MediStim XP™

Universal Patient Protocol

Control Instructions

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. Intensity Buttons – Channel 1 and 2

Each intensity control governs one channel on the same side of the unit. Pressing the upper button ▲ during treatment increases the intensity level by a factor of one for that channel. Similarly, pressing the lower button ▼ decreases the intensity level by a factor of one. A numerical intensity indicator will display in place of the treatment timer when you are making changes to the intensity. During treatment, you will only see the intensity bars next to the timer. The intensity bars on the display will rise and fall during the contraction and relaxation cycles of treatment.

3. Program Select Button P

The program select button enables the user to select the required treatment program. To change the program, hold down the program select button for at least 3 seconds.

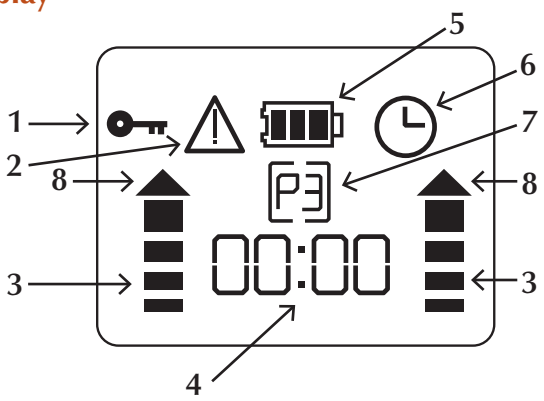
4. Lock Button

The lock button allows the user to lock the intensity controls to prevent accidental changes in the intensity level. It is also used to lock the trigger/burst button.

5. Trigger/Burst Button

When the trigger/burst button is pressed, 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. Use this button to set the desired contraction level so that you are not trying to set the intensity during an "off" or "relaxation" time.

Display



1. The lock button is activated and prevents unwanted changes to the intensity level.
2. Load sense feature: this is activated when a poor connection between a lead and its electrode or between an electrode and the skin is detected.
3. During treatment, the intensity will be displayed here.
4. Displays the length of time elapsed in the current session in hours and minuets or minutes and seconds.
5. Battery status indicator, indicates battery power remaining.
6. The clock icon 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 is enabled (programs 1- 5 and 8 - 9).
9. (Not shown) The pause indicator appears when the treatment has been paused. It is displayed as two vertical lines in place of the treatment time.

To Begin Treatment:
Turn the device on. Select a program by pressing and holding the P (program select) button for at least 3 seconds. There are nine programs available. Slowly increase the intensity on the channel you wish to use by pressing the intensity buttons. As the intensity is increased, a channel bar will rise on the display. If necessary, repeat the process for the other channel.

To Pause Treatment:
Press the on/off ⏻ button. Two vertical lines will appear in place of the timer. To resume treatment, press the on / off ⏻ button again.

The device will run each program for 30 minutes then shut off, except for Program #9 which will run continuously until turned off by you. To turn off the device before the end of treatment, press and HOLD the on/off ⏻ button for two seconds.

Program	Frequency (Hz.)	Pulse Width (μs)	Ramp Up (s)	Ramp Down (s)	On time	Off time	Burst or Trigger
1	50	300	1	1	5	5	Trigger
2	50	300	1	1	5	10	Trigger
3	50	300	1.5	1.5	10	20	Trigger
4	35	400	1	1	5	5	Trigger
5	10	300	1	0.5	5	5	Trigger
6	Ch. 1: 50 Ch. 2: 10	300	1	0.5	5	5	None
7	35	350	1	0.5	5	5	None
8	8	80	1	0.5	5	5	Trigger
9	4-99	150	Continuous (TENS)				Trigger

Electrode Use and Care

Reusable Single Patient Non-sterile Electrodes

IMPORTANT: Read the instructions for the application and use of electrodes found on the electrode package and in the patient operating manual.

