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Saebo Hand Treatment Kit

Intensify Treatment with Evidence-Based Solutions.

The Saebo Hand Treatment Kit is a comprehensive upper extremity program designed for hospitals and clinics that treat neurological patients with limited hand function. The all-in-one kit allows clinicians to intensify their treatment by addressing hand function, sensorimotor recovery, spasticity and soft-tissue management.

*Saebo*Glove

With a lightweight and low profile design, the *Saebo*Glove is the premiere functional solution for impaired hand function with minimal to no spasticity.

*Saebo*Stim Micro

Boost arm and hand recovery through sensory electrical stimulation (SES). Specialized electro-mesh garments provide afferent stimulation, resulting in improved function, weakness and spasticity.

*Saebo*Flex

Our original, ground breaking design is still the first choice for patients with limited hand function and moderate to severe spasticity.

Saebo AvivaStim

This portable electrical stimulation device strengthens weakened muscles. The unique trigger mode allows for timely stimulation during functional tasks.

*Saebo*Stretch

With three interchangeable, spring-loaded plates, *Saebo*Stretch allows individuals suffering from spasticity to stretch comfortably and safely while minimizing/preventing contractures.

Program Benefits:

- All-in-one solution for intensive hand neurorehabilitation.
- Improve ADL performance with increase upper extremity motor recovery.
- Addresses key clinical areas including function, sensorimotor recovery, spasticity and soft tissue management.
- Initiate hand treatment earlier and often.
- Improve documentation.

Training & Support:

- AOTA CE approved training available.
- Online training & support.

Saebo Hand Treatment Kit

Care and Cleaning Instructions

*Saebo*Flex

*Saebo*Flex devices are fabricated so that the foam liners can be removed and replaced with new liners provided in the Saebo Hand Treatment Kit. Replacement straps for the digit caps, hand pieces, and forearm shells are also included.

The remainder of the parts/pieces can be cleaned with the same cleaning solutions used for other rehabilitation equipment and supplies such as Dispatch. Spray or apply solution to a clean cloth and wipe down. If the *Saebo*Flex has only been used a few times, the foam liner, which is closed cell, can be re-used after wiping down and cleaning with the same solution.

*Saebo*Glove

The *Saebo*Glove liner should be cleaned periodically. To clean the *Saebo*Glove, remove the liner and wash with lukewarm water and a mild detergent. After washing, rinse the liner thoroughly with cool water, wring out, and allow it to air dry. If the liner is lightly soiled, disinfectant solution can be lightly sprayed

*Saebo*Stim Micro

Do not immerse the device in liquid. Avoid spilling liquids on the *Saebo*Stim Micro. The surface of the *Saebo*Stim Micro may be wiped with a soft cloth or sponge dampened with a mild soap solution. Avoid caustic cleansers. Garments should be hand washed with a mild detergent in cold water and rinse thoroughly. Allow to air dry; DO NOT place in dryer. directly on the liner and wiped cleaned with a cloth.

*Saebo*Stretch

The *Saebo*Stretch cover should be cleaned periodically. To clean the *Saebo*Stretch, remove the cover as well as the palmar pad connected to the cover, Clean both the cover and the palmar pad with lukewarm water and mild detergent. Allow to air dry. To maintain your *Saebo*Stretch cover in good condition, wash and dry the affected hand thoroughly before every use.

Saebo AvivaStim

The unit should be cleaned regularly using a soft cloth, lightly dampened with soapy water. Do not allow the interior of the unit or any of the connectors to become wet during cleaning. Do not use detergents, alcohol, spray aerosols or strong solvents on your unit.

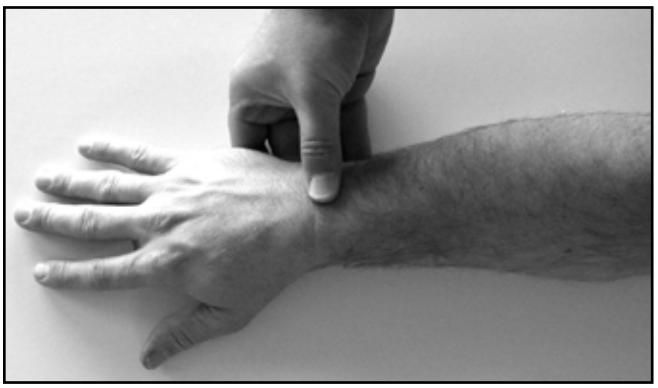
SaeboFlex

Fitting Position:

Sit perpendicular to the patient with the involved side next to you. It is recommended that a chair without arms be used and that the patient's involved arm rest on your knee during the fitting.
If the patient is in a wheelchair, please remove the armrest so an adequate position can be achieved.

Fitting:

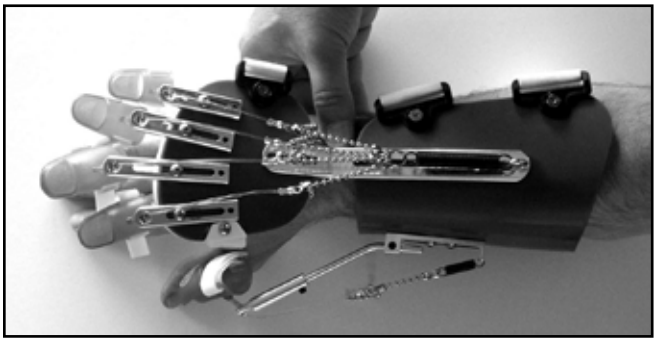
1) When donning the *Saebo***Flex**, place your thumb over the patient's ulnar head.



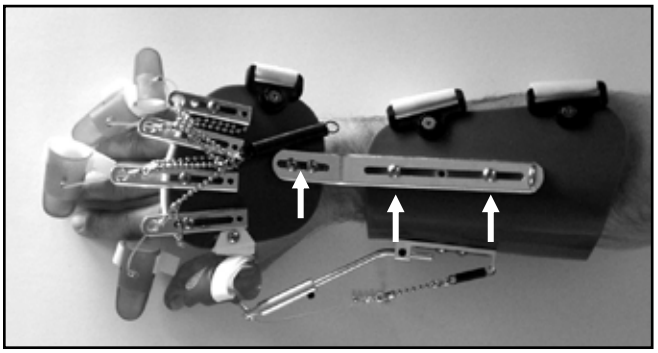
2) Slide the Forearm Shell on the patient.
   Be sure the distal edge of the Forearm Shell is just proximal to your thumb.

   Secure the two forearm straps.

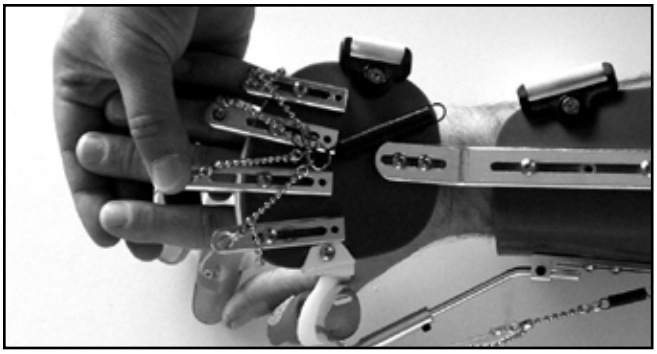
   Do not secure the hand strap at this stage.



3) Unhook the Wrist Spring and let the Digit Caps hang down. Loosen the two Allen screws on the Dorsal Hand Piece and the two Allen screws on the Forearm Shell.



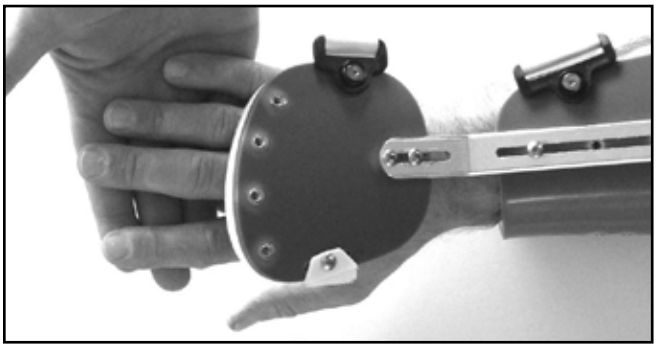
4) Bring the fingers up against the Dorsal Hand Piece. Look at the distal edge of the Dorsal Hand Piece in relation to the PIP joints of digits 2-5.



5) Bring the distal edge of the Dorsal Hand Piece as close to the PIP joint of the third digit as possible without covering the PIP joints of the other digits.

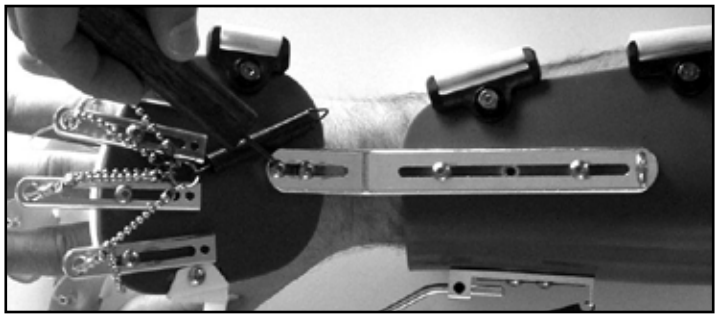
   If you need to move the Dorsal Hand Piece closer to the PIP joints (distal), start with the two Allen screws on the Dorsal Hand Piece.

   If you need to move the Dorsal Hand Piece away the PIP joints (proximal), start with the two Allen screws on the Forearm Shell.

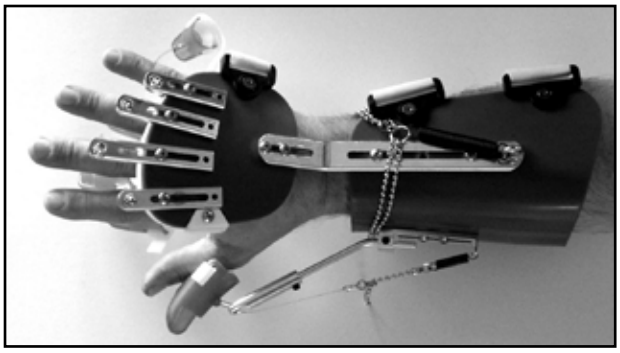


Note: Digit Caps removed for illustration purposes.

6) Once the correct overall length has been determined, tighten the two Allen screws on the Dorsal Hand Piece and the two Allen screws on the Forearm Shell.

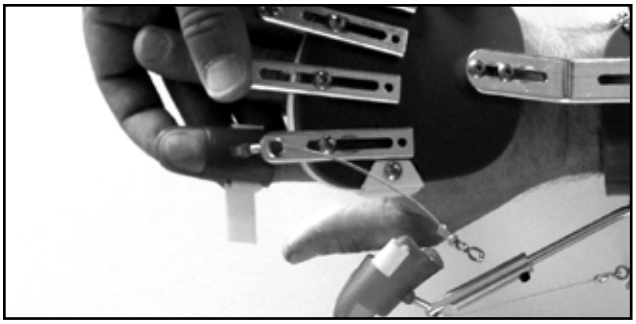


7) Once the Allen screws are tightened, secure the hand strap on the Dorsal Hand Piece. Reattach the Wrist Spring and disconnect all the Bead Lines from the Lead Lines for digits 2-5.

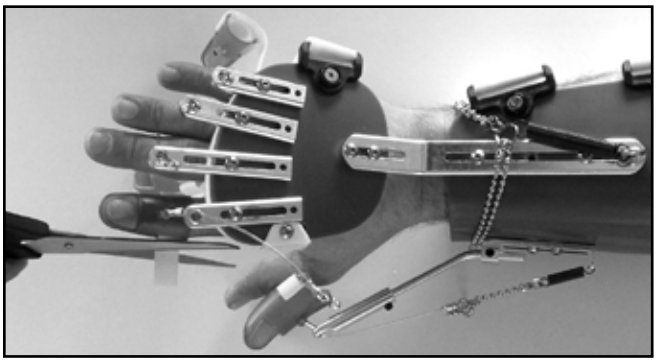


8) Starting with the index finger, don the Digit Cap and fasten the Digit Cap Strap securely. Bring the finger up against the Finger Lead Mount. Adjust the angle of pull using the Allen screw located in the slot on the Finger Lead Mount. Remember the correct angle of pull is slightly behind 90°.

