

SaeboStim Pro



INSTRUCTION MANUAL

Introduction

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

The **SaeboStim Pro** 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 use the **SaeboStim Pro** and the clinician who may provide and setup the device. Please consult your physician prior to starting treatment with the **SaeboStim Pro**. Please be sure to review all information carefully.

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



Saebo, Inc.

2459 Wilkinson Boulevard, Suite 120-B

Charlotte, NC 28208













Tel: 888.284.5433

www.saebo.com

Index

Introduction	1
List of Symbols	3,4
Contraindications	4–6
Warnings	6,7
Adverse Reactions	7
EMC, Caution	8
Guidance and Manufacture's Declaration.....	9–17
Intended Use	19
Description of Device and Controls	20,21
Display Screen Symbols and Description	22,23
Getting Started	24
Installing Batteries	25
Clean Skin	26
Plug in Electrode Wires	26,27
Powering the SaeboStim Pro	28
Select and Start a Program	29–35
Sensory Electrical Stimulation (SES) Program	36,37
Usage of Electrical Pads	38
Care and Maintenance	39,40
Program Information	42–46
Troubleshooting	47
Technical Support, Warranty	48

List of Symbols

-  Contraindications, that may cause danger
-  Mandatory requirement or may cause an injury or physical discomfort
-  Type BF Equipment
-  Use with Caution
-  Non-Ionizing Radiation
-  Date of Manufacture
-  Manufacturer
-  This product must not be disposed of with other household waste
-  Refer to user manual
-  Serial Number
-  The number of the notified body (0123)
-  European Authorized Representative

List of Symbols (continued)



Fragile



Keep upward



Keep dry

IP22 The protection level against water is IP22

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 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.
- Do not use near short-wave, microwave. (such as 1m)
- Patients with heart disease, severe hypertension and skin disorder are forbidden to use this product.
- Patients with epilepsy are forbidden to use this product.
- Patients with active hemorrhage, acute purulent Inflammation, malignant neoplasms, thrombophlebitis, sepsis and cardiopulmonary failure are forbidden to use this product.
- Do not use this product for purpose other than treatment.
- Do not apply this product to unconscious patients.
- Do not disassemble, repair or rebuild this product.
- Do not touch the charging connector/battery and the patient simultaneously when charging/using.

Contraindications (continued)

- Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
- Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.

Warnings

- 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.

Warnings (continued)

- Keep this device out of the reach of children.
- Use this device only with the gel pads and accessories recommended by the manufacturer.
- Please use with caution when the output current density exceeds 10mA/cm² (r.m.s).
- Please use with caution if the used areas have structural deformity.
- Patients should not move the electrode while using this stimulator.
- Please stop using this product if the body shows any physical abnormality.
- If the device has been stored in a cold or hot environment, allow it at least 5 minutes to acclimate to room temperature before operating.

Helpful Hint: Patients with sensory loss should not over-stimulate.
Consult your health professional for proper setup and protocol.

Adverse Reactions

- Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.
- You should stop using the device and should consult with your physician if you experience any adverse reactions from the device or electrodes.
- It is normal to get some skin reddening after a session. This fades quickly.
- You should always take rests between therapy sessions. If the reddening does not disappear after a couple hours, discontinue use of the system, and contact www.saebo.com.
- There is a small percentage of people that may have allergic reactions to gel and will need special hypo allergic gels.

- If any skin irritation or allergy occurs, please stop using the stimulator immediately and follow doctor's instructions.
- Do not position on allergic area.

Electromagnetic Compatibility (EMC)

This equipment generates, uses, and radiates radio frequency energy. The equipment may cause radio frequency interference to other medical or non-medical devices and to radio communications.

If this equipment is found to cause interference, which can be determined by turning on and off the equipment, the operator or qualified service personnel should take following actions:

- Reorient or relocate the affected device;
- Increase the distance between the equipment and the affected device;
- Power the equipment by another source;
- Consult the service engineer for further suggestions.

Caution

- It is the customer's responsibility to assure that this equipment and vicinity equipment comply with the contents of IEC 60601-1-2 4th Edition.
- Do not use any device that might send out RF signals, including cell phone, radio transceiver and radio control products, which might cause operation parameters beyond the standards. please shutdown these devices when you are near the equipment. Operator has the responsibility to warn user or any others to comply with this rule.
- Manufacturer will not responsible for any unauthorized actions that cause interference.

