USER MANUAL

HS-IFU-EN
Revision H
2022-02
Rx Only (US Only)

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Introduction

Device Description

The ReGrasp 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 or upper limb paralysis due to stroke, traumatic or acquired brain injury, or C5 level cervical spinal cord injury.
- NeuroMuscular Electrical Stimulation (NMES):
  - Maintenance and/or increase of range of motion
  - Prevention and/or reduction of disuse atrophy
  - Increase of local blood circulation
  - Reduction of muscle spasm
  - Muscle re-education

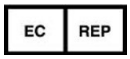
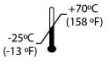
CAUTION: In the United States, Federal law restricts this device to sale by or on the order of a physician.

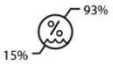
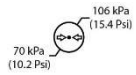
CAUTION: Patients should seek services of an able-bodied care-giver to assist with device setup and configuration.

List of Symbols

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

Symbol	Definition	Application to the ReGrasp 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.
	Model Reference (Catalogue/Re-order Number)	Reference the accompanying model number next to this symbol when re-ordering components.
	Lot/Batch Number	Reference the accompanying batch number next to this symbol if contacting support.
	Medical Device	The ReGrasp is a medical device.

Symbol	Definition	Application to the ReGrasp System
	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.
	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**.
	Transportation and storage temperature limits	Do not transport or store the ReGrasp outside the temperature range indicated.

Symbol	Definition	Application to the ReGrasp System
	Transportation and storage humidity limits	Do not transport or store the ReGrasp outside the humidity range indicated.
	Transportation and storage pressure limits	Do not transport or store the ReGrasp outside the pressure range indicated.
	Arm/Disarm	A button on the **STIM** that toggles arming and disarming of the stimulator.

Safety Information

Contraindications

- Do not use the ReGrasp System if a pacemaker or any other critical medical electrical equipment is in use. There is a remote chance that ReGrasp System may interfere with such devices.
- Do not use the ReGrasp System if fractures or dislocations of the fingers, wrist or elbow are present. Use of the ReGrasp System with these conditions may complicate the existing injury.
- Do not use the ReGrasp 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 ReGrasp 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.
    - Stimulation should not be applied over the neck or mouth. Doing so may cause contractions that affect breathing and/or heart-rate. Severe spasm of the laryngeal and pharyngeal muscles (muscles located in the neck and mouth) may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
    - Stimulation should not be applied transthoracically (across the chest) or upper back, in that the introduction of electrical current into the heart may cause cardiac arrhythmias (irregular heart-beats).
    - Stimulation should not be applied transcerebrally (across the head), or directly on the eyes. Doing so may cause nausea, headache, or dizziness.
- Do not use the ReGrasp on, or close to injured, swollen, infected, or inflamed areas or skin eruptions (e.g. phlebitis, thrombophlebitis, varicose veins, etc.). 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 ReGrasp 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. Doing so may interfere with the equipment, result in burns, or produce device instability.
    - Do not use the device within 1 meter of any shortwave or microwave therapy equipment, as this may affect the performance of the ReGrasp.
- 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 or 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 ReGrasp while sleeping.
- The ReGrasp is to be used only with **GARMENT**, **ELECTRODES**, **DOCK** and **POWER-SUPPLY** components supplied by Rehabtronics Inc.

Precautions

- Patients should seek services of an able-bodied care-giver to assist with device setup and configuration.
- 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.
- 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.
- Talk to your doctor if you have a spinal cord injury at the T6 level or above. Very strong stimulation can trigger autonomic dysreflexia (a sudden onset of excessively high blood pressure) in patients with spinal cord injury at the T6 level and above. Symptoms of autonomic dysreflexia include acute hypertension and slow heart rate.
- Extended use can reduce tenodesis grip (natural tendency for fingers to open and close with wrist movement) 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 ReGrasp 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 ReGrasp again until the skin has fully recovered.
- Do not store or operate the ReGrasp in conditions outside those listed in the Technical Information section of this manual. Doing so can damage components.
- Electrical and wireless components of the ReGrasp System require special precautions for electromagnetic compatibility and immunity. Refer to

Electromagnetic Compatibility tables in the Technical Information section of this manual for details.

- Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
- Caution should be used in the presence of the following:
    - When there is a tendency to hemorrhage (external or internal bleeding) following acute trauma or fracture.
    - Following recent surgical procedures when muscle contraction may disrupt the healing process.
    - Over the menstruating or pregnant uterus.
- Talk to your doctor before using the ReGrasp if you have any one of the following medical conditions in the affected arm:
    - Local insufficiency (insufficient blood flow).
    - Occlusion (a blood flow blockage).
    - Arteriovenous fistula (an abnormal connection between an artery and vein) for the purpose of hemodialysis.
    - Primary disorder of the vasculature (a disease of the arteries, veins, and lymphatics).
    - A bone deformity in the area to be stimulated.
- Motion, muscle activity, and pressure from the ReGrasp **GARMENT** may aggravate any inflammation near the **GARMENT**. Stop using the ReGrasp until any inflammation is gone.
- Always check the skin for redness or a rash when putting on and taking off the ReGrasp **GARMENT**.
- Remove the ReGrasp **GARMENT** before wetting the cloth electrodes.
- Excess body hair where the ReGrasp **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.
- Do not use the ReGrasp without the **ELECTRODES**.

- Be sure the ReGrasp **ELECTRODES** are wet and securely attached to the electrode bases before use.

Adverse Reactions

- Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.
- In the unlikely event that any of the following occurs, stop using your ReGrasp immediately and talk to your doctor or clinician:
    - Signs of significant irritation or pressure sores where the ReGrasp components contact 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.

System Components

GARMENT *(see page 19)*
- Used to position the **ELECTRODES**, and hold the **STIM**
- Includes optional *THUMB-STRAP*

DOCK *(see page 14)*
- Used to charge the **STIM** and **HMS**
- Includes a dedicated power-supply and interchangeable wall-outlet adaptors.

