Introduction

The Ultima Neuromuscular Stimulator produces an electrical stimulus that, when properly applied in accordance with your treating physician’s instructions, activates specific muscles or muscle groups in patients who will not, or cannot, contract these muscles voluntarily.

The Ultima EMS MK2 may also be used as a Transcutaneous Electrical nerve Stimulator (TENS) for the symptomatic relief and management of chronic, intractable pain and as an adjunctive treatment for post-surgical and post-trauma acute pain.

General Description

The Ultima EMS MK2 has:
8 pre-set EMS programs, 2 Manually selectable EMS programs
3 Modulated TENS programs.

It has two independent intensity controls, continuous or cycled stimulation, 24 frequencies from 1-110Hz, 6 pulse widths from 50 to 300µS, and adjustable work/rest and ramp controls.

How EMS Works

Muscular activity is produced by the central and peripheral nervous systems transmitting electrical stimuli to the muscles of our body. EMS uses external electrical impulses that act through the skin to stimulate the nerves supplying a specific muscle or muscle group. The muscle reacts in different ways depending on the strength of current and
duration and frequency of the electrical impulse. The electrodes are normally placed near the muscle motor nerve and the unit transmits a stimulus through the skin, with a choice of specific therapeutic patterns. The correct positioning of the electrodes is important and must be in accordance with your treating physician’s advice.

**How TENS works**

TENS stands for Transcutaneous Electrical Nerve Stimulation. The TENS unit sends a very small electric current through the skin. This stimulates the sensory nerves, which carry touch and temperature signals.

The effect may start to wear off after 1-2 hours. You can stop for an hour and then try again. You can use TENS several times a day, but only in accordance with your treating physician’s advice. Before use please read the instructions carefully.

**Contents**

Your Tenscare “Ultima” E.M.S. pack should contain the following:

1 x Tenscare “Ultima” EMS MK2 Unit  
1 x Belt Clip  
4 x Self Adhesive Electrodes  
2 x Alkaline AA 1.5v (LR6) Batteries  
1 x Carry Pouch  
1 x Instruction Booklet  
Check that all the contents are correct before assembling the unit.
Assembly

1. **Insert Batteries:**
   Insert two batteries. (A diagram inside the battery compartment shows how to insert the batteries correctly.)

   To check that the batteries have been correctly fitted, press the On/Off button once and the LCD display will start up and the LED Lights will come on. Press the On/Off button again to switch the unit off.

   Use only AA Alkaline 1.5volt batteries (LR6).
   Do not mix old and new batteries.

2. **Attach Leads:**
   Unravel leads and insert the plug(s) into either of the sockets in the end of the unit (or into the splitter leads). If using only one lead use L1 (as marked on unit next to socket).

3. **Attach Electrodes:**
   Remove electrodes from the bag and connect to the leads.
   Simply push the plug on the electrode pigtail into the socket on the lead.

4. **Prepare Skin:**
   Ensure that wherever you intend to place the electrodes that the skin is clean and thoroughly dry.

5. **Attach Electrodes:**
   Remove the electrodes from the clear plastic shields and position on your skin as directed by your physician.
1. Follow your treating physician’s instructions. Program and Menu settings have been set by your physician. Do not alter these, as your clinician has selected the most effective settings for your treatment. Several levels of locking are available to your clinician on the Ultima EMS MK2. If these have been used, the key symbol will appear at the lower left of the LCD, and you will be unable to change any settings except the Timer.

2. The Timer control will have been set by your Treating Physician. On his instructions, you can adjust it:
   a. Press the Menu button, \(- M +\). The Timer display will flash.
   b. Press the Set button \(- # +\) to select the desired time.
   c. Press the Enter \(\checkmark\) button to confirm.
3. Press Channel 1 intensity control 
  
  to the desired setting. The bar graph on the LCD shows the level. Increase the intensity until you achieve the same response as with your Treating Physician. Repeat with Channel 2 if you are using two leads.

4. If the Timer is being used, the unit will switch itself off. If Timer is on Const, when your session is complete, press the On/Off button.

5. After Use:
   Always ensure that the unit is switched OFF before removing the electrodes. After use, return the electrodes to the clear plastic shields and place in the resealable bag.

6. Electrode Care:
   Electrodes are water based. If they stop sticking, try putting a little water on the adhesive. Electrodes should last about 30 applications if skin is prepared properly. Replace the electrodes when they stop sticking. Electrodes are available from your local Tenscare dealer, please quote item code E-50x50.

SAFETY FEATURES

If the unit is accidentally switched on and no other button is pressed within the next 5 minutes then the unit will automatically switch itself off.
ADDITIONAL FEATURES

The Ultima EMS MK2 unit has the following special features:

1. **PAUSE**: If you need to interrupt treatment in the middle of a session, press the Menu button and hold for 2 seconds until PAUSE appears at the lower right of the LCD. Repeat to restart at the point in the program that you paused. The intensity will reduce to zero after resuming from PAUSE. Set intensity as if you were starting the treatment session.

