



HAND STIMULATOR

USER MANUAL

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Introduction

Device Description

The Hand Stimulator is a system designed to non-invasively stimulate the nerves of the forearm that control hand opening and closing. It is indicated for use by patients suffering from reduced hand-function due to conditions such as stroke, spinal-cord injury or other central nervous system disorders. Individuals suffering from these conditions can use the Hand Stimulator for any of the following purposes:

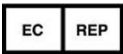
- Functional Stimulation
 - Actively initiate hand-grip and hand-open stimulation to assist with tasks of daily living
- Rehabilitation & Therapy
 - Improvement and/or maintenance of hand-function and range-of-motion
 - Prevention and/or reduction of disuse atrophy
 - Increase blood-circulation in the hand and forearm
 - Reduce muscle spasm
 - Muscle re-education



CAUTION: The Hand Stimulator is intended to be used only under the direction and/or supervision of a licensed healthcare professional.

List of Symbols

The following table lists the symbols that are used on the Hand Stimulator labels and in this manual:

Symbol	Definition	Application to the Hand Stimulator System
	Warning	Important information or instructions that should be observed to avoid potential injury or damage to the device.
	Operating Instructions	Instructions for use can be referenced detailing operating instructions.
	Follow Instructions for Use	The instructions for use contain critical instructions necessary to use the device safely.
IP22	Ingress Protection Rating	The STIM and HMS enclosures are protected against dripping water (e.g. light rain) and ingress of finger-sized objects.
	Non-Ionizing Radiation Emitter	The STIM and HMS components use low-energy radio frequencies.
REF	Model Reference (Catalogue/Re-order Number)	Reference the accompanying model number next to this symbol when re-ordering components.
LOT	Lot/Batch Number	Reference the accompanying batch number next to this symbol if contacting support.
	Type BF Applied Part	Components that make patient contact have a degree of protection against electric shock.
	European Authorized Representative	The contact information accompanying this symbol can be used to contact a representative in the European Community.
	Waste Electrical and Electronic Equipment (WEEE)	Do not dispose electronics with regular household waste. Consult local waste management authorities to determine the acceptable means to dispose of electronic equipment.

Symbol	Definition	Application to the Hand Stimulator System
	Double Insulated (Class II)	The DOCK power-supply adaptor does not require a safety ground connection.
	Do Not Iron or Press	Do not iron the fabric of the GARMENT .
	Do Not Tumble Dry	Do not tumble dry or hot-air dry the GARMENT after washing.
	Hand Wash Only	Hand wash the GARMENT only. Do not use a washing machine.
	Do Not Bleach	Do not use bleach when washing the GARMENT .
	Arm/Disarm	A button on the STIM that toggles arming and disarming of the stimulator.

Safety Information

Contraindications

- Do not use the Hand Stimulator System if a pacemaker or any other critical medical electrical equipment is in use. There is a remote chance that Hand Stimulator System may interfere with such devices.
- Do not use the Hand Stimulator System if fractures or dislocations of the fingers, wrist or elbow are present. Use of the Hand Stimulator System with these conditions may complicate the existing injury.
- Do not use the Hand Stimulator System on areas where a cancerous lesion is present or suspected. Electrical stimulation over cancerous lesions may complicate the condition.

Warnings

- The long term effects of chronic electronic stimulation are unknown. Discontinue use and consult a medical professional if any adverse effects are experienced.
- Never attempt to use the Hand Stimulator to stimulate parts of the body other than the hand and forearm. Stimulation to other areas such as the head, neck or torso can result in serious injury or death.
- Do not use the Hand Stimulator on, or close to injured, swollen, infected, or inflamed areas of the skin. Doing so may complicate the existing condition or prolong healing.
- Long term use can cause skin irritation. Discontinue use if you experience skin pain or a rash on your arm that doesn't fade within 1 hour.
- Interference is possible between the Hand Stimulator and other electrical equipment.
 - Do not use the device with any surgical equipment, or while near diagnostic equipment such as MRI, CT and ultrasound machines.
 - Do not use the device within 1 meter of any shortwave or microwave therapy equipment, as this may affect the performance of the Hand Stimulator.
- Do not use while driving, operating machinery, or during any activity in which involuntary muscle contractions may result in injury.
- Do not immerse the **STIM**, **HMS** or **DOCK** in water. Doing so may result in electrical shock and damage to the device.
- Never attempt to disassemble, modify or repair any components of the system. Doing so may result in electrical shock and damage to the device.
- Do not use if any component is visibly damaged. Wires, connectors and enclosures should be inspected for defects, breaks and obstructions before every use.
- Do not probe under the **GARMENT** with fingers or other objects while the **STIM** is actively stimulating. Doing so may result in electrical shock.

- Do not use the Hand Stimulator while sleeping.
- The Hand Stimulator is to be used only with **GARMENT**, **ELECTRODES**, **DOCK** and **POWER-SUPPLY** components supplied by Rehabtronics Inc.

Precautions

- Safety of powered muscle stimulators for use during pregnancy has not been established.
- Caution should be used for users with suspected or diagnosed heart problems, epilepsy or osteoporosis. Consult a physician prior to use.
- Caution should be used over areas of the skin which lack normal sensation.
- Some patients may experience skin irritation or hypersensitivity due to electrical stimulation. The irritation can usually be reduced by using an alternate electrode placement or by changing the stimulation parameters. If problems persist, discontinue use.
- Electrode placement and stimulation setting should be based on the guidance of a medical professional.
- Keep the Hand Stimulator out of the reach of children not prescribed to use the device. Children prescribed to use the device should do so only under adult supervision.
- Muscle soreness may occur, much like during regular exercise. Limit the amount of usage per day according to exercise-related soreness.
- Hand function may change while using this device. Use caution while attempting new activities.
- Replace the **GARMENT** and **ELECTRODES** if they show signs of advanced wear and tear within suggested replacement period.
- Autonomic Dysreflexia can occur while using the device in people with spinal cord injury above T6 level.
- Extended use can reduce tenodesis grip in users with spinal-cord injuries.
- When using the **STIM** between users, the intensity setting should be reset to minimum between users.
- Do not share the **GARMENT** or **ELECTRODES** between users.
- Do not use the Hand Stimulator continuously beyond four hours at a time. Remove the Garment and allow skin to ventilate between uses. If any skin redness or inflammation is noticed, do not begin using the Hand Stimulator again until the skin has fully recovered.
- Do not store or operate the Hand Stimulator in conditions outside those listed in the Technical Information section of this manual. Doing so can damage components.
- Electrical and wireless components of the Hand Stimulator System require special precautions for electromagnetic compatibility and immunity. Refer to Electromagnetic Compatibility tables in the Technical Information section of this manual for details.

System Components

GARMENT (see page 13)

- Used to position the **ELECTRODES**, and hold the **STIM**
- Includes optional thumb-strap
- Available in three sizes for both left and right arms

DOCK (see page 9)

- Used to charge the **STIM** and **HMS**
- Optionally used to pair different **STIM** and **HMS** units
- Includes a dedicated power-supply and interchangeable wall-outlet adaptors.

