaning/disinfecting agents such as a diluted bleach mixture, Lysol or Clorox wipes. Bioness has not tested these products' effectiveness on the H200 Wireless components.

Metrex products are sold through authorized dealers worldwide; 70% IPA is available at your local drugstore or pharmacy. If you need assistance, please call the**Bioness Client Relations Department at (800) 211-9136, Option 3.**

Chapter 11

Troubleshooting

This section provides troubleshooting tips for clinicians. Refer patients to the H200 Wireless *User's Guide* troubleshooting section and to the **Bioness Client Relations Department: (800) 211-9136, Option 3.**

Problem	Solution
The cloth electrodes are damaged or peeling off of the Orthosis.	Replace the cloth electrodes.
The thenar is damaged.	Replace the thenar.
The wrist insert is damaged.	Replace the wrist insert.
Stimulation is not consistent.	• Rewet the cloth electrodes. • Contact the Bioness Client Relations Department.
Faulty electrode contact	• Make sure the cloth electrodes are wet and attached to the Orthosis. • Make sure the electrode bases are screwed in tightly. • Clean the electrode bases. • Contact the Bioness Client Relations Department.
Stimulation is on, but the patient's fingers are not moving.	1. Turn off the H200 Wireless Control Unit. 2. Remove the Orthosis. 3. Wet the cloth electrodes thoroughly. 4. Reposition the Orthosis on the hand. 5. Turn on the Control Unit and press the stimulation test button or the trigger button. If there is still no finger movement: 1. Turn off the Control Unit. 2. Remove the Orthosis. 3. Contact the Bioness Client Relations Department.
System will not turn on.	The system may be in sleep mode. • Press the Orthosis trigger button to exit sleep mode. • If the Orthosis trigger button is disabled, connect the system charger to the Control Unit to exit sleep mode.
Stimulation is not being delivered with the fitting panels on.	1. Remove the fitting panels. 2. Check that the conducting springs are intact and clean. 3. Use alcohol-based wipes to clean the conducting springs of the fitting panels. 4. Use alcohol-based wipes to clean the corresponding metal contacts of the Orthosis. 5. Attach the fitting panels. 6. Turn on stimulation.

Frequently Asked Questions

If you have any questions or concerns, please contact the **Bioness Client Relations Department at (800) 211-9136, Option 3.**

Our clinic owns multiple NESS H200 Wireless Systems. How can we identify which electronic components belong to which H200 Wireless system?

- Each NESS H200 Wireless System has an alphanumeric System Identification (ID) Number (for example, A123) printed on the back of the H200 Wireless Control Unit and under the wing of the H200 Wireless Orthosis. The System ID Numbers on the two electronic components must match for the system to work. Check the numbers before use to see if they match.

The H200 Wireless Software buttons used to create a new patient record or adjust the settings for a current patient are grayed out and nonfunctional.

- The Clinician’s Programmer and the H200 Wireless Control Unit are not communicating. Both must be connected to the Configuration Cradle communication connector cable to communicate. Turn off the H200 Wireless Control Unit or place it in standby mode. Then reconnect the Configuration Cradle communication connector cable to the H200 Wireless Control Unit and the Clinician’s Programmer.

I connected the H200 Wireless Control Unit to the Configuration Cradle and a message appeared on the Clinician’s Programmer. The message says that the date and time in the H200 Wireless Control Unit differ from those in the Clinician’s Programmer.

- The clocks on the H200 Wireless Control Unit and Clinician’s Programmer must be synchronized for the Use Log and Session Log to record accurately.
  - If the date and time settings of the Clinician’s Programmer are correct, update the H200 Wireless Control Unit clock.
  - If the date and time settings of the Clinician’s Programmer are not correct, press **Exit** to close the H200 Wireless Software and open the PDA settings screen. (See the PDA manufacturer’s instructions.) Use the stylus to adjust the Clinician’s Programmer time zone, clock, and date. Press **Ok** to save the settings. Log back into the H200 Wireless Software, reconnect the H200 Wireless Control Unit, and update the NESS H200 Wireless System clock to match the Clinician’s Programmer clock.