STRAPS & CLASPS *(see page 19)*
- Used to secure the **GARMENT**
- Can be repositioned as needed

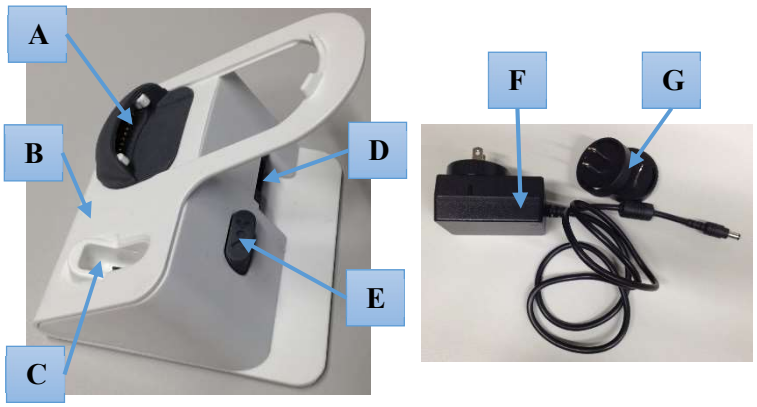
WRIST-SUPPORT *(see page 23)*
- Optional **GARMENT** insert, used to support the wrist if necessary.

ELECTRODES *(see page 22)*
- Wettable electrode pads for use with the **GARMENT**

STIM *(see page 16)*
- Used to configure and activate stimulation when connected to a **GARMENT**

HMS (*see page 17)*
- "Head Motion Sensor"
- Worn over the ear

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.

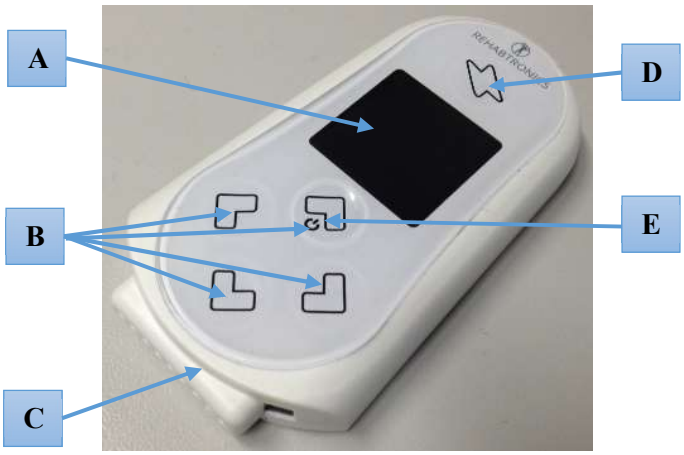
DOCK Setup

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.

The STIM



A	***DISPLAY*** The display screen for the user interface.
B	***NAVIGATION BUTTONS*** Used to navigate menus and options of the *DISPLAY*'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.

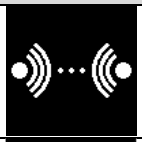
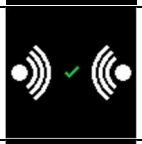
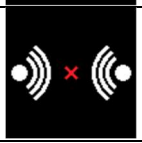
The HMS

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 *STATUS LED* glows green. - To turn off, press and hold until the *STATUS LED* glows yellow.

Pairing a New STIM or HMS

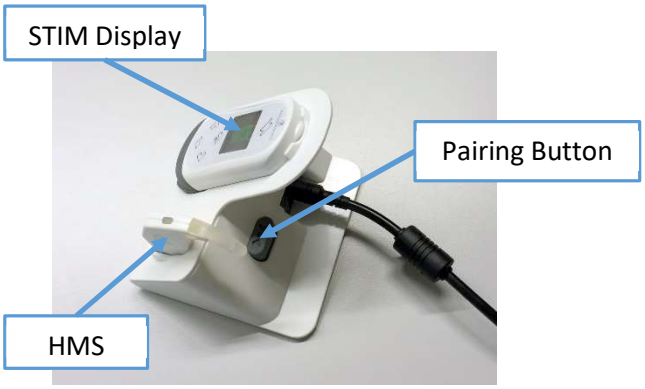
NOTE: The **STIM** and **HMS** units supplied with a system kit will come pre-paired. This section is only applicable if pairing different **STIM** and **HMS** units, or for troubleshooting purposes should a **STIM** and **HMS** be failing to communicate.

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.

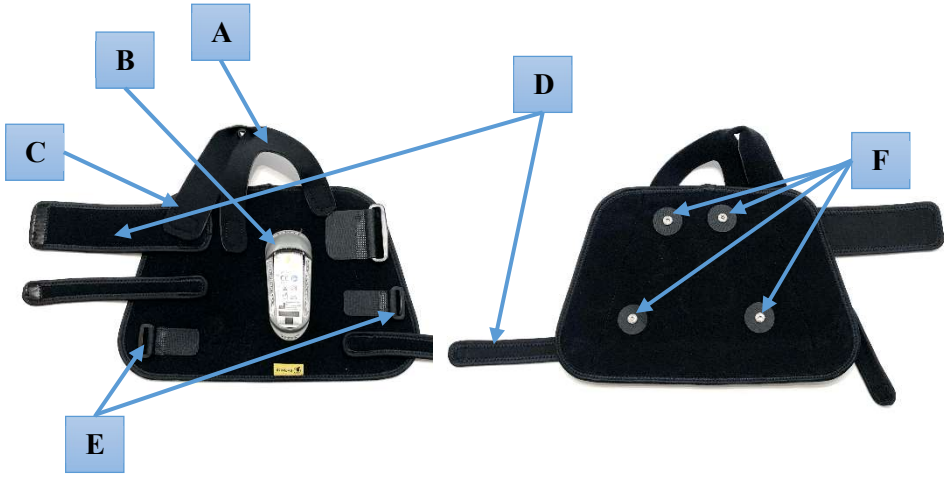
STIM Display	Meaning
	Pairing is in progress
	Pairing successful
	Pairing error

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.



