

SaeboStim One



INSTRUCTION MANUAL





Introduction

Saebo is pleased to provide you with the *SaeboStim One*, a wearable, wireless neuromuscular electrical stimulation device designed to minimize muscle weakness, improve function, re-educate and strengthen weakened muscles.

Maximize the Saebo home program with the revolutionary wearable electrical stimulation device. The *SaeboStim One* complements the Saebo program. Whether applying the stimulation before or after the Saebo treatment or combining stimulation with the Saebo technology, providing multiple evidence-based treatment solutions can enhance overall functional recovery.

This manual contains important information for both the person who will wear the *SaeboStim One* and the clinician who may provide and setup the device. **Please consult your physician prior to starting treatment with the *SaeboStim One*. Please be sure to review all information carefully.**

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



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Indications for Use

- Relaxation of muscle spasm.
- Prevention or retardation of disuse atrophy.
- Increasing of local blood circulation.
- Muscle reeducation.
- Maintaining or increasing range of motion and strength.

Contraindications

- If you are in the care of a physician, consult with your physician before using this device.
- If you have had medical or physical treatment for your pain, consult with your physician before using this device.
- Do not apply stimulation over your neck because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- Do not apply stimulation across your chest because the introduction of electrical current into the chest may cause rhythm disturbances to your heart, which could be lethal.
- Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).

Contraindications (continued)

- Do not apply stimulation over, or in proximity to, cancerous lesions.
- Do not apply stimulation over metal implants.
- Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.
- Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.
- Do not apply stimulation when in the bath or shower.
- Do not apply stimulation while sleeping.
- Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury.
- Apply stimulation only to normal, intact, clean, healthy skin.
- Do not inhale or swallow small parts.
- Replacement by inadequately trained personnel could result in a hazard.

Precautions

- The safety of electrical stimulation during pregnancy has not been established.
- You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
- If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.
- If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
- Use caution if you have a tendency to bleed internally, such as following an injury or fracture.
- Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.
- Use caution if stimulation is applied over areas of skin that lack normal sensation.
- Keep this device out of the reach of children.
- Use this device only with the gel pads and accessories recommended by the manufacturer.
- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across your head, and electrodes should not be placed on opposite sides of your head.

Precautions (continued)

- Interconnection of this device to other equipment not described in the instructions for use could be unsafe.
- Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy ME equipment may produce instability in the stimulator output.
- Keep the device away from nebulizer or steam kettle, as the moisture may affect the device.
- Keep the device away from sunlight, as long-term exposure to sunlight may affect the rubber become less elastic and cracked.
- Keep the device away from lint and dust, as long-term exposure to lint or dust may affect the plug/sockets or connector become bad contact.

Adverse Effects

- You may experience skin irritation and burns beneath the stimulation gel pads applied to your skin.
- You should stop using the device and should consult with your physician if you experience any adverse reactions from the device or gel pads.

Getting Started

Unpacking the Device

Remove the *SaeboStim One* and all of the components from the packaging. Verify that all parts are present. See **Figure 1**.