Do not put the other Digit Caps on the fingers at this time. Address one finger at a time working towards the little finger.



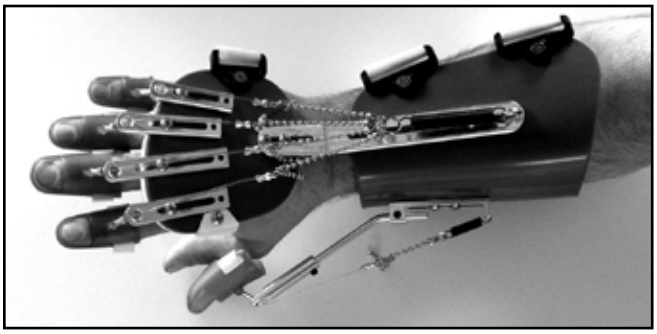
9) Use the scissors to trim the Digit Cap Strap. All straps must be trimmed as they will interfere with grasp.



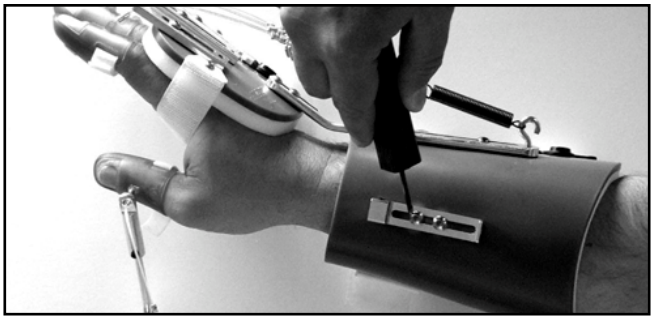
10) Reattach the Bead Line with the Lead Line for the index finger. Tighten the Bead Lines enough so the crimp is close to the Finger Lead Mount.

After attaching the Bead Line to the Lead Line, the PIP joints should be close to a neutral position.

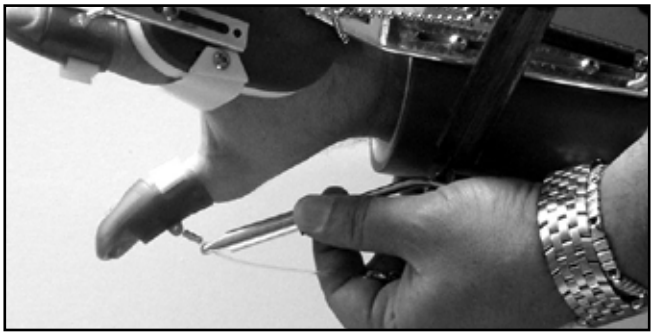
11) Continue this process with the long finger and proceed to the ring finger and finally the little finger. Be sure to adjust the angle of pull for each Finger Lead Mount before tightening down the corresponding Allen screw.



12) Remove the Thumb Lead Mount and loosen the two allen screws on the Thumb Mount. Don the Digit Cap on the thumb.



13) Reinsert the Thumb Lead Mount into the Thumb Mount, leaving the allen screws loose. Do not tighten the set screw. Passively position the patient's thumb in the optimum position ("thumbtion") with the thumb MCP in extension and a stretch on the web space.

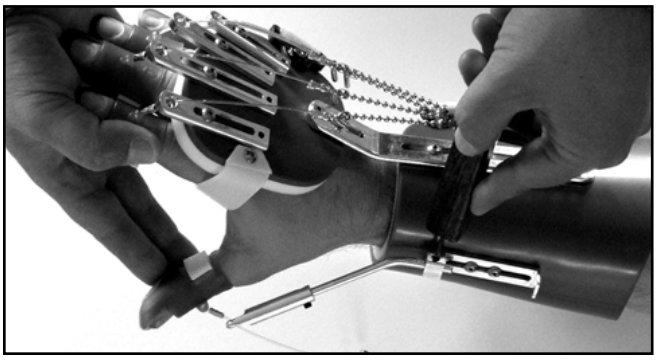


14) Move the Thumb Mount and the Thumb Lead Mount accordingly to maintain the thumb in this position, while also determining the overall length of the Thumb Assembly to set the angle of pull just behind 90 degrees.

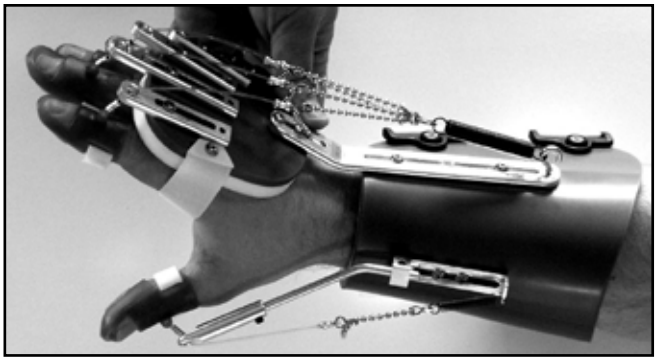
Often the Thumb Mount will slide more proximally to allow for extension of the thumb MCP. Secure the allen screws on the Thumb Mount (this may mean temporarily removing the Thumb Lead Mount again to do so).

15) Re-insert the Thumb Lead Mount (if you removed it to secure the Thumb Mount) and rotate as needed to position the thumb web space on stretch and secure the set screw.

Don't forget, you can slide the Thumb Line Guide distally as needed to be sure the angle of pull is behind 90 degrees and the crimp on the Digit Cap is in contact with the Thumb Line Guide.

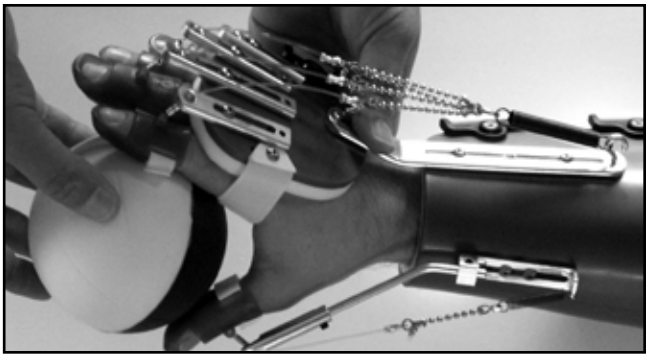


16) Attach the Thumb Spring and tighten the Bead Line so the crimp is close to the Thumb Line Guide.



17) Keep the patient in a seated position. While holding the ulnar side of the patient's hand, place the ball at least halfway in the web space between the thumb and index finger.

    Ask the patient to squeeze.



If your patient can successfully grasp and release the ball, then prescribe activities that target their movement impairments. Progress the activities as the patient improves.

SaeboGlove

*Saebo*Glove

Introduction

Saebo is pleased to provide you with the latest innovation for hand rehabilitation. The *Saebo***Glove** is a low profile functional device that assists neurological and orthopedic clients with finger and thumb extension. The *Saebo***Glove** positions the wrist and fingers into extension in preparation for functional activities. The client grasps an object by voluntarily flexing his or her fingers. The extension system connected to the glove assists with re-opening the hand to release the object.

This manual contains important information for both the person who will wear the *Saebo***Glove** and the clinician who will provide and fit the device. Please be sure to review all information carefully.

*Saebo*Glove Features

- Lightweight, low profile spiral forearm design that secures the wrist in a functional position.
- Finger and thumb extension system made up of IP (interphalangeal) Tensioners provided for each digit and joint.
- Tensioners come in various sizes to accommodate all finger and thumb lengths.
- Comfortable non-slip forearm liner to minimize distal migration.
- Strapping system strategically located to ensure intimate contact with the palm and forearm.
- Non-slip gel located at fingers and thumb for maximum grip during prehensile tasks.
- Includes Lycra material for expandability.
- Palm exposed to increase breathability and ease of donning.
- Glove Liner removable for cleaning.

Indications For Use

- Neurological conditions including but not limited to stroke, brain injury, spinal cord injury, MS, GBS, ALS and muscular dystrophy.
- Brachial plexus injury.
- Radial nerve injury.
- Individuals exhibiting wrist drop and/or lacking finger extension.

NOTE: The *Saebo***Glove** is a low profile splint made from soft fabric, rubber tensioners and semi-rigid parts. The *Saebo***Glove** material does not accommodate neurological clients that exhibit increased tone/spasticity. These clients would be more appropriate for the *Saebo***Flex**/*Saebo***Reach**.

Contraindications

- Not for use with clients exhibiting increased tone/spasticity.
- Not for use with severe contractures or joint deformities in the fingers.
- Not for use over open wounds and infected areas.
- Not for use with severe edema.

Precautions

1. The *Saebo***Glove** must be provided by a licensed occupational/physical therapist or assistant, a licensed orthotist, or a certified fitter. This individual will be responsible for educating the client and/or care provider in the appropriate wearing schedule, skin assessment, correct donning and doffing procedures, as well as the care and cleaning of the glove.
2. All activities using the *Saebo***Glove** should be performed pain-free. If you experience any pain while using the *Saebo***Glove**, stop immediately and contact a health care professional before resuming.
3. Do not give the *Saebo***Glove** to unsupervised children.
4. If unusual swelling, skin discoloration, skin breakdown, discomfort, or numbness occurs, remove immediately and contact a health care professional before resuming.
5. The *Saebo***Glove** should fit snugly and comfortably without interfering with circulation.
6. After removing the *Saebo***Glove**, check for strap marks on the skin. If marks are present and they do not dissipate within thirty minutes, discontinue wearing the glove until you consult with a health care professional.

Parts Included

Fitting Procedure

Place Fingers and Thumb into Glove

Position the wrist into flexion while keeping the fingers straight. See Figure 1. Slide each finger into the appropriate sleeve followed by the thumb. See Figure 2. **To maximize performance and fit, there should not be excess material at the tip of the finger and thumb.** If excess material is observed, consider a smaller glove liner.

Fig. 1

Fig. 2

Apply Wrist Support

Once the fingers and thumb are positioned correctly into the glove, apply the Wrist Splint around the forearm and position as proximal as possible by pulling the Wrist Splint up the arm. See Figure 3. Be sure to keep the head of the ulna free from contact of the Wrist Splint.

Note: like all wearable splints, distal migration may occur. The key is to minimize the migration. Be sure to position the Wrist Splint as proximal as possible.

Fig. 3

Apply Forearm Strap

With the Wrist Splint positioned as proximal as possible, attach the Forearm Strap to the Forearm Post. See Figure 4. To minimize distal migration, be sure that the strap is not loose.

Fig. 4

Adjust Forearm Strap Length

To adjust the length of the Forearm Strap, separate the hook portion of the strap from the loop and readjust accordingly. See Figure 5.

Fig. 5

Apply Hand Strap

Once the Forearm Strap is applied correctly, attach the Hand Strap to the Hand Post. See Figure 6. Be sure that the strap is not loose.

Fig. 6

Adjust Hand Strap Length

To adjust the length of the Hand Strap, separate the hook portion of the Strap from the loop and readjust accordingly. See Figure 7.

