

SaeboStim Spa



INSTRUCTION MANUAL

Introduction

Saebo is pleased to provide you with the **SaeboStim Spa**, an advanced aquatic electrical stimulation device designed to decrease pain, improve sensation, minimize muscle weakness, improve function, and re-educate and strengthen weakened muscles.

Maximize the Saebo home program with the revolutionary electrical stimulation device. The **SaeboStim Spa** complements your program by providing multiple evidence-based treatment solutions that may enhance overall functional recovery.

This manual contains important information for both the person who will use the **SaeboStim Spa** and the clinician who may provide and setup the device.

Please consult your physician prior to starting treatment with the **SaeboStim Spa**. Also, please be sure to review all information carefully.

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



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List of Symbols



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 water drops when enclosure is tilted up to 15°. Vertically falling drops shall have no harmful effects when the enclosure is tilted at any angle up to 15° on either side of the vertical.

Intended Use

The *SaeboStim Spa* delivers muscle and nerve stimulation. The indications for use include relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, maintaining or increasing range of motion, post-surgical and post-traumatic acute pain problems, and chronic pain syndromes.

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).
- Do not apply stimulation over, or in proximity to, cancerous lesions.

Contraindications (continued)

- 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.
- Do not use the device on children, if it has not been evaluated for pediatric use.
- Apply stimulation only to normal, intact, clean, healthy skin.

Precautions

- TENS is not effective for pain of central origin, including headache or stomach ache.
- TENS is not a substitute for other pain management therapies.
- TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that could otherwise serve as a protective mechanism.
- Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.

Precautions (continued)

- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head.
- The safety of electrical stimulation during pregnancy has not been established.
- 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 leads, electrodes, and accessories recommended by the manufacturer; and
- Use this device only under the continued supervision of a licensed practitioner.
- Interconnection of this device to other equipment not described in the instructions for use could be unsafe.
- Potential hazard from simultaneous connection of a patient to a high frequency surgical ME equipment and the device that may result in burns and possible damage to the device.
- Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy ME equipment may produce instability in the stimulator output.

Warnings

- Do not immerse the device in water.
- Do not use if you are pregnant.
- Do not place the device close to excessive heat.
- Use only the specified battery: 3.7V, 900mAH polymer battery (Model: 703048). Using of any other battery could damage the unit.
- Use this device only with accessories recommended by the manufacturer. Use of other parts or materials supplied by other manufacturer can degrade minimum safety.
- If you notice any adverse reactions or burning feeling, discontinue use immediately.
- Keep the device away from sources of high magnetic fields such as TV'S, microwave ovens and hi-fi speakers, as these may affect the LCD screen.
- Keep the device away from a fireplace or radiant heater, as the heat may affect the device.
- 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.
- Temperature & R.H. of storage: -10°C --+60°C, 15%--75% R.H.
Atmospheric Pressure: 700 hPa to 1060 hPa
- Temperature & R.H. of transportation: -10°C --+60°C, 15%--75% R.H.
Atmospheric Pressure: 700 hPa to 1060 hPa.
- No modification of this equipment is allowed.

Warnings

- Do not put the lead wire on or wrapped around the neck.
- Do not inhale or swallow small parts.
- Replacement by inadequately trained personnel could result in a hazard.
- Parts of the ME equipment that are not serviced or maintained while in use with the patient.
- At the end of the session, remove your feet and dry them thoroughly before walking around.

Epsom Salt

Never use a higher dose of magnesium sulfate than recommended in the manual, or as your doctor has directed. **Using too much magnesium sulfate can cause serious, life-threatening side effects.**

Ask a doctor before use if you have:

- Kidney disease
- Stomach pain
- A magnesium restricted diet
- Breast feeding
- Notice a sudden change in bowel habits or rectal bleeding
- A prescription drug regimen

Keep out of reach of children. In case of an overdose, call poison control at 800-222-1222 right away.

Effervescent Tablets

The Tablets are for external use only; **do not ingest**. Keep out of reach of children.

Adverse Effects

- Patients may experience skin irritation and burns beneath the stimulation applied to the skin.
- Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face.
- Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device or redness on the skin that doesn't go away after treatment.

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.

(Note. As indicated in Table 6 of IEC 60601-1-2 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields $d = 3,3$ m at an IMMUNITY LEVEL of 3 V/m).

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. Leave the remaining piece of film on each Gel Pad until the device is ready to use.

Description of Device and Controls



Figure 1 (Front & Back)

Device Features

1. **On/Off Button** – It allows the unit to turn on and off. Press and hold this button for 3 seconds. The LCD display will light up. Press and hold this button for 3 seconds again and the unit will turn off.
2. **Output Ports** – 2 Lead Wires insert into the Ports on the bottom portion of the device.
3. **DC Jack** – the stimulator can be powered through an AC adaptor. Connect one end to the power source and the other to the bottom of the device. The DC Jack is located in between the 2 Output Ports.
4. **Belt Clip** – Located on the back of the unit.