WRIST-SUPPORT (see page 16)

- Optional **GARMENT** accessory used to support the wrist



ELECTRODES (see page 15)

- Wettable electrode pads for use with the **GARMENT**
- Comes in packaged sets of four (3 large and 1 small)

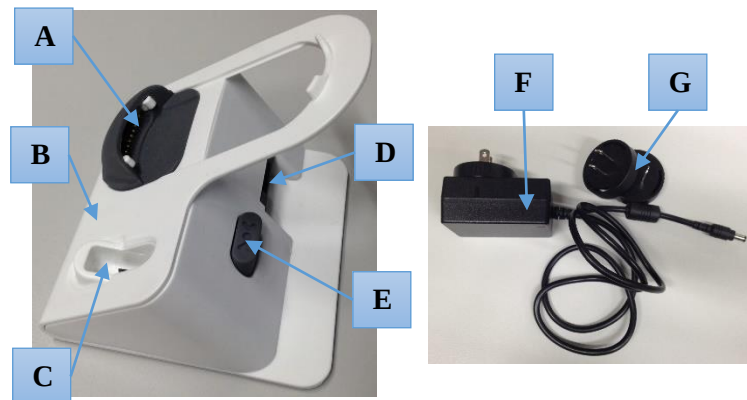
STIM (see page 11)

- Used to configure and activate stimulation when connected to a **GARMENT**

HMS (see page 12)

- “Head Motion Sensor”
- Optional accessory, for use with the **STIM**
- Worn over the ear
- Allows stimulation to be controlled by movements of the head

The DOCK



A	STIM CRADLE Connection for a STIM unit.
B	POWER LED Glows green when the DOCK is receiving power.
C	HMS CRADLE Connection for an HMS unit.
D	POWER INPUT Connection input to the POWER-SUPPLY.
E	PAIRING BUTTON Pairs connected STIM and HMS so they can work together.
F	POWER-SUPPLY (Rehabtronics Part No. DE02) Supplies power to the DOCK from a local AC power outlet.
G	OUTLET ADAPTORS Common types of international adaptors can be interchanged to fit the shape of local power-outlets.

DOCK Setup

To setup the **DOCK**, simply connect the included **POWER-SUPPLY** adapter to the **DOCK's POWER INPUT**, and plug in the **POWER-SUPPLY** to a local 100-240V AC power outlet. When properly plugged-in, the **DOCK's POWER LED** will glow green.



WARNING: Do not attempt to modify or substitute the included *POWER-SUPPLY*. Doing so may result in electrical hazards. If a replacement adaptor is required, see “Contact and Re-Ordering Information” at the end of the Manual.



WARNING: The **DOCK** is intended for indoor use only. Keep dry and away from extreme temperatures.

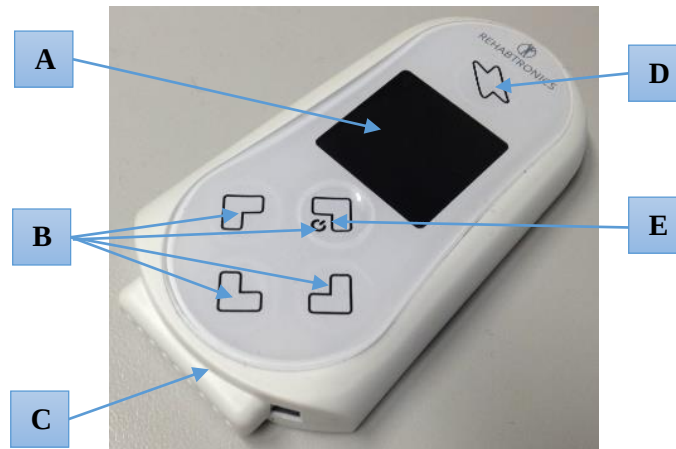
Changing Outlet Adaptors

The **DOCK**'s *POWER-SUPPLY* includes interchangeable *OUTLET ADAPTORS*, allowing it to fit the most common international outlets.

The instructions below describe how to exchange *OUTLET ADAPTORS*:

		
1. Remove the current <i>OUTLET ADAPTOR</i> by pressing the “PUSH” button and twisting the adaptor.	2. Line up the arrows of the new <i>OUTLET ADAPTOR</i> and <i>POWER-SUPPLY</i> as shown.	3. Twist on the new <i>OUTLET ADAPTOR</i> until it clicks into place.

The STIM



A	DISPLAY The display screen for the user interface.
B	NAVIGATION BUTTONS Used to navigate menus and options of the <i>DISPLAY</i> 's user interface.
C	DOCK/GARMENT CONNECTION Allows the STIM to be connected to either a DOCK or a GARMENT .
D	ARM/DISARM BUTTON Toggles arming and disarming. Arming is required for stimulation. Disarming will disable all stimulation. NOTE: The STIM must be connected to a GARMENT to arm.
E	ON/OFF BUTTON Press and hold to turn the STIM on and off.

NOTE: To conserve batteries, the **STIM** will automatically turn off after more than 10 minutes of no activity or movement.

The HMS



A	DOCK CONNECTION Allows the HMS to be connected to a DOCK .
B	STATUS LED Used to monitor the status of the HMS . Will flash dim green when the HMS is powered on.
C	ON/OFF BUTTON - To turn on, press and hold until the <i>STATUS LED</i> glows green. - To turn off, press and hold until the <i>STATUS LED</i> glows yellow.

Pairing a New STIM or HMS

NOTE: The **STIM** and **HMS** units supplied with a system kit will come pre-paired. This section is only applicable if pairing different **STIM** and **HMS** units, or for troubleshooting purposes should a **STIM** and **HMS** be failing to communicate.

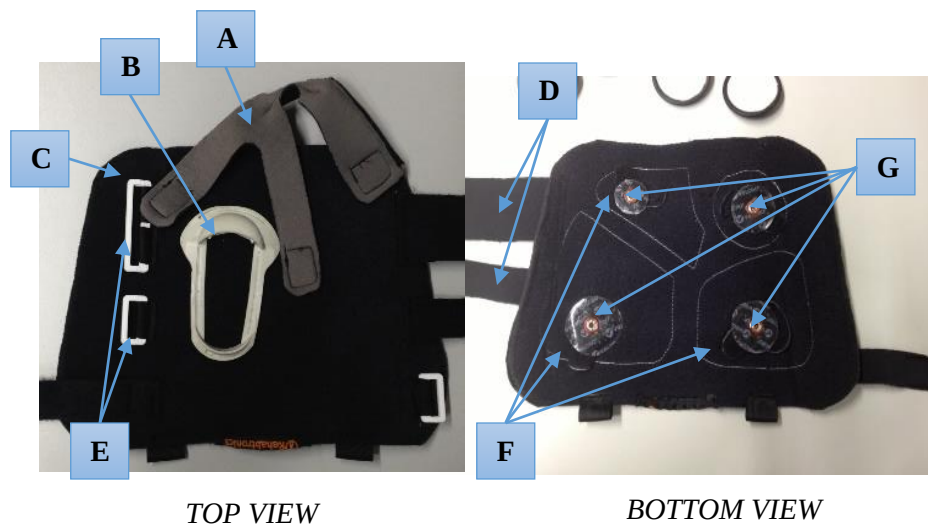
In order for a **STIM** and **HMS** to communicate, they must first be paired. To pair a **STIM** and **HMS**, insert both into the **DOCK** and press the *PAIRING BUTTON*. The pairing progress can be monitored according to the table on the right.

NOTE: Pairing a **STIM** and **HMS** only has to be performed once. Successful pairing is saved automatically.

NOTE: A **STIM** can only be paired with one **HMS** at a time. The pairing process will overwrite any previous pairings.

STIM Display	Meaning
	Pairing is in progress
	Pairing successful
	Pairing error

The GARMENT



A	THUMB-STRAP Detachable strap that allows the THUMB electrode to be placed against the heel of the thumb.
B	STIM-HOLDER Holds the STIM while in use.
C	WRIST-SUPPORT SLOT A slot for inserting the optional WRIST-SUPPORT accessory.
D	STRAPS Velcro straps for tightening and securing the GARMENT .
E	CLASPS Clasps for threading each of the STRAPS .
F	PLACEMENT AREAS Stitched areas indicate recommended placement areas for each of the ELECTRODES .
G	ELECTRODE LEADS Moveable leads can be relocated in the <i>PLACEMENT AREAS</i> and contain a socket for attaching ELECTRODES .



WARNING: Do not share the **GARMENT** between users.

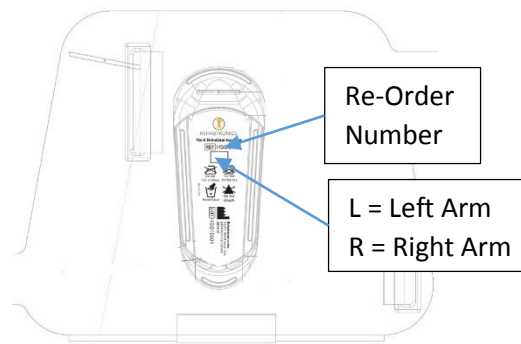


WARNING: Do not machine-wash or tumble-dry the **GARMENT**. Doing so may irreparably damage the **GARMENT**. For washing instructions refer to the “GARMENT Cleaning & Maintenance” section of this manual.