The GARMENT



TOP VIEW *BOTTOM VIEW*

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**.
D	***STRAPS*** Detachable straps for tightening and securing the **GARMENT**.
E	***CLASPS*** Detachable clasps for threading each of the *STRAPS*.
F	***ELECTRODE LEADS*** Moveable leads can be relocated in the *PLACEMENT AREAS* and contain a socket for attaching **ELECTRODES**.

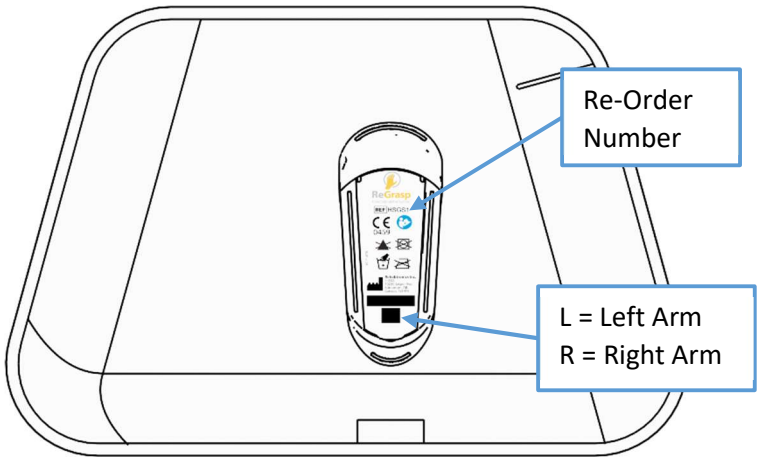
WARNING: Do not share the **GARMENT** between users.

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.

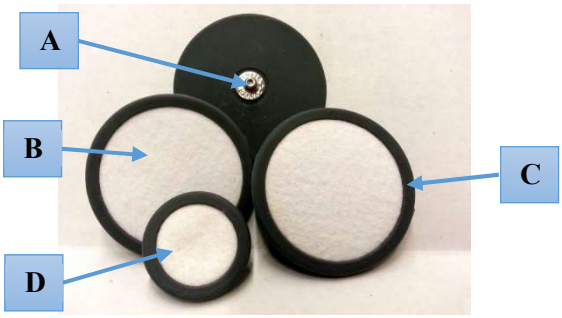
Selecting a GARMENT

The **GARMENT** is available for either left or right arms in three sizes – small, medium, and large. Select the preferred type 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



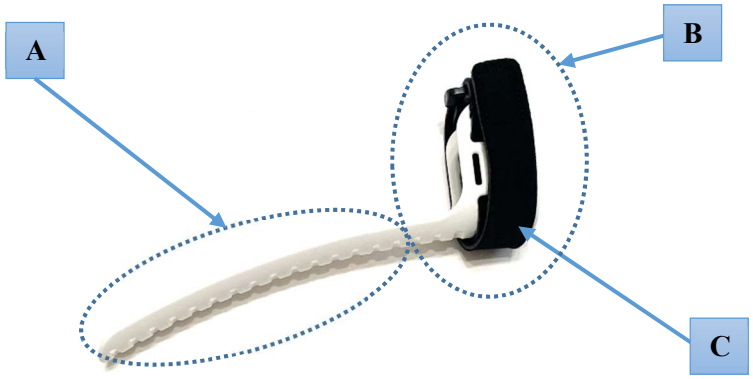
A	***GARMENT SNAP*** Allows connection to **GARMENT** *ELECTRODE LEADS*.
B	***FABRIC PAD*** Cotton pad holds water to conduct and distribute stimulation pulses.
C	***LARGE ELECTRODE*** 4.2cm in diameter. Intended for placement over large areas of the forearm.
D	***SMALL ELECTRODE*** 2.2cm in diameter. 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.

The WRIST-SUPPORT



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

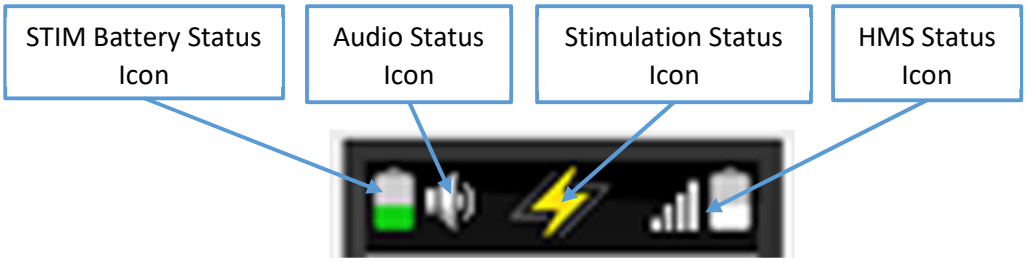
See "Using the WRIST-SUPPORT" section on page 48 of this manual for instructions on using the **WRIST-SUPPORT**.

STIM User Interface

All of the ReGrasp 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
	**Charged** - Fully charged
	**Discharging** - Partially charged
	**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
	**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
*INTENSITY**	Adjust stimulation intensities to the electrodes controlling hand-open, hand-close and thumb-close.
*FES**	Functional Electrical Stimulation mode. Manually control hand-open and hand-close stimulation.
*EXERCISE**	Timer-based stimulation programs that automatically cycle between hand-open and hand-close stimulation.
SETUP	Settings to configure the user interface.
LANGUAGE	Change the language setting.

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

INTENSITY

Selecting the *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 *NAVIGATION BUTTON* 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.

Conductivity Quality

This feature is available in version 1.30 or later.

When adjusting intensity settings, the **STIM** *DISPLAY* indicates the electrode-to-skin conductivity quality:

Conductivity Quality Number†	Meaning
6 to 10	✓ Optimal quality for stimulation.
3 to 5	Minimal quality. **STIM** will work, however full stimulation levels might not be achieved.
0 to 2	Poor quality. Stimulation delivery is unreliable.
*	**STIM** is not armed. Press the button to arm.