I connected the H200 Wireless Control Unit to the Configuration Cradle, and a message appeared on the Clinician's Programmer. The message says that a new patient was found and asks if I would like to add this record to the database.

- Select **Yes**, if you want to review or make changes to the patient's settings. If not, select **No** to return to the Patient List. If you want to copy a different patient record onto the H200 Wireless Control Unit, then, with the H200 Wireless Control Unit still connected to the Configuration Cradle, open another patient record or create a new patient record for use with the H200 Wireless Control Unit. **Note:** If you open another patient record while the H200 Wireless Control Unit is connected, the data on the NESS H200 Wireless System will be permanently overwritten by the record that is opened.

When I connected the H200 Wireless Control Unit to the Configuration Cradle, a message appeared on the Clinician's Programmer saying that the parameters are inconsistent.

- A different Clinician's Programmer was last used to update the connected NESS H200 Wireless System.
  - Press **System** to overwrite the data on the Clinician's Programmer with the data on the H200 Wireless Control System (preferred when patients have been using the NESS H200 Wireless System settings and are returning for a follow-up evaluation).
  - Press **Database** to overwrite the parameters on the NESS H200 Wireless System with the parameters on the Clinician's Programmer database.
  - Press **Ignore** to leave the parameters on the Clinician's Programmer and the NESS H200 Wireless System unchanged.

When charging the NESS H200 Wireless System, how will I know when the batteries are fully charged?

- When the H200 Wireless Control Unit is fully charged, a ▬ horizontal GREEN line will appear in the H200 Wireless Control Unit digital display.
- When the H200 Wireless Orthosis is fully charged, the ⓘ ∼ status light for the RF Stim Unit will be SOLID GREEN.
- Charging takes approximately three hours. After the components are fully charged, keep the components connected to the system charger until ready to use.

⚠ **WARNING: Do not simultaneously charge the H200 Wireless Control Unit, Orthosis, and Clinician's Programmer while the Control Unit is connected to the Configuration Cradle.**

After I fully charged the H200 Wireless Control Unit and Orthosis, I disconnected the system charger and then immediately reconnected it. The charging icons displayed again on the H200 Wireless Control Unit and Orthosis. Do I need to repeat the charging process?

- If you recently charged your system and the fully charged icons were displayed, your system is still fully charged. You do not have to repeat the charging process.

I received a replacement Control Unit/Orthosis and was told I need to register it. Why is registration important, and how do I register a component?

- A replacement H200 Wireless Control Unit or Orthosis needs to be electronically registered to the existing H200 Wireless component to communicate wirelessly. To electronically register a replacement component, see the H200 Wireless *User's Guide*.

I tried the registration procedure, but I never saw the ALTERNATING GREEN arches in the digital display. The replacement component is not working.

- Clinical mode may have been started instead of the registration process. Clinical mode is started by pressing the − minus and ⏻ on/off buttons on the H200 Wireless Control Unit. Registration is started with the H200 Wireless Control Unit off, and then by pressing the − minus and 〜 trigger buttons on the H200 Wireless Control Unit. Turn off the H200 Wireless Control Unit, and press the − minus and 〜 trigger buttons to restart the registration process.