Selecting a GARMENT

The **GARMENT** is available for either left or right arms in three sizes – small, medium, and large. System kits will include all different types, and hence the preferred type must be selected as follows:

1. Check the **GARMENT** labels and select only the ones specific to the affected arm (either left or right).
2. Try on each size of **GARMENT** to select the appropriate size that covers as much of the forearm as possible without interfering with elbow or wrist movement.
3. Note the re-order (REF) number on the label of the selected **GARMENT** for re-ordering purposes. For re-ordering information see “Contact and Reordering Information” at the end of this manual.



The ELECTRODES



A	<i>GARMENT SNAP</i> Allows connection to GARMENT ELECTRODE LEADS .
B	<i>FABRIC PAD</i> Cotton pad holds water to conduct and distribute stimulation pulses.
C	<i>LARGE ELECTRODE</i> 4.2cm in diameter. Intended for placement over large areas of the forearm.
D	<i>SMALL ELECTRODE</i> 2.2cm in diameter. Intended for stimulating smaller areas, such as those required for thumb-close stimulation.



CAUTION: Do not use soaps or detergents on the **ELECTRODES**. Doing so may result in skin irritation and have unknown effects on stimulation performance.

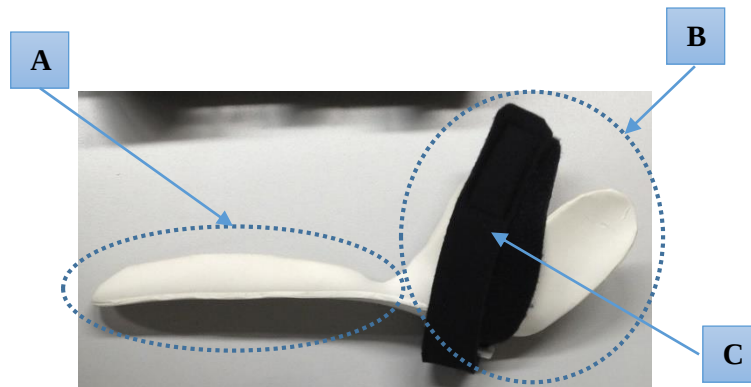


WARNING: Do not share **ELECTRODES** between users.



IMPORTANT: Replace **ELECTRODES** after two (2) weeks of daily use, or sooner if significant odors or discoloration is observed. See “Contact and Reordering Information” at the end of this manual.

The WRIST-SUPPORT



A	<i>GARMENT INSERT</i> Extended portion that inserts into the GARMENT's <i>WRIST-SUPPORT SLOT</i> .
B	<i>HAND-CRADLE</i> U-shaped portion wraps around the palm of the hand
C	<i>STRAP</i> A Velcro strap for holding the <i>HAND-CRADLE</i> to the hand.

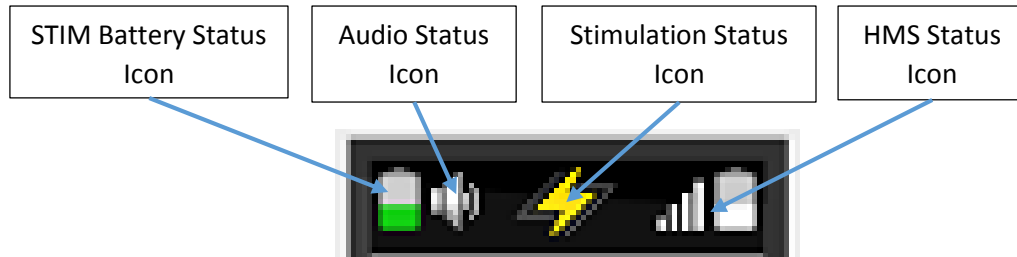
See “Using the WRIST-SUPPORT” section on page 31 of this manual for instructions on using the **WRIST-SUPPORT**.

STIM User Interface

All of the Hand Stimulator system's functions for configuring and activating stimulation are accessed through the **STIM**'s user interface. This section describes in detail how to navigate the user interface, and the available options.

Status Bar

The **STIM**'s user interface contains a persistent Status Bar at the top of the *DISPLAY* that indicates the present status of the device.



STIM Battery Status Icon

Icon	Meaning
[image]	Charged - Fully charged
	Discharging - Partially charged
[image]	Low Battery - Less than 10% charge remaining

Audio Status Icon

Icon	Meaning
	Enabled - Audio is enabled
	Disabled - Audio is disabled

Stimulation Status Icon

Icon	Meaning
[image]	Disarmed – All stimulation functions are disabled. Allows settings to be configured without a GARMENT.
	Armed (Standby) – STIM is connected to a GARMENT and ready to start stimulating.
	Active (Stimulating) – STIM is sending stimulation pulses to the ELECTRODES.

HMS Status Icon

Icon	Meaning
	HMS Not Connected - Tap the STIM to control FES mode.
	HMS Connected - An HMS is detected and FES mode will respond to head-motion detections. - Indicates the wireless connection strength between the STIM and the HMS. - Is a battery meter for the HMS, similar to the STIM Battery Status Icon.

Main Menu

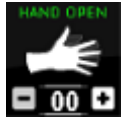
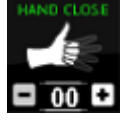
When the **STIM** is turned on by pressing and holding the *ON/OFF BUTTON*, a Main Menu is presented with the following four options:

Menu Option	Description
<i>STIM INTENSITY*</i>	Adjust stimulation intensities to the electrodes controlling hand-open, hand-close and thumb-close.
<i>FES MODE*</i>	<u>F</u> unctional <u>E</u> lectrical <u>S</u> timulation. Manually control hand-open and hand-close stimulation.
<i>EXERCISE MODE*</i>	Timer-based stimulation programs that automatically cycle between hand-open and hand-close stimulation.
<i>DEVICE SETUP</i>	Settings to configure the user interface.

***NOTE:** *STIM INTENSITY*, *FES MODE* and *EXERCISE MODE* stimulation functions require the **STIM** to be connected to a **GARMENT** and armed for stimulation.

STIM INTENSITY

Selecting the *STIM INTENSITY* option from the main-menu will access the following sub-menus:

Sub-Menu	Description	Instructions
	Resets all electrode stimulation intensities to OFF.	Press  twice to perform reset. Press any other <i>NAVIGATION BUTTON</i> to cancel.
	Adjust the stimulation intensity to the electrode controlling hand opening, or turn it OFF.	Use the  and  buttons to adjust the intensity.
	Adjust the stimulation intensity to the electrode controlling hand closing, or turn it OFF.	Use the  and  buttons to adjust the intensity.
	Adjust the stimulation intensity to the electrode controlling thumb closing, or turn it OFF.	Use the  and  buttons to adjust the intensity.

NOTE: Increasing intensities requires the **STIM** to be connected to a **GARMENT**. The person wearing the **GARMENT** will be able to feel the adjusted intensity.



CAUTION: If sharing a single **STIM** between users, use the “reset” feature to reset all electrode intensities to ‘OFF’ between users.

FES MODE

The “Functional Electrical Stimulation” (FES) mode allows manual control of hand-open and hand-close stimulation in one of two ways, depending on whether a paired **HMS** is detected:

- If a paired **HMS** is detected, the **STIM** will respond to head-motion detected by the **HMS**.
- If there is no **HMS** detected, the **STIM** will respond to physical taps.

While in *FES MODE*, the **STIM** will cycle between the following states in response to either physical taps or head-motion detections:

<i>FES MODE</i> State	Description
	Relax (no stimulation) This is the default state when <i>FES MODE</i> is first started.
[image]	Hand-Open Stimulation Electrical pulses are delivered to the hand-open electrode, causing the fingers of the hand to open.
[image]	Hand-Close Stimulation Electrical pulses are delivered to the hand-close and thumb-close electrodes, causing the hand to close.