Table 1

Guidance and Manufacture's Declaration – Electromagnetic Emission		
This equipment is intended for use in the electromagnetic environment specified below. User should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	This equipment is suitable for domestic establishments and those directly connected to the public low-voltage power supply network.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complied	

Table 2

Guidance and Manufacture's Declaration – Electromagnetic Immunity			
This equipment is intended for use in the electromagnetic environment specified below. User should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	$\pm 8\text{kV}$ contact $\pm 2\text{kV}$, $\pm 4\text{kV}$, $\pm 8\text{kV}$, $\pm 15\text{kV}$ air	$\pm 8\text{kV}$ contact $\pm 2\text{kV}$, $\pm 4\text{kV}$, $\pm 8\text{kV}$, $\pm 15\text{kV}$ air	Floors should be wood, concrete or ceramic tile. Humidity should be at least 30% if it is synthetic materials.
Electrical fast transients/ bursts (EFT) IEC 61000-4-4	$\pm 2\text{kV}$ 100kHz repetition frequency	$\pm 2\text{kV}$ 100kHz repetition frequency	Main power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	$\pm 0.5\text{kV}$, $\pm 1\text{kV}$ line-to-line $\pm 0.5\text{kV}$, $\pm 1\text{kV}$, $\pm 2\text{kV}$ line-to-ground	$\pm 0.5\text{kV}$, $\pm 1\text{kV}$ line-to-line $\pm 0.5\text{kV}$, $\pm 1\text{kV}$, $\pm 2\text{kV}$ line-to-ground	

Table 2 (Continued)

Voltage dips IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be typical commercial or hospital environment. UPS power is recommended if this device needs to be used continuously.
	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	
Voltage interruptions IEC 61000-4-11	0% UT; 250/300 cycle	0% UT; 250/300 cycle	
RATED power frequency magnetic fields IEC 61000-4-8	30A/m 50Hz or 60Hz	30A/m 50Hz or 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the A.C. mains voltage prior to application of the test level.			

Table 3

Guidance and Manufacture's Declaration – Electromagnetic Immunity			
This equipment should be used in the electromagnetic environment specified below. User should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80 MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any parts than the recommended separation distance that calculated from the equation applicable to the frequency of the transmitter.
	6Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz (a)	6Vrms	Recommended separation distance: $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz to 2.7GHz
Radiated RF IEC 61000-4-3	10 V/m 80MHz to 2.7GHz	10 V/m	$d = 6\sqrt{P/E}$ at RF wireless communications equipment bands (Portable RF communications equipment)

Table 3 (Continued)


			<p>(including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device).</p> <p>Where “P” is the maximum output power rating of the transmitter in watts according to transmitter manufacturer and “d” is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (b), should be less than the compliance level in each frequency range (c).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>Note1: At 80MHz and 800MHz, the higher frequency range applies.</p> <p>Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

Table 3 (Continued)

- a) The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.
- b) 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 this is used exceeds the applicable RF compliance level above, this should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating.
- c) Field strengths should be less than 3V/m in the frequency range of 150k-80MHz.

Table 4

Test Specifications for ENCLOSURE PORT IMMUNITY to RF Wireless Communications Equipment.						
Test Frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28
1 845						
1 970						

Table 4 (Continued)

2 450	2 400 - 2 570	Bluetooth, WLAN, 802.11 b/g/n. LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5 240	5 100 - 5 800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
5 500						
5 785						

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m test distance to permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz be used because while it does not represent actual modulation, it would be worst case.

Table 5

**Recommended Separation Distance between Portable and Mobile RF
Communications Equipment and the Nerve and Muscle Stimulator**

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Nerve and Muscle Stimulator as recommended below, according to the maximum output power of the communications equipment.

Table 5 (Continued)

This device can be used under the environment that radiated RF disturbances are controlled. User should maintain a minimum distance between portable and mobile RF communications equipment to prevent electromagnetic interference. Following recommended distance is calculated according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150kHz-80MHz $d = 1.2\sqrt{P}$	80MHz -800MHz $d = 1.2\sqrt{P}$	800MHz -2.7GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance “d” in meters can be estimated using the equation applicable to the frequency of transmitter, where “P” is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer.

Note1: At 80M and 800MHz, the separation distance for the higher frequency range applies.

Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and refraction from structures, objects and people.

Intended Use

The *SaeboStim Pro* device delivers muscle and nerve stimulation using the principles of both Neuromuscular Electrical Stimulation (NMES) and Transcutaneous Electrical Nerve Stimulation (TENS).

