Saebo
MyoTrac Infiniti

Product Manual

Rehabilitating Lives.
Empowering Individuals.

Saebo MyoTrac Infiniti

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The Manufacturer:	Thought Technology Ltd.
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Product Name:	Saebo MyoTrac Infiniti System
Product #:	TT9895-EN, TT9890-EN
Device Name:	MyoTrac Infiniti Encoder
Device #:	SA9800

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Symbols

 This symbol means: "Read Instruction Manual"

 This symbol means: "Type BF (**B**attery-powered **F**loating) Equipment"

 This symbol means: "The pins inside the connectors next to this ESD (**E**lectro**S**tatic **D**ischarge) warning symbol should not be touched unless ESD precautionary procedures are known and used".

Safety Information

Caution & Restrictions

The sale and/or operation of this equipment are subject to legislation in many localities. Compliance with the above legislation rests with the importer, dealer, or user of the equipment as appropriate.

US Federal Law restricts this device to sale by, or on order of, a physician or any other practitioner licensed by the law of the state in which he or she practices to use or order the use of this device.

Contra-Indications

Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.

Powered muscle stimulators should not be used on cancer patients.

Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.

General Precautions

Precaution should be observed following recent surgical procedures when muscle contraction may disrupt the healing process.

Precaution should be observed where sensory nerve damage is present through loss of normal skin sensation.

Precaution should be observed where there is a tendency to hemorrhage following acute trauma or fracture.

Take care in arranging patient and sensor cables to avoid risk of patient entanglement or strangulation.

In rare cases some patients may experience skin irritation or hypersensitivity due to electrical stimulation or electrical conductive medium used. The irritation can usually be reduced by use of an alternative conductive medium or alternate electrode placement.

An effective treatment should not cause discomfort.

Intended Purpose

- Biofeedback, Relaxation & Muscle Re-Education purposes
- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Stroke Rehab by Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

Warnings

Not for diagnostic purposes, not defibrillator proof, not for critical patient monitoring.

Not for use with patients with undiagnosed pain conditions.
Do not use with diminished mental capacity or physical competence limiting the use of the device.

Use of any equipment in a biofeedback or stimulation context should be immediately terminated upon any sign of treatment-related distress or discomfort.

Use only the supplied power adaptor (GlobTek Part Number WR92B2500LF9P-Y-MED (WR95/WR93/WR97) or GS889).
Connecting the supplied power adaptor to the MyoTrac Infiniti while attached to a person is safe in clinical environment.

Do not plug third party sensors, electrodes or other accessories. Plug only equipment approved by Thought Technology Ltd.

Avoid accidental contact between connected but unused applied parts and other conductive parts including those connected to protective earth.

Explosion Hazard; Do not use in the presence of a flammable anesthetic mixture with air, or with Oxygen or Nitrous Oxide.

Do not immerse the unit in water or any other liquid substance.

Reusable electrodes present a potential risk of cross-infection especially when used on abraded skin, unless they are restricted to a single patient.

The device should be kept safely out of the reach of children.

Warnings for Electrical Neuromuscular Stimulation (applicable to EMG-Triggered Stimulation)

Patients with a history of arrhythmia or cardiac disturbances should be carefully evaluated before stimulation is prescribed.

Avoid stimulation of muscle under recent scar tissue.

In all cases ensure that stimulation does not exceed the patient's tolerance level.

Patients with an implanted electronic device (for example a cardiac pacemaker) should not be subjected to stimulation unless specialist medical opinion has first been obtained.

Use of stimulation over the menstruating or pregnant uterus should be avoided.

Electronic stimulator devices should only be used for adjunctive therapy for the treatment of medical diseases and conditions.

Long term effects of chronic electrical stimulation are unknown.

Safety has not been established for use of neuromuscular devices in pregnancy.

Adequate precautions should be taken in the case of persons with suspected heart problems.

Adequate precautions should be taken in the case of persons with suspected or diagnosed epilepsy.

The device should not be used to stimulate over the carotid sinus nerves, especially in patients with known sensitivity to the carotid sinus reflex.

Severe spasm of the laryngeal and pharyngeal muscles may occur when the electrodes are positioned over the neck or the mouth.

The contractions may be strong enough to close the airway or cause difficulty in breathing.

Electronic stimulator devices should not be applied transcerebrally.

Electronic stimulator devices should not be used over swollen, infected or inflamed areas or skin eruptions, e.g. phlebitis, thrombophllebitis, varicose veins.

Caution should be used in the transthoracic application of electronic stimulation devices. The application of electrical current into the heart may cause arrhythmias.

Powered muscle stimulators should be used only with the leads and electrodes approved for use by Thought Technology Ltd.

Use only the electrodes designed for stimulation approved by Thought Technology Ltd.

Do not use, for instance, EMG electrodes. This device is capable of generating current densities exceeding 2mA r.m.s./cm² this may require special attention of the operator. Do not exceed 0.1watts/cm². The proper use of the stimulation electrodes approved by Thought Technology Ltd prevents from exceeding these limits. Do not remove, partially or totally, an electrode while stimulation is performed.

Adverse Effects

Skin irritations and burns beneath the electrodes have been reported with the use of electric muscle stimulators.

Warnings for EMG Biofeedback (applicable to EMG-Triggered Stimulation)

Make sure to remove electrodes from sensor snaps immediately after use.

Do not operate the MyoTrac Infiniti within 10 feet (3 meters) of an operating cellular phone, similar radio transmitting device, other powerful radio interference producing sources such as arc welders, radio thermal treatment equipment, x-ray machines, or any other equipment that produces electrical sparks. Portable and mobile RF communication equipment can affect this equipment.

Radiated radio frequency electromagnetic fields can cause performance degradation in the MyoScan EMG sensor and the MyoTrac Infiniti. Do not operate the MyoTrac Infiniti within 3 feet (1 meter) of any electronic equipment, such as monitors or computers. In the worst case, an RF field strength of 22mV/M can cause an increase of 1μV in the signal reading from a MyoScan sensor. Be sure to keep in mind that a very relaxed muscle should provide an EMG reading of approximately 1-3μV.

Warnings for EMG-Triggered Stimulation

Use only stimulation electrodes on active sites (blue and yellow connectors). Use EMG electrode only for the reference (black connector). Stimulation electrodes are suitable for EMG monitoring.

Additional Precautions & Warnings

Medical opinion must be obtained before use on persons who are insulin-dependent diabetics or for persons who are under medical supervision for any cognitive dysfunction. Medical opinion must be obtained before persons with any serious illness or injury applies muscle stimulation.

Avoid placing the electrodes directly over metal implants - they may be placed on the nearest muscle.

Precaution must be observed when applying muscle stimulation within one month of an UD contraceptive device (e.g. coil) being fitted or within 6 weeks after giving birth. We recommend that no stimulation is applied around the abdominal or lower abdominal region during this time.

Precaution must be observed before applying stimulation on areas of injury or restricted movement (e.g. fractures or sprains).

Once the treatment has ceased always remember to reduce all amplitude controls to a minimum or turn off the unit. If in any doubt always seek medical opinion.

Lead pins and electrodes must only be connected as described in this manual and must not be connected to other objects.

Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the site of the stimulator electrodes, and possible damage to the stimulator.

Operation in close proximity to shortwave or microwave therapy equipment may produce instability in the stimulator output.

Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when the stimulator is in use.

The MyoTrac Infiniti must not be used with any other unit which provides electrical current into the body (e.g. Interferential or another muscle stimulator).

It may not be suitable to use the MyoTrac Infiniti on a person at the same time as other equipment. You should check suitability before use.

If damage is evident of the unit or accessories, discontinue use and contact your supplier for further information on repair.

To prevent voiding warranty by breaking connector pins, carefully align white guiding dot on sensor plug with slot on sensor input.

Sensors and equipment damaged by static electricity are not covered under warranty. To prevent static discharge from damaging the sensor and/or the device, use anti-static mats or sprays in your working area. A humidifier may also be used to prevent static environments by conditioning hot, dry air. It is recommended that all staff involved with the unit receive an explanation of the ESD symbol and the precautions described above as a minimum.

Use of accessories, transducers or cables other than those specified by Thought Technology ltd may result in increased emissions or decreased immunity of the equipment to electromagnetic energy (see tables below, for more information).

Technical Information

This product conforms to ISO Medical standards EN60601-1, EN60601-2-10 and EN60601-2-40; some labeling may indicate superseded standards.

Table of Contents

Introduction

The Saebo MyoTrac Infiniti is a total body solution that fits into the palm of your hand. This device is an advanced biofeedback electrical stimulation system that offers over 60 preset programs to choose from. This all-in-one revolutionary device offers 4 treatment modalities which include evidenced based features ranging from EMG biofeedback, electrical stimulation, EMG triggered stimulation, and the ground breaking, patent pending reciprocal EMG triggered stimulation for agonist/antagonist training.

The Saebo MyoTrac Infiniti can measure 2 channels of high resolution surface EMG for biofeedback training. In addition, it provides 2 channels of electrical stimulation. This gives you the ability to combine biofeedback and stimulation as one treatment modality. Therefore, your patients will be required to actively participate by contracting or relaxing their muscles in order to receive the stimulation to the appropriate area.

Finally, the Saebo MyoTrac Infiniti has a new unique foot drop program using cutting edge EMG triggered stimulation technology. Your client's very own EMG signal will trigger the stimulation during gait. This offers a more natural gait cycle that will lead to precise, consistent and timely stimulation.

Chapter 1

Saebo MyoTrac Infiniti Components

USB

Compact
Flash

Touch Screen

AC Power
Adaptor

Rugged
Ergonomic Case

Headphone
Jack

On/Off

2 Channel EMG Biofeedback &
Stimulation

1. Compact Flash for increased memory capacity.
2. USB (for factory reprogramming only).
3. AC Power Adaptor battery charging jack for wall connection enables fast built-in battery charging.
4. Headphone Jack for stereo sound feedback (or use built-in speakers).
5. Push Button On/Off switch with membrane cover to prevent accidental switching.
6. 2 Channels of Surface EMG and Stimulation.
7. Rugged Ergonomic Case designed to withstand the rigors of daily use. Easy to hold or attach to the subject using belt clip.
8. Touch Screen enables graphically guided navigation through the Saebo software.

Tapping

Like using a mouse on the computer screen, the Saebo MyoTrac Infiniti can be used with a finger or stylus to tap the buttons directly on the screen. The first time the handheld unit is on, or if the power has been disconnected for an extended period, a set of welcome screens including calibration time and date setting will be displayed. The calibration allows the handheld unit to detect exactly which button is being pressed.

Note: Never use a pen, pencil or other marking or sharp object on the screen. Damage resulting from misuse of the screen is not covered by warranty.

Power Supply & Battery Charging

The unit comes with a wall mounted AC power adaptor and a battery pack that can be recharged in the unit.

AC Power Adaptor

The AC power adaptor is used to charge the battery pack inside the unit. Connect one end to the wall and the other to the connector on the left side of the unit (shown in the previous section). In a clinical environment, it can also be used to power the unit, while being used on a patient.

Note: The AC adaptor must only be used for charging the batteries when using at home.

Note: Use only Saebo supplied wall mounted chargers with this device. Failure to do so could result in potential injury. Use only GlobTek Part Number WR9אB2500LCP-Y-MED where א= 2 for North America, א=3 for Europe, א=5 for United Kingdom and א=7 for Australia with the exception of Japan where the part number is GS 889.

Charging the Battery Pack

To start charging, connect the AC adaptor to the unit and plug the other end into an outlet. If the unit is off, turn it on. Wait a few seconds and turn the unit off again. The screen displays a battery symbol. Charging action is shown with an animation of the battery filling up. When the battery is fully charged, the symbol shows a full battery.

A full charging cycle from fully empty to fully charged will take approximately 2hrs. The charging cycle does not need to be completed in full; it can be stopped anytime by removing the connector.

If the power adaptor is plugged into the unit while it is turned off, it will start charging within one minute.

Note 1: The rechargeable batteries must be fully charged prior to initial use. In order for the batteries to reach full capacity it may be necessary to charge them several times (~2-8) after initial use.

Note 2: Use only battery packs from Saebo, as use of other battery packs will damage the device.

Using Alkaline Batteries

Note: When changing batteries it is recommended to plug the unit into the power adaptor. Failure to supply external power will result in data loss.

The unit also works with four standard alkaline AAA batteries available in all consumer electrical stores. This can be useful, if you do not have time to recharge the battery pack. To replace the battery pack with alkaline batteries, locate the battery compartment on the back of the unit.

The battery compartment cover slides open by pushing up using the notch provided. Gently pull the battery connector next to the mark BATT and remove the battery.



Place four AAA batteries in the slots, observing the polarity as illustrated. Please note that a diagram of the correct battery polarity is embossed on the inside surface of the compartment. Replace the cover.

Navigation Buttons

The following table lists the most common buttons you will use to navigate in your Saebo MyoTrac Infiniti.

