

SaeboStim Micro



INSTRUCTION MANUAL



Introduction

Saebo is pleased to provide you with the latest in evidence-based upper limb rehabilitation. The **SaeboStim Micro** provides sensory electrical stimulation (SES) to the arm and hand using specialized Electro-Mesh Garment technology. The Electro-Mesh Garments consist of an elbow sleeve (arm stimulation) and glove (hand stimulation). The material is highly conductive and is made of silver treated nylon fibers blended with Dacron® fibers. The stimulation is delivered into the elbow sleeve and glove by a uniquely designed stimulator.

SES has been shown to improve sensory and motor function of the upper limb. Impaired motor function from a neurological injury may result in both sensory and motor system deficits. With SES, the main goal is to maximize sensory input by providing stimulation at very low-level (i.e., without producing a muscle contraction). Studies show that the added stimulation to an impaired sensory system can improve neuroplasticity, motor recovery and function.

This manual contains important information for both the person who will wear the **SaeboStim Micro** and the clinician who may provide and setup the device. Please be sure to review all information carefully.

If you have questions or require further information, please contact:



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Features

- A one channel transcutaneous electrical nerve stimulator and electrical neuromuscular stimulator that delivers a pulsed DC current with a monophasic waveform to the surface area of the Garment Electrodes to provide electrical stimulation where there is an indication for use.
- Microprocessor controlled, allowing easy alteration of the treatment parameters and precise control of each setting.
- Designed for ease of patient use with clearly marked patient intensity buttons.
- Designed for stand-alone use or, when used with an external programmer, as a programmable device for a full variety of frequencies, time settings, and delivery schedules.
- Designed for use with garment electrodes; wearable electrodes that cover a large surface area providing total stimulation to the treatment area.

Indications for Use

TENS (Transcutaneous Electrical Nerve Stimulation)

- Symptomatic relief and management of chronic intractable pain.
- Adjunctive treatment for post-surgical and post-trauma acute pain.

NMES (Neuromuscular Electrical Stimulation)

- Relaxation of muscle spasm.
- Prevention or retardation of disuse atrophy.
- Increasing of local blood circulation.
- Muscle re-education.
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
- Maintaining or increasing range of motion.

Important: Electrical stimulation devices should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

Contraindications

TENS

- Do not stimulate over the carotid sinus nerves, laryngeal or pharyngeal muscles (anterior throat area); severe spasm may occur causing contractions that may be strong enough to close the airway or cause difficulty in breathing.
- Do not use TENS device on undiagnosed pain symptoms until the etiology has been established.
- Do not place electrical current transcerebrally (through the head).
- Do not use TENS on patients wearing a demand type cardiac pacemaker.

NMES

- Electrical stimulation devices are contraindicated for patients with cardiac demand pacemakers.
- Electric stimulation devices should not be used on cancer patients.

Warnings

TENS

- Safety has not been established for the use of electrical stimulation devices during pregnancy.
- TENS is not effective for pain of the central origin. This includes headaches.
- TENS devices should be used only under the continued supervision of a physician or qualified professional.
- TENS devices have no curative value.
- TENS is a symptomatic treatment and as such suppresses the sensation of pain, which would otherwise serve as a protective mechanism.
- Keep electrical stimulators out of the reach of children.
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when TENS stimulation is in use.

NMES

- Safety has not been established for the use of electrical stimulation devices during pregnancy.
- Long-term effects of chronic electrical stimulation are unknown.
- Precautions should be taken in the case of persons with suspected or diagnosed epilepsy.
- Precautions should be taken in the case of persons with suspected heart problems.
- Due to possible arrhythmia, do not place an electrical stimulator across a patient's heart or transthoracically.
- Do not stimulate over the carotid sinus nerves; especially for patients with known sensitivity to the carotid sinus reflex.
- Severe spasm of the laryngeal or pharyngeal muscles may occur when electrodes are placed over the neck or mouth area. Contractions may be strong enough to close the airway or cause difficulty in breathing.
- Do not apply electrical stimulation transcranially.
- Do not use electrical stimulation over swollen, infected or inflamed areas, or skin eruptions such as phlebitis, thrombophlebitis, or varicose veins.
- Keep electrical stimulators out of the reach of children.

Precautions

TENS

- Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
- Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain.

NMES

- Precautions should be taken in the presence of:
 - Recent surgical procedures when muscle contraction may disrupt the healing process.
 - A menstruating uterus.
 - Sensory nerve damage (loss of normal skin sensation).
- Some patients experience skin irritation or hypersensitivity due to the conductive medium or electrical stimulation. This condition can usually be reduced by alternative electrode placement or use of additional or a different conductive medium.