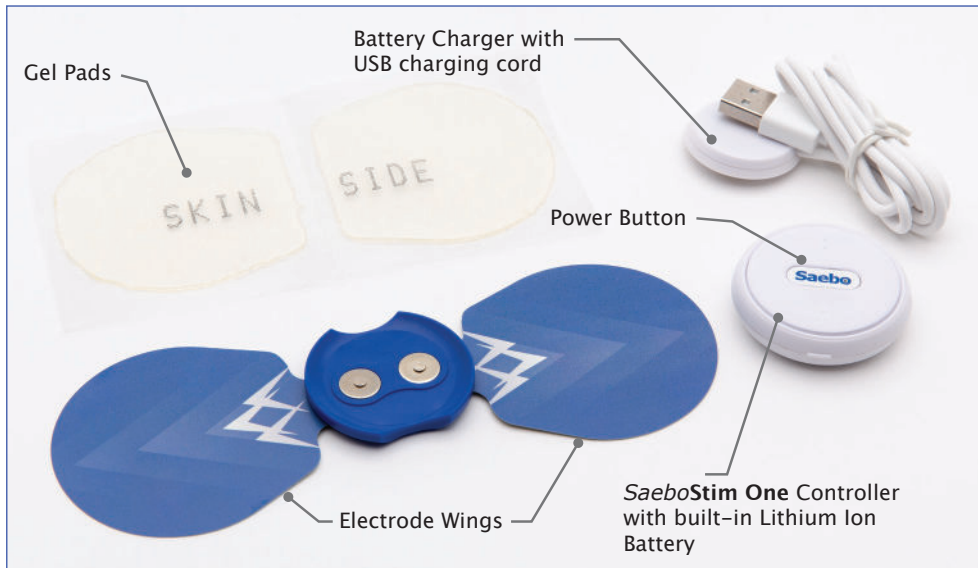


Figure 1

Powering the Device

- Remove the small circle *SaeboStim One* device from Electrode Wings by positioning the thumb between the white Controller and the blue connector. Then, separate both components by using adequate pressure. **DO NOT ATTEMPT TO TWIST THE CONTROLLER TO DISCONNECT.** See Figure 2.
- Connect Controller to the Charger. See Figure 3.
- Charge the device for 2.5 hours before use by plugging it into a USB port of a powered-on device (i.e. laptop). See Figure 4.



Figure 2



Figure 3



Figure 4

Connecting Device to Electrode Wings

Once the device is charged, remove from the Charger and connect the device to the Electrode Wings by snapping it into the holder. See Figure 5.



Figure 5

Adjustable Wings

The ultra-thin rotating flexible Wings are fully adjustable which allows for unlimited electrode positioning. The Wings are made of a silver treated conductive surface to provide an unmatched quality of stimulation. See Figure 6 and Figure 7.



Figure 6



Figure 7

Applying Gel Pads to Electrode Wings

Tear the perforated line of the Gel Pads so they are no longer connected. **See Figure 8.** Peel off the film (thinner side) of both Gel Pads and discard. **See Figure 9.** Apply Gel Pads to the silver space defined on the back side of the Wing. **See Figure 10.** Leave the remaining piece of film on each Gel Pad until the device is ready to use.



Figure 8



Figure 9



Figure 10

Operating the *SaeboStim One*

Important

Remove all jewelry and clean skin thoroughly. Electrodes do not work well if any lotion, oil or dirt is on the skin.

Step 1: Peel and remove film from Electrode Wings and store for future use. **See Figure 11.**

Step 2: Place Electrode Wings on skin at desired location. Press firmly to make sure both Wings are completely covering the skin. **See Figure 12.**



Figure 11



Figure 12

Step 3: Press and hold center button of the Controller for 3 seconds to turn on the device. See Figure 13.

Step 4: The area above and below the Power Button (intensity buttons) can be used for manually controlling the intensity (increase/decrease). To increase intensity to the desired level, press the top portion of the Controller (above the Power Button). To decrease intensity, press the bottom portion of the Controller (below the Power Button). See Figure 14.

Note: See pages 22 – 24 for sample electrode placement suggestions for common treatment areas. Be sure to consult a physician/health professional to confirm appropriate placement.



Figure 13



Figure 14

Powering the Device Off

The *SaeboStim One* will automatically power off after 60 minutes. The unit can also be powered off manually at any time. To manually power off, press and hold the Power Button for 3 seconds and the device will turn off. See Figure 15.

Power Button



Figure 15

Removing the *SaeboStim One*

Do not remove the device until the treatment has stopped and/or you have ended the program, and the intensity is set to zero. After treatment, or when you want to remove the device, pinch the edge of the Electrode Wing and slowly peel the Wings away from the skin. See Figure 16.



Figure 16

Removing the *SaeboStim One* (continued)

Align and place the Gel Pad film back on the exposed side of the Gel Pads.
See Figure 17.

Ensure the Pads are completely covered, and then insert Wings into the resealable poly bag (included with device) for storage.



Figure 17

Helpful Hints:

- Patients with sensory loss should not over-stimulate. Consult your health professional for proper setup and protocol.
- If the Gel Pads lose contact with the skin, the output will be set to zero.

Replacing Gel Pads

Gel Pads may provide between 10–12 uses. After the Gel Pads no longer adhere well, peel the used Gel off the Wings before replacing. **See Figure 18.**

To Reorder:

Replacement Gel Pads can be purchased by visiting www.saebo.com.

Suggestion:

Add a few drops of water onto the Gel to rehydrate and increase the adherence.



Figure 18

Caution

It is normal to get some skin reddening after a session. This fades quickly. You should always take rests between therapy sessions and check your skin underneath the electrode wings periodically. If the reddening does not disappear after a couple hours, discontinue use of the system, and contact www.saebo.com.

General Warnings

1. Do not immerse the *SaeboStim One* in water.
2. Do not place the *SaeboStim One* unit close to excessive heat.
3. To replace batteries, contact Saebo for instructions.
4. Environmental Condition:
 - Operating Temperature: +0°C to +40°C
 - Operating Humidity: 10% RH to 93% RH
 - Operating Atmospheric Pressure: 700 hPa to 1060 hPa
 - Storage/Transport Temperature: -25°C to +70°C
 - Storage/Transport Humidity: 8% RH to 93% RH

Battery

The rechargeable polymer lithium ion battery holds a charge for 24 continuous hours of use or more. Allow 2.5 hours when recharging for full battery use. The light on the *SaeboStim One* device will flash when the battery is low.