	Go to next screen. If used in conjunction with a list (button on the right of the screen), it also validates the selection in the list.
	Go to previous screen.
	Validate settings ("OK button")
	Cancel
	Arrows to move up/down in a list or to increase/decrease a threshold value
	Settings (general settings of the device or parameter settings)
	Database (recorded sessions)
	Line Graph screen
	Bar Graph screen
	EMG session
	Electrical Stimulation (STIM) session
	EMG Triggered Stimulation (ETS) session
	Reciprocal EMG Triggered Stimulation (RETS) session

	Program
	Custom
	EMG Assessment
	Record/Start/Stop
	More information or second screen
	Edit
	Top spyglass allows you to zoom the scale in/out. Bottom spyglass shifts the scale to a specified range.
	Statistics
	Saved sessions can be replayed on Compact Flash.

Settings Menu

The Settings Menu is accessible from the main menu. It controls the global settings of the Saebo MyoTrac Infiniti. The settings menu consists of two display windows. The second window is accessible by clicking the "Welcome" button. The "back arrow" button of the second window is used to go back to the first screen.

Main Menu   First Window   Second Window

To customize settings, first click on the "Welcome" button to advance to the second display window.

1. Calibration

The touch screen must be calibrated to match the touch sensitivity with the LCD display. It takes 3 points: the two corners and the center. The center is used to verify the calibration. Calibration settings are stored and remain as long as the battery is not fully discharged. If the calibration settings are missing, the user is asked to calibrate the screen at power-up.

2. Clock

This screen is used to change the time and date. The time format is 24h. The date format is MM/DD/YYYY. The time and date remain as long as the battery is not fully discharged. If the time and date are lost, the user is asked to calibrate the screen at power-up.

3. Due Date Rental

This feature allows the owner to lend the unit or to rent it out. The owner can set a due date and lock it using a 4-digit code. The device will not work following the due date established. The 4-digit code will be required to re-enable the unit.
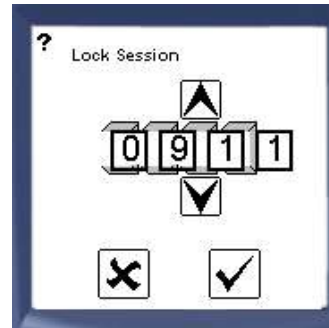
4. LCD Display
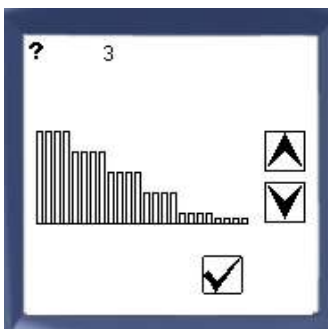
LCD contrast can be adjusted using the up/down arrows. It remains as long as the battery is not fully discharged. The default value is middle contrast.

5. Lock

This feature allows the user to lock the unit so that only a given session (EMG, STIM ETS, or RETS) can be used. The user must first select a program, choose appropriate parameters and then enter a 4-digit code.
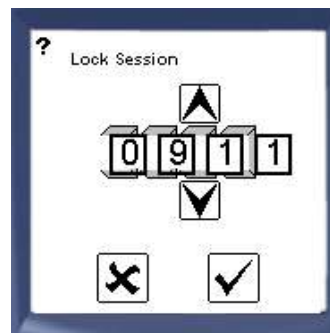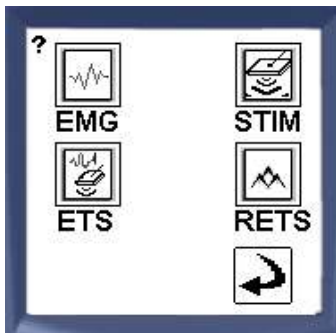
6. About

This screen gives information regarding the in-factory configuration of the unit.

To continue with customizing the unit, return to the first window under "Settings" and tap on the back arrow.

7. Display

The Display setting manages the display of the EMG biofeedback data in EMG, EMG Triggered Stimulation and Reciprocal EMG Triggered Stimulation sessions. The user can decide to always use a given display (Bar Graph or Line Graph) or to be prompted every time a new session starts. The selected option remains when the unit is shut down. By default, "Always ask for display type" option is selected.

Refer to Chapter 2 for detailed information regarding Bar Graph and Line Graph displays.

8. Save

EMG biofeedback sessions can be recorded and saved. Items that can be saved under the EMG biofeedback session consist of patient ID, patient #, time, date, duration, program parameters and performance statistics. The current version of the Saebo MyoTrac Infiniti does not allow the recordings to be exported.

The sessions can be saved in two different locations. The most common way to save a session is internally on the device (On-Board Memory). At the top of the Save screen, an "on-board memory bar" will provide details regarding how much storage is available. When the memory bar is completely full (100%), some of the saved sessions will need to be removed/deleted in order to create more space. If more memory is needed, consider saving to a Compact Flash card. A Flash Card can be inserted on the front end of the device.

Compact Flash Card – This storage medium allows you to record more information. The session can also be replayed on the unit. This information can be reviewed on a computer using the report generator application. Please contact Saebo to purchase the Compact Flash Card.

> **Note 1:** Do not remove the CF card without first stopping recording. If the CF card is removed during recording, you will lose all the data for the current session.

> **Note 2:** Stimulation, EMG Triggered Stimulation, and Reciprocal EMG Triggered Stimulation cannot be recorded and saved.

> **Note 3:** To avoid saving EMG Biofeedback sessions, select the "No Save" icon and the session will not be saved. To save a future session, select either "On-Board Memory" or "Compact Flash".
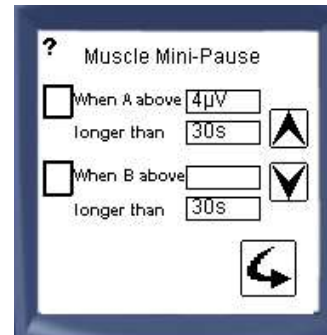
9. Sound

From the Settings menu, the user can change the volume and enable sound feedback for the EMG, EMG Triggered Stimulation and Reciprocal EMG Triggered Stimulation sessions.

Volume: Global sound volume can be adjusted in this screen. The voice in the program (saying "work" or "rest" for instance) can be disabled as well as the touch sound.
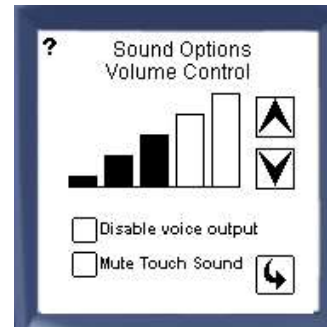
Mini-Pause: This alarm is used to tell the patient to rest the muscle when contracted too long. The timings are adjustable and the alarm can be independently enabled on Channel A or B. This feature is only available for EMG sessions under the Assessment Mode.

Feedback: During an EMG, EMG Triggered Stimulation or Recriprocal EMG Triggered Stimulation sessions, the user can select different styles of sound feedback for each of the two channels independently.
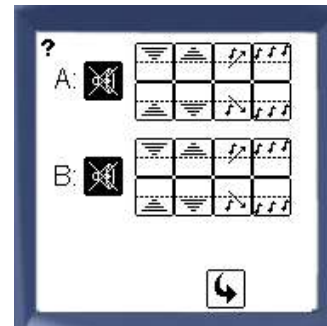
The styles are:

- ![icon] No feedback.

- ![icon] Proportionally increasing above threshold (The higher the EMG signal goes above the set threshold, the quicker the tone of the audio feedback).

- ![icon] Proportionally decreasing above threshold (The higher the EMG signal goes above the set threshold, the slower the tone of the audio feedback).

- ![icon] Proportionally increasing below threshold (The lower the EMG signal falls below the set threshold, the quicker the tone of the audio feedback).

- ![icon] Proportionally decreasing below threshold (The lower the EMG signal falls below the set threshold, the slower the tone of the audio feedback).

- ![icon] Single sound when threshold is crossed above (A tone is heard at the moment the EMG signal crosses above the threshold).

- ![icon] Single sound when threshold is crossed below (A tone is heard at the moment the EMG signal crosses below the threshold).

- ![icon] Continuous sound when EMG signal is above threshold (A tone is heard continuously while the EMG signal remains above the threshold).

- ![icon] Continuous sound when EMG signal is below threshold (A tone is heard continuously while the EMG signal remains below the threshold).

Note that these sound options are also available from the bar graph or line graph before starting a session by clicking on the speaker button.

10. Power

The Power screen gives information regarding power source (power adaptor, USB, rechargeable batteries, or AAA batteries), power source voltage, as well as the charging state of the battery.

Chapter 2

Line Graph & Bar Graph Displays

The Display setting manages the display of the EMG biofeedback data in EMG, EMG Triggered Stimulation and Reciprocal EMG Triggered Stimulation sessions. The user can decide between two display options -- Line Graph or Bar Graph. Below is information for these two displays.

A. Line Graph Display
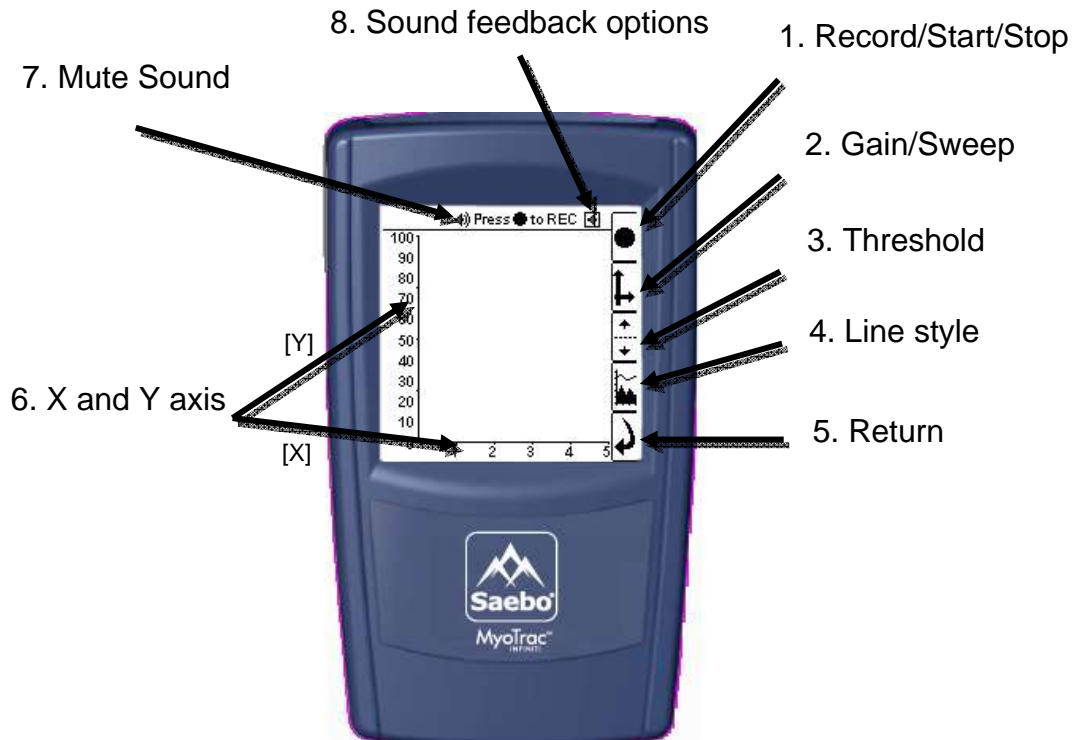
1. Record/Start/Stop – To start recording, press on the circle. It will change to a square. To stop recording, press it once again. During recording, the word "REC" flashes in the status bar at the top of the screen.

Note: This unit will only record the EMG biofeedback sessions. It will not record stimulation, EMG Triggered Stimulation or Reciprocal EMG Triggered Stimulation session. For these sessions, the Record button will serve as a Start/Stop button.

2. Gain/Sweep –To change the scale of either X or Y axis, press . Use the [+] and [–] buttons to increase or decrease the Y scale. To change the "X" scale, press and use the same [+/-] buttons. To go back to "Y", press the button . To return to the main menu, press .

3. Threshold – Allows the user to set a threshold for sound feedback or triggering stimulation. To change a threshold, press . For EMG and EMG Triggered Stimulation

the button ![A/B icon] is used to select the threshold of either channel A or B (selected channel in bold). With either A or B selected, use the + and − buttons to move the position of the threshold up or down on the range. The button below depicts an eye either open or closed (👁 or 😴). This is used to show or hide the selected threshold.

Note: For RETS the thresholds letters are A (for Activation) and D (for Deactivation) and they cannot be hidden.

4. Line Style – This button enables you to select whether Channel A should be filled or unfilled. Here you can also decide to show or hide the signal for each of the channels (👁 or 😴). Only Channel A has the Line Style option.

5. **Return** – To stop the session.

6. X and Y Axis – X axis (horizontal) shows the time and Y axis (vertical) shows the EMG level in micro-Volts.

7. **Mute Sound** – Tap on this button to mute the sound.