Chapter 12

Technical Specifications

H200 Wireless Control Unit Specifications	
Classification	Internally powered, continuous operation
Operation Modes	User, Standby, Clinical
Battery Type	Rechargeable AAA NiMH 1.2 V, 900–1100 mAh
Controls	• On/Off illuminated button • Trigger illuminated button to turn on and pause stimulation • Intensity +/- buttons to fine-tune intensity level • Mute button to mute audio alerts • Program selection buttons (1, 2) • Stimulation test button
Indications	• Four status icons: H200 Wireless Control Unit, RF Communication Status, Selected Program (1, 2) • Digital display designates relative stimulation intensity • Illuminated buttons designate system on/off and stimulation on/off or paused • “Beeps” for audio alerts
Carrying Options	In pocket, neck strap, wrist strap, or belt pouch
Dimensions	Length: 73 mm (2.9 in.); Width: 46 mm (1.8 in.); Height: 18 mm (0.7 in.)
Weight	45 grams (1.5 oz.)
Environmental Ranges	• Transport and storage temperature: -25°C to +70°C (-13°F to +158°F) • Operating conditions temperature: 5°C to 40°C (41°F to 104°F) • Operating conditions relative humidity: 15% to 93% • Charging temperature: 5°C to 40°C (41°F to 104°F)

H200 Wireless Orthosis Specifications			
Classification	Internally powered, continuous operation with type BF applied parts		
Operating Voltage	3.7 V		
Battery Type	Proprietary rechargeable Li-Ion (Lithium Ion) 3.7 V, 280–350 mAh		
Indications	• H200 Wireless Orthosis status (fault, battery, charging) and Stimulation LEDs • “Beeps” for audio alerts		
Material	• Main body cover: Rilsan BZM 30 OTL • Wing cover: TEREZ ABS 5010 • Wrist insert: Flexible foam, two components urethane non-integral skin, Purtec GMBH • Thenar: Dow Corning Silicone Rubber NPC 40		
Configurations	• Size: Small/Medium/Large • Side: Left and Right • Total of 6 configurations		
Environmental Ranges	• Transport and storage temperature: -25°C to +70°C (-13°F to +158°F) • Operating conditions temperature: 5°C to 40°C (41°F to 104°F) • Operating conditions relative humidity: 15% to 93% • Charging temperature: 5°C to 40°C (41°F to 104°F) • IP classification: IP27		
	Small	**Medium**	**Large**
Dimensions (closed)	Length: 270 mm (10.63 in.) Width: 110 mm (4.33 in.) Depth: 90 mm (3.54 in.)	Length: 270 mm (10.63 in.) Width: 110 mm (4.33 in.) Depth: 90 mm (3.54 in.)	Length: 300 mm (11.81 in.) Width: 130 mm (5.11 in.) Depth: 130 mm (5.11 in.)
Estimated Weight	300 grams (10.58 oz.)	300 grams (10.58 oz.)	300 grams (10.58 oz.)

H200 Wireless Orthosis Pulse Parameters	
Pulse	Balanced Biphasic
Waveform	Symmetric
Intensity (Peak)	0–80 mA, 1-mA resolution (positive phase)
Maximum Current Intensity (rms)	Electrodes #1, #2, #3, #5: 13.1 mA rms Electrode #4: 18.6 mA rms
Max Voltage	120 V

	Symmetric		
Positive Pulse Duration (μsec)	100	200	300
Negative Pulse Duration (μsec)	100	200	300
Inter-Phase Interval (μsec)	50		
Max Total Pulse Duration (μsec)	250	450	650
Load Range	0–5000 ohm (Subject to max voltage limitation)		
Nominal Load	500 ohm		
Max Power Load	500 ohm (80 mA, 120 V)		
Pulse Repetition Rate	20–45 Hz, 5-Hz resolution		
Ramp Up	0–3.1 seconds		
Ramp Down	0–3.1 seconds		
Max. Duration of Stimulation Program	4 hours, 5-minute resolution		

H200 Wireless Cloth Electrode Specifications						
Material	Non-woven cloth **Note:** Use only cloth electrodes provided by Bioness Inc.					
Cloth Electrode #	1	2	3 Regular	3 Large	4	5
Area (mm^2)	1784	1185	791	1284	2038	1185
Area (in.^{2})	2.8	1.8	1.2	2.0	3.2	1.8

Power Supply Specifications	
Use medical Class II safety approved power supply provided/approved by Bioness with the following ratings:	
Input	
Voltage	100–240 V AC
Current	400 mA
Frequency	50–60 Hz
Output	
Voltage	5 V ± 5%
Current	2400 mA

Note: The H200 Wireless Control Unit and Orthosis can be used while charging if the Control Unit is not connected to the Clinician Programmer.