NOTE: Hand-Open and Hand-Close states require the **STIM** to be connected to a **GARMENT**, and armed for stimulation.

NOTE: To conserve battery-life the *DISPLAY* will turn off when the **STIM** is left in any of the above states for a prolonged period. The *DISPLAY* will turn back on if any button is pressed, or if the relax/open/close state is changed by a tap or head-motion.

EXERCISE MODE

EXERCISE MODE contains two timer-based programs:

Program	Description
	Condition muscles of the forearm and hand by automatically cycling between relax (no stimulation), hand-open stimulation, and hand-close stimulation.
	Promote blood circulation in the forearm and hand by automatically cycling between relax (no stimulation), hand-open stimulation, and hand-close stimulation at a low intensity.

The following table describes the EXERCISE MODE interface:

Interface	Instructions
Select Program	Use the up/down navigation buttons to select the preferred program.
Start Program	Press the  button to start the program. Stimulation will begin, and a timer will begin counting down from 20 minutes. NOTE: The STIM must be connected to a GARMENT and armed for the program to begin.
Pause Program	Press the  button to pause the program. This will stop stimulation and pause the timer. Press the button again to un-pause and resume stimulation and timer countdown.
Stop Program	Stop the program by pressing the  button. Stimulation will stop, and the timer will be reset.
Panic Protection	In addition to the instructions for pausing and stopping exercise programs described above, the STIM can also be immediately disabled at any time by either: a) Removing the STIM from the GARMENT , or b) Forcibly hitting the STIM .

DEVICE SETUP

Selecting the DEVICE SETUP option from the main-menu allows access to the following device settings:

DEVICE SETUP Menu	Purpose	Instructions
 Audio Setting	Enable or disable audible beeps.	Use the '<' and '>' navigation buttons to select the preferred audio setting.
 Tap Sensitivity	Adjust the tapping force required to cycle hand-open/close/relax in FES mode.	- Use the '<' button to make the STIM less sensitive to taps (harder tap required) - Use the '>' button to make the STIM more sensitive to taps (softer tap required). - The current setting can be tested by tapping the STIM. The dot will flash green if the tap was hard enough for the STIM to detect it at the current sensitivity setting.
 HMS Mode	Select the preferred head-motion detection pattern for use in FES mode.	- Use the '<' and '>' navigation buttons to switch between head-motion patterns. - The currently selected pattern can be tested by donning a connected HMS and performing the selected head-motion. The dot will flash green when selected head-motion patterns are detected.
 Hand	Reorient the <i>DISPLAY</i> and <i>NAVIGATION BUTTONS</i> according to the affected arm.	Use the '<' and '>' buttons to select left or right hand orientation, respectively. The <i>DISPLAY</i> and <i>NAVIGATION BUTTONS</i> will re-orient automatically.
 Usage Log	Displays statistics on the amount of time stimulating.	- The Usage Log screen will automatically record and update the following information: Hand Open – The total amount of time spent stimulating the hand to open. Hand Close – The total amount of time spent stimulating the hand to close. Total Cycles – The total number of times the hand has been stimulated through open/close/relax cycles.

Factory Reset

The **STIM** settings and Usage Log statistics can be reset to their original out-of-the-box settings as follows:

1. Select *DEVICE SETUP* from the **STIM** main-menu.
2. Navigate to the Usage Log screen.
3. Press and hold the  button, and while still holding the  button press the  button. A confirmation screen will appear.
4. From the confirmation screen, press  to confirm the reset, or press  to cancel.

Using the Hand Stimulator System

Overview

This section describes the steps for using the Hand Stimulator system. Below is an overview of the steps and references to the pages of this manual where detailed instructions are given:

1. Charge the **STIM** and **HMS** (*page 25*)
2. Prepare the Arm (*page 26*)
3. Wet **ELECTRODES** and attach them to the **GARMENT** (*page 27*)
4. (If necessary) Reposition **ELECTRODES** in the **GARMENT** (*page 28*)
5. Fit the **GARMENT** over the **ARM** (*page 30*)
6. Configure preferred stimulation intensities (*page 32*)
7. Activate stimulation by selecting either of the following modes:
 - a. FES Mode (*page 34*) – Manually control stimulation of hand-opening and hand-closing
 - b. EXERCISE Mode (*page 37*) – Timer-based automatic stimulation programs

Charging the STIM and HMS

To charge the **STIM** and **HMS**, simply insert them into their cradles in the **DOCK** as shown in the image below:



The charging status can be monitored by observing the **STIM**'s *DISPLAY* and the **HMS**'s *STATUS LED* according to the following table:

	CHARGING STATUS		
	Charging in Progress	Charging Complete	Charging Error
STIM	STIM 's <i>DISPLAY</i> shows an animated battery indicating the current charge progress	STIM 's <i>DISPLAY</i> shows full battery and green checkmark	STIM 's <i>DISPLAY</i> shows an error message
HMS	HMS 's <i>STATUS LED</i> alternately flashes green and yellow	HMS 's <i>STATUS LED</i> is solid green	HMS 's <i>STATUS LED</i> is solid red

NOTE: **STIM** and **HMS** units can be charged separately or simultaneously. It is recommended that either component, when not in use, be placed in the **DOCK** to avoid battery depletion.

GARMENT & ELECTRODES Fitting

Preparing the Arm

The skin over which the **GARMENT** is fitted must be clean, healthy, and free of obstructions. Perform the following preparation steps prior to fitting:

1. Ensure the skin is healthy and free of any cuts, irritations, infections, or other injuries.
2. Ensure the skin is clean and free of any lotions, ointments or other cosmetics.
3. Remove any personal items such as jewelry, watches, bracelets, etc. from the affected arm.
4. If necessary for the **ELECTRODES** to make contact with the skin, trim any excess arm hair from the areas over which the **ELECTRODES** will be placed.



CAUTION: Ensure the skin is clean and free of any ointments, lotions and cosmetics. The presence of other substances can have unknown effects on stimulation delivery.



WARNING: Do not use over irritated, injured or infected skin. Doing so may complicate existing injuries or infections.

Wetting the ELECTRODES

The **ELECTRODES** must be wet with clean water prior to connecting them to the **GARMENT**. This is done as follows:

1. Inspect the **ELECTRODES** prior to use. If there is significant discoloration, bad odors, or any noticeable separation of materials, discard and use a new set instead. For re-ordering information “Contact and Reordering Information” at the end of this Manual.
2. Soak **ELECTRODES** in clean, room-temperature water. Ensure the *FABRIC PADS* have absorbed as much water as possible.
3. Squeeze **ELECTRODES** lightly to remove excess water. The **ELECTRODES** should be as wet as possible, without dripping water.



CAUTION: Use only clean water to wet **ELECTRODES**. Using dirty water or any other liquid can result in skin irritation and unknown stimulation performance.

Attaching the ELECTRODES to the GARMENT

Once the **ELECTRODES** have been wet, they can be snapped into the sockets at the ends of each of the **GARMENT**'s *ELECTRODE LEADS*:

1. Snap the *SMALL ELECTRODE* into the socket of the **GARMENT**'s THUMB LEAD.
2. Snap the remaining three *LARGE ELECTRODES* in to the sockets of the remaining leads.