2. **SOUNDER**: When the unit is switched on an audible beep will sound. When the unit is switched off there will be two audible beeps.

3. **ON/OFF LIGHT**: When the unit is the LED light will light up. The light is located at the front of the unit.

4. **LOW BATTERY WARNING**
   There is a low battery detector incorporated within your unit. The LCD screen will flash the symbol of a battery at two flashes per second when the batteries need replacing. Replace both batteries immediately to ensure that the device continues to perform as intended.

**BELT CLIP**

The Ultima EMS MK2 is supplied with a simple clip that will fit comfortably over a belt or pants top. It is designed so that it is easy to read the LCD while it is attached, and minimizes the risk of detachment if you sit or bend. Simply slide the clip into the recess on the back of the unit—it only fits one way.
Cautions & Warnings

Use of excessive intensity or usage time can cause muscle injury. Always use as instructed by your Treating Physician. Increase intensity gradually. If stimulation causes pain reduce intensity or stop treatment.

DO NOT:

• use the Ultima for conditions other than those for which it was prescribed by your Treating Physician.
• use your Ultima on other people.
• use while driving or operating machinery.
• use on broken skin or on areas where normal sensation is absent.

DO:

• change electrode site at least every 12 hours.

WARNINGS

FOR the TENS functions:
• The safety of TENS devices for use during pregnancy or birth has not been established.
• TENS is not effective for pain of central origin, such as headaches.
• TENS devices should be used only under the continued supervision of a physician.
• 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.
• The user must keep this device 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.
• This TENS device and the accessories supplied with it are intended ONLY for use as set out in this Instruction Manual. Do NOT attempt to use the device and/or its accessories in any other manner than that detailed herein.

FOR the MUSCLE RE-EDUCATION functions:
• 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 carotid sinus reflex.
• Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal 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, ie; phlebitis, thrombophlebitis, varicose veins etc.
• Stimulation should not be applied over, or in the proximity to, cancerous lesions.

CONTRAINDICATIONS

FOR the TENS functions:
• TENS should NOT be used by any patient fitted with a demand-type heart pacemaker.
• Electrodes should NOT be placed such that current is applied to the carotid sinus (neck) region.
• Electrodes should NOT be placed such that current flows transcerebrally (ie through the head).
• TENS should NOT be used when pain symptoms are undiagnosed. Etiology must first be established.

FOR the MUSCLE STIMULATOR functions:
• Powered muscle stimulators must not be used on patients with demand pacemakers.
ADVERSE REACTIONS

FOR the TENS functions:
skin irritation and electrode burns are potential adverse reactions.
For the Muscle Stimulator—skin irritation and burns beneath the electrodes have been reported
with the use of powered muscle stimulators.

CAUTIONS and PRECAUTIONS

BOTH TENS and MUSCLE STIMULATOR functions:

Electrodes should NOT be placed:
• Over the eyes.
• On broken skin.
• On areas where normal sensation is absent.
• 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 patients.
• The 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.
• Caution should be used during the following:
  – Where there is a tendency to haemorrhage following acute trauma or fracture
  – Following recent surgical procedures when muscle contraction may disrupt the healing process
  – Over the menstruating or pregnant uterus
  – Over areas of skin which lack normal sensation
• 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 alternative
conductive medium, or electrode placement.
• Electrode placement and stimulation settings should be in accordance with your treatment
physician’s advice.
• Powered muscle stimulators should be kept out of reach of children.
• Powered muscle stimulators should only be used with the leads and electrodes recommended by the manufacturer.
• 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.

GENERAL PRECAUTIONS

• Do not immerse EMS units in water.
• Do not place EMS unit close to excessive heat.
• Do not attempt to open EMS unit.
• Use only the specified batteries: “Ultima” EMS MK2 unit = 2 x 1.5 volt AA Alkaline (LR6). The use of any other type of battery could damage the unit.
• Remove batteries if unit is not to be used for a long period.
  Do not use the unit while asleep.

Limited Warranty and Disclaimer

I. Warning:

While, in the opinion of Tenscare , Ltd. ("Tenscare"), the use of the Ultima EMS MK2 XL-A3 (the "Product") has met with some success in restoration of atrophied muscle and the relief of chronic pain, Tenscare makes no warranties to the purchaser as to the effectiveness of the product.

II. Warranty:

A. Tenscare warrants to the initial Purchaser ("Purchaser") (and to no other person) that the Product and the components thereof, distributed or manufactured by Tenscare, shall be free from defects in workmanship and materials for two years after the date of purchase (the "Warranty Period").
B. Accessories including, but not limited to the leads, electrodes and batteries are excluded from the Warranty and are sold "As Is" because their structure is such that they may be easily damaged before or during use.