Fig. 7

Attach Tensioners

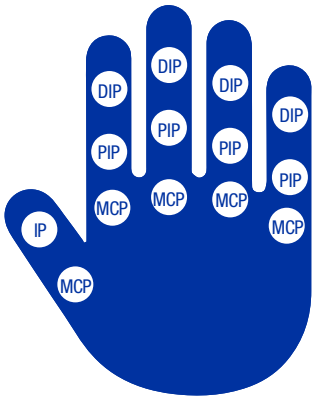
The purpose of the Tensioners are to assist the finger (DIP, PIP, MCP) and thumb joints (IP, MCP) with digit extension. The extension system is made up of 5 various sized Tensioners. See Figure 8. The variety of sizes allow for maximum adjustability and fit based on the digit length.

NOTE: "A" Tensioner = Smallest;
"E" Tensioner = Largest.

Fig. 8

Below is a helpful guide when determining which Tensioner to use for various hand sizes. See Figure 9. The fitter will be required to use his or her clinical judgment when selecting the appropriate sized Tensioners.

Refer to the back side of the Tensioner case included in the box for specific recommended sizing.



Glove Size	DIP Joint	PIP Joint	MCP Joint	IP Thumb	MCP Thumb
XS	A	A	B/C	A/B	D/E
SM	A	A	B/C	A/B	D/E
MD	A	A	C	A/B	D/E
LG	A/B	A/B	C	B/C	D/E
XL	A/B	A/B	C	B/C	D/E

Fig. 9

How to Connect a Tensioner

When connecting the Tensioners to the Finger Hooks, be sure to apply extra tension. See Figure 10. Make sure it locks securely into the groove of the hook. See Figure 11.

NOTE 1: A proper fitting Tensioner should not exhibit any slack when connected. Consider the next smallest size if this is observed.

NOTE 2: Not all IP Joints may require a Tensioner.

Once the *Saebo***Glove** is positioned on the forearm and located as proximal as possible, apply the appropriate size Tensioners to the fingers starting with the index finger MCP joint. See Figure 12. After the MCP joint of the index finger is positioned in sufficient extension, proceed to the PIP and DIP joints (if needed) of the index finger respectively. See Figure 13.

Continue the same process for the remaining fingers (middle, ring, 5th digit). See Figure 14. Finally, apply the appropriate size Tensioner for the Thumb MCP and IP Joint. See Figure 15.

Fig. 10

Fig. 11

Fig. 12

Fig. 13

Fig. 14

Fig. 15

Thumb Fitting Tips

Because the thumb allows for multi-planar motion, various strategies may be required in order to position it correctly. Although, most clients will only require 1 Tensioner to be attached to the Thumb Attachment Site, consider the following if needed:

Fig. 16

Apply 1 Tensioner around both Thumb Attachment Sites.

Fig. 17

Apply 1 Tensioner each around both Thumb Attachment Sites.

Fig. 18

Apply 2 Tensioners around the same Thumb Attachment Site.

Troubleshooting

1. Finger Deviation

If a finger is deviating in a radial or ulnar direction, consider attaching the MCP Tensioner to the adjacent attachment site opposite the direction of the deviation. For example, if the index finger is deviating in a radial direction, instead of attaching the Tensioner to the Hand Attachment Site designed for the index finger, attach the Tensioner to the Hand Attachment Site designed for the middle finger. This attachment may correct the deviation radially by pulling the finger in a more ulnar direction.

NOTE: If the finger that is deviating requires more extension assistance at the MCP joint, consider applying 2 MCP Tensioners instead of one. Each Finger Hook was designed to house 2 Tensioners if more assistance is needed. The 2 Tensioners can either share the same Hand Attachment Site or be positioned separately. Using the finger deviation example above, both Tensioners can be attached to the Hand Attachment Site designed for the middle finger or one Tensioner could be attached to the Hand Attachment Site designed for the middle finger and the second Tensioner could be attached to the Hand Attachment Site designed for the index finger.

2. Finger(s) Remain Slightly Flexed and Need Additional Extension Assistance

As mentioned in the previous note, 2 Tensioners can be applied to the same hook if more extension is needed. Although a majority of appropriate glove candidates will only require 1 Tensioner per Finger or Thumb Joint, all Finger Hooks (DIP, PIP, MCP) and Thumb Hooks (IP & MCP) are designed to receive up to 2 Tensioners if desired.

Another option for obtaining additional extension is by incorporating triggered electrical stimulation (NMES/FES) to the finger extensors while using the *Saebo***Glove**. See Figure 19. For example, when the client attempts to grasp an object, turn the stimulation on to extend the fingers. Once the object is grasped, turn off the stimulation. Then, when the client attempts to release the object, trigger the stimulation once again to facilitate additional extension. Perform this repeatedly until the client can achieve sufficient extension without the stimulation.

Fig. 19

NOTE:

The ideal NMES/FES unit when using the glove is a portable 2 channel unit with a trigger button. Please contact Saebo to learn more about our affordable home units for patients.

3. Distal Migration

Shifting or migration may occur from time to time. Assuming that the client is provided a properly sized device, consider the below to help with distal migration.

- Reposition the Wrist Splint as proximal as possible and tighten the Forearm and Hand Straps. It is important that the straps are not too loose. As a reminder, the liner consists of a non-slip silicone gel. If the straps are loose, then the gel liner will not be as effective.
- Apply shelf liner or Dycem (as an extra layer of non-slip material) around the forearm before donning the *Saebo***Glove**.

4. Unable to Actively Flex Digits (Weak Grasp)

If the client exhibits minimal to no active finger flexion, consider combining electrical stimulation (NMES/FES) while using the *Saebo***Glove**. For example, with respect to grasping, flaccid clients may lack active movement in the extrinsic and intrinsic muscles. Therefore, consider the following:

- Apply 1 channel of electrical stimulation to the long finger flexors.
- Apply 1 channel of stimulation to the thenar/hypothenar muscle groups.

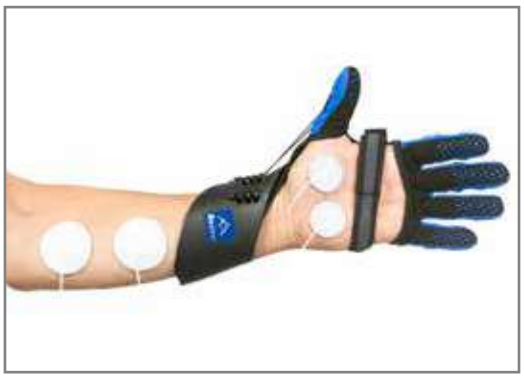


Fig. 20

Fig. 21

With both channels being stimulated, the client will be able to perform sufficient grasping to complete the task. When the stimulation is off, the Tensioners will re-extend the fingers and thumb back to the neutral position so the next grasping attempt can occur. If the client demonstrates some active finger flexion but it is extremely weak, consider removing one or more of the Tensioners at the respective joints to make it easier for the client to grasp/flex fingers.

Removing the *Saebo*Glove

Fig. 22 Detach DIP Tensioner.

Fig 23. Detach MCP Tensioner.

Fig. 24 Detach Thumb MCP & IP Tensioner.

Fig. 25 Detach Forearm & Hand Straps.

Fig. 26 Remove the *Saebo***Glove.**

NOTE 1: By detaching the DIP & MCP Tensioners, the *Saebo***Glove** can be reapplied with greater ease.

NOTE 2: You do not need to completely remove the Tensioner from both sides.

Re-applying the *Saebo*Glove

Fig. 27 Position the *Saebo*Glove in front of the affected hand.

Fig. 28 Slide fingers and thumb into the appropriate sleeves.

Fig 29. Apply the wrist splint up the forearm as high as possible.

Fig. 30 Attach forearm & hand straps.

Fig. 31 Reattach MCP Tensioner for all fingers.

Fig. 32 Reattach DIP Tensioner for all fingers.

Fig. 33 Attach Thumb MCP Tensioner.

Fig. 34 Attach Thumb IP Tensioner.

Care and Cleaning

The *Saebo***Glove** liner should be cleaned periodically. In order to clean the *Saebo***Glove**, remove the liner and wash with lukewarm water and a mild detergent. After washing, rinse the liner thoroughly with cool water, wring out, and allow it to air dry. If the liner is lightly soiled, disinfectant solution can be lightly sprayed directly on the liner and wiped clean with a cloth.

Warning

The *Saebo***Glove** was manufactured to meet Saebo's superior standards. However, regardless of how carefully you use, or how well you care for your glove, it will eventually begin to show age and wear. Saebo's warranty covers manufacture defects for 1 year, but it does not cover damage caused by accident, improper care, negligence, normal wear and tear, or natural breakdown of colors and materials over extended time and use. To extend the life of your *Saebo***Glove**, do not grasp objects that may rip, tear, or damage the Glove Liner.

- Strap sizing goes here

SaeboStim Micro

*Saebo*Stim Micro

Introduction

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

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

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

Features

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

Indications for Use

TENS (Transcutaneous Electrical Nerve Stimulation)

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

NMES (Neuromuscular Electrical Stimulation)

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

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

Contraindications

TENS

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

NMES

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

Warnings

TENS

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

NMES

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

Precautions

TENS

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

NMES

- Precautions should be taken in the presence of:
  - Recent surgical procedures when muscle contraction may disrupt the healing process.
  - A menstruating uterus.
  - Sensory nerve damage (loss of normal skin sensation).
- Some patients experience skin irritation or hypersensitivity due to the conductive medium or electrical stimulation. This condition can usually be reduced by alternative electrode placement or use of additional or a different conductive medium.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing physician.
- Powered muscle stimulators should be used only with the lead wires and electrodes recommended for use by the manufacturer.

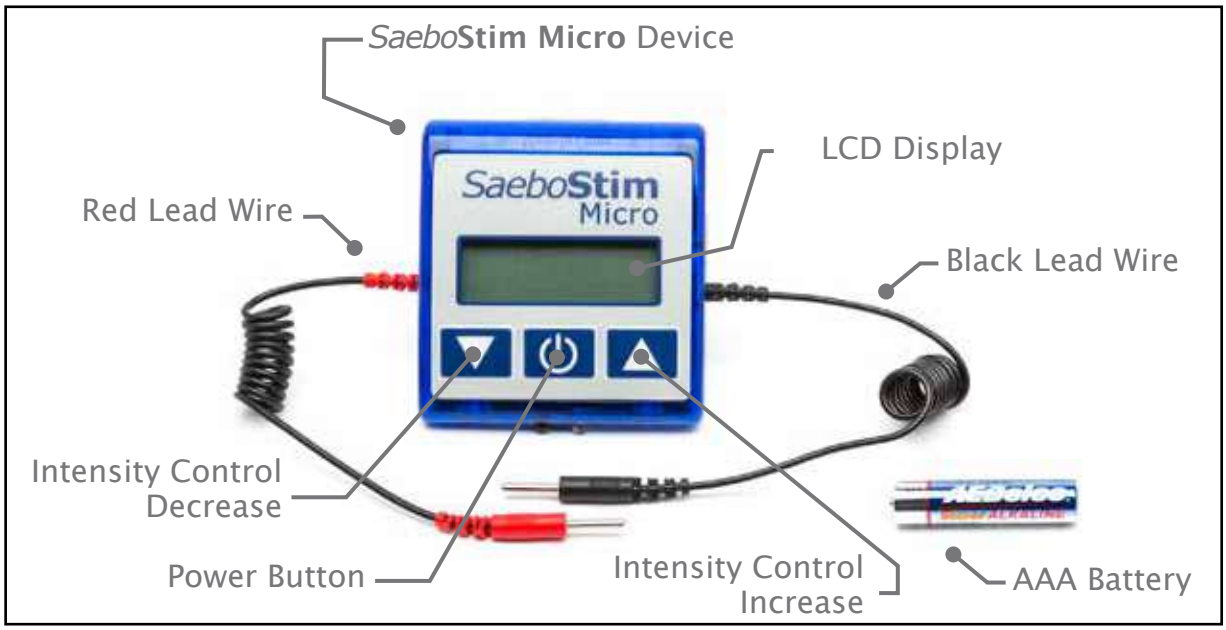
Adverse Effects

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

System Components

Velcro Arm Strap

TheraCream



Getting Started

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

Powering the Device

The *Saebo***Stim Micro** is powered by one (1) AAA battery. Remove the battery compartment cover from the back of the device. See Figure 2. Install the battery according to the illustration inside the battery compartment making certain the positive terminal of the battery aligns with the '+'. Replace the battery compartment cover. See Figure 3.