- Electrode placement and stimulation settings should be based on the guidance of the prescribing physician.
- Powered muscle stimulators should be used only with the lead wires and electrodes recommended for use by the manufacturer.

Adverse Effects

Skin irritation and burns beneath the electrodes have been reported from use of electrical stimulators.

System Components



Getting Started

Remove the *SaeboStim Micro* and all of the components from the packaging. Verify that all parts listed under the **System Components** section are present.

Powering the Device

The *SaeboStim Micro* is powered by one (1) AAA battery. Remove the battery compartment cover from the back of the device. **See Figure 2.**

Install the battery according to the illustration inside the battery compartment making certain the positive terminal of the battery aligns with the '+'. Replace the battery compartment cover. **See Figure 3.**

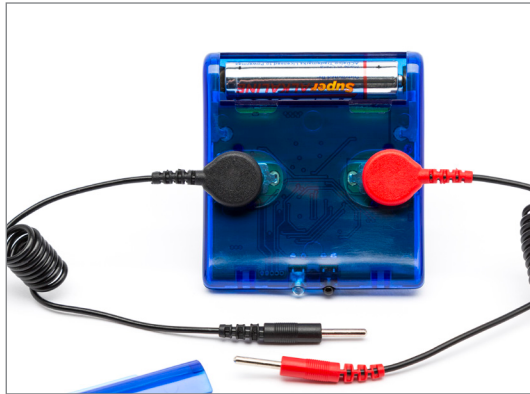


Fig 2



Fig 3

Lead Wires

The Lead Wires are already installed and connected on your device. **See Figure 4.** If they become disconnected for any reason, please follow the instructions below to reconnect.

Reconnecting the Lead Wires

Lead Wires determine the polarity of the current and is coded accordingly; Black is negative and Red is positive.

If you accidentally disengage the Lead Wires from the unit, reconnecting is very simple. To reconnect the Lead Wires, insert the Leads on the side of the unit.

The Red Lead Wire is placed on the right hand side of the unit and the Black on the left side with the battery compartment facing you. **See Figure 5.**

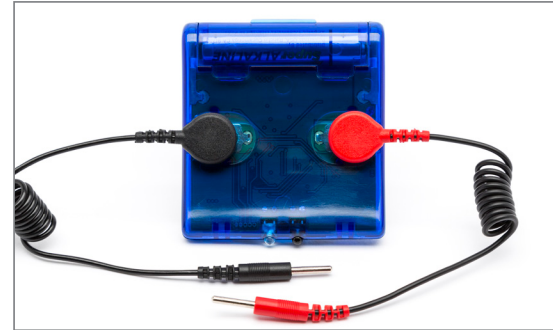


Fig 4

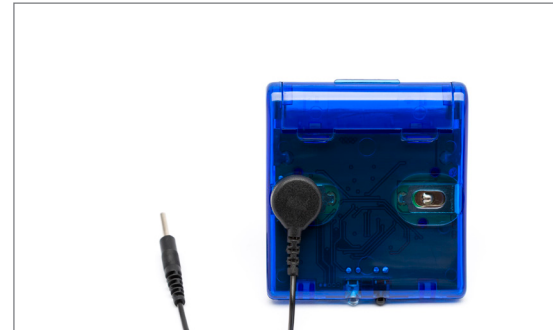


Fig 5

Electro-Mesh Garment Electrode

Warning: The Electro-Mesh Garment Electrodes should only be used with electrical sources designed and approved for medical electrical stimulations. The Garment Electrodes are for single patient use.

The Electro-Mesh Glove and Sleeve are highly conductive and made of silver treated nylon fibers blended with Dacron® fibers. The Garments transmit the stimulation from the unit to the arm and hand. Due to the shape of the hand, the Glove is an ideal choice as it intimately covers the entire hand for full stimulation. **See Figure 6.**