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 and maintaining or increasing range of motion. In addition, Transcutaneous Electrical Nerve Stimulation (TENS) is used as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain problems and chronic pain syndroms.

SaeboStim Pro Features

- 2 Independent Channels
- 10 NMES Programs
- 3 TENS Programs
- 1 Sensory Electrical Stimulation (SES) Program
- Adjustable Pulse Rates and Durations
- Adjustable Ramp up/Ramp Down Time Controls
- Adjustable On/Off Time Controls
- Trigger Function

Description of Device and Controls

1. **On/Off Switch:** Slide the switch to turn the device on/off.
2. **Channel Key:** Press the Channel Key (CH) to switch between the 2 channels. If icon A is flashing on the screen, the user can set the Intensity level or activate the Trigger Mode in Channel A. If icon B is flashing on the screen, the user can set the Intensity level or activate the Trigger Mode in Channel B. The flashing will stop following 10 seconds of no operation.
3. **Pause/Trigger Key:** The Pause/Trigger Key (T) serves both functions.
 - **Pause:** When the stimulator is running a treatment program, press the Pause/Trigger Key once to pause the treatment.



Figure 1

- **Trigger Mode:** Once the desired Channel Key is pressed and flashing, press and hold the Pause/Trigger Key for 3 seconds to activate the Trigger Mode. An “arrow” symbol will appear below the corresponding Channel. The stimulator enters a contraction period for as long as the Key is pressed. When the Key is released the stimulator enters the relaxation period (stimulation is not on).

To stop using the Trigger Mode and return to the programmed contraction/relaxation cycle, press the desired Channel Key first, followed by the desired intensity keys. The Trigger Mode will be deactivated.

Note: Trigger Mode is available in programs 1, 2, 4, 6, 7, 9.

4. **Lock:** Press the Lock Key and hold for 2 seconds to prevent unwanted changes to the output intensity. The Lock icon will display on the screen. Press and hold for 2 seconds to unlock the intensity keys. The lock icon will disappear from the screen.

5. **Intensity:** Once the desired Channel Key is pressed and flashing, press the Intensity Keys (-/+) to the corresponding Channel to adjust the intensity levels in the treatment. The intensity increment is 1 mA. Pressing (+) button during treatment increases the intensity level by a factor of one for that channel. Pressing (-) button during treatment decreases the intensity level by a factor of one. The user can feel the stimulation when he or she increases or decreases the intensity level. Intensity range is 0–60mA at the load of 500Ω.

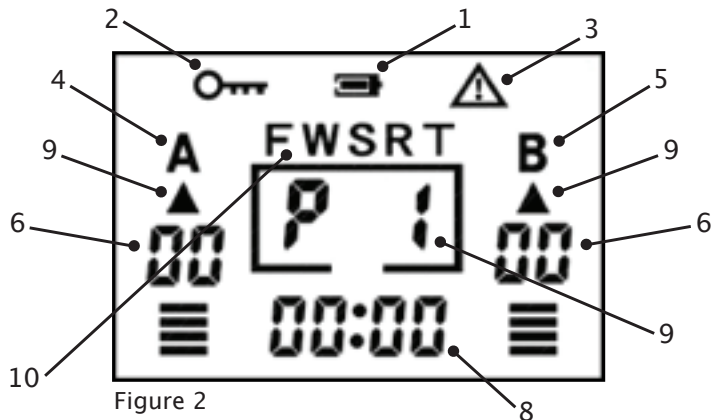
6. **Program:** Once the desired Channel Key is pressed and flashing, Press the Program Key (P) to select the required treatment program. Refer to page 42 for a list of the available programs.

Note: program 1 to 14 are preset, however, program 15 allows for customization.

7. **Output Ports:** Channel A/B cables supplied are inserted into the ports on the top portion of the device.

8. **DC Jack:** The stimulator can be powered through the USB cord. For USA shipments only, an AC adaptor will also be provided. Connect one end to a power source and other to the connector on the left side of the unit.

Display Screen Symbols



Description of Display Screen Symbols

1. **Battery** – remaining battery power.
2. **Lock** – prevents unwanted changes to the intensity level.
3. **Warning** – indicates poor Electrode Wires to Electrode Pads or Electrode Pads to skin connection.
4. **A** – Channel A.
5. **B** – Channel B.
6. **Intensity Bar** – when activated the intensity bar will increase and decrease corresponding to the contraction and relaxation cycle on each Channel.
7. **P1** – indicates the current treatment program.
8. **Time** – length of time remaining.
9. **Arrow** – when Trigger Mode is activated, an arrow symbol will appear below the corresponding Channel.
10. **FWSRT** – custom icons appear when pressing the Program Key for 3 seconds.