Fig 2

Fig 3

Lead Wires

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

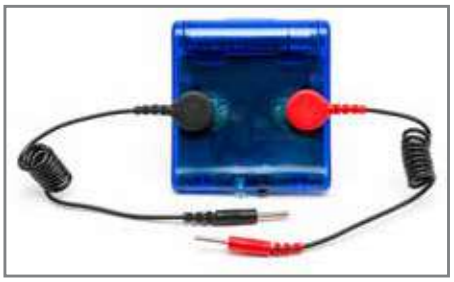


Fig 4

Reconnecting the Lead Wires

Lead Wires determine the polarity of the current and is coded accordingly; Black is negative and Red is positive. If you accidentally disengage the Lead Wires from the unit, reconnecting is very simple.

To reconnect the Lead Wire snaps to the *Saebo***Stim Micro** unit, insert the snap stud end into the inside position of the slot and slide toward the outside position to lock in place.

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

The **Black** Lead Wire will need to be pushed down and slid to the left to secure in place. See Figure 5.

Fig 5

The **Red** Lead Wire will need to be pushed down and slid to the right to secure in place. See Figure 6.

Fig 6

Electro-Mesh Garment Electrode

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

The Electro-Mesh Glove and Sleeve are highly conductive and made of silver treated nylon fibers blended with Dacron® fibers. The Garments transmit the stimulation from the unit to the arm and hand. Due to the shape of the hand, the Glove is an ideal choice as it intimately covers the entire hand for full stimulation. See Figure 7.

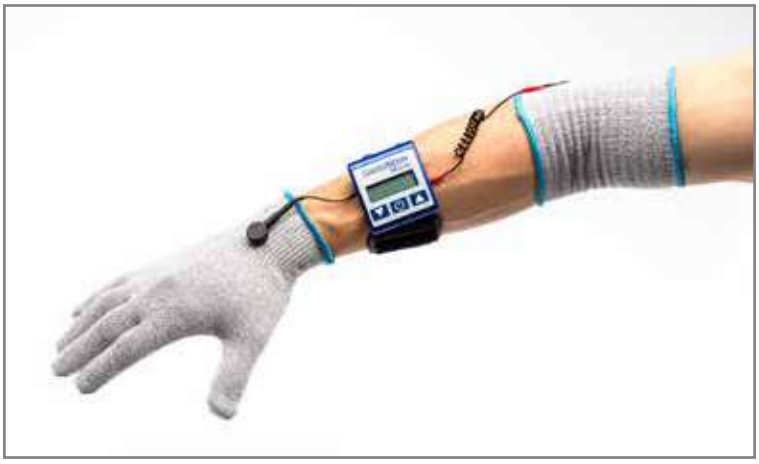


Fig 7

Applying the Device:

Important:

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

2. Prior to putting the device on, it is important that you apply the conductive Thera-Cream over the treatment area (arm and hand). Please be sure to cover the entire treatment area thoroughly to avoid an uncomfortable, stinging sensation.

3. With the Garments on a flat surface, connect the Lead Wires to the Garment Electrodes by inserting the pin ends into the Garment Electrode Connectors so no metal is visible. The Black Lead Wire connects to the Glove and the Red Lead Wire connects to the Arm Sleeve. See Figures 8 and 9.

Fig 8

Fig 9

4. Apply the Arm Sleeve onto the arm and position over the elbow region with the Connector positioned on top. Make sure the Sleeve fits snugly over the entire treatment area. See Figure 10.

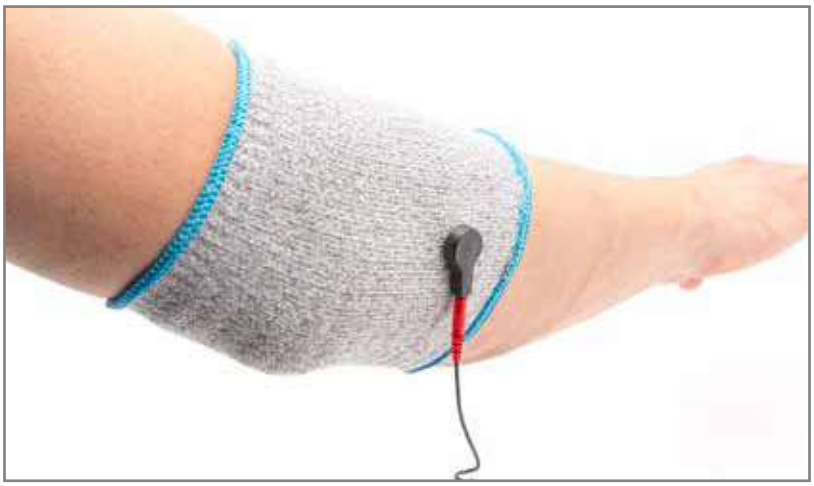


Fig 10

5. Apply the Wrist Strap and secure just below the Arm Sleeve. Please be sure the Strap is not too tight, but is secured. The Strap will be positioned between the Arm Sleeve and the Glove. See Figure 11.

Fig 11

6. Secure the Velcro portion of the *Saebo***Stim Micro** unit onto the Wrist Strap. See Figure 12.

Fig 12

7. Apply the Glove onto the hand. Be sure the Glove fits snugly over the entire hand so stimulation can be provided evenly to the entire treatment area. Be sure the Connector is positioned on the top portion of the hand. See Figure 13.

Fig 13

Turning the Device On

The *Saebo***Stim Micro** is powered on by pressing and releasing the Power button for approximately 2 seconds until the display lights up showing P1 on the screen. See Figure 14. Only the "P" will be flashing. The Unit should be connected to the Garment Electrodes and the Garments should be worn at this point.

WARNING!

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

Fig 14

Program Selection

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

When the unit is powered on, select desired program P1 or P2 (see below). Program selection is made by repeatedly pressing the Power button until the desired program is shown on the far left of the display. Only the "P" will be flashing. See Figure 15.

Fig 15

The *Saebo***Stim Micro** is factory programmed for two treatment programs.

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

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

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

Treatment Intensity

Two buttons on the device control intensity: Increase (▲) and Decrease (▼). See Figure 16. The intensity defaults to 5 when the device is powered on or when the batteries have been removed and replaced.

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

Fig 16

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

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

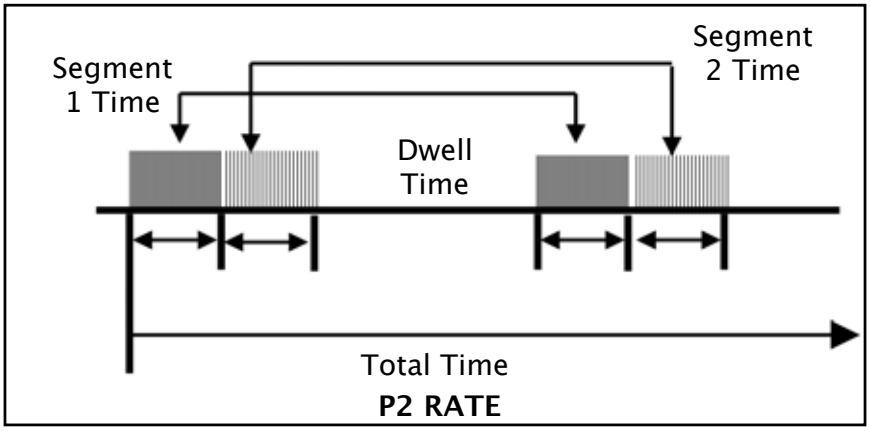
Parameters

Waveform

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

Rate

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



P2 Rate Illustration

Powering the Device Off

The *Saebo***Stim Micro** will automatically power off when treatment is completed. The unit can also be powered off manually at any time. To manually power off, press the Power button for approximately 4 seconds and the device will turn off. See Figure 17. Or you may press and hold the decrease button until the device reads 0, release it and press it again and the device will turn off.

Fig 17

Battery Care

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

Low Battery

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

Care and Cleaning

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

Trouble-Shooting

Device will not turn on:

- Check for proper battery installation.
- Replace battery.

No Stimulation:

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

Helpful Hints

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

Caution

Federal law restricts the device for sale by, or on the order of anyone other than a licensed 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.

SaeboStretch

*Saebo*Stretch

Saebo Inc. is pleased to provide you with the most innovative resting hand splint available. It offers the following revolutionary design changes:

- Patented stretch technology with three interchangeable energy-storing hand plates.
- Comfortable non-slip cover and strapping system to minimize migration.
- Strapping system strategically located to ensure intimate contact with the fingers and hand.
- Straps sewn to cover to maximize proper positioning and ease of donning.
- Adjustable thumb system to allow for radial and palmar adduction/abduction.
- Malleable wrist and thumb section.
- Palmar padding for proper arch support.
- Cover features a zipper closure which can easily be removed for cleaning.

This manual contains important information for both the person who will wear the *Saebo***Stretch** and the clinician/orthotist who will provide and fit the splint.

Please be sure to review all information carefully.

Indications for Use

- To position the hemiparetic hand following a neurological injury (i.e. stroke, traumatic brain injury, cerebral palsy, spinal cord injury).
- For use with patients that have minimum to moderate tone and soft tissue shortening.

Contraindications

- Not for use with severe spasticity.
- Not for use with severe contractures of the wrist and finger joints.
- Not for use if open wounds, sores, or infected areas are present.
- Not for use with moderate or severe edema.

Precautions

- The *Saebo***Stretch** must be fit by a licensed occupational/physical therapist or assistant, a licensed orthotist or certified fitter. This individual will be responsible for educating the client and/or care provider on the appropriate wearing schedule, skin assessment, correct donning and doffing procedures, as well as the care and cleaning of the splint.
- Discontinue wearing the splint if you notice any of the following: pressure areas, skin breakdown, pain or numbness in the fingers. Do not resume wearing the splint until you have consulted with a health care professional.
- When securing the straps, be very careful not to over-tighten as this may interfere with circulation. The innovative strapping system used on the SaeboStretch requires less tension than standard cloth or padded straps in order to maintain proper finger placement.
- After removing the splint, check for strap marks on the skin. If marks are present and they do not dissipate within thirty minutes, discontinue wearing the splint until you consult with a health care professional.

Fitting Procedure

Determine Wrist Angle

It is normal for most chronic neurological patients to have an initial wrist position of neutral or slight flexion. Re-assess your patient's soft tissue periodically so adjustments can be made as appropriate. The ideal position is 35 degrees of extension.

If the client requires a lower wrist angle, the goal will be to gradually position the *Saebo***Stretch** into more extension until you achieve 35 degrees of extension.

Figure 1: Start position

How to determine the correct starting wrist position:

1. Passively position the involved wrist in flexion, keeping the MCP, PIP, and DIP joints in composite extension (Figure 1).

2. Slowly bring the wrist into extension until you feel the first indication of resistance (Figure 2). Make note of this wrist angle. This is called R-1 (Resistance 1) and represents the initial wrist position for the *Saebo***Stretch**.

3. Position the splint over the edge of the table and bend the wrist into the desired position R-1 (Figure 3).

Figure 2: End position R-1

NOTE: The wrist angle should not be positioned below -35 degrees of wrist flexion or above 35 degrees of wrist extension. This splint is designed so that at rest, the client's fingers are in composite extension.

Figure 3: Position for bending wrist angle into extension (dorsal side up)

Forearm Stabilizers

Bend the Forearm Stabilizers up to make sure the proximal forearm is held securely in position (Figures 4-5).