† *NOTE: This feature is optimized to measure quality at intensity levels greater than 5.*

To achieve better conductivity quality, check the following:

- Skin is free of any lotions, ointments or debris, and there are no obstructions such as excess hair between the skin and **ELECTRODES** (see "Preparing the Arm", pg.38)
- **ELECTRODES** are clean and wet (see "Wetting the ELECTRODES", pg.39)
- **ELECTRODES** are placed correctly, and pressed firmly against the skin (see "Positioning ELECTRODES in the GARMENT", pg.40)
- **ELECTRODES** are in good condition (if not, see "Contact & Reordering Information", pg.77)

FES

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:

***FES* State**	**Description**
	**Relax (no stimulation)** This is the default state when *FES* is first started.
	**Hand-Open Stimulation** Electrical pulses are delivered to the hand-open electrode, causing the fingers of the hand to open.
	**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

EXERCISE 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.

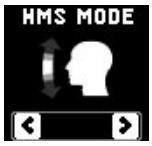
The following table describes the EXERCISE interface:

Action	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**.

SETUP

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

***SETUP* Menu**	**Purpose**	**Instructions**
 **Audio Setting**	Enable or disable audible beeps.	• Use the ‹ and › navigation buttons to select the preferred audio setting.
 **HMS Mode**	Select the preferred head-motion detection pattern for use in HMS mode.	1. Use the ‹ and › navigation buttons to switch between head-motion patterns. 2. 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 *DISPLAY* and *NAVIGATION BUTTONS* according to the affected arm.	3. Use the ‹ and › buttons to select left or right hand orientation, respectively. The *DISPLAY* and *NAVIGATION BUTTONS* will re-orient automatically.

SETUP Menu	Purpose	Instructions
 **Usage Log**	Displays statistics on the amount of time stimulating.	4. The Usage Log screen with 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.

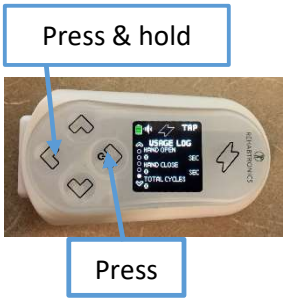
LANGUAGE

The preferred language of the user interface can be changed as follows:

	1. Select *LANGUAGE* from the **STIM** main-menu. You will be presented with a list of available languages.
	2. Select the preferred language from the list and press the button.
	3. Confirm change to the language by pressing the button again.

Factory Reset

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

	1. Select *SETUP* from the **STIM** main-menu.
	2. Use the button to navigate to the "USAGE LOG" screen.
	3. Press and hold the navigation button *<u>furthest</u>* from the **STIM**'s *DISPLAY* and, while still holding the button, press the *ON/OFF BUTTON*. A confirmation screen will appear.
	4. From the confirmation screen, press to confirm the reset, or press to cancel.

Using the ReGrasp System

Overview

This section describes the steps for using the ReGrasp 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 37)*
2. Prepare the arm *(page 38)*
3. Wet **ELECTRODES** and attach them to the **GARMENT** *(page 39)*
4. (If necessary) Reposition **ELECTRODES** in the **GARMENT** *(page 40)*
5. Fit the **GARMENT** over the arm *(page 48)*
6. Configure preferred stimulation intensities *(page 52)*
7. Activate stimulation by selecting either of the following modes:
    a. FES Mode *(page 55)* – Manually control stimulation of hand-opening and hand-closing
    b. EXERCISE Mode *(page 59)* – 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 *DISPLAY* shows an animated battery indicating the current charge progress	**STIM**'s *DISPLAY* shows full battery and green checkmark	**STIM**'s *DISPLAY* shows an error message
HMS	**HMS**'s *STATUS LED* alternately flashes green and yellow	**HMS**'s *STATUS LED* is solid green	**HMS**'s *STATUS LED* is solid red

NOTE: **STIM** and **HMS** units can be charged separately or simultaneously. Batteries should be charged regularly, and 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. It may be necessary to trim any excess arm hair from the areas over which the **ELECTRODES** will be placed in order to ensure good contact with the skin.

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*:

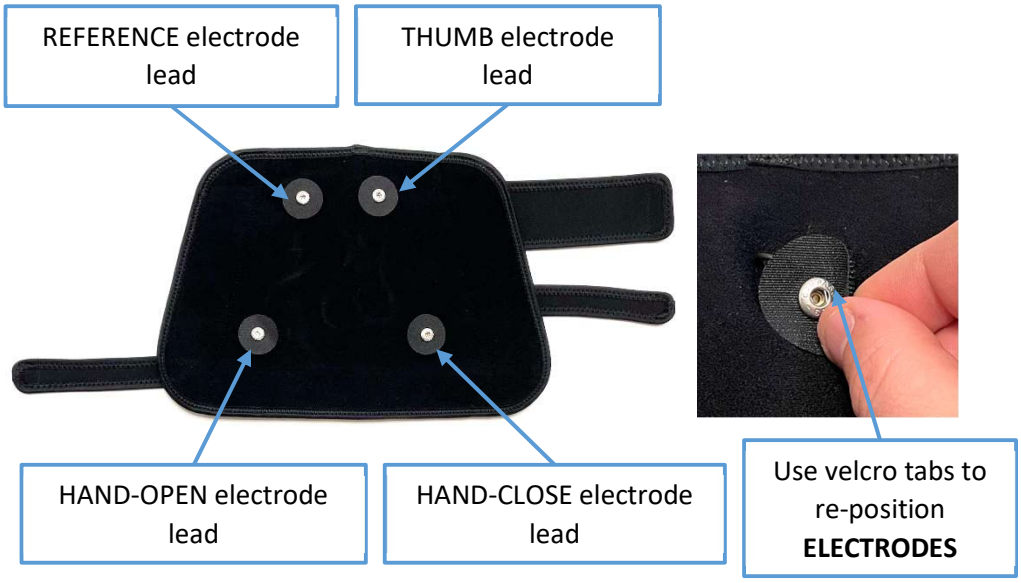
1. Snap the *SMALL ELECTRODE* into the socket of the **GARMENT**'s THUMB LEAD.
2. Snap the remaining three *LARGE ELECTRODES* into the sockets of the remaining leads.

