ELECTRODE POSITIONING KIT

USER MANUAL

HS-IFU-EPK-EN
Revision A
2020-02-20
Rx Only (US Only)

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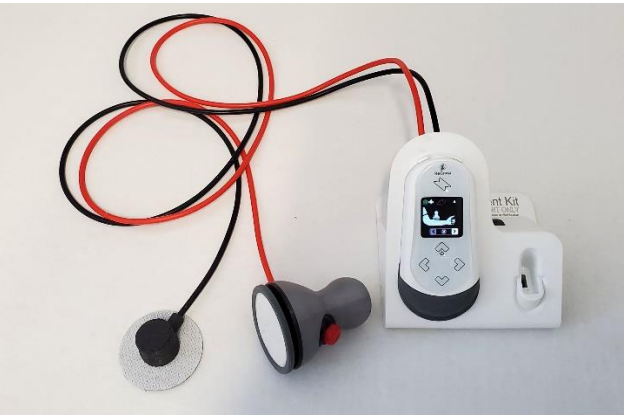
Introduction

Device Description



The Electrode Positioning Kit is an accessory to the ReGrasp electrical stimulation system for use by clinicians. Its intended purpose is to:

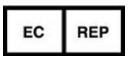
- Identify optimal motor points on the forearm
    - The point where the nerve meets the muscle differs in each muscle and in each person. The Electrode Positioning Kit allows clinicians the ability to identify what are known as the optimal motor points, or where to stimulate the muscle to render the best contraction of the wrist and finger joints.

- Identification of ideal candidates for the ReGrasp
    - Neurological diseases present in a variety of different ways. Symptoms can lead to damage in the nerves connected to muscle but are generally unknown until externally stimulated.

CAUTION: The Electrode Positioning Kit is intended for use by clinicians only.

List of Symbols

The following table lists the symbols that are used on the 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.
	Follow Instructions for Use	The instructions for use contain critical instructions necessary to use the device safely.
	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.
	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.
	Arm/Disarm	A button on the **STIM** that toggles arming and disarming of the stimulator.

Safety Information

Contraindications

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

Warnings

- Never attempt to use the Electrode Positioning Kit 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 Electrode Positioning Kit 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.
- Do not immerse the **STIM**, **PUCK**, or **PLACEMENT 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.
- The Electrode Positioning Kit is to be used only with the **GARMENT FILM LINER**, **ELECTRODES**, and **PLACEMENT DOCK** components supplied by Rehabtronics Inc.
- The **COTTON ELECTRODE**, **GEL ELECTRODE**, **GARMENT FILM LINER**, and **MARKING PEN** are intended for single use. Do not transfer between patients, and discard after use.

Precautions

- The Electrode Positioning Kit is designed to be used exclusively by a clinician on a patient in a controlled setting where no other activity will occur.
- 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.
- 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.
- Do not store or operate the Electrode Positioning Kit in conditions outside those listed in the Technical Information section of the ReGrasp *User Manual*. Doing so can damage components.
- Electrical components of the Electrode Positioning Kit require special precautions for electromagnetic compatibility and immunity. Refer to Electromagnetic Compatibility tables in the Technical Information section of the ReGrasp *User 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.
    - 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.
- Always remove the wettable **COTTON ELECTRODE** from the **PUCK** prior to wetting the electrode.
- Excess body hair where the Electrode Positioning Kit **ELECTRODES** touch may reduce electrode contact with the skin. If necessary, remove excess body hair prior to applying electrodes.
- Do not use the Electrode Positioning Kit without the **ELECTRODES**.

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 Electrode Positioning Kit immediately:
    - Signs of significant irritation or pressure sores where the Electrode Positioning Kit 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**.**