Figure 4: Bending Forearm Stabilizers

Figure 5: Correct position for Forearm Stabilizers

Thumb Position

The *Saebo***Stretch** includes a very unique thumb system. Adjustments can be made to accommodate radial adduction/abduction and palmar adduction/abduction (Figures 6-9).

Figure 6: Radial Adduction

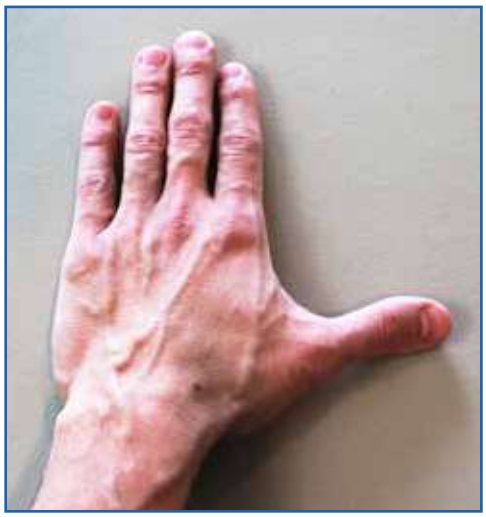


Figure 7: Radial Abduction

Figure 8: Palmar Adduction

Figure 9: Palmar Abduction

Prior to fitting the thumb, check for soft tissue shortening at the web space. The ideal position puts the thumb web space on stretch (Figure 10).

If a patient has a tight web space, you may have to start with the thumb in more radial/palmar adduction and adjust gradually into a greater amount of radial/palmar abduction as the soft tissue shortening is resolved.

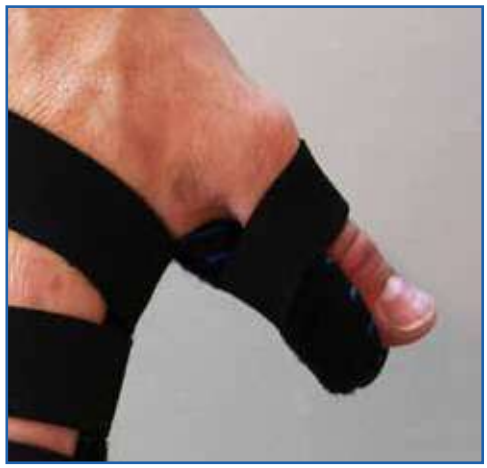


Figure 10: Optimal thumb position

Two steps for properly fitting the thumb include **adjusting the hardware** to set radial adduction/abduction angle and **bending the thumb mount** for palmar adduction/abduction angle.

Step 1: Setting Radial Adduction/Abduction Angle

To adjust for radial adduction/abduction, loosen the thumb screws, rotate the thumb component to the desired angle, and then retighten (Figures 11-12).

NOTE: The metal is universal (can be a left or a right). Identify the side where you see 2 screws.

Figure 11

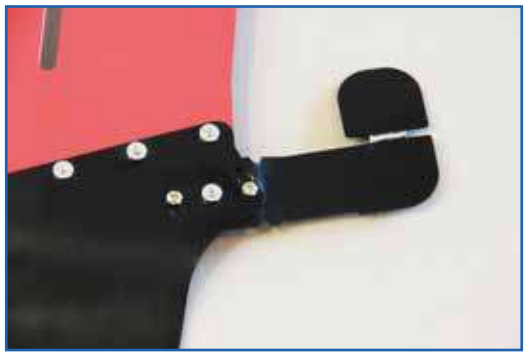


Figure 12

Step 2: Setting Palmar Adduction/Abduction Angle

In order to adjust for palmar adduction/abduction (opposition), the malleable thumb component will require bending.

Place the thumb component of the *Saebo***Stretch** over the edge of a table and gently push down (Figures 13-14). Be careful not to position the thumb into too much palmar abduction (opposition).

The ideal position puts the web space between the thumb and index finger on stretch.

Figure 13:
Position for bending thumb component

Figure 14:
Thumb in palmar abduction

After the thumb component has been positioned, bend the thumb tab so that it is perpendicular to the thumb support (90 degree angle). The thumb tab will act as a stop, reducing any unnecessary migration (Figures 15-16).

Figure 15:
Bending thumb tab into position

Figure 16:
Optimal thumb tab position

Strap Location and Placement

The *Saebo***Stretch** straps are sewn to the cover to assist with ease of donning and to ensure correct placement (Figure 17).

- Two forearm straps secure the forearm to the splint. One strap wraps over the forearm just proximal to the wrist while the other wraps around the forearm at the proximal end of the splint.
- One thumb strap secures the proximal phalanx of the thumb to the thumb mount.
- The SaeboStretch logo strap secures the hand just proximal to the MCP joints.
- Two finger straps (proximal and distal) stabilize the fingers to the hand plate. The proximal strap secures digits 2-4 and is positioned proximal to the PIP joint. The distal finger strap secures the same digits but is applied just distal to the PIP joint.
- The fifth digit strap secures the fifth digit to the hand plate.

Figure 17: Straps

IMPORTANT:

DO NOT cut the straps. The straps are made from an elastic woven material. Trimming the straps may lead to unraveling.

Energy Storing Hand Plates

There are three different color-coded hand plates that offer various grades of resistance (Figure 18). The *Saebo***Stretch** is designed to allow the fingers to move through flexion caused by increased tone and then utilizes stretch technology that gradually repositions the fingers into extension. The goal of the dynamic hand plates is to reduce the pressure generated at the IP joints during periods of increased tone/spasticity.

- Yellow = minimal resistance
- Red = moderate resistance
- Blue = maximum resistance

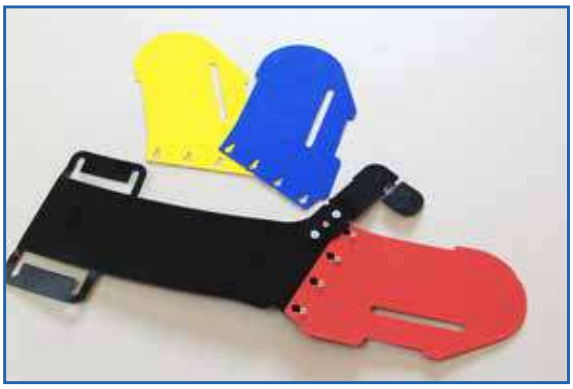


Figure 18:
Forearm Section and Three Hand Pieces

When to Change Hand Plates:

The *Saebo***Stretch** will be shipped with the red hand plate. After fitting the splint, have your client move, transfer, or ambulate while wearing the SaeboStretch to facilitate increased tone or an associated reaction. Reassess the position of the fingers.

If there is no evidence of finger deviation or flexion of the fingers (fingers pulling up) following the exertive activity, continue to use the red hand plate.

However, if any of the following occur, change to a yellow hand plate:

- PIP joints pull out of the strap (i.e., flexion) and DIP joints hyperextend.
- PIP joints volarly sublux/hyperextend and DIP joints flex.
- Fingers deviate.

If at any time the above occurs, change to the hand plate that offers less resistance. It is important that the fingers are allowed to move through flexion to protect the IP joints.

As the client's tone in the long finger flexors improves, consider switching to a more resistive hand plate.

NOTE 1: Sometimes, switching to the less resistive hand plate does not correct the fingers from flexing or deviating. If this occurs, consider decreasing the wrist angle. This will decrease the amount of tension on the long finger flexors and correct the problem.

NOTE 2: If the client's wrist angle is positioned above neutral and his/her fingers exhibit flexing or deviation, consider bending the wrist angle toward neutral first before attempting to change hand plates. Conversely, if the client's wrist angle is positioned below neutral and his/her fingers exhibit flexing or deviation, it is recommended to switch hand plates versus bending wrist angle into further flexion.

How to Change Hand Plates

1. Unzip the cover and remove.
2. Loosen the screws (do not remove) using the screwdriver provided (Figure 19).
3. Remove the current hand plate and replace it with the desired hand plate.
4. Re-tighten the screws.

Figure 19: Using the Screwdriver to Change the Hand Piece

Wearing Schedule

It is important to gradually increase the wearing time. When increasing the wearing time, the client should wear the splint during his/her waking hours. Once the client is able to tolerate the splint for 6 to 8 hours with no adverse reactions, then he/she can begin to wear the splint at night. It is important that the wearing schedule be developed and monitored by a healthcare professional.

Trouble Shooting Tips

IP Joint Flexion

If the IP joint for the thumb or fingers remain in a flexed position, contact Saebo and request a digit cap for the specified thumb/finger. The client can wear the digit cap while in the *Saebo***Stretch**. You will need to gradually increase the wearing time of the digit cap and pad the inside roof when using it for this application (Figures 20-21).

Figure 20

Figure 21

PIP Joint Hyperextension

If the PIP joint(s) for the fingers exhibit hyperextension while wearing the *Saebo***Stretch** (Figure 22), consider applying padding under the cover directly in line with the PIP joints (Figure 23). This will assist with prepositioning the joint in flexion.

NOTE: Figure 23 shows the padding on top of the liner for illustrative purposes only.

Figure 22

Figure 23

Care and Cleaning

The *Saebo***Stretch** cover should be cleaned periodically. In order to clean the *Saebo***Stretch**, remove the cover.

Once the cover is removed, remove the palmar pad from the cover (Figure 24). Clean both the cover and the palmar pad with lukewarm water and mild detergent. Allow to air dry.

To maintain your *Saebo***Stretch** cover in good condition, wash and dry the affected hand thoroughly before every use.

Figure 24

Reapplying the *Saebo*Stretch Cover

When reapplying the *Saebo***Stretch** cover, start at the top of the splint by inserting the hand plate portion into the cover (Figure 25). Then, wrap the cover around the thumb component and forearm (Figure 26).

Once the cover is replaced, zip the liner to secure in position.

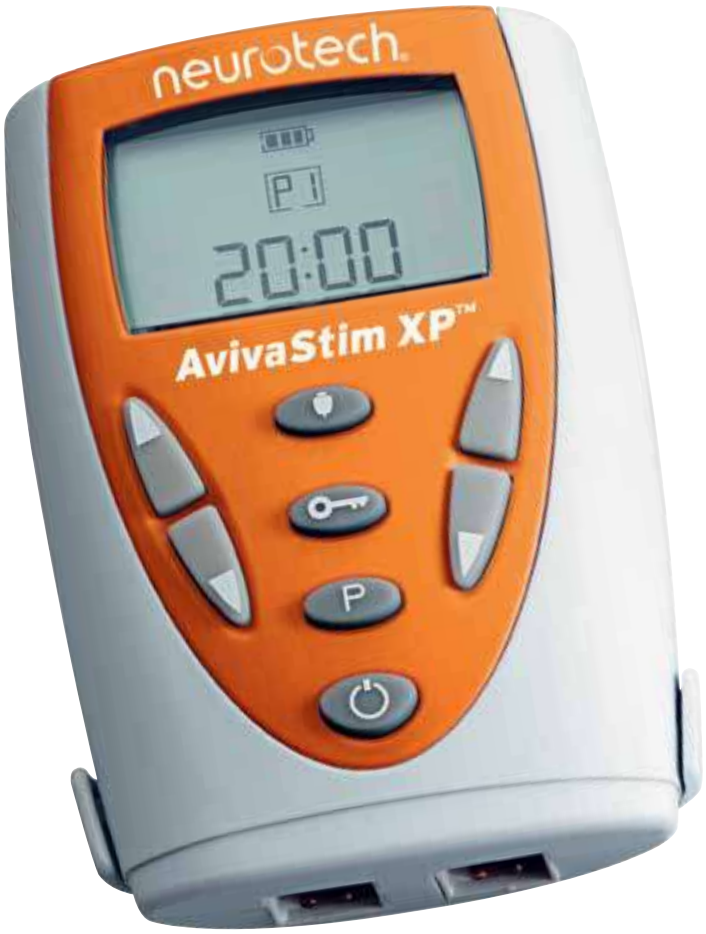
Figure 25

Customer:
If you experience discomfort or have any concerns about the wearing of the *Saebo***Stretch**, please contact the healthcare professional that issued it to you.