Getting Started

Unpacking the Device

Remove the *SaeboStim Pro* and all of the components from the packaging. Verify that all parts are present.

See **Figure 3**.

Parts Included:

- **SaeboStim Pro Device:** 2 Channel Stimulator.
- **Electrode Wires:** The Electrode Wires are used to connect between the device and the Electrode Pads.
- **Electrode Pads:** The Electrode Pads are connected to the stimulator through the Electrode Wires, providing stimulation to the desired muscle.
- **Power Adapter/Power Cord:** This supplies power for the stimulator when it is not powered by batteries. The Power Adapter is for US customers only.
- **Carrying Case:** The stimulator can be stored securely in the Carrying Case.
- **Batteries:** Three AAA batteries are included. These are not rechargeable.



Figure 3

Installing Batteries

The unit is powered by three disposable, standard AAA alkaline (non rechargeable) batteries available in all consumer electrical stores. The battery compartment is located on the rear of the device. In order to open, unscrew and place your thumb onto the symbol shown on the battery compartment and slide firmly to remove. **See Figures 4 & 5.** A directional arrow on the battery cover indicates the direction in which the cover opens.



Figure 4



Figure 5

The correct poles and how to insert the battery is marked by the image of a battery and its connections in the compartment. To close the battery compartment, slide the battery cover so the connections meet and let it click in by applying slight pressure. Re-insert the screw and tighten securely.

Note: Keep the battery cover closed when the unit is on.

Clean Skin

Remove all jewelry and clean skin thoroughly with soap and water. Rinse and dry. Electrodes do not work well if any lotion, oil, dirt is on the skin.

Plug in Electrode Wires

The Electrode Wires provided with the unit are inserted into the Output Ports (OUT A / OUT B) located at the top of the Stimulator. The wire connectors have been designed so they will insert and connect firmly into place. If only one Electrode Wire is needed, plug it into Outlet A. **See Figures 6 & 7.**



Figure 6



Figure 7

Connect Electrode Pads and Position on Skin

Connect the Electrode Pads provided to the Electrode Wires. No metal should be visible. See **Figure 8**.



Figure 8

Remove the Electrode Pads from the film by grasping the edge of the Electrode and peeling it off. See **Figure 9**.



Figure 9

Place the Electrode Pads on the precise skin location by applying the center of the Electrode first and smoothing down the edges. The complete surface of the Electrodes should be in contact with the skin. See Figure 10.



Figure 10

Powering the Device

Slide the toggle switch on the right side of the device to turn on the stimulator. The screen will show all of the icons for 2 seconds before transitioning to the start screen. See Figures 11 & 12.



Figure 11



Figure 12

Select and Start a Program

Step 1

Press the Channel Key (CH) once and icon A will flash. Then, press the Program Key (P) to select the appropriate treatment program. **See Figures 13 & 14.** Displayed on the screen will be “P” followed by the number corresponding with the Program (i.e., P1). **See Figure 15.**

To view the 14 preset Programs, go to page 42 for more information.

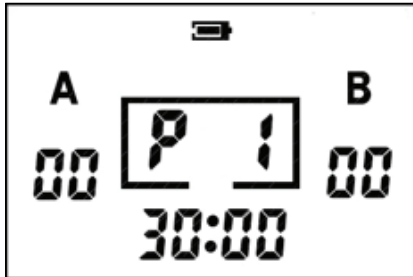


Figure 15



Figure 13



Figure 14

Select and Start a Program

Step 2

Once the program is selected, and while Channel A icon is still flashing, press Intensity Keys (-/+) to adjust the intensity to the desired level in Channel A. Pressing (+) button during treatment increases the intensity level by a factor of one for that channel. Pressing (-) button during treatment decreases the intensity level by a factor of one. **See Figure**



Figure 16

The user can feel the stimulation when he or she increases or decreases the intensity level. The Intensity Bar will increase and decrease corresponding to the contraction and relaxation cycle on each Channel. **See Figures 17 & 18.**