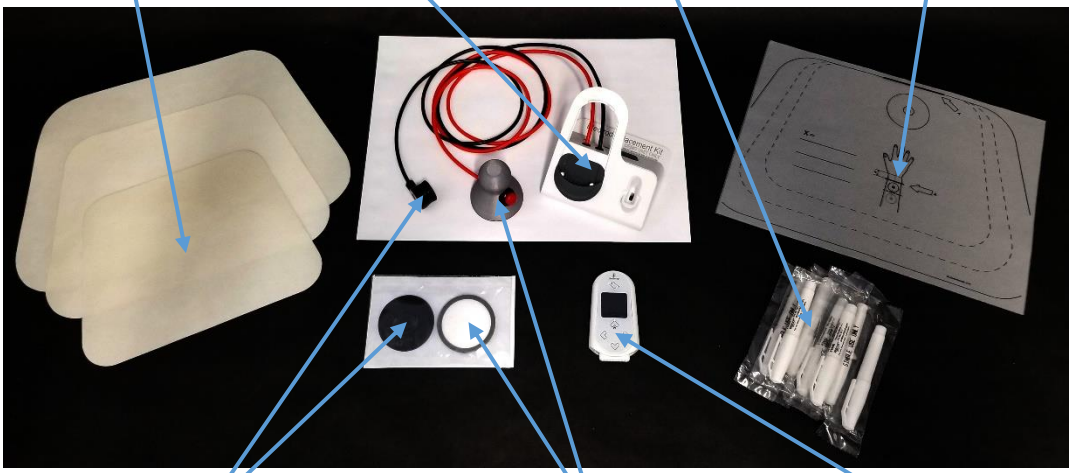
Kit Components

GARMENT FILM LINER
Optional disposable sanitary liner for the system **GARMENT**.

POSITIONING DOCK
Connects to the system **STIM** and delivers stimulation to attached electrodes.

MARKING PEN
Used to marked found motor points on the patient's arm.

TRANSFER SHEET
Used to transfer marked motor points to system **GARMENT** electrode positions.



NEUTRAL LEAD and GEL ELECTRODE
Adhesive **GEL ELECTRODE** attaches to the **NEUTRAL LEAD**, and is placed on the top-side of the patient's wrist.

PUCK and COTTON ELECTRODE
Wettable **COTTON ELECTRODE** attaches to the **PUCK**, and is used to probe the patient arm for stimulation motor points.

SYSTEM STIM
Stim unit from the ReGrasp system.

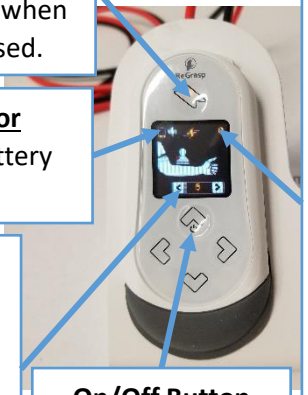
User Interface

When the ReGrasp system **STIM** is placed into the **PLACEMENT DOCK** and powered-on, it will enter an electrode positioning mode:

Arm/Disarm Button
When armed, **PUCK** will deliver stimulation when its button is pressed.

Battery Indicator
Indicates **STIM** battery charge.

Intensity Indicator
Indicates **PUCK** stimulation intensity. Use the and buttons to adjust.



On/Off Button
Press and hold to turn **STIM** On/Off.

Conductivity Quality Number

Value	Meaning
6-10	Optimal Quality
3-5	Minimal Quality
0-2	Poor Quality or No Stimulation
*	**STIM** is not armed

Poor Quality Number may be due to:

- **PUCK** button is not pressed
- **GEL ELECTRODE** not applied properly
- **COTTON ELECTRODE** is not sufficiently wet
- **COTTON ELECTRODE** is not making good contact with patient's skin

Using the Electrode Positioning Kit

Electrode Positioning Kit Setup

1. Ensure that the **STIM** is removed from the **PLACEMENT DOCK**.
2. Thoroughly wet the **COTTON ELECTRODE**.
3. Snap the **COTTON ELECTRODE** onto the **PUCK** (Figure 1).
4. Snap the **GEL ELECTRODE** onto the black **NEUTRAL LEAD** (Figure 2).
5. Stick the adhesive side of the **GEL ELECTRODE** onto the patient at the back of the forearm, just proximal to the ulnar styloid process - the bony part near the wrist (Figure 3).
6. With the **MARKING PEN** provided, draw around the **GEL ELECTRODE** on the patient's skin.
7. Place the **STIM** onto the **PLACEMENT DOCK** and turn on the **STIM** on by holding down the button.
8. Arm the **STIM** by pressing the button.
9. Set the intensity level by toggling the and buttons on the **STIM**.