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 *ELECTRODE LEADS* for attaching **ELECTRODES**. The **GARMENT**'s *ELECTRODE LEADS* each have a fabric tab, allowing the **ELECTRODES** to be moved to different positions.



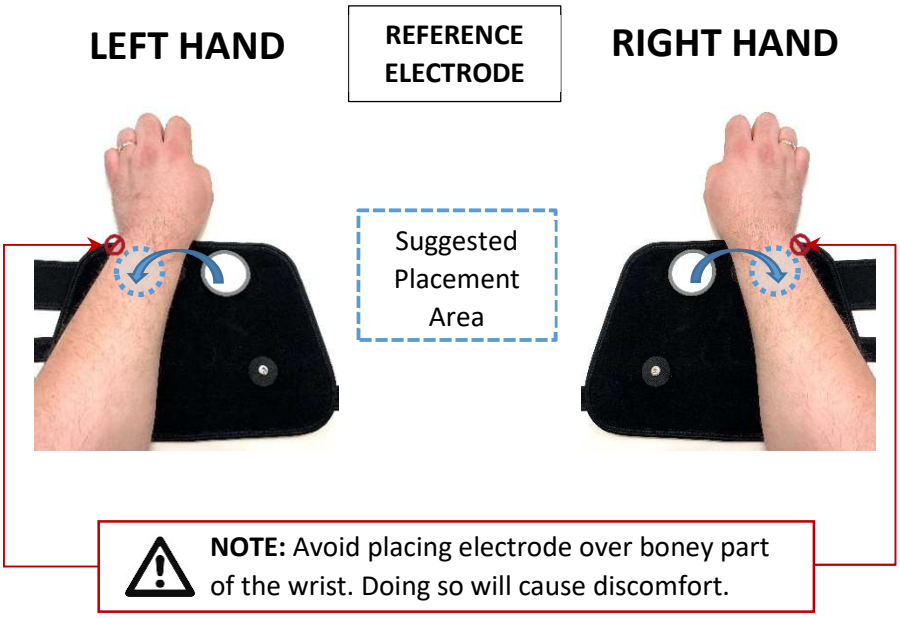
**Right-handed GARMENT shown*

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

REFERENCE Electrode

When the **GARMENT** is donned, the REFERENCE electrode should sit comfortably on top of the wrist, similar to a wrist-watch. Although the REFERENCE electrode does not stimulate directly, it is required for the other electrodes work correctly.

The REFERENCE electrode should remain in a neutral position on the **GARMENT** (where the lead exits the **GARMENT**) and should not require any subsequent position adjustment.

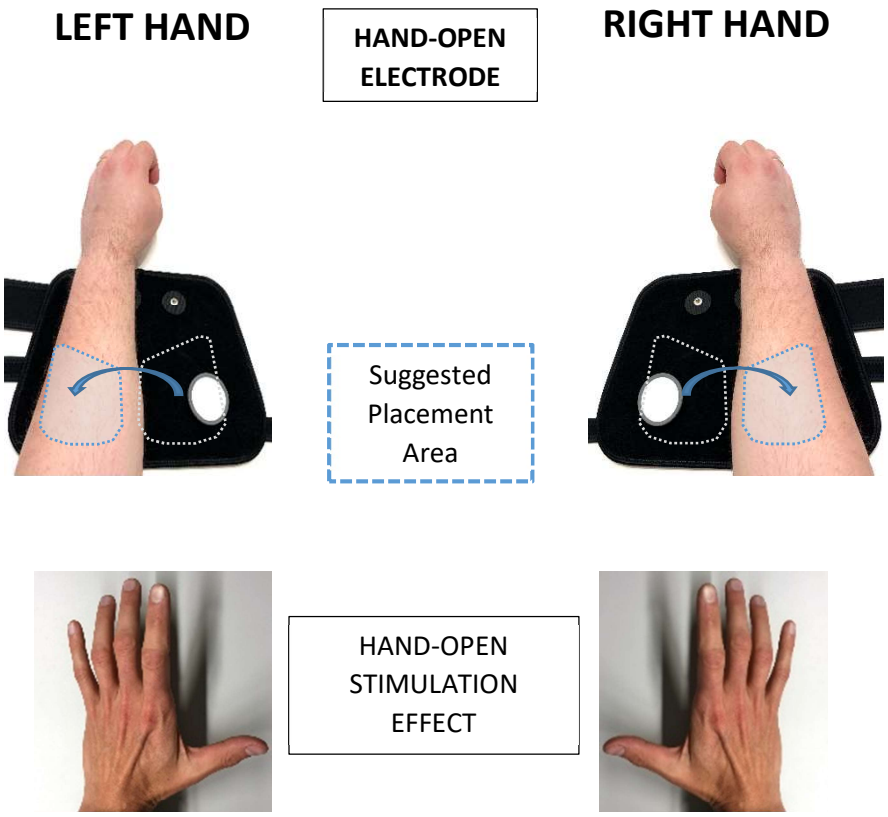


NOTE: The "wrist-watch" position of the REFERENCE electrode can be used as a reference to ensure the **GARMENT** is positioned consistently on the arm each time it is donned.

HAND-OPEN Electrode

When the **GARMENT** is donned, the HAND-OPEN electrode rests against the upper forearm and, when activated, will cause the fingers to extend.

Position the HAND-OPEN electrode within 5cm of its neutral position (where the lead exits the **GARMENT**) on the **GARMENT**. Start by centering the electrode in its neutral position and observing the resulting HAND-OPEN stimulation effect. If the effects are not optimal, consult the troubleshooting section of this manual.



HAND-CLOSE Electrode

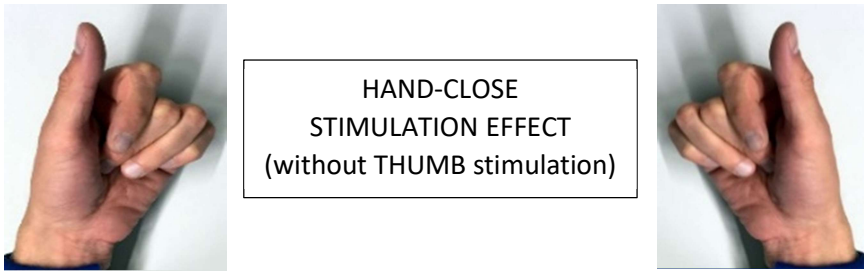
When the **GARMENT** is donned, the HAND-CLOSE electrode rests against the underside of the forearm and, when activated, causes the fingers to close.

