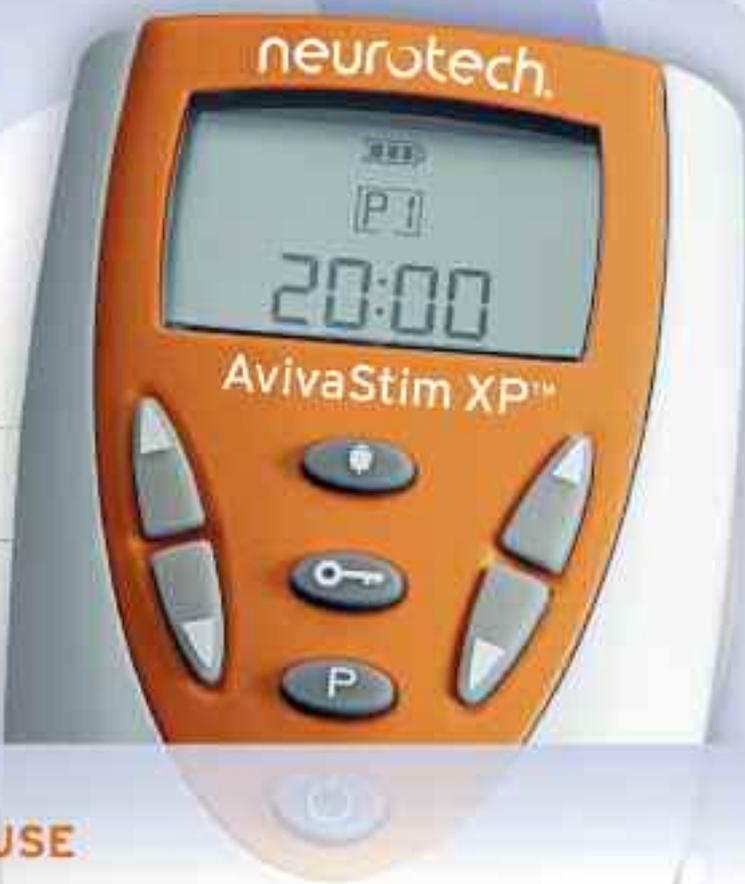


neurotech.
embrace life.

AvivaStim XP™
Muscle Therapy System



INSTRUCTIONS FOR USE



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.

Yours sincerely,
The neurotech Team.

If you have questions or require further information please contact:

neurotech®

A Division of Bio-Medical Research Ltd.

50 Harrison 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.

INDEX

SAFETY INFORMATION - NMES MODE.....	1
SAFETY INFORMATION - TENS MODE.....	4
DESCRIPTION OF APPARATUS & CONTROLS	7
DESCRIPTION OF APPARATUS & DISPLAY	9
STEP BY STEP TREATMENT GUIDE	11
SYSTEM MAINTENANCE	15
TROUBLESHOOTING	17
TECHNICAL INFORMATION	18
PROGRAM INFORMATION	21
WARRANTY	22

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 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.

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.

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 

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.

DESCRIPTION OF APPARATUS & DISPLAY

Battery Information

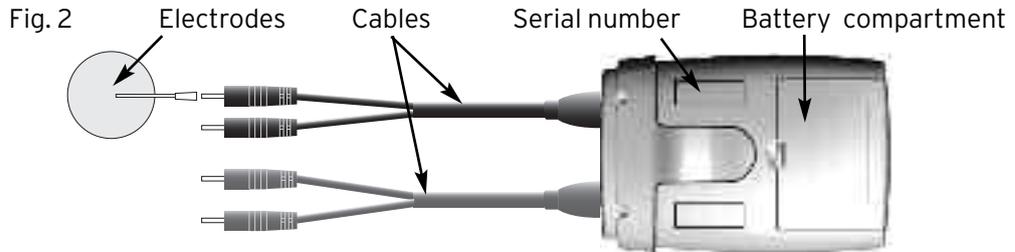
The unit is powered by 1 x 9-volt DC battery. The battery compartment is located on the rear of the unit. We recommend an alkaline battery. The AvivaStim XP has an indicator that shows the battery status. When the battery is nearing discharge, the battery outline will flash. To insert, replace or check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

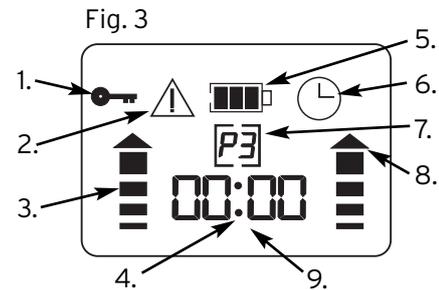
Each lead is a separate channel, one of which is light blue and the other dark blue. Two plastic moulded pins are found at the end of each lead. They are identified with '+' for the positive anode and '-' for the negative cathode.