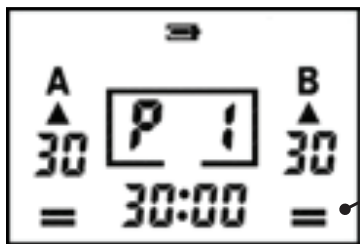


Figure 17: Intensity Bar Decreasing

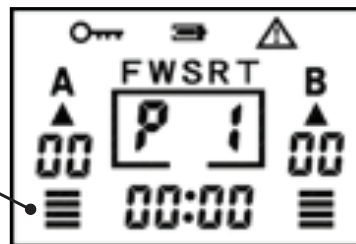


Figure 18: Intensity Bar Increasing

Note: To utilize both channels (4 electrodes instead of 2), press the Channel Key again so icon B is flashing. While Channel B icon is still flashing, press Intensity Keys to adjust the intensity to the desired level in Channel B.

Step 3

Once the desired intensity level(s) are reached, the user can press and hold the Lock Key for 2 seconds to avoid unwanted changes to the intensity level. To disable the Lock function, simply press and hold the Lock Key again for 2 seconds and the key symbol will disappear from the display. See Figure 19.

Note: To pause the treatment session, press and release the Pause/Trigger Key (T). The pause icon will appear and the device will interrupt the program. To resume the session, press the “T” Key again and the treatment session will restart. See Figure 20.



Figure 19



Figure 20

Trigger Mode

The Trigger Mode is possible in Programs 1, 2, 4, 6, 7, and 9. To activate, select the desired Channel by pressing the Channel Key (i.e., Ch A or Ch B), so “A” or “B” is flashing. **See Figure 21.** When the selected Channel is flashing, press the Pause/Trigger Key (T) and hold for 3 seconds to activate the Trigger Mode. **See Figure 22.**

An “arrow” symbol will appear below the corresponding Channel. **See Figure 23.** When pressing the “T” key, the stimulator enters a contraction cycle for as long as the key is pressed. When the key is released the stimulator is off. During the length of the Trigger Mode session, the corresponding Channel will continue to flash and the arrow symbol will remain visible.

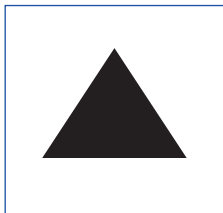


Figure 23

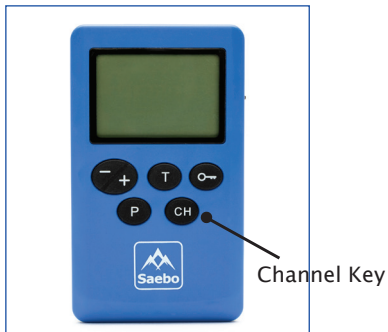


Figure 21



Figure 22

To return to the programmed contraction/relaxation cycle, press the intensity key of the appropriate Channel. **See Figure 24.** The corresponding Channel will stop flashing after approximately 5 seconds and the arrow symbol will turn off.

Caution: In Trigger Mode, where stimulation is held constant for several continuous seconds, muscle fatigue could occur.

Custom Program (Program 15)

To customize the parameters, press the Program Key (P) and hold for 3 seconds. **See Figure 25.**

The icons of F, W, S, R, T will flash simultaneously. **See Figure 26.**



Figure 26



Figure 24



Figure 25

Icon /Range

- F** – Frequency, range: 1~125Hz (below 5Hz: with steps of 1Hz; above 5Hz: with steps of 5Hz)
- W** – Pulse Width, range: 100~350 μ s (\pm 10%, with steps of 50 μ s)
- S** – Contraction time, range: 1~10s (with steps of 1s)
- R** – Relaxation time, range: 1~10s (with steps of 1s)
- T** – Treatment time, range: 5~60 minutes (with intervals of 5 minutes)

Press the Program Key again to select icon F (Frequency). The other 4 icons are temporarily deactivated. This means that the Frequency (F) is now adjustable. Press the Intensity Keys to adjust the Frequency. **See Figures 27 & 28.**

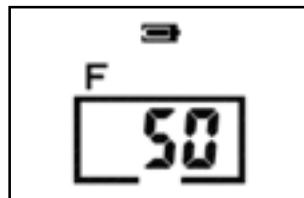


Figure 27



Figure 28

After the Frequency is set, press the Program Key again to switch to Pulse Width. See **Figure 29**.

The icon W is on, and the other 4 icons are off. Press the Intensity Keys to adjust the Pulse Width. To set the other parameters, repeat the above steps.