8. Sound Enabled – Use this button to disable sound feedback in this screen. The speaker symbol has a cross through it if the sound is disabled. Before recording begins, this button ◀ is also used to modify the sound settings (volume, mini-pause if available and audio feedback)

B. Bar Graph Display
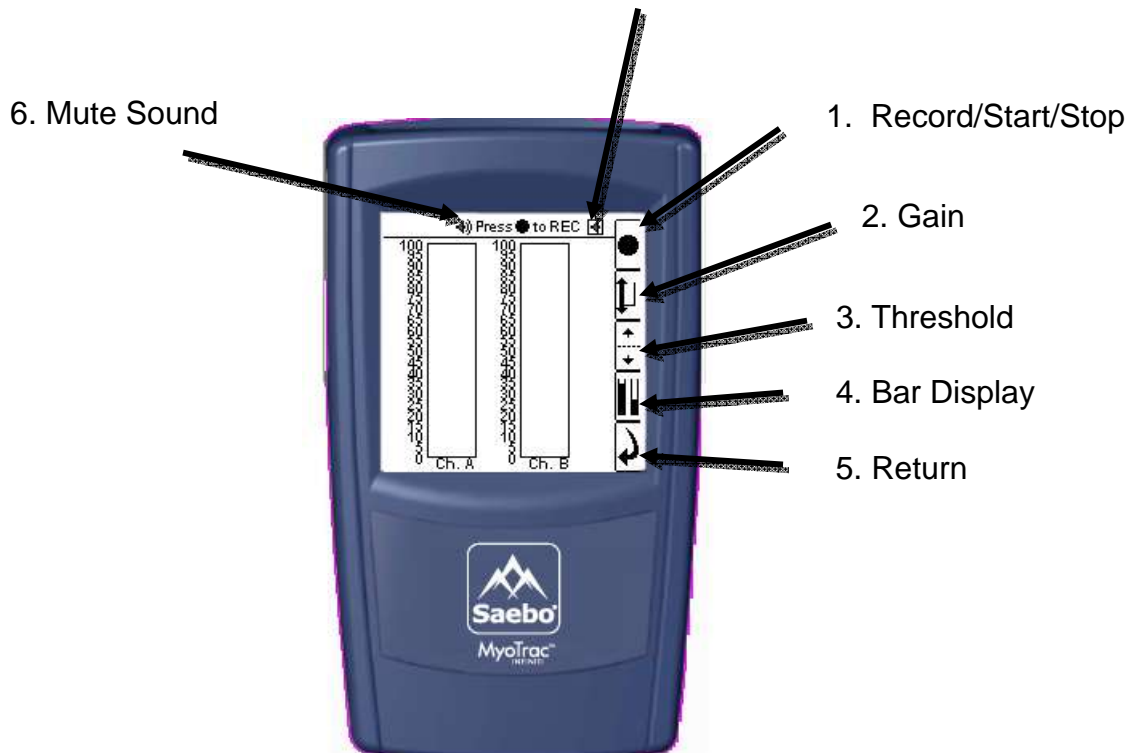
1. Record/Start/Stop – To start recording, press on the circle. It will change to a square. To stop recording, press it once again. During recording, the word "REC" flashes in the status bar at the top of the screen.

Note: this unit will only record the EMG biofeedback sessions. It will not record, stimulation, EMG Triggered Stimulation or Reciprocal EMG Triggered Stimulation session. For these sessions, the Record button will serve as a Start/Stop button.

2. Gain – The Y axis shows the EMG level in micro-Volts. To change the Y-scale, press ⌊. The first button allows you to independently change the scale for the A or B channel; use it to select the channel you want to change (selected channel is bold). Then use the + and – buttons to increase or decrease the scale. To return to the main menu, press ↵.

Note: an arrow is displayed on the bottom or on the top if the data is out of range.

3. Threshold – Allows the user to set a threshold for sound feedback or triggering stimulation. To change a threshold, press ⬍. For EMG and EMG Triggered Stimulation the button is used to select the threshold of either channel A or B (selected channel in bold). With either A or B selected, use the + and – buttons to move the position of the threshold up or down on the range. The button below depicts an eye either open or closed (👁 or 👁). This is used to show or hide the selected threshold. For RETS the thresholds letters are A (for Activation) and D (for Deactivation) and they cannot by hidden.

4. Bar Displays – This button changes the bars displayed in the screen. There are four choices: both bars A and B, just A, just B, or the ratio of A/B and B/A.

5. **Return** – To stop the session.

6. Mute Sound – Tap on this button to mute the sound.

7. Sound Feedback – Use this button to disable the sound feedback being given in this screen. The speaker symbol has a cross through it if the sound is disabled. Before recording begins, this button ◀ is also used to modify the sound settings (volume, mini-pause, if available and audio feedback).

Chapter 3

Skin Preparation

Proper skin preparation is essential for a quality EMG measurement and stimulation. Remove hair to improve adhesion of the electrodes. Clean skin with alcohol or conductive cleaning pastes prior to use for best performance. Inspect the skin for small abrasions or openings. Apply the electrodes so they are smooth on the skin with no wrinkles. Finally, consider Saebo's conductive liners to maintain adequate electrode contact to the skin and prolong electrode use.

Electrode Application

The electrode application for EMG Biofeedback, Electrical Stimulation, EMG Triggered Stimulation, and Reciprocal EMG Triggered Stimulation varies. Please refer to the below to determine proper placement of the electrodes for the various modes.

EMG Biofeedback Electrode Application:
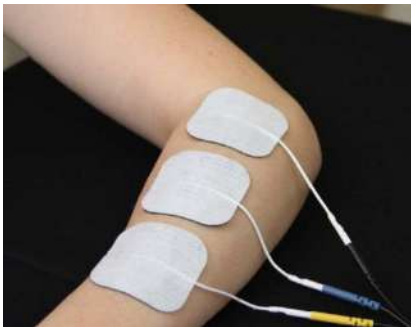
Three (3) electrodes are required for EMG Biofeedback. No stimulation will occur during the EMG sessions.

Black = reference
Blue = (+)
Yellow = (-)

Note: The blue and yellow leads can either be proximal or distal. The black reference lead can be placed anywhere on the body.

Electrical Stimulation Application:
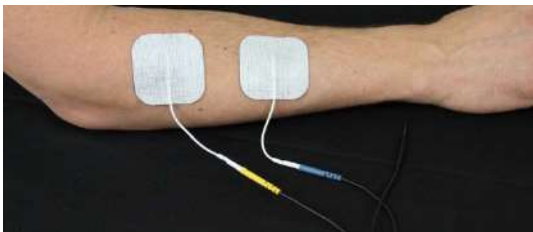
Two (2) electrodes are required for stimulation.

Blue = (+)
Yellow = (-)

Note: The blue and yellow leads can be either proximal or distal. The black reference lead will not be used.

EMG Triggered Stimulation Application:
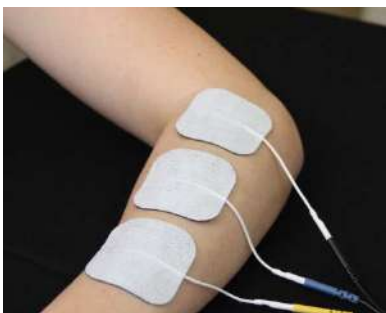
Three (3) electrodes are required for EMG Triggered Stimulation. The same electrodes are used for **BOTH** EMG and Stimulation.

Black = reference
Blue = (+)
Yellow = (-)

Note: The blue and yellow leads can be either proximal or distal. The black reference lead can be placed anywhere on the body.

Reciprocal EMG Triggered Stimulation Application:
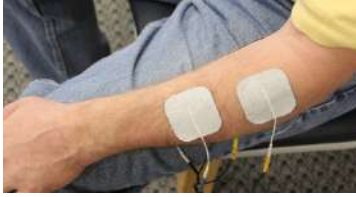
Five (5) electrodes are required for Reciprocal EMG Triggered Stimulation.

- Three (3) EMG electrodes positioned over the hypertonic muscle group (channel B).

- Two (2) stimulation electrodes positioned over the opposite muscle group (channel A).

Note: For the stimulation electrodes, the blue and yellow leads can either be proximal or distal. The black reference lead will not be used.

EMG Biofeedback Tips:

- Use small electrodes to increase the selectivity of your measures.
- Apply electrodes in parallel to the muscle fiber at typically 2 centimeters apart.
- Use the most dominant middle portion of the muscle belly for best results.
- Make sure the electrode site remains on the active muscle mass during muscle shortening.
- Place the reference electrode anywhere on the body.

Chapter 4

Getting Started

Below is the initial screen that is displayed when the unit is turned on:
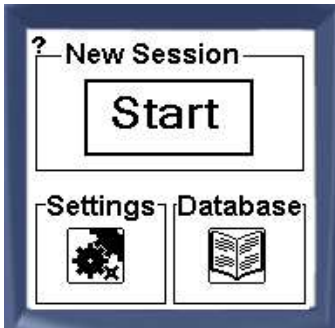
Three (3) options to select:

1. Start
2. Settings
3. Database

START:

Select Start to choose a modality and begin a session. The Saebo MyoTrac Infiniti offers 4 modalities:

1. **EMG** Biofeedback
2. Electrical Stimulation **STIM**
3. EMG Triggered Stimulation **ETS**
4. Reciprocal EMG Triggered Stimulation **RETS**

SETTINGS:

The Settings button opens a menu of settings to configure various features of the device.

Refer to Chapter 1.

DATABASE:

Select Database to view and play saved EMG biofeedback data from previous recorded sessions.

Chapter 4.1

EMG Biofeedback

ElectroMyoGraphy (EMG) is a non-invasive technique used for measuring muscle electrical activity that occurs during muscle contraction and relaxation cycles. EMG amplifies a physiological signal such as muscle activity. EMG feedback is immediate which provides "real time" state of muscle contraction/relaxation.

Biofeedback is a tool (not a treatment) used to help patients learn new tasks or modify existing motor patterns. Auditory and visual cues provide instantaneous feedback.

An EMG biofeedback session is a session where only EMG is used (no stimulation). The patient is connected to one or two channels. EMG requires 3 electrodes (positive, negative, and a reference).

Using Threshold Feedback:

The use of auditory/visual thresholds is an excellent way to maximize your client's performance. Whether the client is activating a muscle to exceed a threshold or relaxing a muscle to fall below a threshold, having the auditory/visual feedback will be essential. Prior to starting an EMG biofeedback session with the client, determine the appropriate threshold level that he/she must exceed (contract) or fall below (relax) in order to receive the sound feedback.

Above Threshold Feedback: the goal is to allow the client to exceed the threshold and sustain a contraction above the threshold for the desired "work" time. If the client is unable to maintain a sufficient contraction above the predetermined threshold, then consider lowering the threshold to a more achievable level.

Below Threshold Feedback: the goal is to allow the client to fall below the threshold by relaxing his/her muscles sufficiently for the desired about of time. If the client is unable to relax his/her muscles enough to fall below the predetermined threshold, then consider raising the threshold to a more achievable level.

To learn how to adjust the threshold(s), refer to Chapter 2.

The user can manually adjust the threshold by using the up/down arrow button (black arrow)

Bar Graph

The user can manually adjust the threshold by using the up/down arrow button (black arrow)

Line Graph

To begin an EMG biofeedback session, select the Start button and then tap on the **EMG** icon. For electrode application, please refer to Chapter 3.
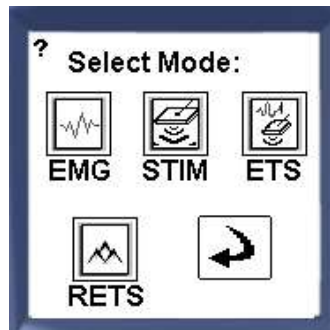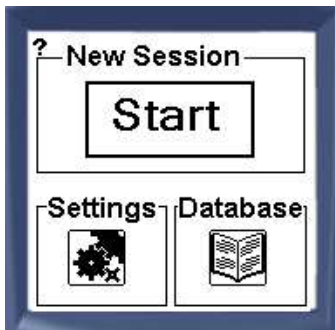
Choose between 3 Modes:

    Program
    Custom
    Assessment
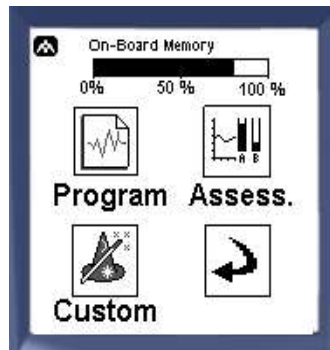
Program Mode:

Program session consists of preset parameters including work time, rest time, and duration. A voice prompt, as well as a visual sign, instructs the client throughout the exercise. The programs are pre-programmed and cannot be changed by the user.

To begin a session under the Program Mode, select the Program icon and proceed with the following:
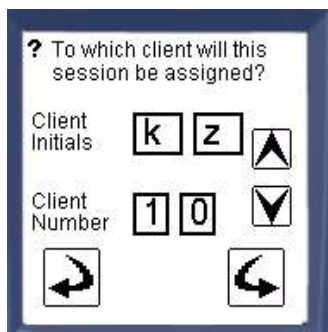
If the user is saving the session, enter the client initials and client ID (number). This will allow the user to retrieve the data for future use.

Note: If "No Save" was previously selected under Settings, then this screen will not appear.

Select the body area. Once the body area is selected, the user has a choice of programs for that given area. Refer to the list of Saebo EMG Biofeedback Programs for specific preset parameters later in this section.