Wireless Technology Description	
Wireless Link Specifications	
Frequency Band	2.4 GHz, ISM band
Transmission Power	Complies with FCC 15.247 (for U.S.) regulations/ETSI EN300-440 (For Europe) regulations.
Transmitters	
Operating Frequency Band	2401–2482 MHz
Type of Modulation	FSK
Type of Modulating Signal	Binary data message
Data Rate [=Frequency of Modulating Signal]	250 Kbps
Effective Radiated Power	<10 dBm
Receivers	
Operating Frequency Band	2401–2482 MHz
Receiver Bandwidth	812 kHz around a selected frequency

Chapter 13

Appendix - EMI Tables

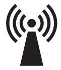
Guidance and Manufacturer’s Declaration Electromagnetic Emissions		
The NESS H200 Wireless System is intended for use in the electromagnetic environment specified below. The customer or the user of the NESS H200 Wireless System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment — Guidance**
RF emissions CISPR 11	Group 1	The NESS H200 Wireless System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The NESS H200 Wireless System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer’s Declaration— Electromagnetic Immunity for All Equipment and Systems			
The NESS H200 Wireless System is intended for use in the electromagnetic environment specified below. The customer or the user of the NESS H200 Wireless System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment—Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV contact 8 kV air	6 kV contact 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line to line 2 kV line to earth	1 kV line to line (Class II equipment without any grounded interconnections)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% UT (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NESS H200 Wireless System requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The NESS H200 Wireless System is intended for use in the electromagnetic environment specified below. The customer or the user of the NESS H200 Wireless System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the NESS H200 Wireless System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	**Recommended separation distance:** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	$[E_1]$ = 3 V/m in 80 MHz to 2.5 GHz $[E_1]$ = 10 V/m in 26 MHz to 1 GHz	**Recommended separation distance:** $d = 0.4\sqrt{P}$, 80–800 MHz range $d = 0.7\sqrt{P}$, 800–1000 MHz range $d = 2.3\sqrt{P}$, 1000–2500 MHz range

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
NOTE 3: *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).
NOTE 4: Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
NOTE 5: Interference may occur in the vicinity of equipment marked with the following symbol: 

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NESS H200 Wireless System is used exceeds the applicable RF compliance level above, the NESS H200 Wireless System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NESS H200 Wireless System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the NESS H200 Wireless System

The NESS H200 Wireless System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NESS H200 Wireless System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NESS H200 Wireless System as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	**Separation Distance According to Frequency of Transmitter**			
	150 kHz to 80 MHz Outside ISM Bands $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 0.4\sqrt{P}$	**800 MHz to 1000 MHz** $d = 0.7\sqrt{P}$	**1000 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	4.7 in. (0.12 m)	1.6 in. (0.04 m)	2.8 in. (0.07 m)	9.1 in. (0.23 m)
0.1	15 in. (0.38 m)	5.2 in. (0.13 m)	8.7 in. (0.22 m)	2 ft 5 in. (0.73 m)
1	3 ft 11 in. (1.2 m)	15 ft 7 in. (0.4 m)	2 ft 4 in. (0.7 m)	7 ft 7 in. (2.3 m)
10	12 ft 6 in. (3.8 m)	4 ft 2 in. (1.3 m)	7 ft 3 in. (2.2 m)	24 ft 11 in. (7.3 m)
100	39 ft 4 in. (12 m)	13 ft 1 in. (4 m)	23 ft (7 m)	75 ft 6 in. (23 m)

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: All calculations were made according to tables 204 and 206 of IEC 60601-1-2 for equipment that is not life-supporting using factors of 3.5 in 0.15–800 MHz and 7 in 800–2500 MHz. There are no requirements for ISM bands in these tables.