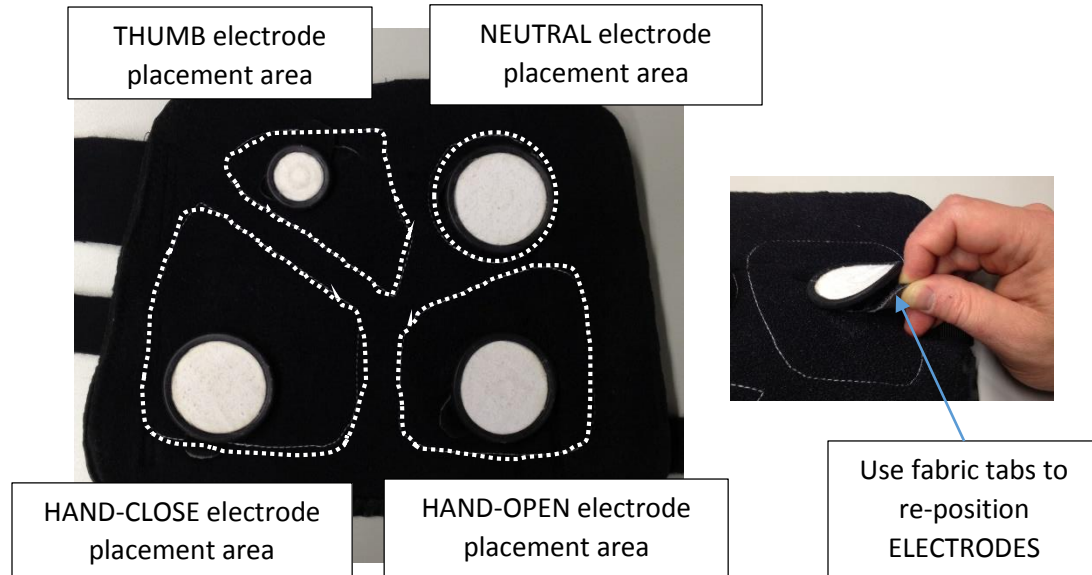
CAUTION: Ensure all four **ELECTRODES** are attached to the **GARMENT** prior to use. Wearing the **GARMENT** with missing **ELECTRODES** can cause discomfort and skin irritation.



CAUTION: Ensure each electrode is securely snapped into the **GARMENT** sockets. Loose connections can result in intermittent stimulation delivery, or **STIM** error messages.

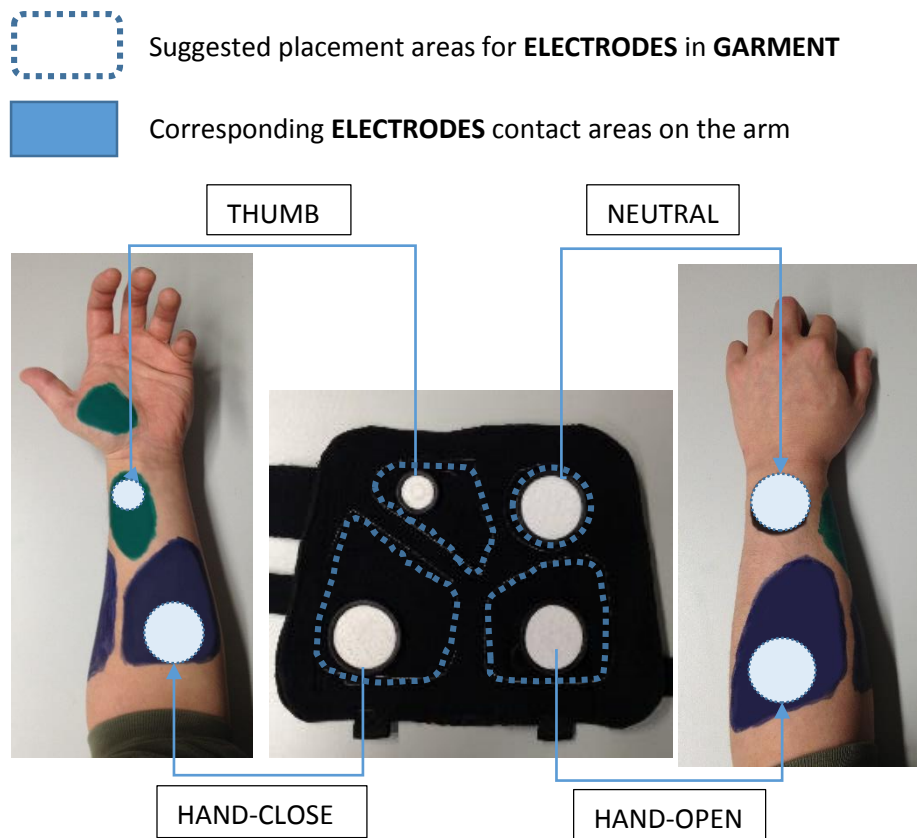
Positioning ELECTRODES in the GARMENT

The underside of the **GARMENT** has stitched areas indicating the common placement areas for each of the **ELECTRODES**. The **GARMENT**'s *ELECTRODE LEADS* each have a fabric tab, allowing the **ELECTRODES** to be moved to different positions.



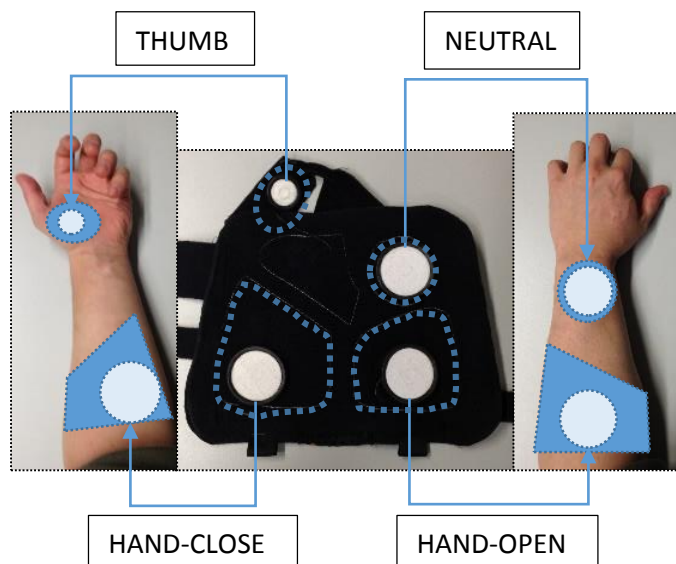
CAUTION: Use care when re-positioning **ELECTRODES** so as not to stress or damage the underlying cables.

The following figure illustrates the approximate areas of the arm corresponding to each of the *PLACEMENT AREAS*:



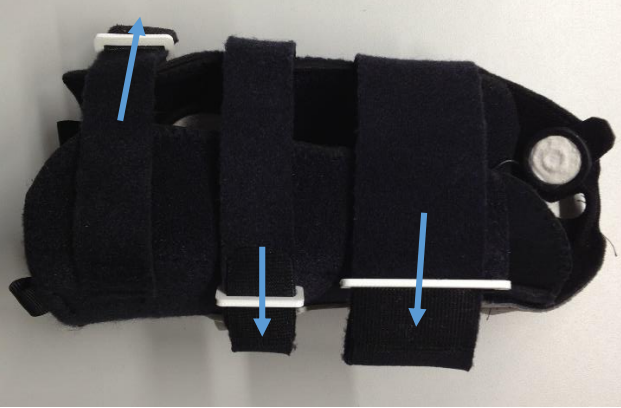
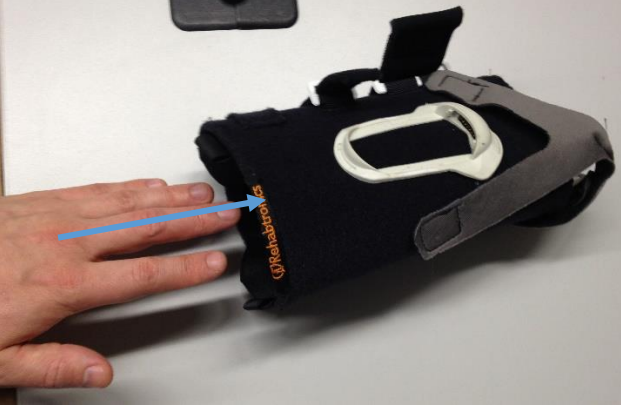
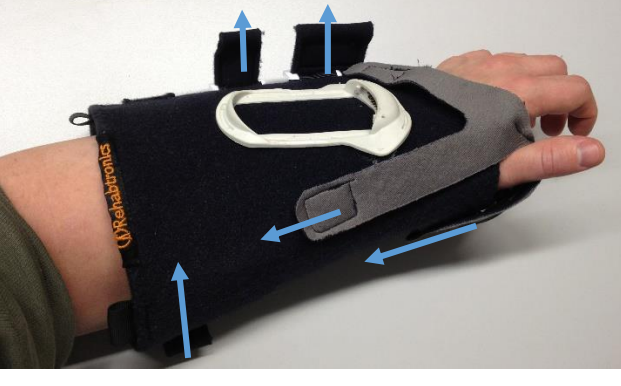
Using the THUMB-STRAP to Place the THUMB Electrode

In addition to the THUMB electrode placement area indicated on the **GARMENT**, the **GARMENT** also comes with a detachable *THUMB-STRAP* that allows the THUMB electrode to be placed against the heel of the thumb.