Position the HAND-CLOSE electrode within 5cm of its neutral position (where the lead exits the **GARMENT**) on the **GARMENT**. Start by centering the electrode in its neutral position and observing the resulting HAND-CLOSE stimulation effect. If the effects are not optimal, consult the troubleshooting section of this manual.

LEFT HAND

HAND-CLOSE ELECTRODE

RIGHT HAND



THUMB Electrode

The position of the THUMB electrode depends on the desired thumb movement during HAND-CLOSE stimulation. There are three options:

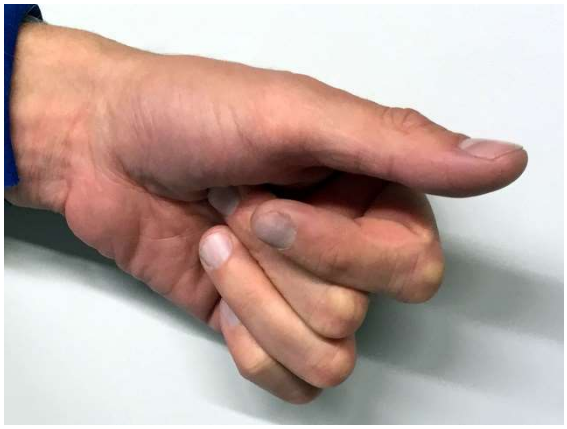
1. No Thumb Stimulation
2. Thumb Pinch-Grip
3. Thumb Fist-Grip

No Thumb Stimulation (Finger-Grip Only)

When thumb movement is not required, the THUMB-CLOSE intensity should be set to “OFF” (see “Adjusting Intensities” on page 51).

Thumb-Close intensity set to "OFF"

The THUMB electrode can be positioned anywhere on the **GARMENT** such that the electrode rests comfortably against the arm when the **GARMENT** is donned.

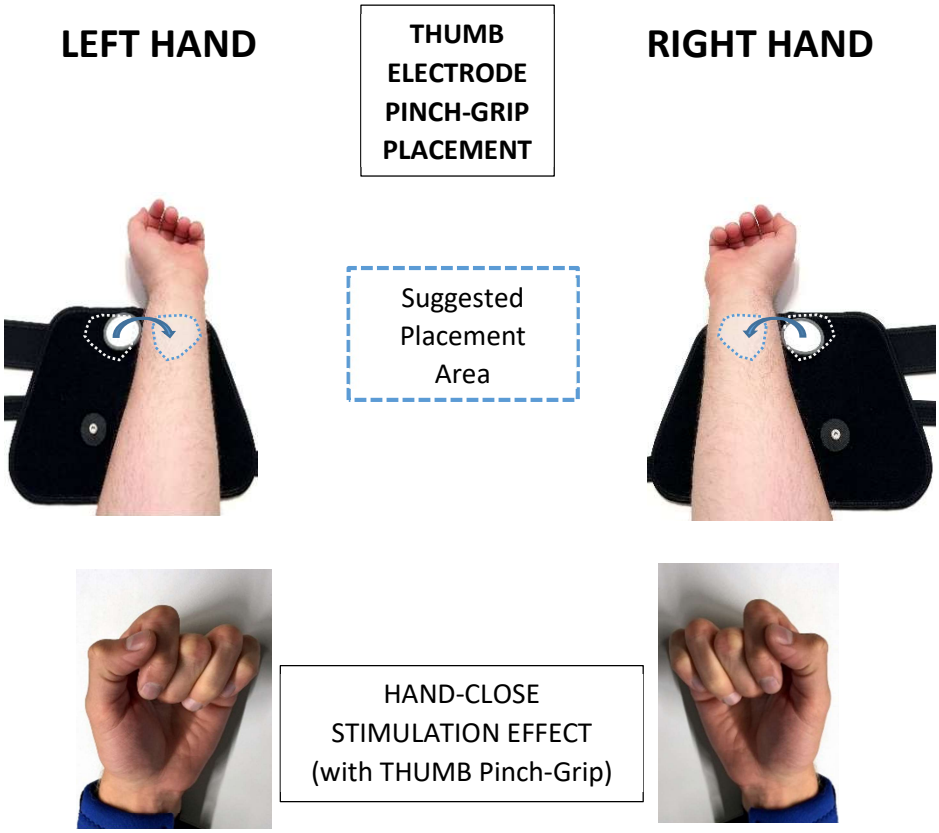


HAND-CLOSE effect when THUMB-CLOSE intensity is set to "OFF" (THUMB electrode disabled)

Thumb Pinch-Grip

The thumb can be stimulated to press against the index-finger during HAND-CLOSE stimulation by positioning the THUMB electrode in the **GARMENT**'s marked suggested placement-area.

When the **GARMENT** is donned in this configuration, the THUMB electrode should rest against the underside of the wrist, just below the heel of the thumb.



Thumb Fist-Grip

By placing the **THUMB** electrode against the heel of the thumb, HAND-CLOSE stimulation will cause the thumb to wrap across closed fingers. This placement is achieved using the **GARMENT**'s *THUMB-STRAP*.

LEFT HAND

THUMB STRAP ATTACHMENT

RIGHT HAND

The *THUMB-STRAP* is attached to the body of the **GARMENT** using the Velcro ends as shown.

LEFT HAND

RIGHT HAND

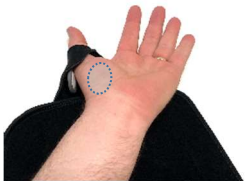
THUMB ELECTRODE FIST-GRIP PLACEMENT

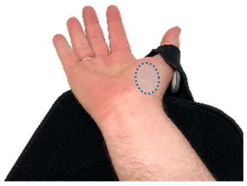
1. Attach the *THUMB-STRAP* to the top of the **GARMENT** as shown on the previous page.