- Reusable, self-adhering electrodes are included in your kit and can be used as soon as sterile electrodes have been removed.
- Do not use alcohol to clean skin surface.
- Apply electrodes to dry, clean, unbroken skin surfaces only, checking all edges for proper adhesion.
- Do not apply skin lotion prior to application of electrodes.
- Electrodes should always be placed **at least one inch apart.**
- Do not trim electrodes, as cut edges may affect the even distribution of stimulation.
- Remove electrodes before showering.
- If you experience symptoms of skin irritation while using the MediStim XP ™ device, discontinue use immediately and contact VQ OrthoCare's Patient Care Department at 800.452.7993, or consult your healthcare practitioner.

Sterile Single Use Electrodes

IMPORTANT: Read the instructions for the application and use of electrodes found on the electrode package and in the patient operating manual.

- Sterile (surgical) electrodes should not be removed until you have seen your physician for a follow up appointment or within 10 days, whichever occurs first.
- If your sterile electrodes have an adhesive border, always use adhesive-remover towelettes to remove sterile electrodes. Gently grasp edge or the plastic tab of electrode and slowly peel away from skin while wiping the towelette back and forth between the sticky surface of the electrode and your skin.

Applying Electrodes

- Apply the electrodes over the area of pain, unless your physician indicates a different placement.
- Place electrodes at least 1 inch apart.
- Electrode placement over the area of pain is the most common application, but other placements may also be used and recommended by your healthcare practitioner.

Battery Use and Care

The MediStim™ device operates on one 9-volt battery.

- To insert the battery, press your thumb against the latch to unlock the battery compartment and lift the door open.
- Place a battery into the battery compartment, matching proper polarity as indicated on the battery and the compartment. When closing the door, make sure the latch "clicks" to ensure it is locked.

When the battery needs replacing, an empty battery sign will appear at the top of the screen.

Replacement 9-volt battery packs can be ordered by calling VQ OrthoCare's Patient Care Department at 800.452.7993.

Caution

Electrodes should be discarded and replaced if damaged or when proper adhesive tack can no longer be obtained, the gel has separated, or you sense a change in stimulation intensity. If in doubt about the integrity or proper function of any electrode, replace it before proceeding with treatment. **IF USING PAIN MEDICATION AND/OR OTHER PAIN MANAGEMENT DEVICES, EXERCISE CAUTION WHEN INCREASING AMPLITUDE ON THE VQ MEDISTIM XP DEVICE.**

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.
- 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 hear problems.

- Caution should be used for patients with suspected or diagnosed epilepsy.
- Medical advice must obtained before use on persons who are insulin-dependent diabetics or for persons who are under medical supervision for any cognitive dysfunction.
- Caution should be used in the presence of the following:
    - When there is a tendency to hemorrhage following acute trauma or fracture;
    - Following recent surgical procedures when muscle contraction may disrupt the healing process;
    - Over the menstruating or pregnant uterus; and
    - Over areas of the skin which lack normal sensation.
- Avoid placing the electrodes directly over metal implants if there is not at lease 1cm 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.
- 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 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 damages 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 MediStim XP™ on a person at the same time as other equipment. You should check suitability before use.
- The MediStim XP™ unit should be used only for its intended purpose and in the manner described in 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 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/cm^2 when used at a high intensity with small electrodes. See "Technical Data" in the instruction manual for more details.
- If any irritations, skin reactions, over-sensitivity or other side effects occur, please contact the Patient Care Department at VQ OrthoCare or consult with your healthcare practitioner. In such cases stop use immediately. Irritations can usually be reduced by changing the position of the electrodes. Be aware, however, that a slight reddening of the skin is quite normal under the electrodes during and for short time after treatment.
- Do not use the MediStim XP™ unit with the electrodes positioned on the injection sites (of medication/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 comfortable 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.
- MediStim 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.

VQ OrthoCare®
Patient-Centered Solutions

18011 Mitchell South, Irvine, CA 92614
PHONE 800.266.6969 FAX 800.821.8012
www.vqorthocare.com
customerservice@vqorthocare.com

VQO061550REVA