Fitting the GARMENT

Once all four **ELECTRODES** are wet and attached to the **GARMENT**, the **GARMENT** can be fitted on the arm as follows:

	1. Loosely thread the GARMENT's STRAPS through the CLASPS, creating a wide "sleeve" shape.
	2. With the GARMENT's STIM HOLDER on top, insert the arm through the GARMENT.
	3. Tighten and secure the STRAPS so that the ELECTRODES are pressed firmly against the skin, and the GARMENT does not twist or slide on the arm.  CAUTION: Do not over-tighten to the point of restricting blood-flow to the hand.

Using the WRIST-SUPPORT

The **WRIST-SUPPORT** is an optional **GARMENT** accessory used to support the wrist in a neutral position. It should be used only if the person wearing the **GARMENT** requires wrist support.



Conditions that may require the **WRIST-SUPPORT**:
Unsupported, the wrist is held in a naturally flexed position



With the **WRIST-SUPPORT**:
Wrist is supported in a neutral position

To use the **WRIST-SUPPORT**, simply insert the long end into the **GARMENT**'s *WRIST-SUPPORT SLOT*.



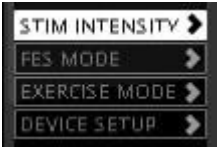
Configuring Stimulation Intensity

Resetting Intensities

Prior to configuring **STIM** intensities, it is recommended that all settings be first reset to “OFF”. This should be done in either of the following situations:

- If the **STIM** is being used for the first time
- If the **STIM** is being shared between users, such as in clinical settings

Resetting all intensities to “OFF” is accomplished as follows:

	1. Turn the STIM on by pressing and holding the <i>ON/OFF BUTTON</i> .
	2. Select “STIM INTENSITY” from the Main Menu.
	3. Press the  button at the screen asking if you would like to reset intensities.
	4. A screen will ask to confirm the reset. ○ Press  to confirm. ○ Press any other navigation button to cancel.
	5. If confirmed, the <i>DISPLAY</i> will show a green checkmark indicating that all intensities have been successfully reset to ‘OFF’.

Adjusting Intensities



IMPORTANT: If sharing the **STIM** between users, intensities should always be reset between users prior to following these instructions (see previous section).

NOTE: Increasing intensities requires the **STIM** to be connected to a **GARMENT**, allowing the person wearing the **GARMENT** to feel the effects as the intensity is adjusted.

Stimulation intensity can be adjusted individually to the HAND-OPEN, HAND-CLOSE and THUMB ELECTRODES as follows:

1. Wet the **ELECTRODES** and fit the **GARMENT** according to the instructions in the previous sections.
2. Insert the **STIM** into the **GARMENT**'s *STIM-HOLDER*.
3. Turn the **STIM** on by pressing and holding the *ON/OFF BUTTON*.
4. Press the  button to arm the **STIM**.
5. Select "STIM INTENSITY" from the Main Menu.
6. Use the  button to access the "HAND OPEN", "HAND CLOSE" and "THUMB CLOSE" screens.
7. Use the  button to gradually increase the intensity of stimulation to the each electrode, until the desired hand-response is achieved.



CAUTION: Do not increase to painful levels. The desired hand-response should be achievable without pain or discomfort. If significant discomfort is experienced without achieving the desired response, reposition the electrode to another location in the *PLACEMENT AREAS* and try again.

NOTE: In most cases, effects will not be felt until the setting has increased beyond 5.

NOTE: Stimulation can be stopped at any time by pressing the  button.

NOTE: Not all circumstances require thumb stimulation. If thumb stimulation is not needed, the THUMB-CLOSE screen can be left at a setting of 'OFF'.

Functional Stimulation

The **STIM** has a dedicated mode for functional electrical stimulation (FES), which allows manual control over hand-opening and hand-closing stimulation. This control is accomplished by either physically tapping the **STIM**, or by executing head-motion patterns with the **HMS**.

NOTE: this section assumes that the following pre-requisite steps have already been taken:

- ✓ The **ELECTRODES** are wet and the **GARMENT** has been fitted according to the instructions in the previous sections (see page 27).
- ✓ The **STIM** has been inserted into the **GARMENT**'s *STIM-HOLDER* and is turned on.
- ✓ Stimulation intensity has been configured to desired levels (see page 33).



CAUTION: Hand function may change as a result of using the Hand Stimulator. Use caution when engaging in activities that depend on controlled hand function.



WARNING: Do not use while driving, operating machinery, or during any activity in which involuntary muscle contractions may result in injury.

Controlling Stimulation by Tapping

Functional stimulation control by tapping the **STIM** is achieved as follows:

	1. Check that there is no HMS connected to the STIM. The top right of the <i>DISPLAY</i>'s Status Bar should show "TAP". If "TAP" is not shown in the Status Bar, check that any nearby HMS unit has been turned off.
[image]	2. Press the  button to arm the STIM. The Stimulation Status icon at the center of the <i>DISPLAY</i>'s Status Bar should be solid gray .
	3. Select "FES MODE" from the Main Menu.
[image]	4. Tap the STIM to cycle between hand-opening, hand-closing and relax (no stimulation). NOTE: Stimulation can be stopped at any time by pressing the  button.

Adjusting the Tap Sensitivity

To adjust how sensitive the **STIM** is to taps, do the following:

	1. Select "DEVICE SETUP" from the STIM's Main Menu. 2. Press the  button until the "TAP SENSITIVITY" screen is reached.
	3. Use the  and  buttons to adjust the tap sensitivity: Press the  button to make the STIM less sensitive (harder tap required) Press the  button to make the STIM more sensitive (softer tap required)

NOTE: The current setting can be tested by tapping the **STIM**. The dot on the screen will flash green if the tap was hard enough for the **STIM** to detect it at the current sensitivity setting.

Controlling Stimulation by Head-Motion

To control functional stimulation using movements of the head, follow the instructions below:

1. Turn on the **HMS** by pressing and holding the ON/OFF BUTTON until the *STATUS LED* glows green.
 - After a moment, the **STIM**'s *DISPLAY* should indicate that an **HMS** has been detected, and the connection-strength should be visible at the top-right of the Status Bar.
2. Don the **HMS** over the preferred ear.
3. Set the preferred pattern by selecting "DEVICE SETUP" from the **STIM**'s Main Menu, and then navigating to the "HMS Mode" screen.
4. Use the  and  navigation buttons to switch between head-motion patterns. There are four detection patterns available:
 - (1) Down-Up – Nod the head down then return to normal
 - (2) Up-Down – Nod the head up, then return to normal
 - (3) Right-Left – Turn the head to the right, then return to normal
 - (4) Left-Right – Turn the head to the left, then return to normal

NOTE: The currently selected pattern can be tested by performing the selected head-motion. The dot on the screen will flash green when selected head-motion patterns are detected.

5. Press the **STIM**'s  button to arm the **STIM**. The Stimulation Status icon at the center of the *DISPLAY*'s Status Bar should be solid gray.
6. Return to the Main Menu and select "FES MODE".
7. Hand-opening, hand-closing and relax (no stimulation) can now be cycled by executing the head-motion pattern selected in step 4.