The programs are sorted by body area for easier access:

Area 1: Upper extremities
Area 2: Head & neck
Area 3: Abdominal
Area 4: Back
Area 5: Lower extremities
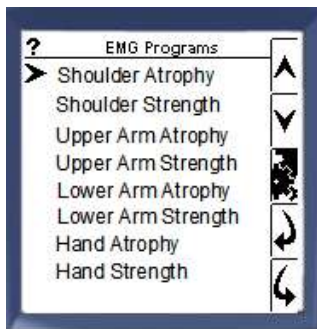
Select a program using the up/down arrows and continue using the forward arrow.

To go back to the previous screen, select the backward arrow. Tap the settings button to view the program settings.

Once the settings button is selected, a screen displaying the program settings will appear.

The **play** button is used to continue with this program.
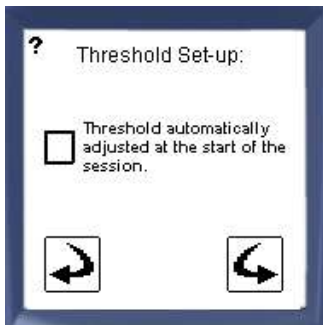
Check the box if you would like to use the Auto Threshold feature.

How does it work?
Auto-threshold will adjust the EMG threshold during the 3 first work repetitions. It takes 75% of the average of the three maximum readings recorded during these 3 work reps. The threshold is only auto adjusted at the beginning of the session.

Note: If you do not wish to use Auto Threshold feature, feel free to manually set the clients threshold when the session begins. To learn how to manually adjust thresholds, refer to the Display section under Settings.
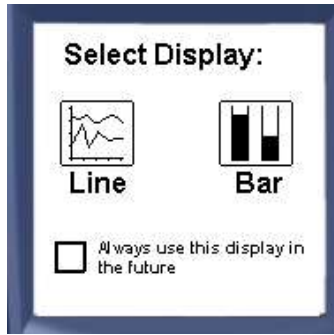
If "always ask" was selected in the display settings under the Settings menu, the user will be asked to choose the display type. They can use the checkbox at the bottom to make their selection permanent. If they do, they will have to go to the settings menu to change it back.

Once you choose the desired Display, the session is ready. Select the Record/Start button ⬛ to begin. If the user selected "On-Board Memory" or "Compact Flash" under the Save section in Settings, then the session will be recorded. If "No Save" was selected then the session will not be recorded.

Saebo EMG Biofeedback Programs

Name	Body area	Get Ready Time	Work(sec)/Rest(sec) x # of repetitions
Shoulder Atrophy	Area 1: upper extremities	10 seconds	4 x 8 x 100
Shoulder Strength	Area 1: upper extremities	10 seconds	8 x 15 x 50
Upper Arm Atrophy	Area 1: upper extremities	10 seconds	4 x 8 x 75
Upper Arm Strength	Area 1: upper extremities	10 seconds	8 x 15 x 40
Lower Arm Atrophy	Area 1: upper extremities	10 seconds	4 x 10 x 65
Lower Arm Strength	Area 1: upper extremities	10 seconds	6 x 15 x 30
Hand Atrophy	Area 1: upper extremities	10 seconds	4 x 10 x 55
Hand Strength	Area 1: upper extremities	10 seconds	6 x 15 x 20
Cervical Atrophy	Area 2: head & neck	10 seconds	6 x 6 x 125
Cervical Strength	Area 2: head & neck	10 seconds	8 x 12 x 75
Abdominal Atrophy	Area 3: abdominal	10 seconds	6 x 6 x 125
Abdominal Strength	Area 3: abdominal	10 seconds	8 x 12 x 75
Back Atrophy	Area 4: back	10 seconds	6 x 6 x 125
Back Strength	Area 4: back	10 seconds	8 x 12 x 75
Buttocks Atrophy	Area 4: back	10 seconds	4 x 8 x 100
Buttocks Strength	Area 4: back	10 seconds	8 x 15 x 50
Hip Atrophy	Area 5: lower extremities	10 seconds	4 x 8 x 100
Hip Strength	Area 5: lower extremities	10 seconds	8 x 15 x 50
Upper Leg Atrophy	Area 5: lower extremities	10 seconds	4 x 8 x 100

Upper Leg Strength	Area 5: lower extremities	10 seconds	8 x 15 x 50
Lower Leg Atrophy	Area 5: lower extremities	10 seconds	4 x 10 x 75
Lower Leg Strength	Area 5: lower extremities	10 seconds	6 x 15 x 40
Foot Atrophy	Area 5: lower extremities	10 seconds	4 x 10 x 65
Foot Strength	Area 5: lower extremities	10 seconds	6 x 15 x 30

Custom Mode:

The custom session is similar to the preset Program Mode except that the programs can be changed by the user. The user can create up to 4 custom programs.

To create a program under the Custom Mode, select the Custom icon and proceed with the following:
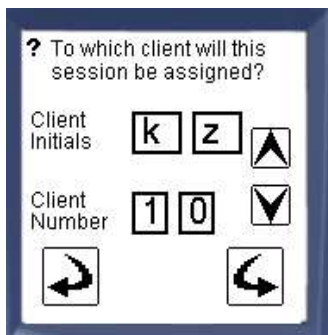
To retrieve the data for future use, enter patient initials and client ID (number).

Note: If "No Save" was previously selected under Settings, then this screen will not appear.
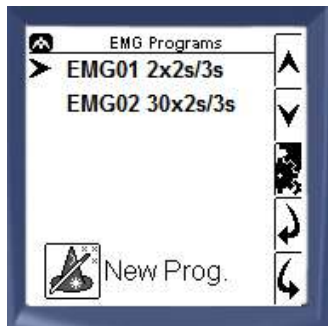
The user can select a previously created custom program using the up/down arrows and continue using the forward arrow. To go back to the previous screen, select the backward arrow. Tap the settings button to view the program settings.

The list is initially empty and the user can create up to 4 programs. When the On-Board memory is full, the "New Prog" button is greyed out.

Tap the Settings button to see the program settings.

The play button is used to continue with this program.

The edit button allows the user to change the settings of this given program and the delete button (trash bin) to remove it and free some memory space.

When the user chooses New Program "New Prog" (or the edit button) they can create/edit the program as follows:

Determine "Get Ready" time prior to the program starting
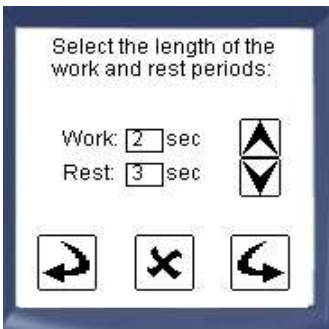
Select how much time the client should contract the muscle "Work" above the threshold and how long the client should "Rest" before the next repetition.
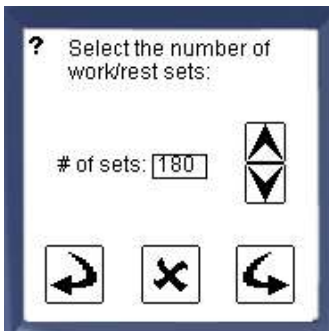
Determine how many repetitions you would like the client to perform during the session

Select "Save Program" if you would like to use this program in the future. If there is no need to reuse the custom program for future use then continue without saving.

The session will begin once the threshold is determined and the display screen is chosen.

Assessment Mode:

The assessment session allows the user to do a quick assessment of the EMG levels of the client. There is no time limit and no instructions to the client (such as a voice prompt). It just measures and displays the two EMG signals on a graph.

To begin a session under Assessment Mode, select the Assessment icon and proceed with the following:
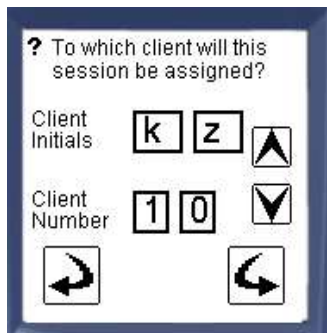
To retrieve the data for future use, enter client initials and client ID (number).

Note: If "No Save" was previously selected under Settings, then this screen will not appear.

If "always ask" was selected in the display settings under the Settings menu, the user will be asked to choose the display type.

Check the box at the bottom of the screen to make the selection permanent. Go to the Settings menu to change it back.

Once you choose the desired Display, the session is ready. Select the Record/Start button to begin. If the user selected "On-Board Memory" or "Compact Flash" under the Save section in Settings, then the session will be recorded. If "No Save" was selected then the session will not be recorded.

Chapter 4.2

Electrical Stimulation

Electrical stimulation utilizes electrical currents to artificially generate an action potential by depolarizing a motor nerve. Electrical impulses mimic the action potential coming from the CNS causing the muscle to contract. Impulses are delivered to targeted muscles via electrodes.

An electrical stimulation session is a session where only stimulation is provided (no EMG). The patient is connected to one or two channels. Stimulation requires 2 electrodes (blue + and yellow -). The black (reference) wire will not be used.

To begin a Stimulation session, select the Start button and then tap on the **STIM** icon. For electrode application, please refer to Chapter 3.
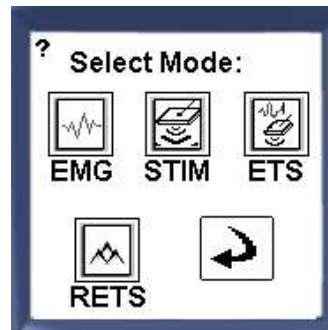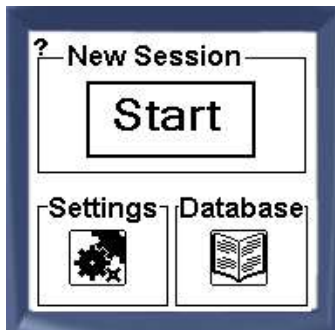
Choose between 2 Modes:

1. Program
2. Custom

Program Mode:

Program session consists of preset parameters including work time, rest time, number of repetitions, ramp up/down, pulse rate, and pulse width. The programs are pre-programmed and cannot be changed by the user.

To begin a session under the Program Mode, select the Program icon and proceed with the following:

Select the body area. Once the body area is selected, the user has a choice of programs for that given area. Refer to the list of Saebo Stimulation Programs for specific preset parameters later in this section.

The programs are sorted by body area for easier access:

Area 1: Upper extremities
Area 2: Head & neck
Area 3: Abdominal
Area 4: Back
Area 5: Lower extremities
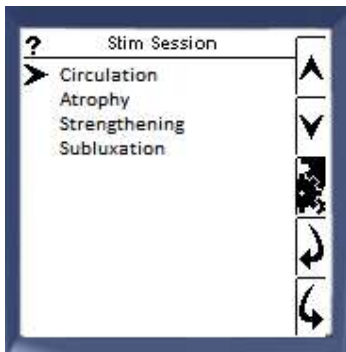
Select a program using the up/down arrows and continue using the forward arrow.

To go back to the previous screen, select the backward arrow. Tap the settings button to view the program settings.

If the settings button is pressed, the user can see the program parameters.

- The durations of Work (on time) and Rest (off time) as well as the number of reps.

- Ramp – The return time it takes for the intensity of successive pulses to reach the preset maximum or return to zero from the start or the end of a series of pulses.

- Pulse Rate - The rate at which a number of pulses are delivered.

- Pulse Width – The duration of each individual pulse.
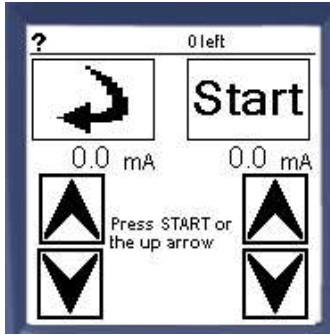
Once you select the appropriate program and tap the forward arrow, the Stim delivery screen (on the left) will appear. The Stim delivery screen will be used to deliver current to the electrodes.
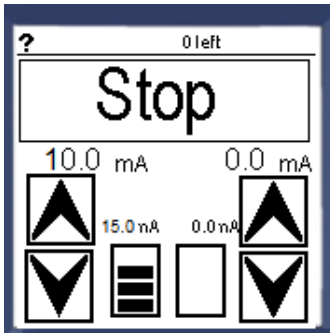
The Stim delivery screen displays the current intensity, maximum intensity and the controls for each of the 2 channels. The client must be connected to one or two channels via electrodes.

The current amplitude is displayed in real time (0 during rest, then ramps up, stays steady and ramps down during the work period).

When stimulation is ON, a sound is played to notify that current is being delivered. A bar shows the current percentage relative to the maximum current. For instance, in the example to the left, the current is still ramping up (10mA when the max is 15mA).

To start, tap the Start button followed by the up arrow (of the appropriate channel) to incrementally control the current being delivered. Tap the down arrow to decrease the current being delivered.

To stop/pause the session, tap the Stop button at the top of the screen.
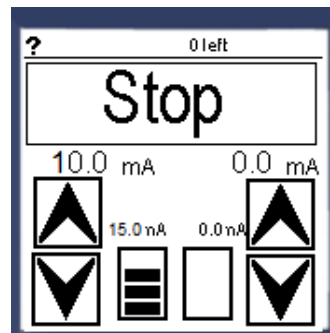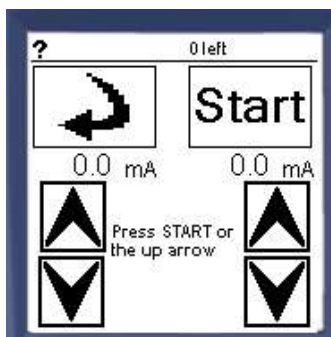
When the Stop button is pressed, the screen on the left will appear.