III. Limitation of Liabilities and Disclaimer of Warranties:

A. Tenscare 's sole obligation in the case of any breach of the limited warranty set forth in Paragraph IIA above, shall be, at Tenscare 's option, to repair or replace the Product without charge to Purchaser or to refund the purchase price of the Product. In order to recover under this Warranty, Purchaser must send Tenscare written notice of the defect (setting forth the problem in reasonable detail) prior to expiration of the Warranty Period, and within 30 days of discovery of the defect. Upon Tenscare 's written request and authorization, Purchaser shall return the Product to a Tenscare authorised agent, freight and insurance prepaid, for inspection. Notice and return shipment shall be sent to a Tenscare authorised agent. To locate the appropriate authorised agent, or to request shipment approval, contact Tenscare directly at 81 East Street, Epsom, Surrey, UK KT17 1DT (www.tenscare.co.uk). Tenscare will not be responsible for damage due to improper packaging or shipment. If Tenscare determines in its sole reasonable discretion that the Product contains defective workmanship or materials, Tenscare will refund to the Purchaser the purchase price for the defective product, or return the repaired Product or a replacement thereof to Purchaser, freight and insurance prepaid, as soon as reasonably possible following receipt of the Product by Tenscare. If Tenscare determines in its sole reasonable discretion that the Product does not contain defective workmanship or materials, Tenscare will return the Product to the Purchaser, freight and Insurance billed to the Purchaser.
B. This Limited Warranty is voided immediately as to any Product which has been repaired or modified by any person other than authorized employees or agents of Tenscare or which has been subjected to misuse, abuse, neglect, damage in transit, accident or negligence.

C. EXCEPT AS PROVIDED IN PARAGRAPH IIA, THE PRODUCT IS BEING SOLD ON AN "AS IS" BASIS, ALL ACCESSORIES ARE SOLD "AS IS", AND THE ENTIRE RISK AS TO THE QUALITY AND PERFORMANCE OF THE PRODUCT IS WITH PURCHASER. THE LIMITED WARRANTY PROVIDED IN PARAGRAPH IIA IS INTENDED SOLELY FOR THE BENEFIT OF THE INITIAL PURCHASER AND TENS CARE DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE; PROVIDED, HOWEVER, THAT NOTWITHSTANDING THE FOREGOING SENTENCE, IN THE EVENT AN IMPLIED WARRANTY IS DETERMINED TO EXIST, THE PERIOD FOR PERFORMANCE BY TENS CARE THEREUNDER SHALL BE LIMITED TO THE LIFETIME OF THE INITIAL PURCHASER. NO EMPLOYEE, REPRESENTATIVE OR AGENT OF TENS CARE HAS ANY AUTHORITY TO BIND TENS CARE TO ANY AFFIRMATION, REPRESENTATION OR WARRANTY EXCEPT AS STATED IN THIS WRITTEN LIMITED WARRANTY.

(This Warranty gives the Purchaser specific legal rights and Purchaser may also have other rights which vary from state to state. Some states do not allow limitations of how long an implied warranty lasts, So the above limitation may not apply to the Purchaser.)

D. TENS CARE SHALL NOT BE LIABLE TO ANY PERSON FOR ANY DIRECT, INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, LOST PROFITS OR MEDICAL EXPENSES CAUSED BY ANY DEFECT.
FAILURE, MALFUNCTION OR OTHERWISE OF THE PRODUCT, REGARDLESS OF THE FORM IN WHICH ANY LEGAL OR EQUITABLE ACTION MAY BE BROUGHT AGAINST TENSCARE (I.E. CONTRACT, NEGLIGENCE OR OTHERWISE) THE REMEDY PROVIDED IN PARAGRAPH IIIA ABOVE SHALL CONSTITUTE PURCHASER’S SOLE REMEDY. IN NO EVENT SHALL TENSCARE’S LIABILITY UNDER ANY CAUSE OF ACTION RELATING TO THE PRODUCT EXCEED THE PURCHASE PRICE OF THE PRODUCT.

(This Warranty gives the Purchaser specific legal rights and Purchaser may also have other rights which vary from state to state. Some states do not allow the exclusion or limitation of Incidental or consequential damages, so the above limitation may not apply to the Purchaser.)

Trouble Shooting

If your Ultima EMS does not function at all:
1. Check that the batteries are inserted correctly.
2. Try new batteries.

If there is no stimulus from one channel: Try changing leads or electrodes. If it still does not work correctly, return it to your Tenscare dealer.

Cleaning

The case and lead wires can be cleaned by wiping with a damp cloth and a solution of mild soap and water. Wipe dry. DO NOT immerse your TENS machine in water. DO NOT use any other cleaning solution than soap and water.
Distributor of TensCare XL-A3 Neuromuscular Stimulators, consumables such as probes and batteries, and spares such as replacement lead wires

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ULTIMA
EMS MK2 XL-A3
Neuromuscular Stimulator

Instructions for Use

Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order use of this device.