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.

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.  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).
- 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.

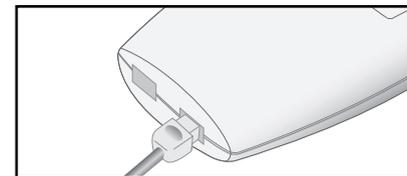


Fig. 4 Insert plugs into sockets

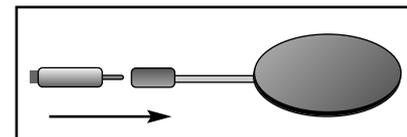


Fig. 5

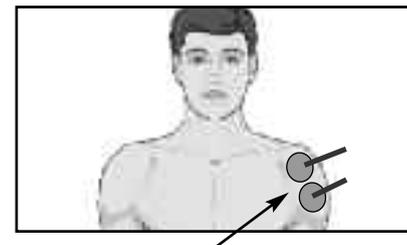


Fig. 6 The complete surface of the electrodes should make contact with the skin.

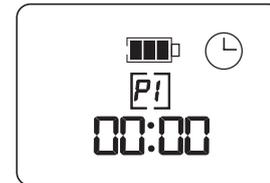
6. When the AvivaStim XP is switched on you hear a high sound. The screen will display the Total Treatment Time in hours and minutes for a period of 3 seconds (Display 1). After 3 seconds the screen in Display 2 will appear on the screen.
7. To change the program **hold down the program selection button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



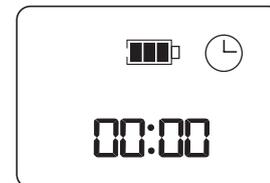
Display 1 up to 3 seconds



Display 2 After 3 seconds



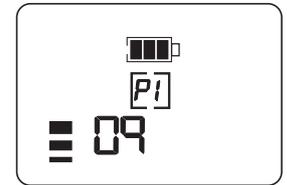
Display 3



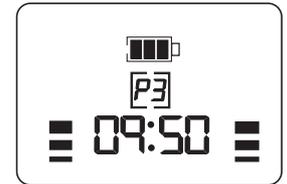
Display 4

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.
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.
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.
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 5



Display 6

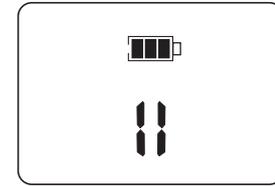


Display 7



Display 8 Lock key activated.

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.

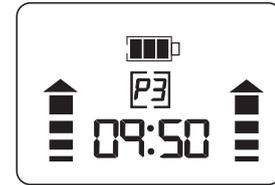


Display 9 Pause activated

- 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.

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 10



Display 11



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.

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.

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.



Fig. 7



Fig. 8

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.

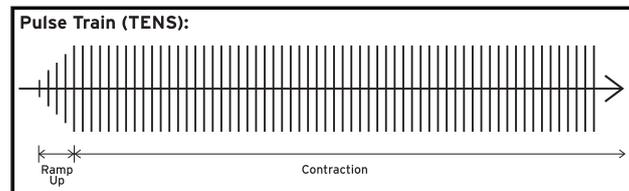
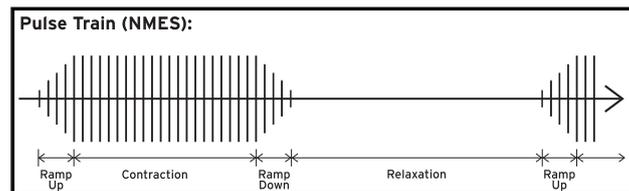
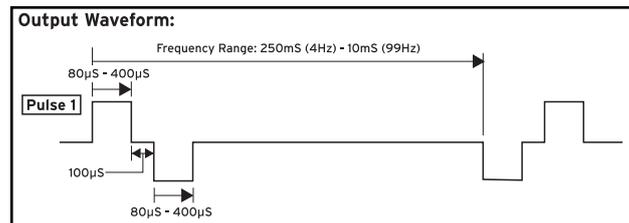
TROUBLESHOOTING

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 cm² can cause current densities in excess of 2m/cm² 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.



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 (μ sec)	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 (μ sec)	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

neurotech.

AvivaStim XP™

Designed by & manufactured for:

Neurotech
A Division of Bio-Medical Research Ltd.
PO Box 5129
Roslindon, N.J. 07068

866-652-0576
www.neurotech.us

Copyright © 2009 Bio-Medical Research Ltd. All rights reserved.

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 the practice commences, and in both the U.S. and elsewhere of Bio-Medical Research Ltd.

Part No: XXXX-XXXX
Rev: 1A
Issued: 12/09