To resume the session, tap the Resume button. To end the session, tap the End button.
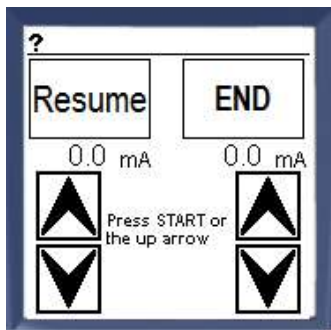
Saebo Stimulation Programs

Name	Body area	Stim(sec)/Rest(sec)	Ramp-up/down (s) Pulse Rate(Hz), Pulse Width(µs)
Arm Circulation	Area 1: upper extremities	3s/2s	0s/0s 5Hz, 200µs
Atrophy	Area 1: upper extremities	5s/8s	2s/1s 35Hz, 200µs
Strength	Area 1: upper extremities	8s/15s	2s/1s 60Hz, 250µs
Subluxation	Area 1: upper extremities	15s/15s	3s/3s 30Hz, 300µs
Hand Atrophy	Area 1: upper extremities	5s/10s	2s/1s 35Hz, 200µs
Circulation	Area 2: head & neck	3s/2s	0s/0s 5Hz, 300µs
Atrophy	Area 2: head & neck	6s/6s	2s/1s 25Hz, 300µs
Strength	Area 2: head & neck	8s/12s	2s/1s 35Hz, 300µs
Circulation	Area 3: abdominal	3s/2s	0s/0s 5Hz, 300µs
Atrophy	Area 3: abdominal	6s/6s	2s/1s 35Hz, 300µs
Strength	Area 3: abdominal	8s/12s	2s/1s 60Hz, 300µs
Back Circulation	Area 4: back	3s/2s	0s/0s 5Hz, 300µs
Back Atrophy	Area 4: back	6s/6s	2s/1s 25Hz, 300µs
Back Strength	Area 4: back	8s/12s	2s/1s 35Hz, 300µs
Buttocks Circulation	Area 4: back	5s/4s	2s/1s 5Hz, 200µs
Buttocks Atrophy	Area 4: back	6s/15s	2s/1s 60Hz, 200µs
Buttocks Strength	Area 4: back	6s/12s	2s/2s 40Hz, 200µs
Leg Circulation	Area 5: lower extremities	3s/2s	0s/0s 5Hz, 400µs

Atrophy	Area 5: lower extremities	5s/8s	2s/1s 30Hz, 400μs
Strength	Area 5: lower extremities	8s/15s	2s/1s 60Hz, 400μs
Foot Circulation	Area 5: lower extremities	3s/2s	0s/0s 5Hz, 200μs
Foot Atrophy	Area 5: lower extremities	5s/10s	2s/1s 40Hz, 200μs

Custom Mode:

The custom session is similar to the preset Program Mode except that the programs can be changed by the user. The user can create up to 5 custom programs.

To create a program under the Custom Mode, select the Custom icon and proceed with the following:

The user can select a previously created custom program using the up/down arrows and continue using the forward arrow. To go back to the previous screen, select the backward arrow. Tap the settings button to view the program settings.

The list is initially empty and the user can creates up to 5 programs. When the memory is full, the button is greyed out.

By pressing the settings button, the user can see the program parameters.
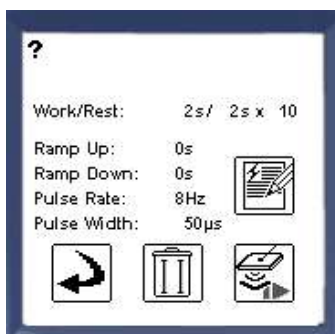
- The durations of Work (on time) and Rest (off time) as well as the number of reps.

- Ramp – The time it takes for the intensity of successive pulses to reach the preset maximum or return to zero from the start or the end of a series of pulses.

- Pulse Rate - The rate at which a number of pulses are delivered.

- Pulse Width - The duration of each individual pulse.

The play button is used to continue with this program. The edit button allows the user to change the settings of this given program and the delete button (trash bin) to remove it and free some memory space.
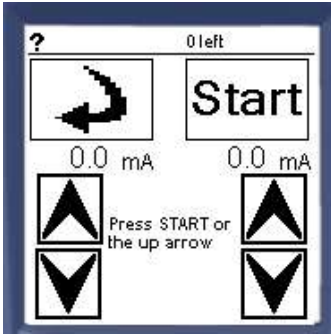
Once you select the appropriate program and tap the forward arrow, the Stim delivery screen will appear on the left.

Refer to the Program section of the Electrical Stimulation mode to learn how to use the Stim delivery screen.

When the user chooses New Program "New Prog" (or the edit button) they can create/edit the program as follows:
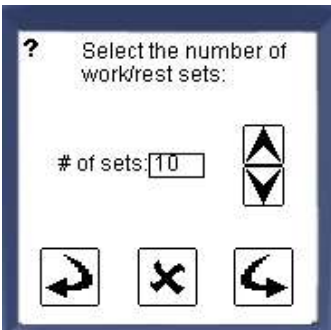
Select how many repetitions the client should perform in one session.
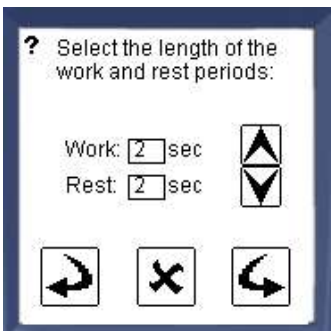
Select the Work time (on) and the Rest time (off). Below are the ranges for the Stimulation Mode:

Work (Stim ON):	2s – 20s
Rest (Stim OFF):	2s – 50s

Stim Setup

Ramp Up   0s
Ramp Down   0s
Pulse Rate   8Hz
Pulse Width 50µs
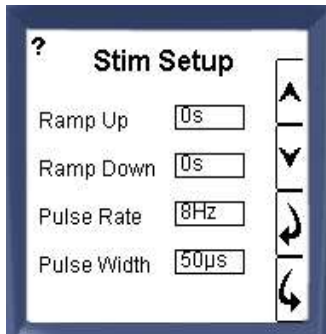
Enter the stimulation paramaters. Below are the ranges for the Stimulation Mode:

Ramp Up/Down Time:	0-20 sec
Pulse Rate:	2Hz – 100Hz
Pulse Width:	50-400µs
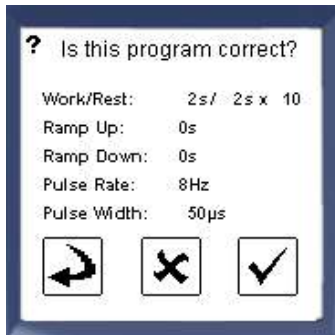
? Is this program correct?

Work/Rest: 2s/ 2s x 10
Ramp Up: 0s
Ramp Down: 0s
Pulse Rate: 8Hz
Pulse Width: 50µs

Review the custom parameters and confirm by tapping the check mark, cancel by tapping the X, or go back to edit by tapping the back arrow.

? Do you want to save this program for future reuse?

Save program
Continue w/o save
Back

Select "Save Program" if you would like to use this program in the future. If there is no need to reuse the custom program for future use then continue without saving.

0 left

Start

0.0 mA   0.0 mA

Press START or the up arrow
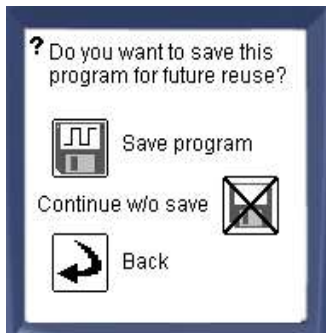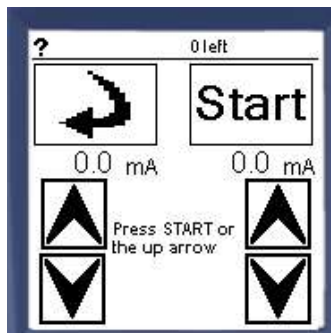
Once the user selects "save program" or "continue w/o save", the Stim delivery screen will appear on the left.

Refer to the **Program** section of the **Electrical Stimulation Mode** to learn how to use the Stim delivery screen as well as how to pause and end a session.

Chapter 4.3

EMG Triggered Stimulation (ETS)

EMG triggered stimulation (ETS) is a combination of 2 modalities (EMG and Stimulation) to form a third treatment possibility. Traditional stimulation uses time based triggering or cyclical stimulation. ETS is based on the client's voluntary muscle activation. The client's generated EMG signal triggers the stimulation. This "volitional based" application requires the client to actively participate in order to receive the stimulation.

Following neurological injury, electrical impulses originating from the brain which are transmitted to the muscles via the nerve cells, are poorly generated. Normal muscle contraction is no longer possible. Often times very small EMG signals can still be detected. These signals are transmitted to specialized surface electrodes over the weakened muscles. When the clinically prescribed threshold is reached, the client is "rewarded" with stimulation to the activated muscles. Through this cognitive relearning process, ETS can improve electrical muscle activity as well as cortical plasticity.

To begin an EMG triggered stimulation session, select the Start button and then tap on the **ETS** icon. For electrode application, please refer to Chapter 3.
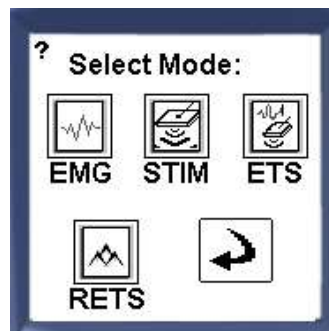
Choose between 2 Modes:

1. Program
2. Custom

Program Mode:

Program session consists of preset parameters including work time, rest time, number of repetitions, ramp up/down, pulse rate, and pulse width. The programs are pre-programmed and cannot be changed by the user.

To begin a session under the Program Mode, select the Program icon and proceed with the following:

Select the body area. Once the body area is selected, the user has a choice of programs for that given area. Refer to the list of Saebo ETS Programs for specific preset parameters later in this section.

The programs are sorted by body area for easier access:

Area 1: Upper extremities
Area 2: Head & neck
Area 3: Abdominal
Area 4: Back
Area 5: Lower extremities

Note: The ETS Program stimulation parameters (on/off time, ramp up/down, rate, width etc.) are identical to the Stimulation Program stimulation parameters. The only difference between the 2 Programs is **ETS Mode** is biofeedback triggered where the **Stimulation Mode** is cyclical or time based triggered (i.e., 4 sec on time/8 sec off time).

Select a program using the up/down arrows and continue using the forward arrow.

To go back to the previous screen, select the backward arrow. Tap the settings button to view the program settings.

By pressing the settings button, the user can see the following:

- Get Ready Time
- Stim Time
- Rest Time

To view more parameter details, tap the more information icon to the right of the screen.

When the more information icon is selected, additional parameter details can be viewed consisting of:

- Ramp – The time it takes for the intensity of successive pulses to reach the preset maximum or return to zero from the start or the end of a series of pulses.

- Pulse Rate - The rate at which a number of pulses are delivered.

- Pulse Width – The duration of each individual pulse.

- Stim Delay – Delay time before the stimulation is triggered.

- Trigger – All programs are set to above threshold only. Below threshold can be created under the Custom mode.

Tap the arrow to advance to the next screen

How Does Above/Below Threshold Triggered Stimulation Work?

For EMG Triggered Stimulation Mode only, stimulation can occur either when crossing **above** the threshold or when the signal falls **below** the threshold. When the trigger is above the threshold, it can be referred to as "reward" mode. When the target threshold has been reached, stimulation is delivered to the client in order to complete the contraction. This mode motivates the client and involves them in the rehabilitation process.

When the trigger is set to activate below the threshold, it can be referred to as "assistance" mode. When the client is unable to hold the contraction for a long-enough duration, this mode will assist them in finishing the contraction.

Note: The Below Threshold Trigger Mode can only be applied to a Custom session. In the case of predefined programs, the Trigger Mode is already selected to Above Threshold.
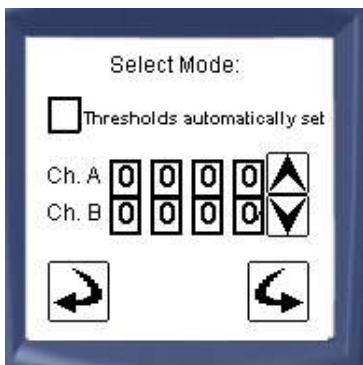
Select the microVolt threshold value(s) for the appropriate channel(s). The threshold should be challenging for the client to reach but not too difficult. There are 2 ways to determine the correct thresholds:

1. Analyze the client's muscle activity using the **EMG Assessment Mode**. Once determined, enter the values under the ETS program and begin the session

2. Enter a generic threshold value under the ETS Mode and begin the session. Manually adjust the values as appropriate.

How to Manually Adjust the Threshold?