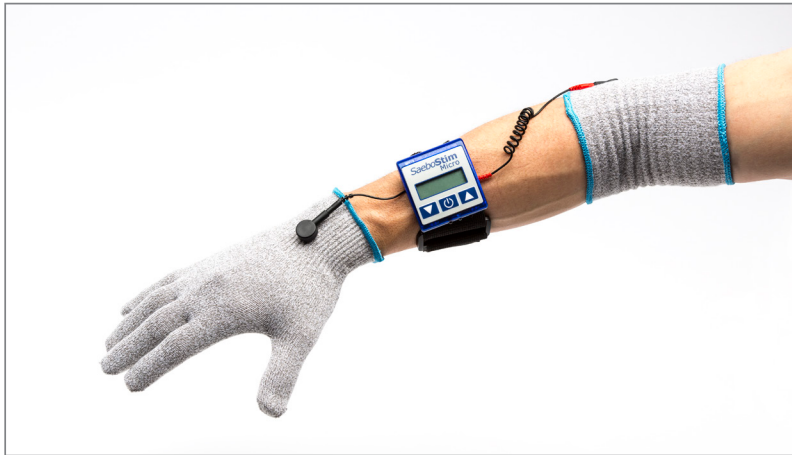


Fig 6

Applying the Device:

Important:

1. Remove all jewelry and clean skin thoroughly. Electrodes do not work well if any lotion, oil, or dirt is on the skin.
2. Prior to putting the device on, it is important that you apply the conductive Thera-Cream over the treatment area (arm and hand). Please be sure to cover the entire treatment area thoroughly to avoid an uncomfortable, stinging sensation.
3. With the Garments on a flat surface, connect the Lead Wires to the Garment Electrodes by inserting the pin ends into the Garment Electrode Connectors so no metal is visible. The Black Lead Wire connects to the Glove and the Red Lead Wire connects to the Arm Sleeve. **See Figures 7 and 8.**



Fig 7



Fig 8

4. Apply the Arm Sleeve onto the arm and position over the elbow region with the Connector positioned on top. Make sure the Sleeve fits snugly over the entire treatment area. **See Figure 9.**



Fig 9

5. Apply the Wrist Strap and secure just below the Arm Sleeve. Please be sure the Strap is not too tight, but is secured. The Strap will be positioned between the Arm Sleeve and the Glove. **See Figure 10.**



Fig 10

6. Secure the Velcro portion of the *SaeboStim Micro* unit onto the Wrist Strap. **See Figure 11.**



Fig 11

7. Apply the Glove onto the hand. Be sure the Glove fits snugly over the entire hand so stimulation can be provided evenly to the entire treatment area. Be sure the Connector is positioned on the top portion of the hand. **See Figure 12.**



Fig 12

Turning the Device On

The **SaeboStim Micro** is powered on by pressing and releasing the Power button for approximately 2 seconds until the display lights up showing P1 on the screen. **See Figure 13.** Only the “P” will be flashing. The Unit should be connected to the Garment Electrodes and the Garments should be worn at this point.

WARNING!

- Do not place an electrical stimulator across a patient's heart or transthoracically.
- Do not stimulate over the carotid sinus nerves.
- Severe spasm of the laryngeal or pharyngeal muscles may occur when electrodes are placed over the neck or mouth area. Contractions may be strong enough to close the airway or cause difficulty in breathing.
- Do not apply electrical stimulation transcerebrally.
- Do not use electrical stimulation over swollen, infected or inflamed areas, or skin eruptions such as phlebitis, thrombophlebitis, or varicose veins. Place electrodes according to prescribed treatment with the above cautions in mind. Follow all instructions for the electrode use.



Fig 13

Program Selection

Research indicates that increased stimulation to the affected limb can lead to improved motor recovery. The **SaeboStim Micro** offers 2 novel programs (P1 and P2) that are widely used in scientific studies. The **SaeboStim Micro** and Electro-Mesh Glove and Arm Sleeve are very safe to use and can be used as often as possible – both daily (P1) and at night (P2). Although, performing both programs at home is ideal, feel free to only use the daily program (P1) initially if desired.

When the unit is powered on, select desired program P1 or P2 (see below). Program selection is made by repeatedly pressing the Power button until the desired program is shown on the far left of the display. Only the “P” will be flashing. **See Figure 14.**

The **SaeboStim Micro** is factory programmed for two treatment programs.

1. P1 – 30 Minute Treatment used 2 times per day. P1 is a 30-minute session with parameters consisting of 50 pulses per second (pps).

2. P2 – 8-Hour Treatment for night-time use. P2 is an 8-hour session that consists of 20 minutes of therapy followed by 40 minutes of rest every hour for 8 hours. Each 20-minute treatment segment consists of 10 minutes at 80 pps and 10 minutes at 8 pps.

After P1 or P2 treatment is complete, the **SaeboStim Micro** will automatically turn itself off. Every 10 seconds during operation, the display will show time remaining in hours and minutes or minutes and seconds. During the rest time of P2, the intensity setting will flash.



