NeuroTrac™ MultiTENS

DUAL CHANNEL TENS & EMS UNIT

Operators Manual

Visit our website: www.veritymedical.co.uk
for detailed application protocols

EN

VERITY MEDICAL LTD

Warnings

* This unit must be used with the guidance of a Physiotherapist or Doctor.
* Type BF equipment, Continuous Operation.
* Do not insert lead wires into a mains power supply.
* Do not immerse unit into water or any other substance.
* Do not use the NeuroTrac™ Multi-TENS unit in the presence of a flammable anaesthetic gas mixture and air or with Oxygen or Nitrous Oxide.
* If using rechargeable 9 Volt PP3 Nickel Metal Hydride batteries, be sure to use a CE approved battery charger. Never connect the NeuroTrac™ Multi-TENS directly to a battery charger or to any other mains powered equipment.
  We advise not to use Ni-Cad rechargeable batteries.
* Patient Electrodes are for single patient use only.
* Keep out of reach of children.
* Do not use this stimulator on your facial area unless you are under strict guidance from a qualified Clinician.
* Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
* Operation in close proximity (e.g. 1m) to a shortwave or microwave therapy equipment may produce instability in the stimulator output.
* Simultaneous connection of a patient to a high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
* This device can deliver current densities in excess of 2mA/cm2 when used at a high intensity with small electrodes. See page 19 for more detail.
* No modification of this equipment is allowed!

Symbols on the rear cabinet of NeuroTrac™ Multi-TENS explained:


Caution (output)

Type BF Equipment


Follow instructions for use


Do not dispose in normal dustbin (see page 30 for the disposal instructions)

Contents

Introduction

The NeuroTrac™ Multi-TENS is a dual channel device combining several treatment programmes into one unit.

The NeuroTrac™ Multi-TENS features:
Multi TENS mode:
The front of the unit has two programme buttons allowing the unit to run a separate TENS programme on each channel.
PRG 1 selects the TENS programme to run on Channel A.
PRG 2 selects the TENS programme to run on Channel B.
This allows the therapist to select the best combination of output to more effectively control pain.
NOTE: The unit cannot run a combination of TENS, STIM or custom programmes.

Backlight:
A clear bright backlight and large LCD allow the display to be read more easily in low light or dark conditions. The backlight will automatically turn off after one minute to conserve battery power.

Comprehensive Statistics:
Comprehensive statistics backed up by a real time clock record up to 5 sessions daily for 60 days. An easy to use menu system allows the therapist to review the statistics to ensure that the patient is using the unit correctly.

Multi Phase Custom Programmes:
Up to 5 phases can be configured for each of the three custom programmes. The custom programmes feature a simple setup of one phase only or an advanced setup of up to 5 phases.

What is Pain?

When we feel pain it is the body's process of informing us that something is wrong. To feel pain is important, without this feeling abnormal conditions may go undetected, creating damage or injury to critical parts of the body.

Although pain is essential in warning our body of trauma or malfunction, nature may have gone too far in its design. Continued long-term chronic pain has no useful value apart from its importance in diagnosis. Pain begins when a coded signal travels to the brain where it is decoded, and analysed. The pain message travels from the injured area of the body along small diameter nerves leading to the spinal cord. At this point the message is switched to a different kind of nerve that travels up the spinal cord to the brain area. The brain then analyses the pain message, refers it back and the pain is felt.

What is TENS?

Transcutaneous Electrical Nerve Stimulation (TENS) uses a small battery operated unit to provide a non-invasive, drug free method of controlling acute and principally long term intractable pain. It can also be used as an adjunctive treatment in the management of post surgical traumatic pain problems. In TENS mild electrical impulses are transmitted through the skin via surface electrodes to modify the body's pain perception. TENS does not cure problematic physiological conditions; it only helps to control the pain perception. TENS will not work for every user. Please seek advice from your Doctor.

There are millions of small nerve fibres throughout the body and it only requires a few impulses to produce chronic pain. In addition to small fibres, which allow the sensation of pain to be felt, the body is also made up of larger diameter nerve fibres. These larger nerve fibres transmit less unpleasant sensations such as touch or warmth, assisting us to form an impression of our environment. Stimulating the larger nerve fibres using TENS may have the effect of inhibiting the transmission of pain along the smaller nerve fibres to the spinal cord [known as the 'Pain Gate Theory'].

What is STIM?

Neuromuscular Stimulation has been used for many years to stimulate muscle and nerve fibres to treat a number of muscle and nerve related conditions. Over the last 30 years numerous clinical trials and papers have been written.