Display Screen Symbols

1. **Battery** – remaining battery power.
2. **Lock** – prevents unwanted changes to the intensity level. To lock, simply tap the lock icon in the top right corner. To unlock, tap again.
3. **Time** – length of time remaining.
4. **Body Part** – treatment can be provided to the feet and/or hands.
5. **Intensity Arrow** – press the up or down arrow keys to adjust the intensity.
6. **Pause** – when the stimulator is running a treatment program, press the pause button once to pause the treatment. To continue the treatment, press the pause button again. If the unit has been paused for more than 5 minutes, the device will shut off automatically.

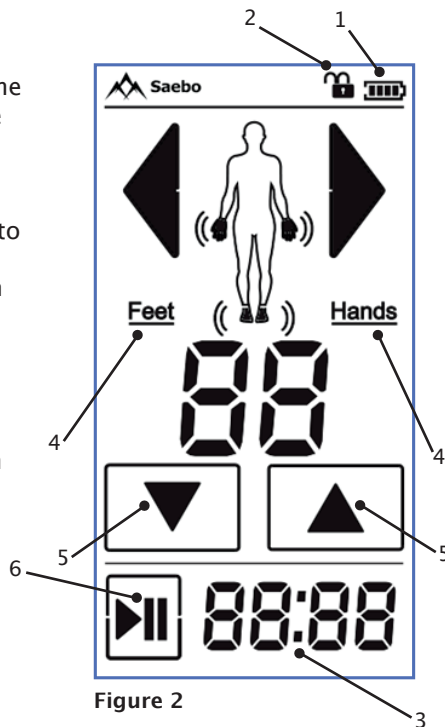


Figure 2

Unpacking the Device

Remove the *SaeboStim Spa* and all of the components from the packaging. Verify that all parts listed under the System Components section are present. See **Figure 3**.

1. *SaeboStim Spa* Device
2. Conductive Foot Bath
3. Lead Wires
4. 2" Carbon Rubber Electrodes
5. Power Adaptor/Power Cord
6. Carrying Case (not shown)
7. Epsom Salt
8. Effervescent Tablets



Figure 3

Getting Started

Although many individuals use the *SaeboStim Spa* for their feet, the instructions below are also applicable for the hands. For convenience purposes, the foot application will be described below.

Step 1: Powering the Device

To charge the *SaeboStim Spa*, connect the Power Cord to the Power Adaptor and insert the cord into the bottom of the device between the 2 Ports. See Figures 4 and 5.



Figure 4



Figure 5

Note: The first charge will take approximately 16 hours and typically 8–10 hours from there. Since it is a Li-ion battery, never let the battery go to zero, and charge periodically even if not used. Li-ion batteries, if well maintained are good for 4–5 years before degrading.

Step 2: Connecting Lead Wires to Device

Plug the “T-shaped” end of the red Lead Wire into Port 2 and the “T-shaped” end of the black Lead Wire into Port 1 found on the bottom of the device.
See Figures 6 and 7.



Figure 6



Figure 7

Step 3: Connecting Lead Wires to Carbon Rubber Electrodes

Connect the pin side of the Lead Wires to the 2" Carbon Rubber Electrodes.
See Figure 8.

Note: This system includes custom Lead Wires and Rubber Electrodes. If you need to replace your Lead Wires or Electrodes, only use the manufacture versions.

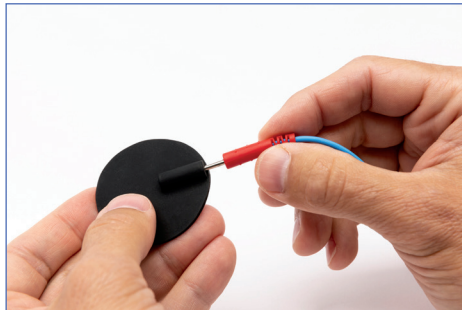


Figure 8

Step 4: Preparing the Conductive Foot Bath

- A. Fill each side of the Foot Bath to ankle height (typically fill half-way full of water), with warm water (or cool if you prefer) and place in front of where you will be sitting for your treatment. Be sure to have a towel to dry your feet after use.

See Figure 9.

- B. Add 1 tablespoon of Epsom Salt to each side of the Foot Bath and stir. The Salt is highly conductive allowing for efficient stimulation. For dry feet, reduce to 1 teaspoon.

See Figure 10.