Figure 1: Attach Wetted Cotton Electrode to Puck

Figure 2: Attach Gel Electrode to Neutral Lead

Figure 3: Gel Electrode Placement

It is recommended to start at a low intensity (less than 10) for a patient exposed to FES for the first time.

Do not share electrodes between users. Discard electrodes after use.

Finding the Optimal Motor Points

NOTE: The Electrode Positioning Kit is intended to help find the optimal motor points on the patient's forearm. For thumb electrode positioning, refer to the ReGrasp system User Manual.

1. Place the wetted **COTTON ELECTRODE** attached to the **PUCK** against the muscles of the patient's forearm.
    - Place against the posterior aspect of the forearm (extensor muscles) to probe for hand-open response.
    - Place against the anterior aspect of the forearm (flexor muscles) to probe for hand-close response.

2. Press the button on the **PUCK** to start stimulating and observe the patient's hand response.

    Only press the button when the electrode is firmly pressed on the desired location on the user's skin.

3. Probe for the optimal motor point by moving the **PUCK** around on the surface of the patient's forearm and observing where the strongest hand response is achieved (greatest movement in the fingers with minimal discomfort).
    - Finding the right intensity and location may take time. Ensure firm contact is maintained while the **PUCK** is in contact with skin.

    Be sure to ***release the button*** on the **PUCK** ***prior*** to removing from the user's skin; this will reduce any stinging sensation to the user or inadvertent stimulation to yourself.

4. Once the optimal motor point is found, trace the **PUCK**'s position on the patient's forearm using the **MARKING PEN** (Figure 4).

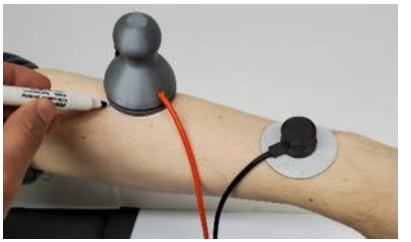


Figure 4: Mark optimum motor points

5. Repeat steps 1-4 on the other side of forearm, so that the optimal motor points for hand-open (posterior forearm) and hand-close (anterior forearm) are marked.

⚠ Avoid touching the user while stimulation is active. It is also recommended to wear a suitable medical glove to reduce the probability of being exposed to the stimulation.

⚠ If a stronger contraction is desired and the user is comfortable with the existing stimulation levels, the stimulation intensity can be increased.

6. Remove the **STIM** from the **POSITIONING DOCK**. This will turn off any functionality of the unit.

Transferring the Electrode Position to the GARMENT

1. Place the **TRANSFER SHEET** onto the patient's forearm (Figure 6).
    - Make sure the thumb image on the **TRANSFER SHEET** is on the same side as the patient's thumb.
    - Line up the circle on the **TRANSFER SHEET** where the **GEL ELECTRODE** was marked on the patient's wrist.

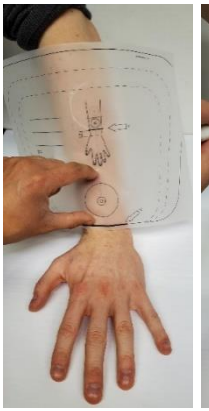


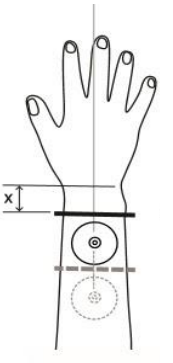
Figure 6: Place TRANSFER SHEET

Figure 5: Trace marked motor points

2. Find the marked motor points on the patient's arm, and trace the outlines onto the **TRANSFER SHEET** (Figure 5).
    - Be sure not to shift the **TRANSFER SHEET** at all when copying the marked points.

NOTE: If TRANSFER SHEET is too short to copy the marked motor points, you can move the TRANSFER SHEET up the arm, but the distance must be recorded to properly fit the system GARMENT.

Once the TRANSFER SHEET is positioned so that the marked motor points can be traced, measure the distance between thick bold line on the TRANSFER SHEET and the wrist joint, and record this distance as X on the TRANSFER SHEET.



3. Remove the **TRANSFER SHEET** and clean the marks off the patient's arm.

4. Place the **TRANSFER SHEET** onto the inner aspect of the ReGrasp system **GARMENT** with the circle outline matched up with the *REFERENCE* electrode of the ReGrasp **GARMENT** (Figure 7).
    - Be sure to ***flip*** the **TRANSFER SHEET** over. If you miss this step, the electrodes will sit on the wrong side of the **GARMENT**.