Clinician:
If you experience any difficulty fitting or adjusting this splint, please contact Saebo Inc. at 1-888-284-5433 for technical assistance.

Figure 26

Saebo AvivaStim



Introduction

Dear Customer

Thank you for choosing the AvivaStim XP™ Muscle Therapy System. Neurotech® developed AvivaStim XP as a highly portable and effective dual channel muscle stimulation device that re-educates and strengthens atrophied, weakened or immobilized muscles. Our goal is to design products that help accelerate recovery and return patients to a more active lifestyle.

If you have further questions regarding AvivaStim XP, please contact your prescribing physician or distributor that provided you with AvivaStim XP or neurotech at the address/phone number below.

If you have questions or require further information please contact:
neurotech®
A Division of Bio-Medical Research Ltd.
50 Harrision Street, Suite 114
Hoboken, NJ 07030
Tel: 800-901-5667
Web: www.neurotech.us

Validity

The information and technical data contained in this document relates to the AvivaStim XP™ muscle stimulator provided with this manual. Each AvivaStim XP unit is attributed a serial number which is located on the back of the unit.

The information and technical data disclosed in this document are proprietary to Bio-Medical Research Ltd. and may only be used and disseminated for the purposes and to the extent specifically authorised in writing by the company.

Disclaimers

All items of equipment manufactured and sold by Bio-Medical Research Ltd. are rigorously checked and tested prior to shipment. However the use of these units is beyond the area of the company's control. Bio-Medical Research Ltd. only accepts responsibility for the safety, reliability and performance of the equipment when it is operated in accordance with the instructions herein and within the given specifications. Therefore, the user must bear full responsibility for any actions arising out of the use or misuse of this equipment. Any modifications, repairs or servicing must be undertaken by authorised Bio-Medical Research Ltd. personnel.

This manual is intended for the guidance of the clinician, who should also decide the location of the electrodes.

The AvivaStim XP unit is produced by:
Bio-Medical Research Ltd., Parkmore Business Park West, Galway, Ireland

Restrictions

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

Prescription Warning

Caution: In the United States of America federal law restricts the device to sale or use by, or on the order of a physician or other practitioner licensed by the laws of the state in which he/ she practices

Device Warning
Dangerous Voltage: This device may deliver a charge of 25 microcoulombs (μC) or greater per pulse, which may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax, as it may cause cardiac arrhythmia.

Safety Information - NMES Mode (Prog. 1-8)

Intended Use:
AvivaStim XP applies muscle and nerve stimulation using the principles of Neuromuscular Electrical Nerve Stimulation (NMES) which are defined below. The unit sends short electrical impulses through the surface of the skin via adhesive electrodes.

Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the indications listed below.

Neuromuscular Electrical Stimulation (NMES):
NMES may be defined as the application of electrical stimulation of the peripheral nervous system to contract a muscle either through the direct activation of the motor neurons in the mixed peripheral nerve, or indirectly through reflex recruitment.

General description of AvivaStim XP for NMES
The AvivaStim XP is a battery operated, two-channel Neuromuscular Electrical nerve Stimulator (NMES) intended for the re-education and strengthening of atrophied muscle. Please see page 21 Programs 1-8 for details.

Indications:
- Neuromuscular Electrical Stimulation for relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis and maintaining or increasing range of motion.

Contraindications
- Patients with electronic implants (e.g. cardiac pacemaker or defibrillator - as your neurotech product may interfere with the proper functioning of the implanted stimulator) or if you suffer from any other heart problem.

Warnings
- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
- Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.

- Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Stimulation should not be applied transcerebrally.
- Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.

Precautions

- If in doubt, always seek medical advice.
- Safety of powered muscle stimulators for use during pregnancy has not been established.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Medical advice 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 apply muscle stimulation.
- Caution should be used in the presence of the following:
  a) When there is a tendency to haemorrhage following acute trauma or fracture;
  b) Following recent surgical procedures when muscle contraction may disrupt the healing process;
  c) Over the menstruating or pregnant uterus; and
  d) Over areas of the skin which lack normal sensation.
- Avoid placing the electrodes directly over metal implants if there is not at least 1 cm of muscle fiber in between. However placement on the nearest muscle is possible. If in doubt, seek medical advice.
- Precautions should also be taken if muscle stimulation occurs during heavy menstruation or in the same month as the insertion of an IUP (inter-uterine pessary, e.g. coil). The same applies to the period (6 weeks) after giving birth. We recommend that stimulation is only applied around the abdominal or lower abdominal region following medical approval.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
- In all cases, ensure that stimulation does not exceed the patient's tolerance level.
- When repositioning electrodes during treatment, always turn the intensity to minimum or pause the unit.
- Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
- When the cables are attached to the electrodes, ensure that the plugs are fully inserted into the electrode sockets. Ensure that no metal is visible.
- Powered muscle stimulators should be kept out of the reach of children.
- 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.
- It may not be appropriate to use AvivaStim XP on a person at the same time as other equipment. You should check suitability before use.
- The AvivaStim XP unit should be used only for its intended purpose and in the manner described in this manual. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- A small number of isolated skin reactions have been reported, including allergies and acne.
- Stimulation should not be applied until the cause of the pain is identified and a precise diagnosis rendered.
- To avoid infection electrodes may only be used by a single individual.
- TENS is not intended to treat psychosomatic illness.
- TENS primarily treats symptoms by suppressing pain, which in turn serves as a protective mechanism.
- This device can deliver current densities in excess of 2mA/cm2 when used at a high intensity with small electrodes. See "Technical Data" for more details.
- If any irritations, skin reactions, over-sensitivity or other side effects occur, please contact Bio-Medical Research Ltd. In such cases stop use immediately. Irritations can usually be reduced by changing the position of the electrodes. Note, however, that a slight reddening of the skin is quite normal under the electrodes during and for a short time after treatment.
- Do not use the AvivaStim XP unit with the electrodes positioned on injection sites (of medications/drugs), such as hormone treatment sites.
- An effective treatment should not cause undue discomfort. If the stimulation level is uncomfortable or becomes uncomfortable, reduce the stimulation amplitude to a comfort level and contact your physician if problems persist.
- [FOR PORTABLE DEVICES ONLY]: 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.
- AvivaStim XP must not be used with any other unit that delivers electrical current to the body (e.g. interferential or another muscle stimulator).

Adverse Reactions

- Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.

Safety Information - TENS Mode (Prog. 9)

Intended Use:
AvivaStim XP delivers stimulation based on the principles of transcutaneous electrical nerve stimulation (TENS) as described in the following. Short electrical pulses are sent via self-adhesive electrodes to the surface of the skin.

Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the indications listed below.

Transcutaneous Electrical Nerve Stimulation (TENS)
TENS is a pain therapy based on the application of electrical stimuli to the skin via stimulation of the nerve fibers. There are two methods: The "pain gate" theory, which blocks the pain signals to the brain and/or through the increased release of endorphins, which inhibits the emergence of pain.

General description of AvivaStim XP for TENS
AvivaStim XP also has a Transcutaneous Electrical Nerve Stimulation (TENS) program for the treatment of acute pain. Please see page 21 Program 9 for details.

Indications:
- Transcutaneous Electrical Nerve Stimulation (TENS) for an adjunctive treatment in the management of post-surgical and post-traumatic acute pain problems.

Contraindications
- Patients with electronic implants (e.g. cardiac pacemaker or defibrillator - as your neurotech product may interfere with the proper functioning of the implanted stimulator) or if you suffer from any other heart problem.

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

Precautions
- If in doubt, always seek medical advice.
- Safety of powered muscle stimulators for use during pregnancy has not been established.
- Caution should be used for patients with suspected or diagnosed heart problems.• Caution should be used for patients with suspected or diagnosed epilepsy.
- Medical advice 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 apply muscle stimulation.
- Caution should be used in the presence of the following:
  a) When there is a tendency to haemorrhage following acute trauma or fracture;
  b) Following recent surgical procedures when muscle contraction may disrupt the healing process;
  c) Over the menstruating or pregnant uterus; and
  d) Over areas of the skin which lack normal sensation.
- Avoid placing the electrodes directly over metal implants if there is not at least 1 cm of muscle fiber in between. However placement on the nearest muscle is possible. If in doubt, seek medical advice.
- Precautions should also be taken if muscle stimulation occurs during heavy menstruation or in the same month as the insertion of an IUP (inter-uterine pessary, e.g. coil). The same applies to the period (6 weeks) after giving birth. We recommend that stimulation is only applied around the abdominal or lower abdominal region following medical approval.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
- In all cases, ensure that stimulation does not exceed the patient's tolerance level.
- When repositioning electrodes during treatment, always turn the intensity to minimum or pause the unit.
- Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
- When the cables are attached to the electrodes, ensure that the plugs are fully inserted into the electrode sockets. Ensure that no metal is visible.
- Powered muscle stimulators should be kept out of the reach of children.

- Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
- When the cables are attached to the electrodes, ensure that the plugs are fully inserted into the electrode sockets. Ensure that no metal is visible.
- Powered muscle stimulators should be kept out of the reach of children.
- 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.
- It may not be appropriate to use AvivaStim XP on a person at the same time as other equipment. You should check suitability before use.
- The AvivaStim XP unit should be used only for its intended purpose and in the manner described in this manual. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- A small number of isolated skin reactions have been reported, including allergies and acne.
- Stimulation should not be applied until the cause of the pain is identified and a precise diagnosis rendered.
- To avoid infection electrodes may only be used by a single individual.
- TENS is not intended to treat psychosomatic illness.
- TENS primarily treats symptoms by suppressing pain, which in turn serves as a protective mechanism.
- This device can deliver current densities in excess of 2mA/cm2 when used at a high intensity with small electrodes. See "Technical Data" for more details.
- If any irritations, skin reactions, over-sensitivity or other side effects occur, please contact Bio-Medical Research Ltd. In such cases stop use immediately. Irritations can usually be reduced by changing the position of the electrodes. Note, however, that a slight reddening of the skin is quite normal under the electrodes during and for a short time after treatment.
- Do not use the AvivaStim XP unit with the electrodes positioned on injection sites (of medications/drugs), such as hormone treatment sites.
- An effective treatment should not cause undue discomfort. If the stimulation level is uncomfortable or becomes uncomfortable, reduce the stimulation amplitude to a comfort level and contact your physician if problems persist.
- [FOR PORTABLE DEVICES ONLY]: 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.
- AvivaStim XP must not be used with any other unit that delivers electrical current to the body (e.g. interferential or another muscle stimulator).

Adverse Reactions
- Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.

Nine treatment programs are available for selection. See Program information on Page 21 for details.

Your AvivaStim XP package covers:

1. AvivaStim XP unit	2. Instruction Manual	3. A 9 volt battery
3. Connecting Leads	5. Adhesive electrodes	6. Device box

DESCRIPTION OF APPARATUS & CONTROLS

The AvivaStim XP is easy to use. All keys are controlled by push buttons. The functions are defined by printed icons on each key (see below).

The AvivaStim XP has a built-in audio indicator which will emit a raised tone when there is a valid key press and a low tone when an invalid key is pressed.

Fig. 1

Keys and Key Functions (Fig. 1)
The AvivaStim XP has the following controls and functions:

1. On / off (Pause) button ⏻
This button switches the unit on and off and is also used to pause the treatment session. You must press and hold the button (for 2 seconds) to switch the unit off at the end of a treatment.

2. Amplitude Controls - Channels 1 and 2
Each intensity control controls one channel on the same side of the unit. Pressing the upper key (▲) during treatment increases the intensity level by a factor of one for that channel. Similarly, pressing the lower key (▼) can decrease the intensity level by a factor of one. The numerical intensity indicator displayed on the display changes by one.