Once the Display Graph is chosen and the session begins, if the user is not pleased with the thresholds originally created, he/she can adjust the threshold(s) for the channel(s) manually.

To learn how to adjust the threshold(s), refer to Chapter 1, Settings, Display.

The user can manually adjust the threshold by using the up/down arrow button (black arrow)

Bar Graph

The user can manually adjust the threshold by using the up/down arrow button (black arrow)

Line Graph

How to Set Auto Threshold for ETS?

Check the box if you would like to use the Auto Threshold feature. If the user has selected auto-threshold, the threshold(s) will be updated on a regular basis according to how the client performs. Once the user has pressed the start button, ETS begins. It starts with a "Get ready" period for the patient to prepare. Then a voice prompt saying "WORK" can be heard and the word "WORK" will be displayed on the screen. The device is measuring the client's EMG muscle activity on channels A and/or B and is waiting for the signal to go above (or below) the respective threshold (threshold A for channel A, threshold B for channel B), depending on the option selected.

If the threshold is on auto mode, the device will keep track of the maximum contraction (for above) or the minimum contraction (for below) and will adjust the activation threshold every 30 seconds, if the client is not able to reach either threshold.

Note 1: With auto threshold, the user must first manually enter the appropriate threshold values. Once the session starts, the auto threshold function will be enabled.

Note 2: If you do not wish to use Auto Threshold feature, uncheck the auto threshold box and manually set the clients threshold.
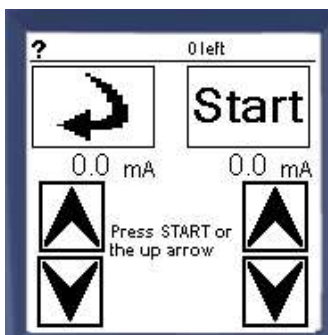
Once the user enters the threshold values (or selects Auto Threshold) and taps on the forward arrow, the Stim delivery screen will appear on the left.

Refer to the **Program** section of the **Electrical Stimulation Mode** to learn how to use the Stim delivery screen as well as how to pause and end a session.

Once the desired current is reached, tap STOP and then NEXT to continue.
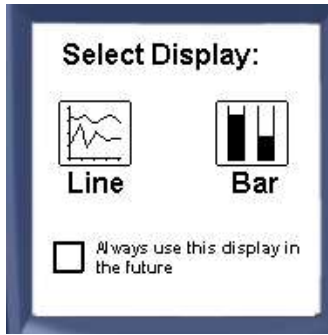
If "always ask" was selected in the display settings under the Settings menu, the user will be asked to choose the display type.

Check the box at the bottom of the screen to make the selection permanent. Go to the Settings menu to change it back.

Once you choose the desired Display, the session is ready. Select the Start button ▣ to begin.

Saebo EMG Triggered Stimulation Programs (ETS)

Name	Body area	Stim(sec)/Rest(sec) Trigger mode	Ramp-up/down (s) Pulse Rate(Hz), Pulse Width(µs)
Atrophy	Area 1: upper extremities	5s/8s Above	2s/1s 35Hz, 200µs
Strength	Area 1: upper extremities	8s/15s Above	2s/1s 60Hz, 250µs
Subluxation	Area 1: upper extremities	15s/15s Above	3s/3s 30Hz, 300µs
Hand Atrophy	Area 1: upper extremities	5s/10s Above	2s/1s 35Hz, 200µs
Atrophy	Area 2: head & neck	6s/6s Above	2s/1s 25Hz, 300µs
Strength	Area 2: head & neck	8s/12s Above	2s/1s 35Hz, 300µs
Atrophy	Area 3: abdominal	6s/6s Above	2s/1s 35Hz, 300µs
Strength	Area 3: abdominal	8s/12s Above	2s/1s 60Hz, 300µs
Back Atrophy	Area 4: back	6s/6s Above	2s/1s 25Hz, 300µs
Back Strength	Area 4: back	8s/12s Above	2s/1s 35Hz, 300µs
Buttocks Atrophy	Area 4: back	6s/15s Above	2s/1s 60Hz, 200µs
Buttocks Strength	Area 4: back	6s/12s Above	2s/2s 40Hz, 200µs
Atrophy	Area 5: lower extremities	5s/8s Above	2s/1s 30Hz, 400µs
Strength	Area 5: lower extremities	8s/15s Above	2s/1s 60Hz, 400µs
Foot Atrophy	Area 5: lower extremities	5s/10s Above	2s/1s 40Hz, 200µs

Custom Mode:

The custom session is similar to the preset Program Mode except that the programs can be changed by the user. The user can create up to 4 custom programs.

To create a program under the Custom Mode, select the Custom icon and proceed with the following:

The user can select a previously created custom program using the up/down arrows and continue using the forward arrow. To go back to the previous screen, select the backward arrow. Tap the settings button to view the program settings.

The list is initially empty and the user can create up to 4 programs. When the memory is full, the button is greyed out.

If the settings button is pressed, the user can see the following:

- Get Ready Time
- Stim Time
- Rest Time

To view more parameter details, tap the more information icon to the right of the screen. To edit the existing saved program, select the edit button.

When the more information icon is selected, additional parameter details can be viewed consisting of:

- Ramp – The time it takes for the intensity of successive pulses to reach the preset maximum or return to zero from the start or the end of a series of pulses.

- Pulse Rate - The rate at which a number of pulses are delivered.

- Pulse Width – The duration of each individual pulse.

- Stim Delay – Delay time before the stimulation is triggered.

- Trigger – All programs are set to above threshold only. Below threshold can be created under the Custom mode.

When the user chooses New Program "New Prog" or the edit button, they can create/edit the program as follows:
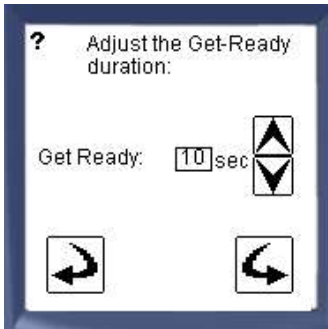
Determine "Get Ready" time prior to the program starting
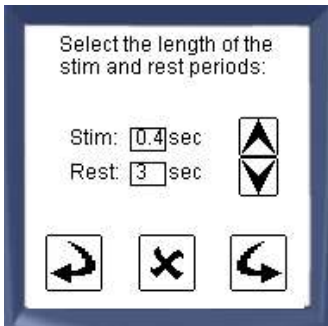
Select the Stim time (on) and the Rest time (off). Below are the ranges for the ETS Mode:

Work (Stim ON):	100ms – 20s
Rest (Stim OFF):	100ms – 50s
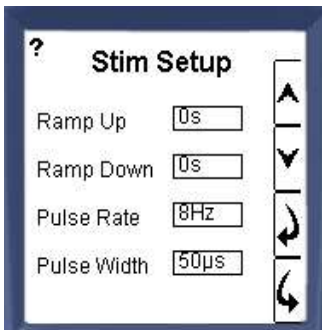
Enter the stimulation parameters. Below are the ranges for the ETS mode:

Ramp Up/Down Time:	0-10 sec
Pulse Rate:	2Hz – 100Hz
Pulse Width:	50-400μs
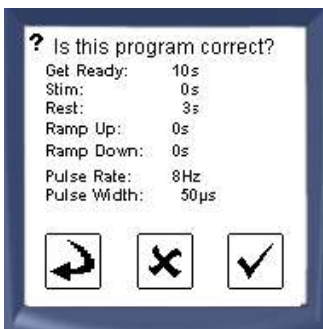
Is this program correct?

Get Ready:	10s
Stim:	0s
Rest:	3s
Ramp Up:	0s
Ramp Down:	0s
Pulse Rate:	8Hz
Pulse Width:	50µs

Review the custom parameters and confirm by tapping the check mark, cancel by tapping the X, or go back to edit by tapping the back arrow.

Set the delay time before stimulation is triggered:
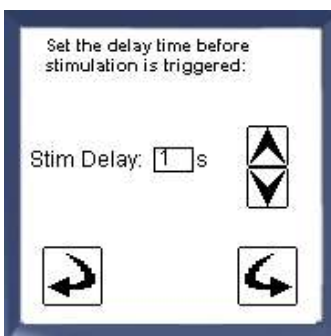
Stim Delay: [1] s

Enter the time delay before the stimulation can be triggered. When the client exceeds or falls below the prescribed threshold, stimulation will be delivered following the time delay established.

Stim Delay:	(0-10sec)

For each channel, select moment at which stim should be triggered.

ChA
ChB

In order to receive the stimulation, the client will be required to either exceed the threshold (left icon) or fall below the threshold (right icon).

Highlight the correct channel and select the appropriate icon. Tap the forward arrow to continue.

Note: see Above/Below Threshold Triggered Stimulation in this section for more information regarding trigger functions.
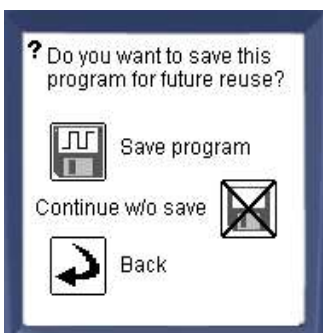
Do you want to save this program for future reuse?

Save program

Continue w/o save

Back

Once the appropriate trigger mode is selected, tap "Save Program" if you would like to use this program in the future. If there is no need to re-use the custom program for future use, then continue without saving.
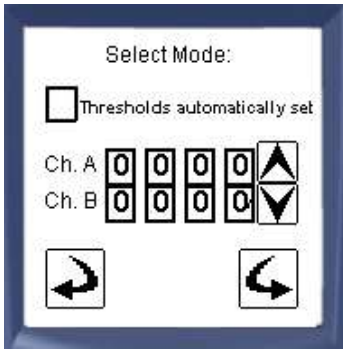
Select the microVolt threshold value(s) for the appropriate channel(s). There are 2 ways to determine the correct thresholds:

1. Analyze the client's muscle activity using the **EMG Assessment Mode**. Once determined, enter the values under the ETS program and begin the session

2. Enter a generic threshold value under the ETS Mode and begin the session. Manually adjust the values as appropriate. To learn how to adjust the threshold(s), refer to Chapter 1, Settings, Display.
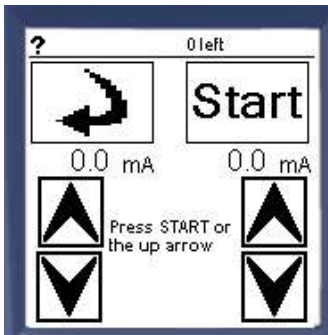
Once the user selects the appropriate microvolt levels, the Stim delivery screen will appear.

Refer to the **Program** section of the **Stimulation Mode** to learn how to use the Stim delivery screen as well as how to pause and end a session.

Once the desired current is reached, tap STOP and then NEXT to continue.
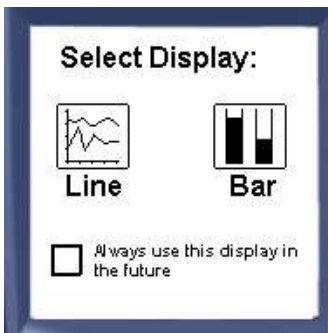
If "always ask" was selected in the display settings under the Settings menu, the user will be asked to choose the display type.

Check the box at the bottom of the screen to make the selection permanent. Go to the Settings menu to change it back.

Once you choose the desired Display, the session is ready. Select the Start button ⬛ to begin.

Chapter 4.4

Reciprocal EMG Triggered Stimulation (RETS)

RETS is a proprietary specialized form of biofeedback triggered electrical stimulation. Although it can be used for orthopedic conditions, the RETS program was designed mainly for the neurological population. This unique feature engages and disengages the agonist and antagonist muscles sequentially to produce coordinated functional movements.

Traditional EMG triggered stimulation primarily focuses on providing stimulation to the same muscle group that the client is attempting to voluntarily activate. This is accomplished once the client's EMG signal exceeds the prescribed threshold set by the clinician. The entire session involves the agonist only (i.e., 1 muscle group).
With RETS, the session involves both the agonist and antagonist muscles and is triggered upon relaxation of a muscle versus activation. Stimulation is triggered to the desired muscle group once the client deactivates or relaxes the opposite muscle group (antagonist) sufficiently (i.e., EMG signal falls below the threshold). Therefore, the emphasis is placed on relaxing the overactive (hypertonic) muscle (i.e., finger flexors) in order for the stimulation to be triggered to the opposite muscle group (i.e., finger extensors).

Although traditional EMG Triggered Stimulation (ETS) has been proven to be effective for the neurological population, ETS may not be as effective for clients that exhibit moderate to severe hemiparesis. Depending on the severity of the neurological injury, it may be difficult for the client to generate consistent signals from the brain to the muscle via the nerve cells. Additionally, while attempting to fire the muscle, tone may increase or co-contraction may occur. When this happens the EMG signal may not reach the prescribed threshold. Therefore, ETS will not consistently allow the client to receive the "reward" for their active attempts to fire the muscle.

How Does RETS Work?