Neuromuscular Stimulation is increasingly understood by Therapists and Doctors. There is a better understanding of the mechanisms which exist between nerves and muscles that makes it possible to stimulate the neuromuscular system with precise electrical signals. The NeuroTrac™ Multi-TENS offers precision giving full control of Pulse Widths, Rates, Ramp up times, Work / Rest cycles as well as alternating or synchronous application if two channels are being applied.

Customer Care

We welcome constructive comments regarding our equipment particularly those that might help us to improve existing features, add new ones or develop new products for the future.

Contra Indications & Precautions

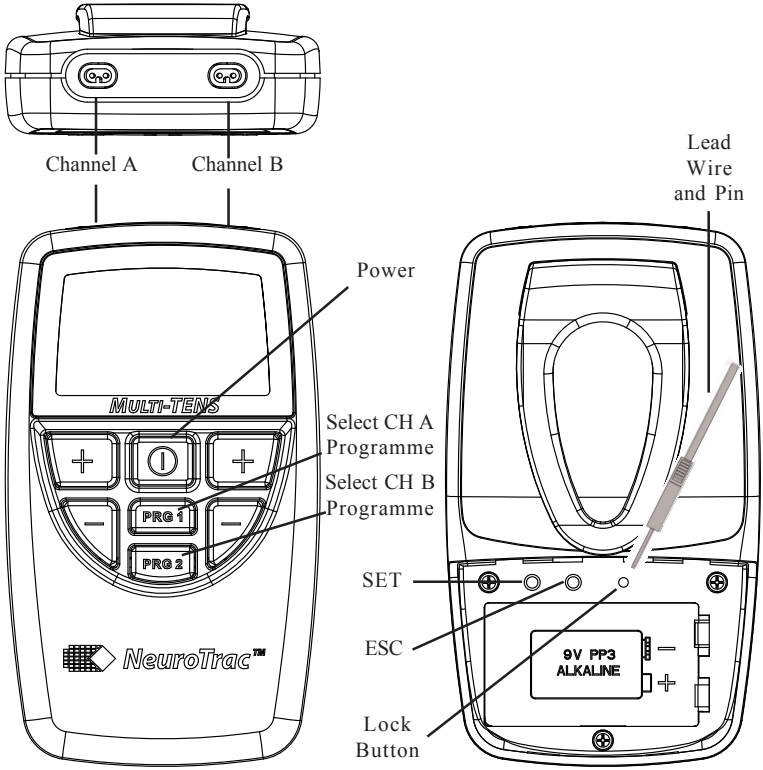
Before using this equipment you must first seek the advice of your Physiotherapist or Doctor.

Read this operating manual before using the unit

TENS and STIM should not be used:

* By patients fitted with a demand style cardiac pacemakers unless so advised by their Doctor
* During pregnancy [unless medically advised]
* By patients with undiagnosed pain conditions
* By patients with undiagnosed skin conditions
* With patients who have diminished mental capacity or physical competence who cannot handle the device properly
* On anaesthetised or desensitised skin
* When driving a vehicle or operating potentially dangerous equipment
* Do not place electrodes:
  - > Over carotid sinus nerves
  - > Over larynx or trachea
  - > Inside mouth
  - > Over the area of the heart unless so advised by your Doctor
  - > On your facial area unless under strict guidance from a qualified Clinician
* The patient should use the unit only as prescribed
* Do not immerse the unit in water or any other liquid
* If you experience skin irritation this may be due to over-stimulation. In this case leave the skin to heal and use TENS only for the periods prescribed. Turning the current up too high can cause skin irritation. In this case allow the skin to heal and use TENS at a lower intensity. Some people experience an allergic reaction to the adhesive coating on the surface of the electrode. If this happens use a different make of electrode or change the electrode. If it continues try reducing the pulse width. If the problem still persists try moving the electrode position each day by just the width of the electrode, making sure the electrode positioning is still over the dermatome
* Keep unit out of reach of children
* Only use CE approved skin electrodes
* If in doubt about the use of the NeuroTrac™ Multi-TENS unit, call your Doctor, Therapist, Clinician or your distributor for advice

Description of Unit & Functions



*** PRG 1 button** Selects the desired programme:
P01 ~ P13 - TENS programmes (Channel A).
P14 ~ P17 - STIM programmes (Channel A & B).
PC1 ~ PC3 - Custom programmes (Channel A & B).