2. Flip the **GARMENT** to the reverse (electrodes) side.

3. Move the *THUMB ELECTRODE-LEAD* to the *THUMB-STRAP* as shown.

4. Hook thumb through *THUMB-STRAP* when donning the **GARMENT**.





5. Once **GARMENT** is donned (see next page), tighten *THUMB-STRAP* ends to ensure electrode is pressed firmly against the heel of the thumb.

HAND-CLOSE
STIMULATION EFFECT
(with THUMB Fist-Grip)

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. Attach the *STRAPS* and *CLASPS* to the outside of the **GARMENT**, roughly aligning the *STRAPS* as shown.
	2. Loosely thread the **GARMENT**'s *STRAPS* through the *CLASPS*, creating a wide "sleeve" shape.
	3. With the **GARMENT**'s *STIM HOLDER* on top, insert the arm through the **GARMENT** such that the REFERENCE electrode is positioned on top of the wrist in "wrist-watch" position.
	4. 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. No straps should be unattached or left dangling.

	5. If the **GARMENT** does not sit comfortably or **ELECTRODES** are not firm against the skin, loosen the *STRAPS* and adjust the positioning of *STRAPS* and *CLASPS*. Repeat until a comfortable and secure fit is achieved.
	6. Insert **STIM** into the **GARMENT**'s *STIM-HOLDER*.

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** insert 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*.

WRIST-SUPPORT INSERT

LEFT HAND

RIGHT HAND

Locate the *WRIST-SUPPORT SLOT* at the side of the **GARMENT**

Fully insert the long end of the WRIST-SUPPORT into the 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 *ON/OFF BUTTON.*
	2. Select "INTENSITY" from the Main Menu.
	3. Press the button at the screen asking if you would like to reset all electrode intensities to OFF.
	4. A screen will ask to confirm the reset. ○ Press to confirm. ○ Press any other navigation button to cancel.
	5. If confirmed, the *DISPLAY* 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. Select "INTENSITY" from the Main Menu.
5. Press the  button to arm the **STIM**.
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 39).
- ✓ 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 52).

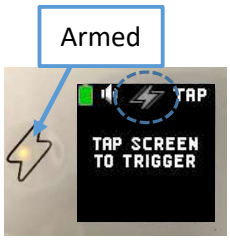
ReGrasp's GARMENT, ELECTRODES & STIM are ready to stimulate!

CAUTION: Hand function may change as a result of using the ReGrasp. 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

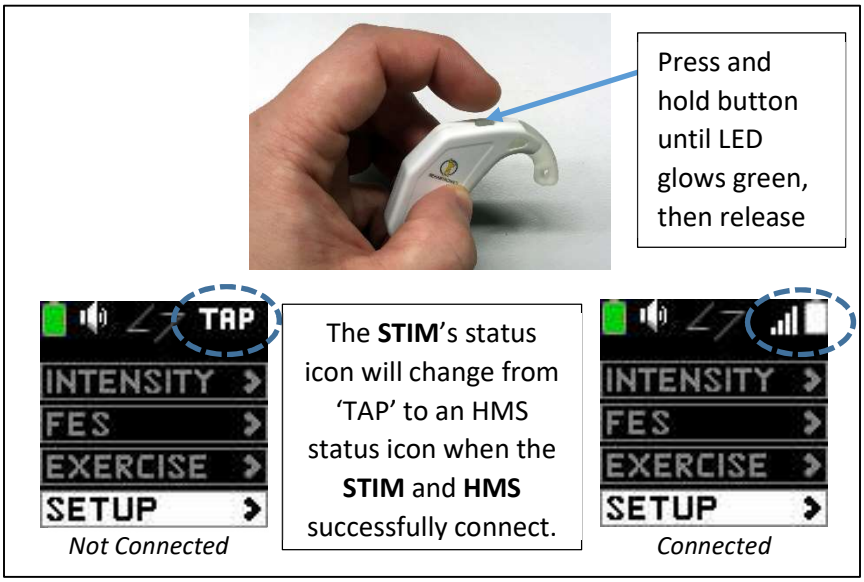
Functional stimulation control by tapping the **STIM** is achieved as follows:

	1. Check that there is no **HMS** connected to the **STIM**. The top right of the *DISPLAY*'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.
	2. Select "FES" from the Main Menu.
	3. Press the button to arm the **STIM**. The Stimulation Status icon at the center of the *DISPLAY*'s Status Bar should be solid gray .
	4. Tap the **STIM**'s *DISPLAY* to cycle between hand-opening, hand-closing and relax (no stimulation). **NOTE:** Stimulation can be stopped at any time by pressing the button.

Controlling Stimulation by Head-Motion

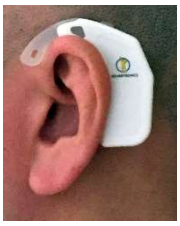
To control functional stimulation using movements of the head, follow the instructions below:

1. Turn on the **HMS** by pressing and holding the ON/OFF BUTTON until the *STATUS LED* glows green, and then release the button.
    - 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.



Not Connected *Connected*

2. Don the **HMS** over the preferred ear.
3. Set the preferred pattern by selecting "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:


HMS worn over the ear

- (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. A checkmark will appear when head-motions are successfully detected.
TIP	Generating detectable head-motions will take some getting used to. Start by focusing on the tip of your nose. Use quick, *non-exaggerated* (small) movements of your head, according to the selected pattern. The tip of your nose should move no more than 1cm (1/2").