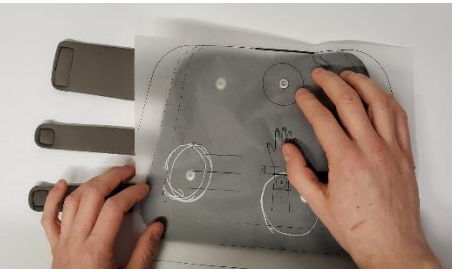


Figure 7: Line up TRANSFER SHEET with ReGrasp GARMENT

5. Move the velcro for the **GARMENT**'s *HAND-OPEN* and *HAND-CLOSE* electrodes so that their positions correspond to the traced positions on the **TRANSFER SHEET** (Figure 8).

Figure 8: Move GARMENT electrode sockets

(Optional) GARMENT FILM LINER Placement

If increased sanitary protections are desired, an optional **GARMENT FILM LINER** can be applied to the ReGrasp **GARMENT** prior to donning on the patient as follows:

1. Remove the paper side of the **GARMENT FILM LINER**, ensuring that the adhesive side of the liner does not fold in on itself.
2. Place the **GARMENT FILM LINER** on the ReGrasp system **GARMENT**, with the adhesive side down so that it sticks to the inner aspect of the **GARMENT**.
3. Using a sharp-edged tool, cut the areas of the **GARMENT FILM LINER** that sits on top of the electrode sockets.
4. ***Remove the shiny layer*** of the **GARMENT FILM LINER**. This layer is rather slippery and will chafe if left on the **GARMENT** when worn.
5. Once the cutout pieces of the liner have been removed over the electrode sockets, reapply the **GARMENT**'s electrodes to their respective positions.

The **GARMENT FILM LINER** is not to be relied upon completely for protection from communicable disease. Consider disinfection or disposing of glove if patient has communicable disease or after extended use.

Fitting the GARMENT

1. After the ReGrasp **GARMENT** electrodes have been positions according to the markings on the **TRANSFER SHEET**, fit the **GARMENT** on the patient according to the instructions in the ReGrasp system *User Manual*.
    - Ensure that the **GARMENT**'s *REFERENCE* electrode is in the same position as the **GEL ELECTRODE** was during use of the Electrode Positioning Kit (Figure 10).
    - NOTE: if a distance, *X*, was recorded on the **TRANSFER SHEET** during the *"Transferring the Electrode Position to the GARMENT"* step, the edge of the **GARMENT** should be this distance from the wrist joint (Figure 9).

Figure 10: Default Garment Position

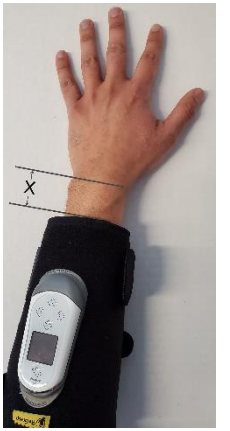


Figure 9: Adjusted Garment Position

2. Place the **STIM** into the **GARMENT** and follow the instructions in the ReGrasp system *User Manual* to set the intensities to each electrode.
    - Check for any differences between the initial set up.
    - Intensity and location may differ slightly between the two so a little bit of adjustment may be necessary.

Cleaning and Disposal

- Plastic parts of the Electrode Positioning Kit may be cleaned by wiping with a wet cloth, or low-level disinfected using Isopropyl alcohol. Allow to dry completely before reusing.

Do not immerse any components in water.

- The **COTTON ELECTRODE**, **GEL ELECTRODE**, **TRANSFER SHEET**, **GARMENT FILM LINER**, and **MARKING PEN** are intended for single-patient use, and should be disposed of after use. These components can be safely disposed with local municipal waste.

Do not attempt to wash or reuse these components. Doing so may result in skin irritation, infection, or have unknown effects on performance.

Contact and Reordering Information

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

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

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

For inquires or reordering outside Canada, contact your local ReGrasp distributor.

European Union

The manufacturer declares that the CE marked device is in compliance with the applicable essential requirements of the Council Directive 93/42/EEC.

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