3. Program Select Key P
The Program Select key enables the user to select the required treatment program. **To change the program hold down the program selection button P for at least 3 seconds.**

4. Lock key
The Lock key allows the user to lock the intensity controls preventing accidental changes in the intensity level.

Reset the Total Treatment Time.
The user must first press the Lock key and then the Program Select for around 3 seconds. A tone will sound and the display will reset to zero. This function is available only at the start of a treatment session.

5. Trigger Key
Trigger mode: When the key is pressed Trigger mode is enabled and the unit enters a contraction cycle for as long as the key is pressed. When the key is released the unit enters the relaxation cycle.
To return to the programmed contraction/ relaxation cycle, press any of the intensity keys. The stimulation builds over a 2 second period to the previously set intensity level.

4. Lock key
The Lock key allows the user to lock the intensity controls preventing accidental changes in the intensity level.

Reset the Total Treatment Time.
The user must first press the Lock key and then the Program Select for around 3 seconds. A tone will sound and the display will reset to zero. This function is available only at the start of a treatment session.

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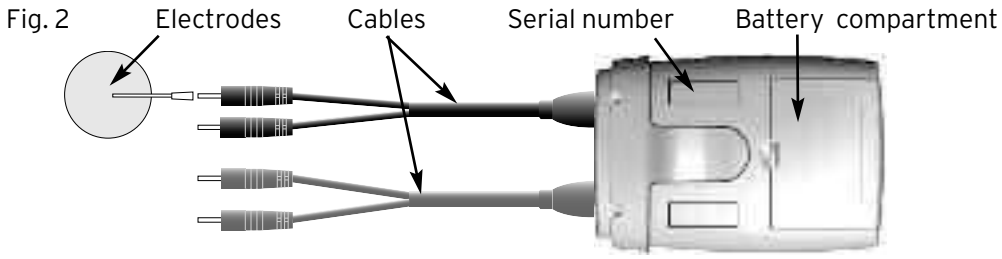
Trigger mode: When the key is pressed Trigger mode is enabled and the unit enters a contraction cycle for as long as the key is pressed. When the key is released the unit enters the relaxation cycle.
To return to the programmed contraction/ relaxation cycle, press any of the intensity keys. The stimulation builds over a 2 second period to the previously set intensity level.

DESCRIPTION OF APPARATUS & DISPLAY

Battery Information
The unit is powered by 1 x 9-volt DC battery. The battery compartment is located on the rear of the unit. We recommend an alkaline battery. The AvivaStim XP has an indicator that shows the battery status. When the battery is nearing discharge, the battery outline will flash. To insert, replace or check the battery, follow the instructions provided on page 15.

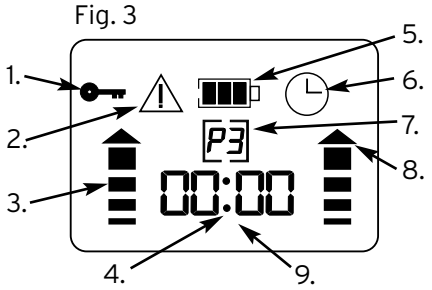
Connecting Leads
Two sockets are positioned at the base of the unit for the insertion of the leads (Fig. 2).
The leads are connected to the electrodes via moulded pins. The electrodes and leads are removable and can be replaced if necessary.
Each lead is a separate channel, one of which is light blue and the other dark blue. Two plastic moulded pins are found at the end of each lead. They are identified with '+' for the positive anode and '-' for the negative cathode.



AvivaStim XP display (Fig. 3)

The AvivaStim XP has a unique display that gives the user a precise overview of the battery status, the completed treatment time, contraction/relaxation phases and program selection.

Fig. 3



1. Lock key is activated and prevents unwanted changes to the intensity level.

2. ⚠ Load Sense Feature, activated when a poor lead-electrode or electrode-skin connection is detected.

3. During treatment the intensity bars will rise and fall corresponding to the contraction/ relaxation cycle on each channel.

4. Displays the length of time left/elapsed in the current session in hours, minutes and seconds. For a set treatment time program, the timer will count down in minutes and seconds. For an open treatment time it will count up from zero in minutes and hours.

5. Battery status indicator, indicates battery power remaining.

6. Clock symbol appears when the Total Treatment Time is displayed and when the clock is counting upwards.

7. P3 Indicates which treatment program you are running (1 to 9).

8. Trigger mode enabled.

9. Pause indicator, appears when the treatment has been paused.

STEP BY STEP TREATMENT GUIDE

1. Using a mild soap and water solution, clean the skin thoroughly where you will be placing the electrodes. The electrodes do not adhere well if any dirt, oils, creams or other cosmetics are still on the skin.

2. Ensure that the device is switched off.

3. Insert, exchange or check battery as described on page 15. The battery should be exchanged when the 3 bars have disappeared and the battery symbol icon ( ) flashes in the display.

4. The cables supplied with the AvivaStim XP are inserted into the sockets on the underside of the device. The plugs have been designed so that they click firmly into place after insertion (Fig. 4). After connecting the leads to the unit, attach each lead to an electrode (Fig. 5).

5. The AvivaStim XP is supplied with a set of electrodes. The electrodes should be handled as stated in the manual.

   Please note the following points:
   - A clinician must provide instruction on electrode placement and determine electrode sizes to be used.
   - The safety information provided in this manual must be followed.
   - The lead pins must be fully inserted into the electrode connector with no metal pin visible.
   - The complete surface of these electrodes should be in contact with the skin (refer to example in Fig. 6).

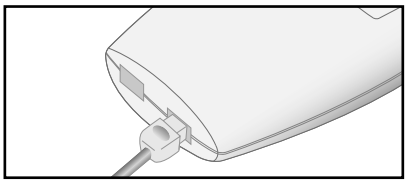


Fig. 4 Insert plugs into sockets

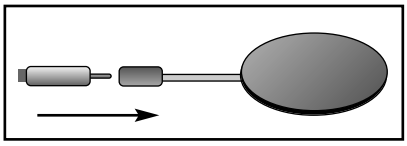


Fig. 5

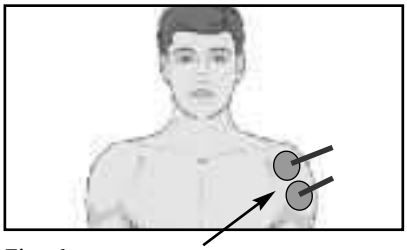


Fig. 6 The complete surface of the electrodes should make contact with the skin.

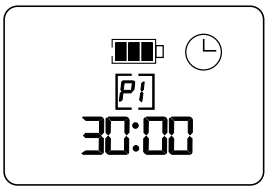
- Once the electrodes are attached, you may separate the leads to allow for better electrode placement.
- The AvivaStim XP is equipped with a belt clip. You may attach the unit at the waist by attaching it to a belt. Alternatively, the unit can be hand-held.

6. When the AvivaStim XP is switched on you hear a high sound. The screen will display the Total Treatment Time in hours and minutes for a period of 3 seconds (Display 1). After 3 seconds the screen in Display 2 will appear on the screen.

Display 1 up to 3 seconds

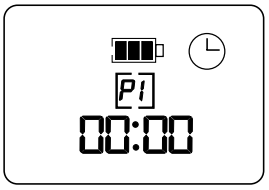
7. To change the program **hold down the program selection button P for at least 3 seconds**. The user is then presented with each available program (1-9) in turn. **Note:** You cannot change a program during treatment.

8. Programs 1 - 8 are limited in terms of time (Display 2). Program 9 is not limited in terms of time (Display 3).



Display 2 After 3 seconds

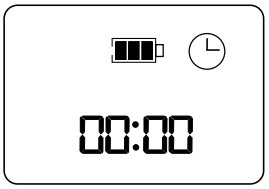
9. If you wish to reset the Total Treatment Time press the Program Select and Lock keys simultaneously for a period of 3 seconds. The Total Treatment Time will reset to zero (Display 4). The maximum Total Treatment Time is 99 hours and 59 minutes. It will reset back to 00:00 when the maximum treatment time is reached.



Display 3

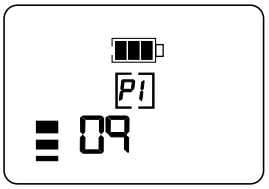
10. Slowly begin to increase the intensity on the channel you wish to use, by pressing the corresponding intensity control. As the intensity is being increased for a particular channel, the stimulus will be felt from the corresponding electrodes and a channel bar will rise and fall with the contraction/ relaxation cycles of the channel being used. The level will be indicated (0 to 99) on the display (Display 5). The treatment timer will begin once the intensity is first increased.

11. If necessary repeat the process for the other channel. The intensity height of each channel is shown on the display.

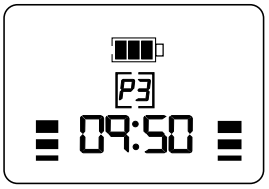


Display 4

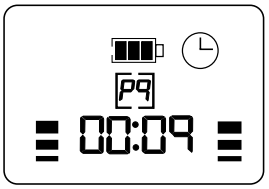
12. Continue to increase the intensity until the desired level has been achieved. Where more than one channel is being used, you may increase the intensity completely from one channel before increasing the intensity from the other. Display 6 shows the screen during a contraction cycle for a timed treatment program. The Timer displays minutes and seconds, and is counting down. Display 7 shows the screen during a contraction cycle for an open treatment time program. The timer displays hours and minutes, and is counting up.



Display 5

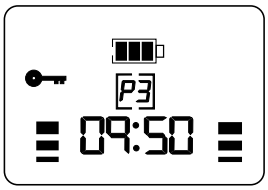


Display 6



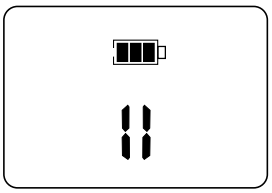
Display 7

13. Once the desired intensity level has been reached the user can press the lock key to avoid unwanted changes to the intensity level. If you press the lock key the display shown appears (Display 8). To disable the Lock function, simply press the lock key once again and the key symbol will disappear from the display.



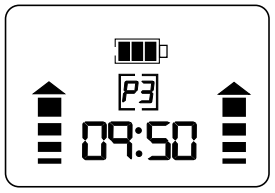
Display 8 Lock key activated.

14. If you want to interrupt the treatment session (e.g. to replace the electrodes), briefly press the on/off (pause) button. The unit issues a beep and the pause icon appears on the display in order to signal the pause to the program (Display 9). To deactivate the pause function, press the on/off (pause) button again. Then the treatment session is restarted from where it was paused and the pause icon disappears from the display.


Display 9 Pause activated

15. The Trigger mode (▲) is possible in Programs 1 – 5, 8 and 9. When the button is pressed the trigger mode is activated and the unit enters a contraction cycle for as long as the key is pressed. When the key is released the unit enters the relaxation cycle. To return to the programmed contraction/ relaxation cycle, press any of the intensity keys. The stimulation builds over a 2 second period to the previously set intensity level (Display 10).

    Caution: In trigger mode, where stimulation is held constant for several continuous seconds, muscle fatigue could occur. This mode of operation may provide relief only from muscle spasm.

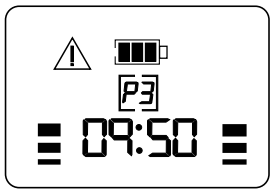


Display 10

16. The AvivaStim XP has a load sense function that monitors the connection between the cable/electrode and the user. When poor skin contact is detected:
    - The amplitude bar of the channel being used will flash.
    - The warning symbol (⚠) will appear flashing on the display (Display 11).
    - An audible beep will emit from the unit.
    - The treatment session timer pauses.

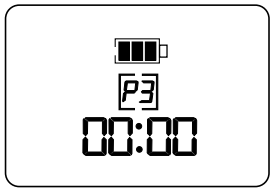
    - The intensity value falls to zero and the up-arrow intensity button is deactivated.