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".
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 ReGrasp system contains two passive, timer-based exercise programs:

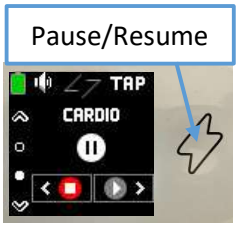
Program	Stimulation Behavior	Uses
STRENGTH	Automatically cycles between relax (no stimulation), hand-open stimulation and hand-close stimulation at the currently configured intensity settings.	- Condition muscles of the forearm and hand - Increase or maintain range-of-motion - Muscle re-education
CARDIO	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 - Reduction of muscle-spasm

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 exercise-mode 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:

<table>
<tr><td> 
</td><td>1. Select “EXERCISE” from the STIM’s Main Menu.</td></tr>
<tr><td> 
</td><td>2. Use the and buttons to select either the “STRENGTH” or “CARDIO” screens.</td></tr>
<tr><td> 
</td><td>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 ( ).</td></tr>
<tr><td> 
</td><td>4. Press the button to start the exercise. Stimulation will begin to cycle automatically, and the timer will begin to countdown.</td></tr>
<tr><td> 
</td><td>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.</td></tr>
<tr><td colspan="2">6. Stop the exercise at any time by pressing the button. This will stop stimulation and reset the timer.</td></tr>
</table>

System Cleaning and Maintenance

General System Maintenance

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

- Inspect all components prior to use. Do not use any components showing signs of damage.
- Do not store or operate any of the system components outside their specified operating and storage conditions (see "Environmental 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.

Some clinical or hospital protocols may require low-level disinfection of the **STIM** and **HMS**, between use by multiple patients. In such cases, 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. Submerse 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**.

As necessary for clinical protocols, the garment may also be wiped with low-level disinfectants such as 70% isopropyl alcohol (IPA) solution.

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 ReGrasp 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

Electrode Placement Troubleshooting

If stimulation is not producing desired results, the **ELECTRODES** may have to be re-positioned in the **GARMENT**. The following table provides guidelines for moving electrodes within their respective placement areas to achieve better stimulation responses:

Issue	Suggested Electrode Re-Positioning
HAND-OPEN causes wrist to flex upwards	Move HAND-OPEN electrode closer to the wrist.
HAND-OPEN causes wrist to flex outwards	Move HAND-OPEN electrode closer to the center of the arm.
HAND-OPEN causes muscles around elbow to flex	Move HAND-OPEN electrode closer to the center of the arm.
HAND-CLOSE causes wrist to flex downwards	Move HAND-CLOSE electrode closer to the wrist.
HAND-CLOSE does not affect index and/or middle finger	Move HAND-CLOSE electrode closer to index-finger side of the arm.
HAND-CLOSE causes muscles around elbow to flex	Move HAND-CLOSE electrode closer to the center of the arm.
Electrodes are causing pain or discomfort	Refer to “Pain or Discomfort” section on the following page.

Physical Reactions

Pain or Discomfort

If used as directed, the ReGrasp should not cause any pain, however mild discomfort may occur during use of the ReGrasp 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(s)
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 may 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.
Thumb electrode pain (pinch-grip)	Ensure the electrode is placed only over fleshy part of the arm, and not over the bone at the side of the wrist. During use, ensure that the electrode does not shift position.

IMPORTANT: Use of the ReGrasp 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 ReGrasp 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 Messages

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

DISPLAY Message	Potential Cause(s)	Recommended Action(s)
A number	- An internal 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.
"Connect Stim"	- **STIM** is not in **GARMENT** - **STIM** has been dislodged from the **GARMENT**	Check that the **STIM** is firmly pushed into the **GARMENT**'s *STIM HOLDER*.

Technical Information

Environmental Specifications

Operating Conditions	Temperature: +5 °C to +40 °C (41 °F to 104 °F) Relative Humidity: 15% to 93% (non-condensing) Pressure: 70 kPa to 106 kPa (10.2 psi to 15.4 psi)
Transport & Storage Conditions	Temperature: -25 °C to +70 °C (-13 °F to 158 °F) Relative Humidity: 5% to 100% (non-condensing) Pressure: 70 kPa to 106 kPa (10.2 psi to 15.4 psi)

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 ReGrasp system:

Stimulation Characteristic	**ReGrasp Specification**
Waveform Phase	Biphasic
Waveform Shape	Rectangular
Maximum Output Voltage (±10%)	20V @ 500 Ω 80V @ 2 kΩ 35V @ 10 kΩ (fault state)
Maximum Output Current (±10%)	40 mA @ 500 Ω 40 mA @ 2 kΩ 0mA @ 10 kΩ (fault state)
Pulse Width	250 µsec (primary), 500 µsec (secondary)
Pulse Duration	750 µsec
Pulse Frequency	30-31 Hz
Maximum Current Density (across smallest electrode)	1.12 mA/cm^2 r.m.s @ 500 Ω
Maximum Power Density (across smallest electrode)	2.38 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	Antenova; -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).

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 ReGrasp 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 60601-1-2:2014.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The ReGrasp System and all its system components are intended for use in the electromagnetic environment specified below. The customer or the user of the ReGrasp 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 ReGrasp System			
The ReGrasp 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 ReGrasp System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the components of the ReGrasp 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 ReGrasp System and all its system components are intended for use in the electromagnetic environment specified below. The customer or the user of the ReGrasp 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	±8 kV contact ±15 kV air	±8 kV contact ±15 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	30 A/m	30 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 ReGrasp System and all its system components are intended for use in the electromagnetic environment specified below. The customer or the user of the ReGrasp 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	6 Vrms 150 kHz to 80 MHz	6 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 $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 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]
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol: 
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:

Manufactured By:
Rehabtronics Inc.
#4350, 10230 Jasper Avenue
Edmonton, Alberta, Canada T5J 4P6

Web: www.rehabtronics.com
Email: support@rehabtronics.com
Toll Free (US & Canada): 1-800-481-3214
International Phone: (+1) 780-701-5167

European Union

The manufacturer declares that the CE marked device meets the provision of Council Directive 93/42/EEC for Medical Devices (MDD), Directive 2014/30/EU, and Directive 2011/65/EU.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the appropriate regulatory authority in which the user and/or patient is established.

CE 0459

EC REP

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18,
CP29006,
Málaga-Spain

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

For inquires or re-ordering outside Canada, contact your local ReGrasp distributor.
For health-related concerns, contact your health care professional.