Once finished, Press the Pause/Trigger Key to exit the parameters setting mode. See **Figure 30**.

Note 1: The unit will automatically save the latest entries. To access the custom program for future use, select Program 15.

Note 2: To start the custom program, follow the steps under "Select and Start a Program" on page 29.



Figure 29



Figure 30

Sensory Electrical Stimulation (SES) Program (Program 14)

Sensory Electrical Stimulation (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. Clients suffering from impaired function, weakness and spasticity can benefit from the much-needed stimulation.



Figure 31

SaeboStim Pro offers a Sensory Electrical Stimulation program. Program 14 provides SES to the arm and hand using a specialized Electro-Mesh garment technology (sold separately). 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 through the stimulator.

To effectively perform sensory electrical stimulation, conductive garments and lotion will be required. They are NOT included with this device. To purchase, contact your Saebo representative for details.

Loose Electrode Indication

The *SaeboStim Pro* monitors the connection between the Electrode Pads and the user. When the Electrodes Pads exhibit a poor connection, the treatment will be paused and an audible beep will emit from the unit. The Warning symbol will display on the screen.

See **Figure 32**.

The user should check and reconnect the Electrode Pads or ensure good skin contact is present. The intensity level will be reset to zero requiring the user to press the intensity increase button to return to the desired level.



Figure 32

Treatment Completion

When the treatment is complete, the stimulation will stop automatically. At this stage, the unit should be turned off and all of the Electrode Pads can safely be removed from the skin by peeling the edge. Place Electrode Pads on film and store in a protective sleeve for future use.

Note: The unit will power off automatically after 15 minutes.

Helpful Hint: Patients with sensory loss should not over-stimulate. Consult your health professional for proper setup and protocol.

Usage of Electrode Pads

- It is advisable to consult a physician before or after use to avoid any complications.
- Remove body hair for better electrical conductivity. An electric razor or a pair of scissors is recommended.
- Please retain the film of the Electrode Pads when using it and cover after use.
- The Pads are for personal use only. Please do not share the Electrode Pads with other individuals.
- This product is consumable; improve the adhesiveness by adding a few drops of water and then drying it or replacing it with a new electrode.
- The replacement cycle of Electrode Pads varies by user. It is recommended that the user replaces the Electrode Pads every 2 weeks.
- Please do not use detergent or hot water to wash the Electrode Pads.
- Use plain water to clean the Electrode Pads and air dry.
- Please do not bend the Electrode Pads.
- This product's packaging and product appearance must be checked before use; it is forbidden to use if there is damage, dirt, or deformation.
- Electrodes cannot be placed near the heart.
- Electrodes cannot be placed near wounds or scars.
- If there is any pain during stimulation, it may be caused by following reasons: the placement of the electrode is inappropriate, please reposition; the electrode surface is damaged, please replace with a new one.
- Please stop using Electrode Pads if there is redness, swelling, or other allergic symptoms during usage. These are rare symptoms.
- Electrode Pad type: CM50D, diameter: 50mm
- Electrode Pad resistance is not greater than 180Ω ; keep electrode pad smooth, trimming neatly; physical electrode pad with an evaluation of cytotoxicity is not greater than 1.

Care and Maintenance

Device Storage

- Do not store in direct sunlight, high temperature, moist, dusty, or corrosive gas.
- Store where children cannot reach.
- Use a wet cloth with mild detergent or alcohol to clean the surface of the device.
- Do not immerse the electronic components into water.

Electrodes Maintenance

- Keep the gel surface of the Electrode Pad clean.
- After using the Electrode Pad, use the film cover to protect it.
- When the Electrode Pad is dirty or when the skin is tingling, rinse with a small amount of water and gently scrub with your fingers for a few seconds. After drying, it can temporarily restore its viscosity. If the water is too much, the viscosity will decrease.
- Please do not use tissue or cloth to wipe the gel surface.
- Please do not use fingernail or brush to scrape the gel surface.

Replace Batteries

- The battery icon will appear at all times during operation in the top center of the display.
- When the stimulator is in use, the individual bars on the battery icon disappear sequentially. When the battery has one bar left, the icon will flash to indicate the replacement of batteries or power via DC jack.
- Once all the bars have disappeared, the stimulator will beep for 10 seconds, battery icon will flash, and the stimulator will stop and power off.