- To begin, the client attempts to volitionally recruit/activate the hypertonic muscle group (i.e., flex fingers, elbow flexors, plantarflexors etc). The EMG mode monitors the muscle activation. The unit is enabled once the client's muscle activity exceeds the predetermined **"Activation Threshold"**.

- Following the activation of the muscle (i.e., contraction), the client will attempt to deactivate (i.e., relax) the hypertonic muscle group as much as possible.

- During the relaxation phase, the EMG signal from the hypertonic muscles will fall below the prescribed **"Deactivation Threshold"**.

- Once the client's signal falls below the **"Deactivation Threshold"**, stimulation is triggered to the opposite muscle group (i.e., xtensors).

For the RETS program, EMG Biofeedback and Stimulation are on two different channels. Two (2) **Stimulation** electrodes are on **channel A** and three (3) **EMG** electrodes on **channel B**. Refer to Chapter 3 for more information on electrode application.

Activation
Threshold

Deactivation
Threshold

Channel B EMG muscle signal
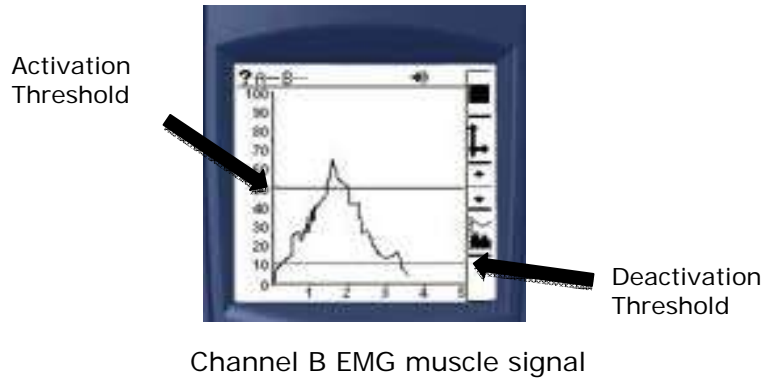
Example of RETS for the Neurologically Impaired Hand

EMG electrodes placed on the hypertonic flexors

Stimulation electrodes placed on the weakened extensors

Upon contraction of the flexors (during grasp), the unit is enabled when the client exceeds the prescribed Activation Threshold

Upon relaxation of the flexors (during release), the EMG falls below the prescribed Deactivation Threshold

Once EMG activity falls below the Deactivation Threshold, stimulation is automatically triggered to the extensors to assist with opening

(Grasp Phase)

- Finger flexors activated
- EMG signal exceeds prescribed Activation Threshold to enable the unit
- Stimulation off

(Release Phase)

- Finger flexors deactivated
- EMG signal falls below the prescribed Deactivation Threshold
- Stimulation automatically triggered to the wrist/finger extensors to open the hand

To begin a Reciprocal EMG Triggered Stimulation session, select the Start button and then tap on the **RETS** icon. For electrode application, please refer to Chapter 2.
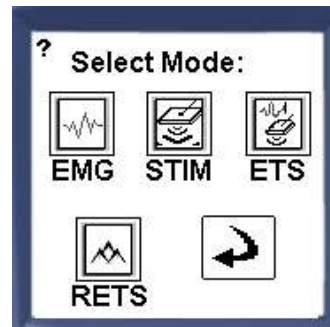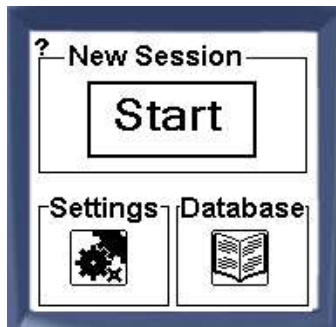
Choose between 2 Modes:

1. Program
2. Custom

Program Mode:

Program session consists of preset parameters including work time, rest time, ramp up/down, pulse rate, and pulse width. The programs are pre-programmed and cannot be changed by the user.

To begin a session under the Program Mode, select the Program icon and proceed with the following:

Select the preset program. Refer to the list of Saebo RETS Programs for specific preset parameters later in this section.

The programs consist of:

1. Task Training – Slow
2. Task Training – Fast
3. Foot Drop – Slow
4. Foot Drop - Fast

Select a program using the up/down arrows and continue using the forward arrow.

To go back to the previous screen, select the backward arrow. Tap the settings button to view the program settings.

If the settings button is pressed, the user can see the following:

Get Ready Time
Stim Time
Rest Time

To view more parameter details, tap the more information icon to the right of the screen.

When the more information icon is selected, additional parameter details can be viewed consisting of:

- Ramp – The time it takes for the intensity of successive pulses to reach the preset maximum or return to zero from the start or the end of a series of pulses.

- Pulse Rate - The rate at which a number of pulses are delivered.

- Pulse Width – The duration of each individual pulse.

- Activation Delay – Delay time when the client exceeds the Activation Threshold.

- Deactivation Delay – Delay time before the stimulation is triggered once the client falls below the Deactivation Threshold.

Tap the arrow to advance to the next screen
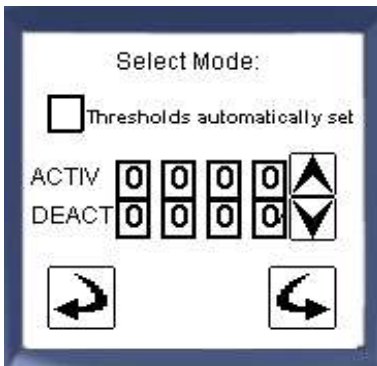
Check the box for auto threshold if appropriate. Next, enter the initial threshold values.

How to Set Auto Threshold for RETS

Check the box to use the Auto Threshold feature. Once the user has selected auto-threshold, the thresholds will be updated on a regular basis according to how the client performs. Once the user has pressed the start button, RETS begins. It starts with a "Get ready" period for the client to prepare. Then a voice prompt saying "WORK" can be heard and the word "WORK" will be displayed on the screen. The device is measuring the client's EMG muscle activity on channels B and is waiting for the signal to go above the Activation Threshold. The device will keep track of the maximal contraction and will adjust the Activation Threshold every 30 seconds if the client is not able to reach the threshold.

Once the signal exceeds (goes above) the Activation Threshold, a voice prompt saying "RELAX" can be heard and the word "RELAX" will be displayed on the screen. The device is then waiting for the signal to go below the deactivation threshold. The device will keep track of the minimal contraction and will adjust the Deactivation Threshold every 30 seconds if the patient cannot reach the threshold.

Note 1: With auto threshold (similar to ETS), the user must first manually enter the appropriate threshold values. Once the session starts, the auto threshold function will be enabled.

Note 2: If you do not wish to use Auto Threshold feature, uncheck the auto threshold box and manually set the client's threshold.

Entering the Threshold Values

Select the microVolt threshold values for the Activation and Deactivation Thresholds. The thresholds should be challenging for the client to exceed the Activation Threshold as well as fall below the Deactivation Threshold, but not too difficult. There are 2 ways to determine the correct thresholds:

1. Analyze the client's muscle activity using the **EMG Assessment Mode**. Once determined, enter the values under the RETS program and begin the session.

2. Enter a generic threshold value under the RETS Mode and begin the session. Manually adjust the values as appropriate.

How to Manually Adjust the Activation and Deactivation Thresholds

To manually adjust the thresholds, select the appropriate display screen (Line or Bar Graph) and begin the session by tapping the start button ⊡. To change a threshold, press ⊡ button on the display screen. At the top right of the screen, the A/D button will appear. It is used to select the Activation Threshold (A) and Deactivation Threshold (D). The selected channel will be highlighted. For instance, if (A) is currently highlighted, tap A/D button and (D) will be highlighted. With either (A) or (D) selected, use the (+) and (–) buttons to move the position of the threshold up or down on the range.

It is recommended to first determine the Activation Threshold. To do this, select (A) for Activation. Have the client activate the targeted muscle so a signal can be generated. Adjust the ⊡ button to the appropriate level. The threshold should be high enough so it is consistently achievable for the client to exceed. Once the Activation Threshold is set, then determine the Deactivation Threshold. Select (D) for Deactivation. Have the client activate the targeted muscle so a signal can be generated. Then, tell the client to relax.

When the client relaxes the muscle, the signal will drop. Adjust the ⊡ button to the appropriate level. The threshold should be low enough so it is consistently achievable to reach.

Note: To further challenge the client, feel free to manually adjust the Activation or Deactivation threshold higher (for grip strength) or lower (biofeedback/tone reduction) respectively.

Once the user enters the threshold values and taps on the forward arrow, the Stim delivery screen will appear on the left.

Refer to the **Program** section of the **Electrical Stimulation Mode** to learn how to use the Stim delivery screen as well as how to pause and end a session.

Note: For the RETS program, only Channel A provides stimulation. The user will be unable to provide stimulation to Channel B.

If "always ask" was selected in the display settings under the Settings menu, the user will be asked to choose the display type.

Check the box at the bottom of the screen to make the selection permanent. Go to the Settings menu to change it back.

Once you choose the desired Display, the session is ready. Select the Start button to begin.

Saebo Reciprocal EMG Triggered Stimulation (RETS) Programs

Name	Stim(sec)/Rest(sec)	Ramp-up/down (s) Pulse Rate(Hz), Pulse Width(µs)
Task Training – Slow	5s/0s	0s/0s 35Hz, 200µs Activation Delay 0s Simulation Delay 0s
Task Training – Fast	3s/0s	0s/0s 35Hz, 200µs Activation Delay 0s Simulation Delay 0s
Foot Drop – Slow	500ms/0ms	0s/0s 35Hz, 250µs Activation Delay 0s Simulation Delay 0s
Foot Drop – Fast	300ms/0ms	0s/0s 35Hz, 250µs Activation Delay 0s Simulation Delay 0s

Task Training Program

The Task Training programs are designed for agonist/antagonist retraining of any muscle group (upper and lower extremities). It is ideal for clients that lack the ability to adequately recruit (contract) as well as relax or "shut off" the involved muscle. Through the biofeedback application, once the client relaxes below the prescribed threshold, stimulation is delivered to the opposite muscle.

It consists of 2 programs (slow and fast). Task Training (slow) has a stimulation time of 5 seconds while Task Training (fast) has a stimulation time of 3 seconds. The fast program is often used for quick mass practice.

Common Muscle Groups Targeted for the Task Training Program:

Wrist flexors/extensors
Finger flexors/extensors*****
Elbow flexors/extensors******
Knee flexors/extensors
Ankle/foot plantarflexors/dorsiflexors*******

*Consider using the *Saebo***Stretch** or *Saebo***Flex** inconjunction with the RETS program. Refer to the online training portal for more information

** Consider using the *Saebo***Reach** inconjunction with the RETS program. Refer to the online training portal for more information.

***Similar to the wrist and finger flexors, often times the plantarflexors of a neurologically impaired client are very weak and lack proper control. The Task Training program can be used to maximize activation and deactivation of the plantarflexors (contract/relax) while improving dorsiflexion strength through stimulation.
Through the biofeedback application, once the client relaxes below the prescribed threshold, stimulation is delivered to the opposite muscle (i.e., dorsiflexors). This approach is ideal as a preconditioning strategy that can be used in conjunction with a foot drop program.

Tip: To complement the RETS for plantarflexion/dorsiflexion training, consider using the EMG Triggered Stimulation program to the plantarflexors to maximize strength and control (i.e., 3 EMG/Stim electrodes on the calf muscles). Refer to the ETS section of the manual for more information.

Foot Drop Program

The Foot Drop program is designed specifically for gait training. It is an EMG triggered stimulation application. It offers a natural gait cycle that leads to timely stimulation. There are no heel switches or tilt sensors required.

Biofeedback is provided to the client's plantarflexors during the gait cycle. Following deactivation of the plantarflexors at toe off (pre swing), electrical stimulation is triggered to the client's dorsiflexors. This natural triggered event provides constant cueing to the client and assists him or her with problem solving new functional movements based on the principles of motor relearning.

The Foot Drop program consists of 2 programs (slow and fast). Foot Drop (slow) has a stimulation time of 500 milliseconds while Foot Drop (fast) has a stimulation time of 300 milliseconds. The user will decide which program to select based on the walking speed of the client. A custom program can be created if the predetermined programs are not suitable for the client.