*** PRG 2 button** Selects the desired programme:
P01 ~ P13 - TENS programmes (Channel B).
NOTE: PRG 2 is disabled for P14 ~ P17 and PC1 ~ PC3.

*** SET button** Configures custom programmes.
Sets time for TENS programmes (P01 ~ P13).

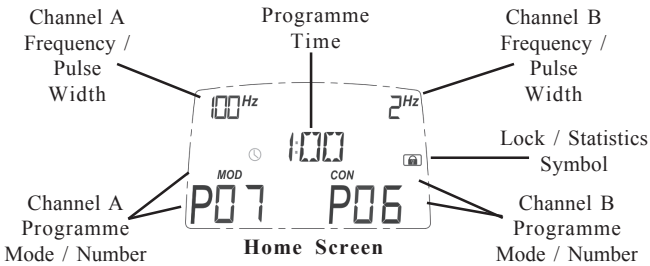
*** ESC button** Stores customised programme / time and returns to the home screen.

*** Power button** Turns unit on / off and ends the current programme.

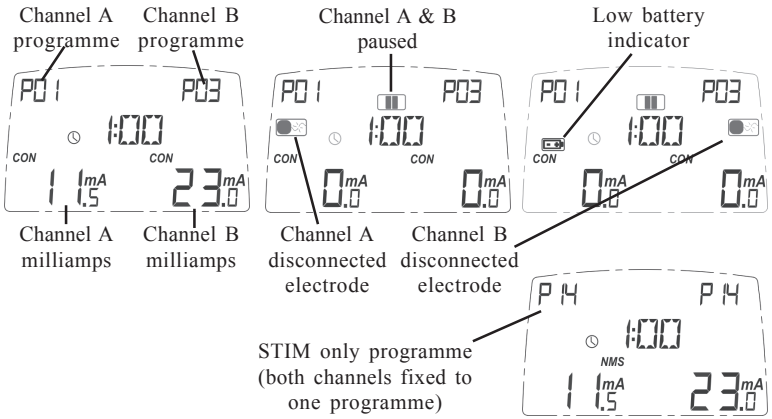
Quick Start Instructions

1. Insert a 9 volt PP3 Alkaline battery. Alternatively insert a rechargeable Nickel Hydride battery [Which is safer and has a much longer life than the Ni-Cad rechargeable batteries] into the battery compartment.
2. Insert lead wire/s to channel A and B if both channels are to be used.
3. Switch on the unit by pressing the Power button.
4. Press the PRG 1 [Programme] button to select:
   P01 ~ P13 for preset TENS programmes. (Channel A only).
   P14 ~ P17 for preset STIM programmes. (Channel A and B)
   PC1 ~ PC3 for custom programmes. (Channel A and B).
5. To start press channel A+ and B+ button if you are using both channels, increase the stimulation to the desired level.
6. To stop the programme, press the ON/OFF button which will turn the unit off.

LCD Display



Running Programme



Setting Time in Pre-set Programmes:

1. Select P01 ~ P17 using the PRG 1 button.
2. Press the SET button and the Clock symbol will flash ON/OFF, then press the either + or – button to adjust the time between:
   TENS: 30 minutes, 1,4,9 hours, CON - no time limit.
   NMS: 30 minutes, 1 or 2 hours.
3. Press ESC to save the time for the selected programme.

Setting Custom Programmes

1. Select PC1, 2 or 3 by pressing the PRG 1 button on the front panel. Remove the battery lid where you will see two buttons SET and ESC.

2. Press the SET button once to customise a single phase.
   Hold the SET button for three seconds to enter advance mode and customise up to 5 phases. Press the SET button once to select the next phase.

3. Press B + / - to set the phase time.
   Press A + to select the phase mode.

4. Press B + / - to select the phase mode: continuous (**CON**), modulated (**MOD**), burst (**BST**), Neuromuscular stimulation (**NMS**).
   Press A+ to configure the phases parameters.

CON (continuous TENS mode)

1. Press B + / - to set the frequency (**Hz**) between 2Hz and 200Hz
   Press A + to set the Pulse Width.

2. Press B + / - to set the pulse width (**µS**) between 50µS and 450µS.
   NOTE: If frequency 105 Hz or higher is set, the pulse width will be restricted to 300µS maximum for safety.