Parameters

- Waveform Type – Symmetrical Biphasic
- Pulse Width – 100–350 μ s (\pm 10%), (with steps of 50 μ s)
- Pulse Rate – 1–125 Hz (\pm 10%), (below 5Hz: with steps of 1Hz; above 5Hz: with steps of 5Hz)
- Intensity: 0–60mA (\pm 10% or \pm 2mA, whichever is greater, 500 Ω load)

Performance Parameters

Power: 3* LR03 4.5V; or Power adapter, input AC 100–240V 50/60Hz 0.3A, output DC 5V /1.2A

Protection against electric shock: Class II

Safety class: BF type

Protection Grade: IP22

Shutdown current: \leq 0.1mA

Operating current: \leq 1200mA

Environmental Specifications

Working Condition

Temperature: 5° C – 40° C

Relative Humidity: \leq 80%

Atmospheric pressure: 86Kpa–106Kpa

Storage and Transport Condition

Temperature: –20° C–55° C

Relative Humidity: \leq 93%

Atmospheric pressure: 70 Kpa–106Kpa

Product size: 114mm \times 66mm \times 20mm

Product weight: 96g

Program Information

NOTE: Contraction time includes Ramp up and Ramp down times.

No	Prescription	Frequency (Hz)	Pulse Width (μ s)	Contraction (sec)	Relaxation (sec)	Ramp Up (sec)	Ramp Down (sec)	Trigger	Treat Time (mins)
1	Upper Extremity – Short Contraction	35	250	9	5	2	2	Yes	30
2	Upper Extremity – Long Contraction	35	250	14	10	2	2	Yes	30
3	Upper Extremity – Alternating <small>Note 1</small>	35	250	9	5	2	2	No	30
4	Upper Extremity – Advanced	60	250	14	10	2	2	Yes	30
5	Shoulder Subluxation	35	300	12	8	2	2	No	60
6	Lower Extremity – Short Contraction	35	350	9	5	2	2	Yes	30

Program Information (Continued)

No	Prescription	Frequency (Hz)	Pulse Width (μ s)	Contraction (sec)	Relaxation (sec)	Ramp Up (sec)	Ramp Down (sec)	Trigger	Treat Time (mins)
7	Lower Extremity - Long Contraction	35	350	14	10	2	2	Yes	30
8 Note 2	Lower Extremity - Alternating	35	350	9	5	2	2	No	30
9	Lower Extremity - Advanced	60	350	14	10	2	2	Yes	30
10	Edema	5	200	3	2	0	0	No	30
11	Pain 1	4	200					No	45
12	Pain 2	125	175					No	45
13 Note 3	Pain 3 (Alternating)	125	150					No	45
		4	250						
14 Note 4	SES	50	100					No	30
15	Custom	1~125	100 ~ 350	1-10	1-10	0	0	No	5-60

Program Information (Continued)

Note 1 (Program 3):

Channel A stimulates for 9 seconds (including Ramp up/down) and Channel B is off. Then, Channel B stimulates for 9 seconds (including Ramp up/down) and Channel A is off.

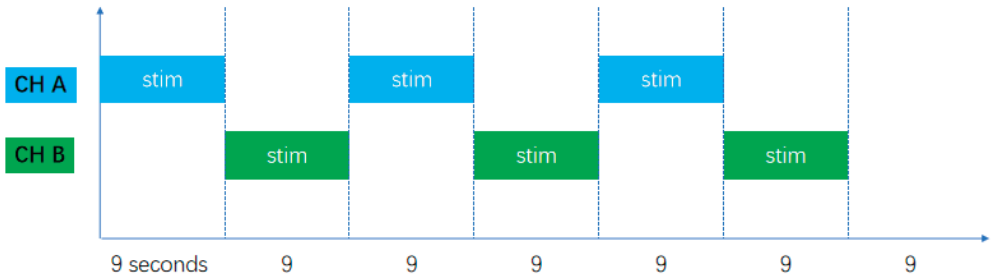
Repeat.

Note 2 (Program 8):

Channel A stimulates for 9 seconds (including Ramp up/down) and Channel B is off. Then, Channel B stimulates for 9 seconds (including Ramp up/down) and Channel A is off.

Repeat.