Exercise Programs

The Hand Stimulator system contains two passive, timer-based exercise programs:

Program	Stimulation Behavior	Uses
STRENGTH	Automatically cycles between relax (no stimulation), hand-open stimulation and hand-close stimulation at the currently configured intensity settings.	- Condition muscles of the forearm and hand - Increase or maintain range-of-motion
CARDIO	Automatically cycles between relax (no stimulation), hand-open stimulation and hand-close stimulation at 30% of the currently configured intensity settings.	- Promote blood circulation to the forearm and hand

NOTE: Both programs run for a maximum of 20 minutes per session, but can be stopped or paused at any time.



CAUTION: Do not exceed one 20 minute session per day unless instructed otherwise by a medical professional.



WARNING: Muscle soreness may occur, much like during regular exercise. Limit the amount of usage per day according to exercise-related soreness. If pain is experienced, immediately discontinue exercise and contact your medical professional.

Use the exercise programs as follows:

1. Select “EXERCISE MODE” from the **STIM**’s Main Menu.
2. Use the  and  buttons to select either the “STRENGTH” or “CARDIO” screens.
3. Use the  button to ensure that the **STIM** is armed.

The Stimulation Status icon at the center of the Status Bar will be solid gray .

4. Press the  button to start the exercise. Stimulation will begin to cycle automatically, and the timer will begin to countdown.
5. Pause the exercise at any time by pressing the  button. This will stop stimulation and pause the timer. Press the  button again to resume the exercise.
6. Stop the exercise at any time by pressing the  button. This will stop stimulation and reset the timer.

System Cleaning and Maintenance

General System Maintenance

The following general maintenance guidelines should be followed to ensure safe and effective use of the Hand Stimulator system:

- Inspect all components prior to use. Do not use any components show signs of damage.
- Do not store or operate any of the system components outside their specified operating and storage conditions (see “General Specifications” section of this manual).
- All system components can be cleaned of surface debris as necessary by wiping with a soft cloth dampened with clean water.



WARNING: Do not perform any cleaning or maintenance while the equipment is in use. Ensure components are powered off prior to following any of the cleaning instructions in this section.

DOCK Cleaning & Maintenance

Cleaning the **DOCK** can be performed as necessary to remove surface debris and prevent obstruction of the *STIM CRADLE* and *HMS CRADLE*. If there is noticeable dirt, dust or other substance accumulating on the surface or within either of the **STIM** or **HMS** cradles, perform the following:

1. Unplug the **DOCK**.
2. Wipe the **DOCK**'s outer surfaces with a soft cloth dampened with clean water.
3. Use compressed air to dislodge any obstructions from the **STIM** and **HMS** cradles.

STIM and HMS Cleaning & Maintenance

The **STIM** and **HMS** can be cleaned, as needed, by simply wiping with a soft cloth dampened with clean, warm water.

If low-level disinfecting is required, such as in clinical settings, the **STIM** and **HMS** can be wiped with a cloth soaked with 70% isopropyl alcohol (IPA) solution. Continue to wipe as necessary to ensure all surfaces are kept wet with the solution for at least three (3) minutes.



WARNING: Do not immerse the **STIM** or **HMS** in water or any other liquid. Doing so can permanently damage the electronics.

When not in use, it is recommended that the **STIM** and **HMS** be stored in the **DOCK**. This will prolong the battery life, and ensure that the **STIM** and **HMS** are fully charged when next used.

ELECTRODES Cleaning & Maintenance

Between uses, **ELECTRODES** can be maintained as follows:

1. Disconnect **ELECTRODES** from the **GARMENT**.
2. Rinse **ELECTRODES** with clean water.
3. Squeeze out excess water, and allow **ELECTRODES** to air-dry.
4. When not in use, store the **ELECTRODES** in a dry, ventilated area.



CAUTION: Do not use soaps, detergents, or other chemical cleaners on the **ELECTRODES**. Doing so may cause skin-irritation, or affect stimulation.



CAUTION: Do not store **ELECTRODES** wet. Allow the **ELECTRODES** to fully air-dry prior to storing.

The **ELECTRODES** are intended to be replaced regularly to prevent bacterial or other buildup, or degradation of materials. **ELECTRODES** should be replaced in either of the following cases:

1. If there is significant discoloration, bad odors, or any noticeable separation of materials; or,
2. After two (2) weeks of daily use.



CAUTION: Inspect **ELECTRODES** prior to use. Damaged or dirty electrodes will affect stimulation efficacy, and hence should be replaced regularly.

For re-ordering information see “Contact & Reordering Information” at the end of this manual.

GARMENT Cleaning & Maintenance

The **GARMENT** can be washed by hand as necessary in a solution of mild laundry detergent and warm water.

1. Remove the **STIM** from the **GARMENT**.
2. Remove all **ELECTRODES** from the **GARMENT**.
3. Fill a sink or medium-sized basin with clean warm water and a small amount of mild, unscented laundry detergent.
4. Submerge the **GARMENT** in the soapy water and *gently* agitate by hand for 2 to 5 minutes.
5. Rinse the **GARMENT** under running warm water, and lightly squeeze - but do not twist or wring - until there is no sign of residual detergent.
6. Lightly squeeze out any excess water and dab-dry using a clean towel.
7. Hang the **GARMENT** on a clothes-line or drying rack, and allow time to air-dry.



CAUTION: Do not use bleach, fabric-softener, or any other products.



CAUTION: Handle the **GARMENT** with care. Do not twist, wring the **GARMENT**.



CAUTION: Air-dry only. Do not tumble-dry or hot-air dry the **GARMENT**.

The **GARMENT** is intended to be replaced regularly, as the fabrics and electronics are subject to wear. The **GARMENT** should be replaced in either of the following cases:

1. If there noticeable damage to materials; or,
2. After eight (8) weeks of daily use.

For re-ordering information see “Contact & Reordering Information” at the end of this manual.

Disposal Information

Rehabtronics Inc. considers the environment in all aspects of the product lifecycle, from design and engineering to packaging and recycling. We recommend that customers dispose of their used Hand Stimulator components in an environmentally sound manner.

It is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, your household waste disposal service or the shop where you purchased the product.



CAUTION: Do not dispose of electronic components with normal household waste. Contact your local waste-management services for information on how to best dispose of electronic equipment.

Troubleshooting

Physical Reactions

Pain or Discomfort

If used as directed, the Hand Stimulator should not cause any pain. Mild discomfort may occur during use of the Hand Stimulator system. In most cases, however, such discomfort is easily remedied. The following table describes possible sources of discomfort, and the appropriate actions to take:

Source of Discomfort	Recommended Action
Increase in sensitivity to stimulation over time	Decrease stimulation intensities to comfortable levels. If discomfort persists, discontinue use and consult your healthcare professional.
Change in arm physiology over time (e.g. weight change, change in muscle mass...)	If the arm's physical characteristics change, stimulation intensities and electrode positions will have to be adjusted to compensate. Refer to the instructions in this manual for configuring stimulation intensities and electrode placements.
Fatigue or soreness following prolonged use	Discontinue use until symptoms have cleared. If symptoms do not dissipate within a day of ceasing use, consult your healthcare professional.



IMPORTANT: Use of the Hand Stimulator is intended to be directed or supervised by a healthcare professional.



WARNING: If persistent pain is experienced, discontinue use immediately and contact your healthcare professional.

Allergic Reactions

All the Hand Stimulator materials have been selected and tested to ensure they are biocompatible, hypoallergenic, and free of any toxic substances. All system components are constructed from materials commonly used in medical devices such as polyester, cotton, silicone, and ABS/PC plastic to ensure freedom from allergic reactions. Nevertheless, if allergic reaction to materials is suspected, discontinue use immediately and contact your healthcare professional.

Skin Irritation

Some reddening and indentation of the skin under electrodes is normal following a period of use, and further mild skin irritation may be experienced depending on factors such as the environment, duration of use, and patient skin-sensitivity.