Figure 9



Figure 10

- C. Add 1 Effervescent Tablet to each side of the Foot Bath and stir. The Tablets help improve dry feet, as it contains collagen, vitamin C, and other moisturizing agents. In addition, the Tablet also contains menthol to provide a topical analgesic effect.

See Figure 11.

Caution:

Refer to **Pages 8 & 9** before use.



Figure 11

Step 5: Using the Device

Important: If using for your feet, remove any jewelry around your feet or ankles. Do the same if treating your hands.

Submerge the red Carbon Rubber Electrode (Port 2) so it is completely underwater. Place electrode on same side as the affected foot. Next, submerge the black Carbon Rubber Electrode (Port 1), on the other side. The black Electrode will be used for the non-affected foot. If both sides are affected, it is recommended to alternate the Electrodes per session.

See Figure 12.

In a seated and comfortable position, place your feet into the Foot Bath.

See Figure 13.



Figure 12



Figure 13

Why Use Port 2 on the Affected Side?

The *SaeboStim Spa* program includes a specialized therapeutic waveform which consists of Port 2 being more “active” during the session, thus, maximizing therapeutic results.

Note 1: the above steps are the same if using for your hands instead of the feet.

Note 2: The red and black Electrodes should not touch during treatment nor should they touch your feet.

Step 6: Turn On

Turn the device on by pressing the On/Off button on the side of the unit for 3 seconds.

See Figure 14.

The LCD display will light up.
There will be no feeling from either Leads at this point as the intensity always starts at zero.



Figure 14

Step 7: Choose Body Part

The Feet program is automatically selected (i.e., left arrow highlighted). If you would like to use the *SaeboStim Spa* for hands, then select “Hand” by tapping the right arrow. See Figure 15.

Step 8: Start Treatment

The advanced program automatically starts once the user increases the intensity level. The program will run for a total of 30 minutes with alternating treatment parameters for maximum clinical effect. The device will shut off when the 30 minutes is complete.

Two buttons on the device control the intensity (Increase ▲ and Decrease ▼) . The intensity defaults to zero when the device is powered on.

Increase the intensity by pressing the up arrow on the screen until you feel a comfortable tingling sensation. See Figure 16.

Note: If the stimulation feels weak, make sure to add at least a tablespoon of Epsom salt.



Figure 15

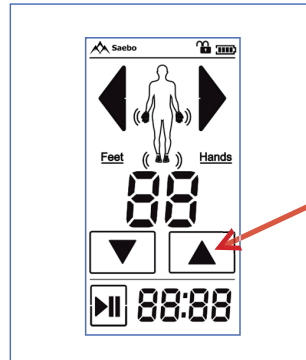


Figure 16

Step 9: Powering the Device Off

The *SaeboStim Spa* will automatically power off when treatment is completed.

Ensure that the unit is turned off before removing the Electrode Pads from the Foot Bath. After use, dry the Pads and store. There is no need to disconnect the Pads from the lead wires between sessions.

Treatment Frequency

It is recommended that you perform 1 session per day as needed until symptoms improve.

Program Parameters

Channel:	Single
Output:	Maximum 48V (peak value) across 500 Ohm load
Waveform:	Bi-phasic rectangular Mono-phasic Pulse
Treatment Time:	30mins
Programs:	1

Program Parameters (continued)

Phase 1 – 4 Minutes

Pulse Width	2.1ms (Foot)
Pulse Width	1.2ms (Hand)
Frequency	80Hz
Waveform	Biphasic Rectangular

Phase 2 – 13 Minutes

Pulse Width	0.5ms (Foot & Hand)
Frequency	8Hz
Waveform	Mono-phasic Pulse

Phase 3 – 13 Minutes

Pulse Width	5.0ms (Foot)
Pulse Width	3.0ms (Hand)
Frequency	7.83Hz
Waveform	Biphasic Rectangular

Charging the Battery

The *SaeboStim Spa* is powered by a built-in rechargeable polymer battery. Separate Power adaptor and Power Cord are included in the kit.

When the battery is running low, the battery symbol  on the top right of the screen is empty and keeps flashing. It is time to charge the battery.

- When charging is in progress, the battery indicator bar cycles from zero to the max. When the battery charging has completed, the bar stops cycling and remains at maximum to indicate full capacity. Remove the charging cable and adapter from the device when charging is completed.
- Although the display fades as the battery runs down, the strength of the output does not change until the warning is shown.

Troubleshooting

Cleaning

Clean the case and lead wires at least once a week by wiping with a damp cloth and a solution of mild soap and water. Wipe dry.

Do not immerse your device in water.

Do not use any other cleaning solution than soap and water.

Service and Maintenance

- The patient is an intended operator.
- Do not service and maintain the device while in use.
- 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.
- The user must not attempt any repairs to the device or accessories. Please contact the retailer for repair.
- 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.



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