3. Press the SET button to configure the next phase or press the ESC button to save the parameters.

MOD (modulated TENS mode)

1. Press B + / - to set the low frequency (**Hz, LO**) between 2Hz and 200Hz.
   Press A + to set the high frequency.

2. Press B + / - to set the high frequency (**Hz, HI**) between 2Hz and 200Hz.
   Press A + to set the low pulse width.

3. Press B + / - to set the low pulse width (**µS, LO**) between 50µS and 450µS.
   NOTE: If a frequency of 105 Hz or higher is set, the pulse width will be restricted to 300µS maximum for safety.
   Press A + to set the high pulse width.

4. Press B + / - to set the high pulse width (**µS, HI**) between 50µS and 450µS.
   NOTE: If a frequency of 105 Hz or higher is set, the pulse width will be restricted to 300µS maximum for safety.
   Press A + to set the milliamp modulation adjustment.

5. Press B + / - to set a milliamp modulation (**ADJ**) between 50% and 100% (100% is no milliamp modulation).
   Press A + to set the modulation time.

6. Press B + / - to set the modulation (**TME**) time between 3 and 60 seconds.

7. Press the SET button to configure the next phase or press the ESC button to save the parameters.

BST (BURST TENS mode)

1. Press B + / - to set the frequency (**Hz**) between 35Hz and 200Hz
   Press A + to set the Pulse Width.

2. Press B + / - to set the pulse width (**µS**) between 50µS and 200µS.
   Press A+ to set the number of bursts per second.

3. Press B + / - to set the frequency (**FRQ**) of bursts per second between 2 and 9.

4. Press the SET button to configure the next phase or press the ESC button to save the parameters.

NMS (Neuromuscular (STIM) mode)

1. Press B + / - to set the frequency (**Hz**) between 2Hz and 200Hz
   Press A + to set the Pulse Width.

2. Press B + / - to set the pulse width (**µS**) between 50µS and 450µS.
   NOTE: If frequency 105 Hz or higher is set, the pulse width will be restricted to 300µS maximum for safety.

3. Press B + / - to set the work seconds (**WRK**) between 2 and 99 seconds.
   Press A + to set the rest seconds.

4. Press B + / - to set the rest seconds (**RST**) between 2 and 99 seconds.
   Press A + to set the ramp up time.

6. Press B + / - to set the ramp up time (**R:UP**) between 0.0 and 9.9 seconds.
   Press A + to set the ramp down time.

7. Press B + / - to set the ramp down time (**R:DN**) between 0.0 and 9.9 seconds.
   Press A + to set the current type.

8. Press B + / - to set the current type to either synchronous or alternating (**SYN or ALT**).
   NOTE: The SYN current stimulate both channels at the same time. The ALT current stimulates channel A and then channel B.
   If SYN is selected, press A + to set the delay between channel A & B.

9. Press B + / - to set the delay (**DLY**) between channel A & B from 0.0 to 4.0 seconds.

10. Press the SET button to configure the next phase or press the ESC button to save the parameters.

Programmes

	Mode	Frequency	Pulse Width	Work	Rest	Ramp Up	Ramp Down	Default Time
TENS								
P01	CON							4 Hrs
P02	CON							4 Hrs
P03	CON							4 Hrs
P04	CON							4 Hrs
P05	CON							4 Hrs
P06	CON							4 Hrs
P07	CON							4 Hrs
P08	CON							4 Hrs
P09	CON							4 Hrs
P10	BST							4 Hrs
P11	MOD							4 Hrs
P12	MOD							4 Hrs
P13	HAN							4 Hrs
STIM								
P14	WR			6	8	2	2	2 Hrs
P15	WR			6	6	1	1	2 Hrs
P16	WR			6	8	1	1	2 Hrs
P17	WR			10	10	1	1	2 Hrs
CUST								
PC1	CON, BST, MOD,WR							
PC2	CON, BST, MOD,WR							
PC3	CON, BST, MOD,WR							

MODALITIES

CON - Constant TENS
Stimulates constant frequency and pulse width on both channels.

BST - Burst TENS
Stimulates nine pulses of 200µS at 150Hz repeated two times per second.

MOD - Modulated TENS
Stimulates over a six second cycle modulating frequency and / or pulse width.
P11: Frequency starts at 100Hz decreasing exponentially to 65Hz.
Pulse width starts at 200µS decreasing exponentially to 100µS.
P12: Frequency starts at 10Hz increasing exponentially to 90Hz.
Pulse width fixed at 200µS.

HAN
3 second of 100Hz, followed by 3 seconds of 2 Hz.