The following guidance should be followed to mitigate possible skin irritation:

- Limit wearing the **GARMENT** to a maximum of 4 hours a day.
- Periodically remove the **GARMENT** when not stimulating to allow the skin time to ventilate uncovered.
- If any sort of skin irritation develops, discontinue use until the symptoms have cleared.

- If irritation does not clear within an hour of removing the **GARMENT**, contact your healthcare professional.



WARNING: If persistent skin irritation is experienced that does not clear within an hour of removing the **GARMENT**, discontinue use and contact your healthcare professional.

Device Use Troubleshooting

General Troubleshooting

Issue	Recommended Action(s)
Device performance issues or unanticipated behavior.	Discontinue use and contact customer support. (see “Contact and Reordering Information” at the end of this manual)

STIM Error Messages

The following table lists possible error messages that may appear on the **STIM**’s *DISPLAY*, and the recommended actions to take:

DISPLAY Message	Potential Cause(s)	Recommended Action(s)
A red X and a number	- An internal hardware diagnostic test has failed	Recharge the STIM and HMS in the DOCK . If the same error screen persists, take note of the number displayed and contact Rehabtronics support (see “Contact and Reordering Information” at the end of this manual).
“Check Electrodes” Or “Impedance Error”	- ELECTRODES are not making good contact with the skin - ELECTRODES are not sufficiently wet - ELECTRODES are not properly snapped into the GARMENT	Check that all ELECTRODES are sufficiently wet and pressed against the skin. Reattach the ELECTRODES to the GARMENT , ensuring that they are securely snapped to the sockets.
“Put Stim in Garment”	- STIM is not in GARMENT - STIM has been dislodged from the GARMENT	Check that the STIM is firmly pushed into the GARMENT ’s <i>STIM HOLDER</i> .

Technical Information

General Specifications

Environmental Specifications

Operating Conditions	Temperature: +5 °C to +40 °C. Relative Humidity: 15% to 93% (non-condensing) Pressure: 70 kPa to 106 kPa
Storage Conditions	Temperature: +15°C to +25 °C. Relative Humidity: < 50% (non-condensing) Pressure: 70 kPa to 106 kPa
Transport Conditions (up to 48 hours)	Temperature: -25 °C to +70 °C Relative Humidity: 5% to 100% (non-condensing) Pressure: 70 kPa to 106 kPa

Electrical Component Specifications

	System Component		
	DOCK	STIM	HMS
Model Number	HSDK1	HSST1	HSHM1
Equipment Usage & Type	Non Transit-Operable Portable Equipment Class II ME Equipment	Transit-Operable Body-Worn Equipment	Transit-Operable Body-Worn Equipment
Mode of Operation	Continuous	Continuous	Continuous
Applied Part Type	N/A	BF Applied Part	BF Applied Part
Means of Supply Mains Isolation	Direct plug-in adaptor	N/A (battery-powered)	N/A (battery powered)
Power Specifications	Mains Powered AC Input: 100 – 240 VAC, 0.5 - 0.3A, 50 – 60 Hz DC Output: 6 VDC, 2.5A MAX	Internally Powered 3.7V, 310 - 330 mAh Rechargeable Lithium Ion Battery	Internally Powered 3.7V, 45 - 55 mAh Rechargeable Lithium Ion Battery

Stimulation Specifications

The following table provides technical details of the stimulation pulses delivered by the Hand Stimulator system:

Stimulation Characteristic	Hand Stimulator Specification
Waveform Phase	Asymmetrical, Biphasic
Waveform Shape	Rectangular
Maximum Output Voltage ($\pm 10\%$)	20V @ 500 Ω 80V @ 2 k Ω 150V @ 10 k Ω
Maximum Output Current ($\pm 10\%$)	40 mA @ 500 Ω 40 mA @ 2 k Ω 0mA @ 10 k Ω (fault state)
Pulse Width	250 μ sec (primary), 500 μ sec (secondary)
Pulse Duration	750 μ sec
Pulse Frequency	30-31 Hz
Maximum Current Density (across smallest electrode)	1.74 mA/cm ² r.m.s @ 500 Ω
Maximum Power Density (across smallest electrode)	5.24 mW/cm ² @ 500 Ω

Wireless Specifications

The following table details the wireless specifications for the **STIM** and **HMS**:

Operating Frequency Range	2403 – 2481 MHz
Operating Frequencies	Uses 3 randomly-selected frequencies assigned to each unit
Data Rate	1 Mbps
Maximum Transmit Power	4 dBm
Modulation Scheme	GFSK
Modulating Signal Type	Binary Data
Modulation Baud Rate	1 MHz
Modulation Bandwidth	160 kHz deviation around the carrier
Receiver Bandwidth	160 kHz around the selected frequency
RF Frequency Channels	79 Channels
Channel Spacing	Minimum 20 MHz, Maximum 25 MHz
Antenna Type	Antenna; -1.9 dBi Average Gain; 0.8 dBi Peak Gain
Transceiver Duplex Scheme	Time Division Duplexing
Bit Error Rate	Less than 0.1%
Packet Error Rate	Less than 5%
Receiver Sensitivity	-86 dBm at 0.1% Bit Error Rate
Command Delay	Maximum 1 Second
Transmitter Duty Cycle	Less than 0.05%
Operating Range	Up to 5 meters

This device complies with Part 15 of FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of this device.

Changes or modifications to this equipment not expressly approved by Rehabtronics Inc. could void the user's authority to operate the equipment.

NOTE: The Federal Aviation Administration rules require that all radio-transmitting devices be turned off during flight.

This device complies with the Canadian Interference-Causing Equipment Standard #3 (ICES-003).

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Electromagnetic Compatibility



WARNING: The Hand Stimulator System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.



WARNING: Use of any system components other than those specified or supplied by Rehabtronics Inc. may result in increased emissions or decreased immunity of the equipment, and may cause the system to be non-compliant with the electromagnetic compatibility requirements of IEC 60601-1-2:2007.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Hand Stimulator System and all its system components are intended for use in the electromagnetic environment specified below. The customer or the user of the Hand Stimulator System should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The equipment 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 equipment 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	

Recommended separation distances between portable and mobile RF communications equipment and the Hand Stimulator System			
The Hand Stimulator System and all its system components are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Hand Stimulator System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the components of the Hand Stimulator 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 (m)		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}] \sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}] \sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E_1}] \sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Hand Stimulator System and all its system components are intended for use in the electromagnetic environment specified below. The customer or the user of the Hand Stimulator 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 Test N/A for input/output lines	Mains power quality should be that of a typical commercial/residential or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial/residential or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 UT = 240 Vac, 120Vac	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial/residential or hospital environment. If the user of the equipment 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 magnetic field (50 Hz/60Hz) 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/residential or hospital environment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Hand Stimulator System and all its system components are intended for use in the electromagnetic environment specified below. The customer or the user of the Hand Stimulator System should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the equipment including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ where 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). 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 Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	
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. 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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Contact & Reordering Information

For device support, or to reorder components, contact Rehabtronics Inc. via any of the following channels:

Web: www.rehabtronics.com
Email: support@rehabtronics.com
Phone: 1-866-896-727

Mailing Address:
Rehabtronics Inc.
#4352, 10230 Jasper Avenue
Edmonton, Alberta, Canada T5J 4P6

If reordering components, please refer to the model (REF) number as indicated in the table below, or on the component labels:

System Component Re-Ordering		
System Component	Model (REF) / Re-order Number	Recommended Re-order Interval (component service life)
Dock	HSDK1	4 years
Stim	HSST1	4 years
HMS	HSHM1	4 years
Electrode Set	HSE1	2 weeks
Garment (small)	HSGS1	8 weeks
Garment (medium)	HSGM1	8 weeks
Garment (large)	HSGL1	8 weeks

Rehabtronics Inc. declares that the CE marked device is in compliance with the applicable essential requirements of the Council Directive 93/42/EEC. For device feedback within the European Economic Community, use the following contact information:



For inquiries or re-ordering outside North-America or Europe, contact your local Hand Stimulator distributor.

For health-related concerns, contact your health care professional.