Gel Pads

The Gel Pad should be used for 10–12 uses. Beyond this point, the quality of stimulation will diminish. To enhance the Gel Pad stickiness, add a few drops of water onto the Gel to re-hydrate the electrode. Dry it before applying to the skin. Once Gel Pads are no longer sticky, rub and pull Gel Pad away from Wings to remove. Replacement Gel Pads are available for purchase on www.saebo.com.

Storage life of the unopened pack of Gel Pads is 2 years. This may be affected by very high temperature or very low humidity.

Care and Cleaning

Clean the Controller and Electrode Wings using a damp cloth and mild soap. A disinfectant or alcohol can be used.

Note: This device is manufactured with water detection technology. Do not submerge the device in water or other liquids. Water damage to the electronics will void the warranty.

Storage

The device should be stored at a temperature between 50° F and 104° F. Always store the Electrode Wings and Gel Pads in their re-sealable bag.

Shelf Life

1. The expected shelf life of this device is 5 years.
2. The expected shelf life of the battery is 5 years.
3. The expected shelf life of Gel Pads is 2 years.

Parameters

- Waveform Type – Symmetrical Biphasic
- Pulse Width – 300uS
- Pulse Rate – 35Hz
- On Time – 8 sec
- Off Time – 8 sec
- Ramp Up/Down – 2 sec
- Total Treatment Time – 60 min
- Maximum intensity: 110mA at 500 Ohm load

Service and Maintenance

1. The patient is an intended operator.
2. Do not service and maintain the device while in use with a patient.
3. Maintenance and all repairs should only be carried out by an authorized agency. The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.

Service and Maintenance (continued)

4. The user must not attempt any repairs to the device or accessories. Please contact the retailer for repair.
5. Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.

WARNING: Do not modify this device without authorization of the manufacturer.

Disposal of Waste – Electrical and Electronic Products (WEEE)

One of the provisions of the European Directive 2002 / 96 / CE is that anything electrical or electronic should not be treated as domestic waste and simply thrown away. New products are now being marked with the symbol to remind you. Your local council or retailer will be able to tell you where your nearest facility is. The collection facilities will send items for treatment, recovery and recycling, so by using them you'll help to save resources and minimize the effects on the environment.

Symbols Used



TYPE BF EQUIPMENT: Equipment providing a degree of protection against electric shock, with isolated applied part. Indicates that this device has conductive contact with the end user.



This symbol on the unit means “Refer to User Manual”.



Serial Number: indicates the manufacturer’s serial number so that a specific medical device can be identified.



Do not dispose in household waste. It is compliance with WEEE



Manufacturer

IP22

The first number 2: Protected against access to hazardous parts with a finger, and the jointed test finger of 12mmø, 80mm length, shall have adequate clearance from hazardous parts, and protected against solid foreign objects of 12.5mmø and greater.

The second number 2: Protected against vertically falling waterdrops when enclosure is tilted up to 15°. Vertically falling drops shall have no harmful effects when the enclosure is tilted at any angle upto 15° on either side of the vertical.

EMC Precautions

Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance $d = 3,3$ m away from the equipment.

Sample Electrode Placement Locations

Patent pending ultra-thin, rotating wing structure is fully flexible, which allows the user to apply the device to specific areas. Feel free to rotate the wings to improve placement.

Shoulder Flexion/Subluxation

Place the Electrode Wings over the Deltoid muscles in a horizontal position. See **Figure 19**.



Figure 19

Elbow Flexion

Place the Electrode Wings over the elbow flexors in a vertical position. See **Figure 20**.



Figure 20

Elbow Extension

Place the Electrode Wings over the elbow extensors in a vertical position. See Figure 21.



Figure 21

Wrist / Finger Extension

Place the Electrode Wings over the wrist and finger extensors in an oblique position. See Figure 22.



Figure 22

Wrist / Finger Flexion

Place the Electrode Wings over the wrist and finger flexors in an oblique position. See Figure 23.



Figure 23

Dorsiflexion (Foot Drop)

Place the Electrode Wings over the dorsiflexors in a vertical position. See Figure 24.

Note: Due to various physical factors, some individuals may not experience a sufficient contraction at the dorsiflexors using the *SaeboStim One*.

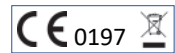


Figure 24

SaeboStim One



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