See below illustration

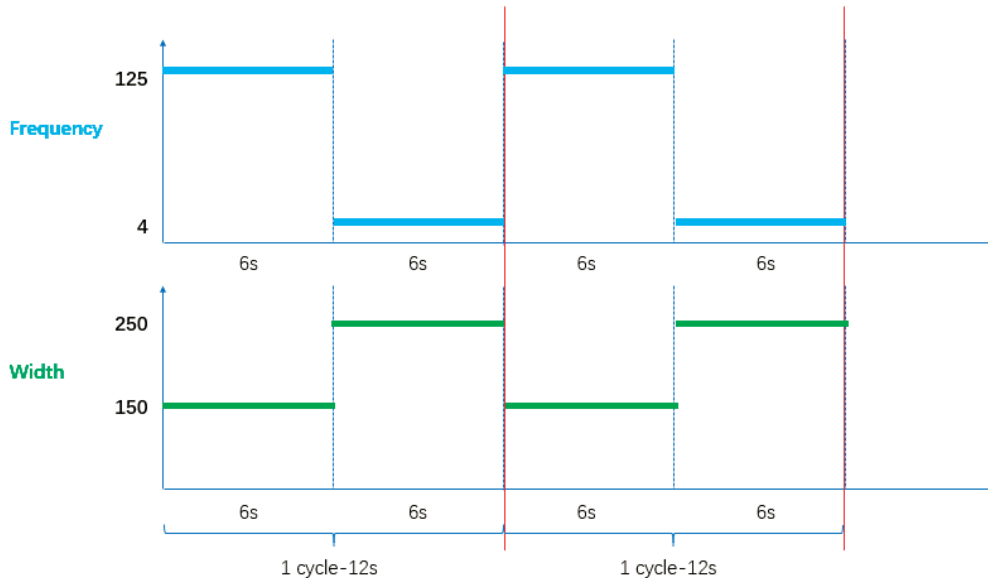


Program Information (Continued)

Note 3 (Program 13):

Constant stimulation for 45 minutes. In 12 seconds cycle, it remains at 125Hz, 150 μ s for the first 6 seconds, and 4Hz, 250 μ s for the second 6 seconds.

See below illustration




Note 4 (Program 14):

Program 14 is a Sensory Electrical Stimulation Program (SES). 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. Clients suffering from impaired function, weakness and spasticity can benefit from the much-needed stimulation.

Program 14 provides SES to the arm and hand using a specialized Electro-Mesh garment technology (sold separately). The Electro-Mesh garments consist of an elbow sleeve (arm stimulation) and glove (hand stimulation).

For optimum effectiveness, conductive garments and lotion will be required. To purchase, contact your Saebo representative for ordering details.

Troubleshooting

Problem	Possible	Solution
The display does not come on & there is no signal from the unit	Battery discharged	Replace battery
	Battery was incorrectly positioned	Remove battery, replace correctly
Battery symbol flashing, and the stimulator beeps for 10 seconds	The battery is low	Replace the battery
Stimulation received irregularly, only at a high intensity, or not at all	Faulty electrode wire	Replace electrode wire
Stimulator stops stimulation, and icon  display on the screen	electrode loose	<p>Check the connection between the stimulator and electrode wire</p> <p>Check the connection between the electrode wire and the electrode pads</p> <p>Check the connection between the electrode pads and skin</p> <p>Wet the skin with enough water for better conductivity.</p>

Technical Support

For technical support, please e-mail or call the number below:

Email: sales@saebo.com

Phone: 888-284-5433

Warranty

SaeboStim Pro carries a one year warranty, starting at the date of purchase.

Saebo will not provide free repair for the malfunctions caused by the following behaviors:

- Disassemble or modify the product without authorization.
- Accidentally drop the product during use or transportation.
- Lack of reasonable maintenance.
- Operate not according to the instructions.
- Repaired by unauthorized repair store.

Product Name: Nerve and Muscle Stimulator**Model: XFT-2000**

Shenzhen XFT Medical Limited



Room 203, Building 1, Biomedicine Innovations Industrial Park

#14 Jinhui Road, Pingshan New District

Shenzhen, China

Post Code: 518118

Tel: 86-755-29888818 Fax: 86-755-28312625

Hotline: 400-830-0991

E-mail: xft@xft.cnWebsite: <http://www.xft-china.com>**Authorized Distributor**

Saebo, Inc.

2459 Wilkinson Blvd.

Suite 120-B

Charlotte, NC 28208

Phone: (888) 284-5433

Fax: (855) 414-0037

Website: <https://www.saebo.com/>**US Agent**

Yang Lingyun

605 Sherwood Forest Place

Cary, North Carolina 27519

Phone: (919) 475-1044



www.saebo.com

CE rev 1/20