Fig 14

Treatment Intensity

Two buttons on the device control intensity: Increase (▲) and Decrease (▼). **See Figure 15.** The intensity defaults to 5 when the device is powered on or when the batteries have been removed and replaced.

Press the Increase button (▲) to set the protocol and intensity level. The “P” will stop flashing and as you continue to press the button, the intensity will increase and the LCD will display the numeric value. The intensity will increase in increments of 5, up to the maximum intensity of 100. To decrease the intensity, press the Decrease (▼) button.



Fig 15

How much intensity do I need?

Press the Increase button (▲) until you feel a light tingling sensation. Next, reduce the sensation by pressing the decrease button (▼) until you no longer feel the tingling. According to research, the optimum therapeutic level of stimulation should be just below “sensory” level. In other words, try to reduce the stimulation to the point where you no longer feel the electricity or tingling sensation.

Note: The Increase and Decrease buttons lock out after 20 seconds of non-use so that stimulation cannot be inadvertently changed during treatment. To reactivate the intensity controls, press and release the Power button. Intensity controls will remain active for 20 seconds after the last button was pressed.

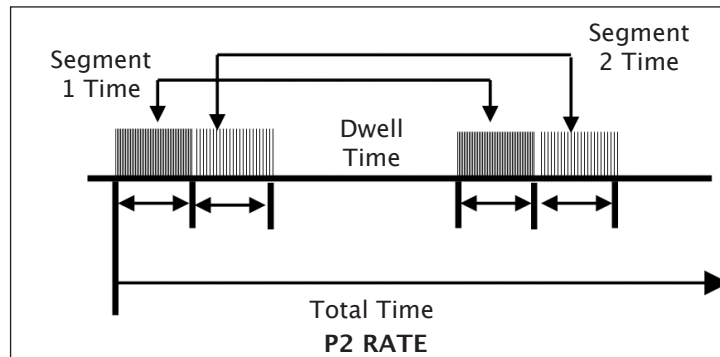
Parameters

Waveform

The **SaeboStim Micro** delivers a high voltage twin peak monophasic waveform. The maximum voltage coincides with the numeric intensity value on the LCD display (5–100 volts in increments of 5).

Rate

Rate selects the number of times the waveform repeats every second. Note that P1 is programmed at 50 (pulses per second) pps for 30 minutes for a total treatment of 30 minutes. P2 is programmed at 80 pps for 10 minutes and 8 pps for ten minutes totaling 20 minutes of treatment for each hour of the 8-hour routine.



P2 Rate Illustration

Powering the Device Off

The **SaeboStim Micro** will automatically power off when treatment is completed. The unit can also be powered off manually at any time. To manually power off, press the Power button for approximately 4 seconds and the device will turn off.

See Figure 16.

Or, you may press and hold the decrease button until the device reads 0, release it and press it again and the device will turn off.



Fig 16

Battery Care

The **SaeboStim Micro** uses one AAA battery. To replace the battery, open the battery compartment on the back of the device and insert a new battery.

Low Battery

When the battery is low, a battery symbol will flash on the far right of the display. Replace the battery at the first indication of low battery life. The device will turn off automatically if there is not enough voltage to sustain therapy.

Care and Cleaning

- Do not store the *SaeboStim Micro* with the battery installed.
- Battery acid causes irreparable damage, which is not covered by the warranty.
- When not in use, make certain the device is turned off.
- Turn the power off when cleaning the device.
- Do not immerse the device in liquid.
- Avoid spilling liquids on the *SaeboStim Micro*.
- The surface of the *SaeboStim Micro* may be wiped with a soft cloth or sponge dampened with a mild soap solution. Avoid caustic cleansers.
- Garments should be hand washed with a mild detergent in cold water and rinse thoroughly. Allow to air dry; DO NOT place in dryer.

Trouble-Shooting

Device will not turn on:

- Check for proper battery installation.
- Replace battery.

No Stimulation:

- Check Lead Wires for proper connection onto the device.
- Check for proper patient electrode application.
- Apply Conductive Spray or Cream to the area to be stimulated.
- Check treatment time for expiration.

Helpful Hints

- Patients with sensory loss should not over-stimulate. Consult your health professional for proper setup and protocol.
- Always prepare the skin correctly by washing it and removing all dirt, oils, and dead skin before applying electrodes.
- If the stimulation becomes uncomfortable, causing a stinging sensation, when using the Electro-Mesh garments during treatment, re-apply TheraCream™ over the treatment area.





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