    When proper contact is restored, stimulation builds over a 2 second period to the previously set intensity level.



Display 11

17. When the treatment is complete, the stimulation will stop automatically. You will hear a 10 second beep alerting you that the treatment session is complete and the display screen will appear as in Display 12. At this stage the unit should be switched off and all electrodes removed from the body. Repackage the electrodes carefully. The protective sheets should be stuck over the adhesive electrodes again.
    Note: The unit power will turn off automatically after 10 seconds.



Display 12

SYSTEM MAINTENANCE

The unit should be cleaned regularly using a soft cloth, lightly dampened with soapy water.

Do not allow the interior of the unit or any of the connectors to become wet during cleaning. Do not use detergents, alcohol, spray aerosols or strong solvents on your unit.

The battery symbol ( ) will appear at all times during operation in the top centre of the display. When the battery of the AvivaStim XP is discharging the three bars on the battery symbol disappear after each other. Once all three bars has disappeared the contour of the battery icon starts to flash. This means that the batteries must be exchanged.

Fig. 7

The battery compartment is located on the rear of the AvivaStim XP unit. In order to open the battery compartment turn the AvivaStim XP onto the front. Insert your thumb into the symbol shown ( ) on the battery compartment to unlock it and press it forwards. This unlocks the battery compartment.

Now unfold the cover completely. A directional arrow (Fig. 7) on the battery cover indicates the direction in which the cover opens.

Fig. 8

To remove a battery, press firmly against the lower end of the battery and lift it out carefully.

The correct poles and how to insert the battery is marked by the image of a battery and its connections in the battery compartment. (Fig. 8). You need a 9 volt battery. This information is also included in the battery compartment.

To close the battery compartment, open the battery cover downwards and let it click in by applying slight pressure.

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

It is advisable to use a leak-proof battery to help prevent corrosion. We suggest using alkaline batteries. Never leave a battery in the unit if it is not intended to be used for a long period of time. If you do, the battery may leak causing damage to the unit. You should be aware that some batteries sold as 'leak-proof' can still release corrosive substances, which may damage the unit. Under no circumstances should anything other than the correct type of battery be used.

Accessories

Only electrodes and leads specified by Bio-Medical Research Ltd. for use with AvivaStim XP may be used. Using other electrodes and leads may degrade performance levels.

Do not dispose of used electrodes and batteries in household rubbish or in an open flame; dispose of them in accordance with regulations in your country.

Electrodes wear out over time: If they are dirty or no longer adhere properly, they need to be replaced. Replace the leads if the sheathing is damaged and exposes the copper wire.

Repair, Service & Modification

Access to the interior is not required for maintenance purposes.

Repair, service and modifications may not be carried out by anyone other than qualified service personnel authorised by **neurotech®**.

Do not use the unit if it is defective. Please return it to **neurotech®** or Bio-Medical Research Ltd. will not accept any responsibility where the guidelines and instructions are not followed.

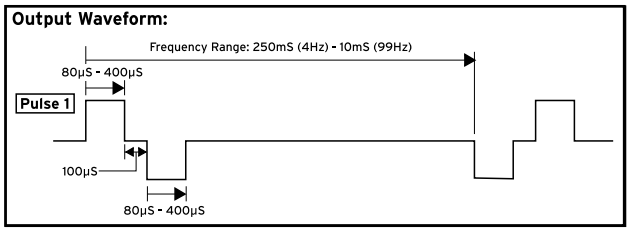
TROUBLESHOOTING

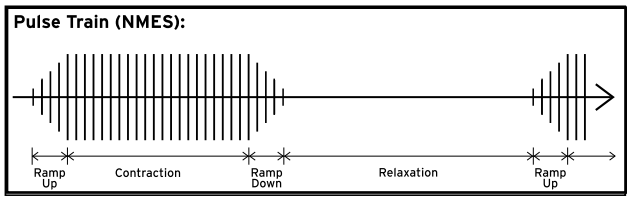
Problem	Possible Cause	Solution
The display does not come on & there is no signal from the unit	Battery discharged	Replace battery
	Battery was incorrectly positioned	Remove battery, replace correctly
The unit is switched on but does not respond to commands	Lead not fully inserted	Remove plug, re-insert
	Broken lead	Replace electrode/ lead assembly
Battery symbol flashing: Ineffective stimulation	The battery is low	Replace the battery
Stimulation received irregularly, only at a high intensity, or not at all	Faulty lead	Replace lead
Increasing intensity causes unpleasant sensation	Check your skin for lotions, pigment marks, dry marks or other factors that could increase resistance.	Slowly move electrode to locate area where stimulus feels strongest
		Moisten electrodes
		Wash any oils from the skin
Alarm symbol on, unit beeping	Faulty lead assembly	Check connections, replace if broken
	Electrode faulty	Replace electrode
	Poor skin/electrode contact	Check electrode contact with skin

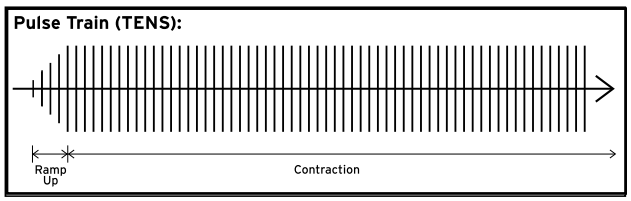
TECHNICAL INFORMATION

General Specifications:

Product Type: 281
No. of Channels: 2
Waveform: Symmetric Bi-Phasic







Electrode area less than 7.5 cm^2 can cause current densities in excess of 2m/cm^2 at maximum intensity. If in doubt, contact **neurotech®** or your clinician.

Environmental Specifications:

Operation:	Temperature	32° to 95° C
	Humidity	20 to 65 % RH
Storage:	Temperature	32° to 131° C
	Humidity	10 to 90 % RH

XP units are products of Bio-Medical Research Ltd., Parkmore Business Park West, Galway, Ireland.
A number of symbols are provided on your unit. Those not already explained are described below:

Power Requirements: 9-Volt, DC Battery (Type 6F22). Inside the battery compartment '+' indicates positive polarity and '-' indicates negative polarity. DC (Direct Current) is indicated by the symbol: ⎓

Physical Specifications:

Unit Dimensions: 105 x 68 x 28mm
Weight:
• Unit 3.35 oz
• Unit with battery 5 oz

Safety Features:

Safe start: The intensity is set automatically to zero when the unit is turned on.

Multiplexing: Pulse delivery to each channel is off-set so that only one channel is energised at any instant. This ensures there is no interaction between the electrodes of each channel.

Nominal output voltage / power			
Parameter	500Ω	1kΩ	1.5kΩ
Output RMS voltage (RMSV)	7.5 V	12.32 V	13.74 V
Output RMS current (RMSA)	15 mA	12.3 mA	9.16 mA
Output frequency	4-99 Hz	4-99 Hz	4-99 Hz
DC Component	0 C	0 C	0 C
Pulse Width	80–400 µs	80–400 µs	80–400 µs
Current Intensity Range (per pulse)	0–75 mA	0–75 mA	0–75 mA

Output RMS Current (RMSA): Stands for the effective current output, which is the root mean square current measured at a specified resistance.

Output RMS Voltage (RMSV): Stands for the effective voltage output, which is the root mean square voltage measured at a specified resistance.

Power (P): Maximum power output measured in Watts (W) into a 500Ω load.

Frequency (F): Number of pulses output by the unit per second, measured in Hertz (Hz).

⚠ This icon means "Warning, read the accompanying documentation".

This symbol means "Type BF equipment"

SN stands for "serial number".

On the rear of each XP model is the unit's individual serial number. The letter preceding the serial number indicates the year of manufacture, where "K" denotes 2005, "L" denotes 2006, etc.

CE 0366 This icon on your XP model shows that the device meets the 93/42/EEC Directive for medical devices. 0366 is the number of the notified body (VDE).

Disposal of device

At the end of the product lifecycle, do not throw this product into the normal household garbage, but bring it to a collection point for the recycling of electronic equipment.

Some product materials can be re-used if you bring them to a recycling point. By re-using some parts or raw materials from used products you make an important contribution to the protection of the environment. Please contact your local authorities if you need more information about collection points in your area.

Waste Electrical and Electronic Equipment can have potentially harmful effects on the environment. Incorrect disposal can cause harmful toxins to build up in the air, water and soil and can be harmful to human health.

ACCESSORIES

Electrodes:
Valutrode Lite/ Valutrode by Axelgaard Manufacturing Company Inc.
Sizes: 45mm x 45mm, 50mm x 50mm, 70mm x 70mm.

Pals Flex Stimulation by Axelgaard Manufacturing Company Inc.
Sizes: 50mm x 50mm, 70mm x 70mm.

Synapse (Medicom TENS electrodes) by Ambu A/S.
Sizes: 50mm x 50mm.

Leads:
AvivaStim XP/ AvivaTens XP Lead (Part No.: 1600-9301).
Size: Length = 1m

PROGRAM INFORMATION

NMES Programs

Program No.	Frequency (Hz)	Contraction (sec.)	Relaxation (sec.)	Ramp Up (sec.)	Ramp Down (sec.)	Length of pulse (μsec)	Burst or Trigger	Treat Time (mins)
1	50	5	5	1	1	300	Trigger	30
2	50	5	10	1	1	300	Trigger	30
3	50	10	20	1.5	1.5	400	Trigger	30
4	35	5	5	1	1	300	Trigger	30
5	10	5	5	1	0.5	300	Trigger	30
6 (Note 1)	ch1: 50 ch2: 10	5	5	1	0.5	300	None	30
7 (Note 2)	35	5	5	1	0.5	350	None	30
8 (Note3)	8	5	5	1	0.5	80	Trigger	30

TENS Program

Program No.	Frequency (Hz)	Contraction (sec.)	Relaxation (sec.)	Ramp Up (sec.)	Ramp Down (sec.)	Length of pulse (μsec)	Burst or Trigger	Treat Time (mins)
9	4 - 99	Continuous stimulation				150	Trigger	Open

Note 1: For this program, the output signal sequence is as follows:
Channel 1 enters a contraction cycle at frequency of 50Hz for 5 seconds and Channel 2 is off;
Channel 1 is off and Channel 2 enters a contraction cycle at frequency of 10Hz for 5 seconds;
Both channels are off for a relaxation cycle of 5 seconds.

Note 2: For this program, the output signal sequence is as follows:
Channel 1 enters a contraction cycle for 5 seconds and Channel 2 is off;
Both channels are off for a relaxation cycle of 5 seconds;
Channel 1 is off and Channel 2 enters a contraction cycle for 5 seconds;
Both channels are off for a relaxation cycle of 5 seconds.

Note 3: For this program, when the amplitude is at maximum, the value written to the R2R resistor network is less than half the maximum of 255.

The **Trigger mode** (▲) is possible in Programs 1 – 5, 8 and 9. When the button is pressed the trigger mode is activated and the unit enters a contraction cycle for as long as the key is pressed. When the key is released the unit enters the relaxation cycle. To return to the programmed contraction/ relaxation cycle, press any of the intensity keys. The stimulation builds over a 2 second period to the previously set intensity level.

WARNING: The selection and setting of the program should only be made by the treating clinician.

WARRANTY

Should your unit develop a fault within two years of purchase, **neurotech®** will undertake to replace or repair the unit and parts found to be defective with no charge for labor or materials, provided the unit:
- has been used for its intended purpose and in the manner described in this instruction manual.
- has not been connected to an unsuitable power source.
- has not been subjected to misuse or neglect.
- has not been modified or repaired by anyone other than an approved **neurotech** agent.

This warranty complements existing national guarantee obligations and does not affect your statutory rights as a consumer.

Service and maintenance
For service or repair please send your electrical stimulation unit to:
neurotech
PO Box 5179
Hoboken, NJ 07030