Example of RETS for Foot Drop

EMG electrodes placed on plantarflexors

⇓

Stimulation electrodes placed on the weakened dorsiflexors

⇓

Upon contraction of the plantarflexors (during stance phase), the unit is enabled when the client exceeds the prescribed Activation Threshold

⇓

Upon relaxation of the flexors (during toe off), the EMG falls below the prescribed Deactivation Threshold

⇓

Once EMG activity falls below the Deactivation Threshold, stimulation is automatically triggered to the dorsiflexors to lift the foot

Muscle Activity During Stance Phase

-Mid Stance
-Heel Off
-Toe Off

(calf muscles activated)
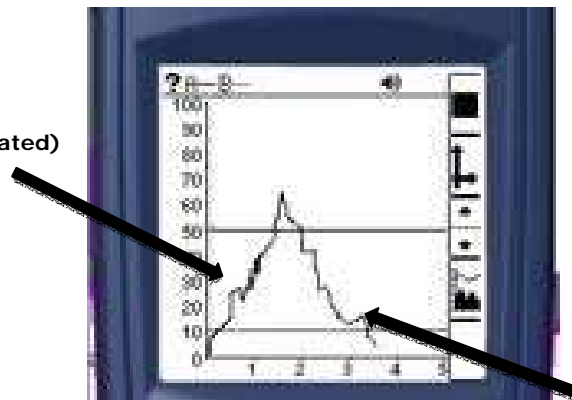
-Swing Phase

(Calf muscles deactivated)

Saebo Foot Drop Treatment Program
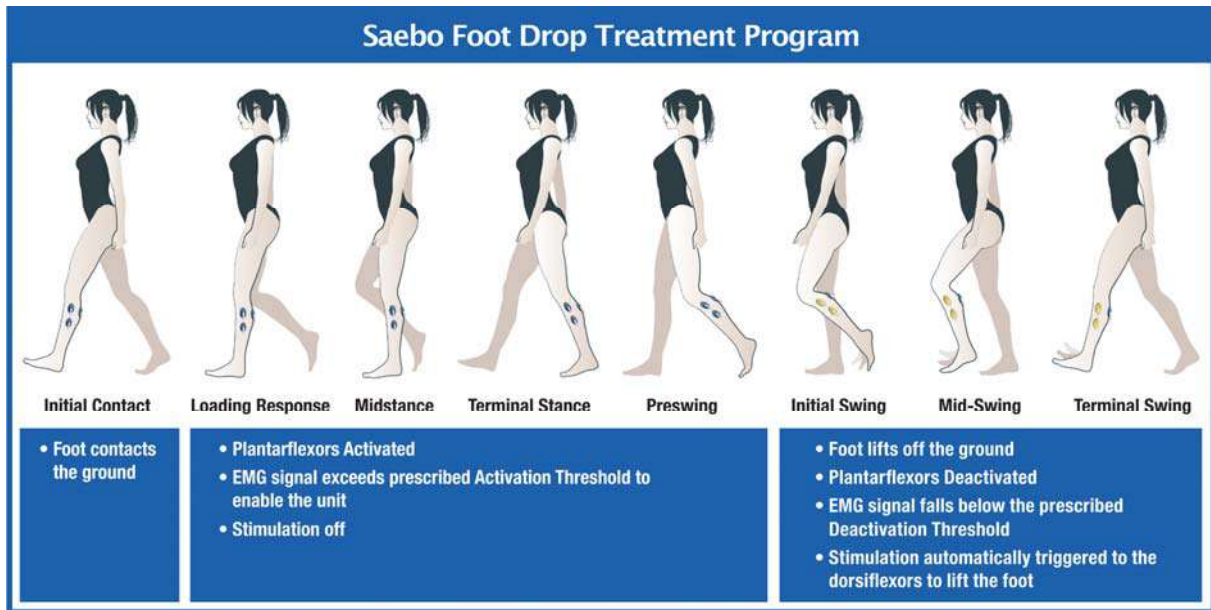
Saebo MyoTrac Foot Drop Program Criteria:

1. Does not exhibit severe hypertonicity of the plantarflexors
2. Can passively achieve plantargrade position at the ankle
3. Exhibit some activation of the plantarflexors

Important: If the client cannot effectively participate in the "Foot Drop" stimulation program due not meeting the above criteria, consider first utilizing the "Task Training" activities as a preconditioning technique. Once the client demonstrates better control of the agonist and antagonist muscles in the ankle and foot, then transition to the "Foot Drop" program to further challenge the patient.

Warning: The RETS Foot Drop Program can only be used for gait rehabilitation when approved by a Physical Therapist or Occupational Therapist. It is not intended for daily functional use.

Custom Mode:

The custom session is similar to the preset Program Mode except that the programs can be changed by the user. The user can create up to 4 custom programs.

To create a program under the Custom Mode, select the Custom icon and proceed with the following:

The user can select a previously created custom program using the up/down arrows and continue using the forward arrow. To go back to the previous screen, select the backward arrow. Tap the settings button to view the program settings.

The list is initially empty and the user can create up to 4 programs. When the memory is full, the button is greyed out.

If the settings button is pressed, the user can see the following:

Get Ready Time
Stim Time
Rest Time

To view more parameter details, tap the more information icon to the right of the screen. To edit the existing saved program, select the edit button.

When the more information icon is selected, additional parameter details can be viewed consisting of:

- Ramp – The time it takes for the intensity of successive pulses to reach the preset maximum or back to zero from the start or the end of a series of pulses.

- Pulse Rate - The rate at which a number of pulses are delivered.
- Pulse Width – The duration of each individual pulse.

- Activation Delay – Delay time when the client exceeds the Activation Threshold. Once the client goes above the threshold, he/she must then maintain the contraction above the threshold for the prescribed time.

Deactivation Delay – Delay time before the stimulation is triggered once the client falls below the Deactivation Threshold.

When the user chooses New Program "New Prog" or the edit button, they can create/edit the program as follows:
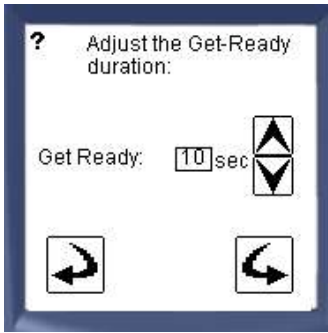
Determine "Get Ready" time prior to the program starting
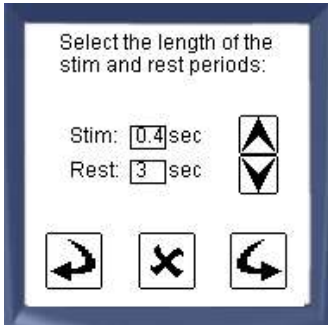
Select the Stim time (on) and the Rest time (off). Below are the ranges for the RETS Mode:

Stim time (ON):	100ms – 20s
Rest time (OFF):	100ms – 50s
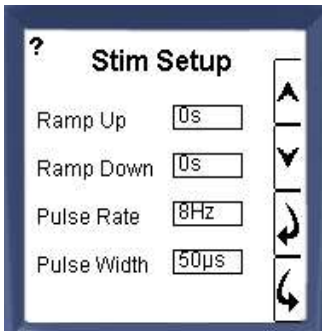
Enter the stimulation parameters. Below are the ranges for the RETS mode:

Ramp Up/Down Time:	0-10 sec
Pulse Rate:	2Hz – 100Hz
Pulse Width:	50-400µs
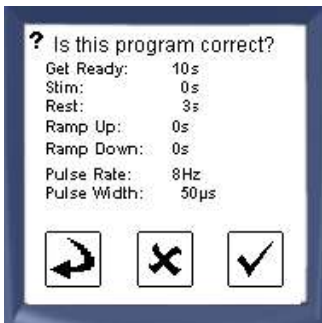
Review the custom parameters and confirm by tapping the check mark, cancel by tapping the X, or go back to edit by tapping the back arrow.
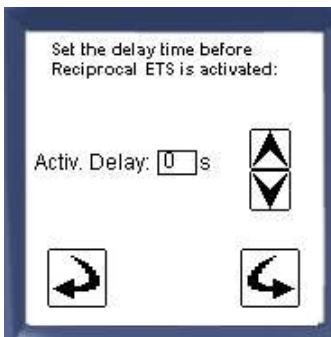
The Activation Delay is the time when the client exceeds the Activation Threshold. Once the client goes above the threshold, he/she must then maintain the contraction above the threshold for the prescribed time. If the time is set to zero then no delay is required by the client.

The Deactivation Delay is the time before the stimulation is triggered once the client falls below the Deactivation Threshold. If it is zero then stimulation will be triggered immediately once the threshold is reached.
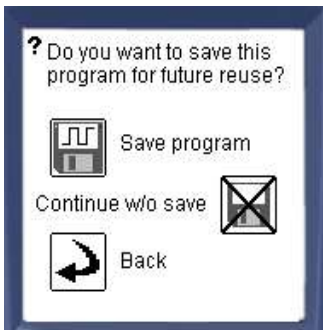
Once the appropriate trigger mode is selected, tap "Save Program" if you would like to use this program in the future. If there is no need to reuse the custom program for future use then continue without saving.
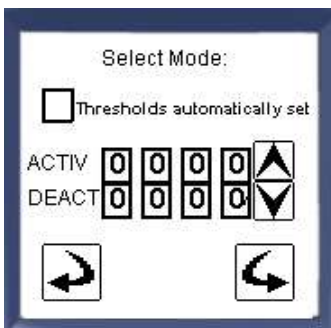
Check the box for auto threshold if appropriate. Next, enter the initial threshold values.

Once the user enters the threshold values and taps on the forward arrow, the Stim delivery screen will appear on the left.

Refer to the **Program** section of the **Electrical Stimulation Mode** to learn how to use the Stim delivery screen as well as how to pause and end a session.

Note: For the RETS program, only Channel A provides stimulation. The user will be unable to provide stimulation to Channel B.

If "always ask" was selected in the display settings under the Settings menu, the user will be asked to choose the display type.

Check the box at the bottom of the screen to make the selection permanent. Go to the Settings menu to change it back.

Once you choose the desired Display, the session is ready. Select the Start button ⊏ to begin.

Technical Information

This product conforms to ISO Medical standards EN60601-1, EN60601-2-10 and EN60601-2-40; some labeling may indicate superseded standards.

Specifications

Saebo MyoTrac Infiniti (SA9800)

Size (approx.)	102mm x 152mm x 51mm (4" x 6" x 2")
Weight (approx.)	330 g (11oz) with Batteries
Power Source	4AAA batteries, single use alkaline or Rechargeable battery pack
	6V Medical Grade AC wall adaptor
	5V USB
Battery Life, Alkaline cells (1200mAh)	3 – 4h typical
Battery Life, Battery Pack (700mAh)	3 – 4h typical
Low-battery warning	Before shut down
ADC output	14bits
Sample rate	2048 samples/second nominal
Channel bandwidth (3dB)	
Internal EMG amplifier	20 – 500Hz
External Sensor Input	DC – 500Hz
Anti-aliasing Filter	4th order Butterworth -3dB at 500Hz
Alias rejection	24 dB typical
Gain accuracy	±0.5 %
Accuracy including external sensor	± 5 % +0.6μV RMS
STIM SETTINGS	**VALID BETWEEN 500Ω to 1kΩ load impedance.**
Stimulation intensity	0mA – 100mA
Stimulation Pulse Rate	2Hz – 100Hz
Pulse Width	50-400μs
Ramp Time (Up and Down)	0 – 10 sec

Note: The **Saebo MyoTrac Infiniti** and its sensors are sensitive electronic instruments and should be handled as such. Be especially careful to avoid both pulling on the electrode cable and getting moisture or electrode gel on the sensor snaps. If necessary, wipe the surface with a damp cloth or use a moistened Q-tip to remove gel from inside the sensor snaps. Wipe with a dry cloth.

Disposal

After use, the batteries must be disposed of in accordance with local, state and federal regulations and laws.

After use, the disposable electrodes may be a biohazard: they present a potential risk of cross-infection especially when used on abraded skin, unless they are restricted to a single patient.

Handle, and when applicable, dispose of these materials in accordance with accepted medical practice and any applicable local, state and federal laws and regulations.

Maintenance and Calibration

No preventative inspections required; maintenance must be performed by qualified personnel. Factory re-calibration can be requested.

Factory testing and calibration ensure equipment accuracy and frequency response. Contact Thought Technology for factory re-calibration if necessary.

Wipe device with a clean cloth.

Storage and Tranportation

Store in its original case at up to 90% humidity / 30C°.
Transport in its original case.

Guidance and manufacturer's declaration – electromagnetic immunity

The MyoTrac Infiniti is intended for use in the electromagnetic environment specified below. The customer or the user of the MyoTrac Infiniti should assure that it is used in such an environment, and that precautions regarding that environment are heeded.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV contact 8 kV air	6 kV contact 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	1 kV differential mode 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MyoTrac Infiniti requires continued operation during power mains interruptions, it is recommended that the MyoTrac Infiniti be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The MyoTrac Infiniti is intended for use in the electromagnetic environment specified below. The customer or the user of the MyoTrac Infiniti should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the MyoTrac Infiniti, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a]   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 the MyoTrac Infiniti is used exceeds the applicable RF compliance level above, the MyoTrac Infiniti should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MyoTrac Infiniti.

[b]   Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

**Recommended separation distances between
portable and mobile RF communications equipment and the MyoTrac Infiniti**

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – electromagnetic emissions

The MyoTrac Infiniti is intended for use in the electromagnetic environment specified below. The customer or the user of the MyoTrac Infiniti should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The MyoTrac Infiniti uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The MyoTrac Infiniti is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Warranty

The Saebo MyoTrac Infiniti device is guaranteed to be free from defects in material and workmanship for 1 year from the date of purchase. The lead wires (Channel A & Channel B cables) include a 3 month warranty from date of purchase.

This warranty does not apply to damage incurred through accident, alteration, or abuse, nor to sensor damage created by static electricity, or to screen damage resulting from misuse. Do not use this equipment in dry, static area unless using an anti-static mat or anti-static spray on carpeted areas.

IMPORTANT: Remove dead batteries promptly to prevent corrosion damage.