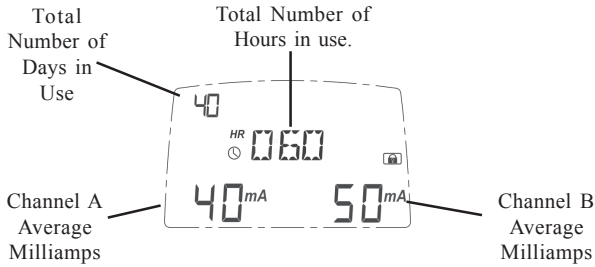
W/R - Work / Rest Stimulation
Stimulates constant frequency and pulse width on both channels with work / rest intervals.

Home Compliance

Lock Mode Function
A "concealed" Lock button is included in the NeuroTrac™ Multi-TENS unit, which allows the clinician to accurately monitor the "Home Compliance" of the patient between appointments. Whenever you lock the device, it resumes or starts to record the statistics of use. If the unit is not locked, the statistics are not stored in the memory. You can lock the unit in two ways:
Press the concealed button and {L:T} or {L:P} will be flashing on the LCD, press B+ to select one of the options:
L:P - This will lock the selected programme and will not allow user to alter any parameter, such as the programme number and time, programme type (Constant, Burst, etc). Use this option if you want to keep the same settings through out a course.
L:T - This option will allow you to alter all the parameters during the course: programme, time, etc. Use this option if you are an advanced user and you are allowed to alter the parameters during the treatment.
The recorded statistics are the same for both {L:P} and {L:T} options.

Locking the Unit and recording statistics
Remove the battery cover and using the end of the lead wire, gently press on the concealed lock button as shown in the diagram on page 7 until you hear a double bleep. The lock symbol will appear on the LCD screen and {L:T} or {L:P} will be flashing. Your unit will start recording the daily statistics. It is very important to set up the timer and calendar correctly - see page 15.

Displaying Global Statistics
To display the global statistics, remove the battery cover and using the end of the 2mm dia pin press the concealed switch once and you will hear a single beep. On the diagram below, the basic global statistics are displayed on the LCD: how many days the unit was used, number of hours in total the unit was used and the average intensity [m A] used.
When you have noted the information press the OFF/ON button to bring the unit back to the Home position.



The NeuroTrac™ Multi-TENS records up to five sessions per day for a period of 60 days. This feature allows the therapist to check each individual session to ensure that the patient is using the device properly at the prescribed times.

Viewing Detailed Statistics

When your device is locked, and you press the concealed button, it displays the global statistics, as described in previous chapter. You can see more of your recorded home compliance by pressing the following buttons:

A+ to scroll the Days.

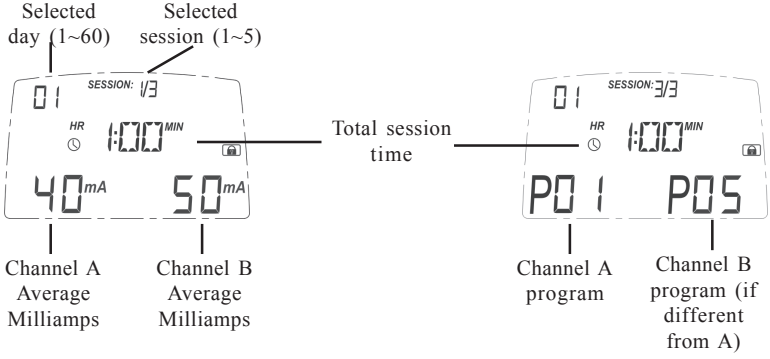
Press A+ to view the total time and average intensity [mA] for each day. The day number is displayed on the top left corner of the LCD. Press A+ and scroll through the days, after the last day, the Global statistics will be displayed.

B+ to scroll Sessions of the selected day

Press B+ to see the session time and sesson average mA for each channel. The number of sessions recorded for the selected day is displayed on top middle of the LCD, as "SESSIONS: X/Y" where "X" is the selected session and "Y" is the total number of sessions recorded this day.

SET - which programme was used

Select the session and see which programme was used on each channel by pressing the SET button.



A+, then SET, then A+ to see the calendar day

Press A+ to select the Day, press SET then A+ to see the calendar date of the selected Day (the date and time should be set correctly when you lock the unit).

NOTE: Additional sessions are added to the fifth session if a patient uses the device more than 5 times a day.
Sessions less than two minutes are not recorded.

Unlocking the unit.

If you see the LOCK symbol on the LCD, your unit is locked. To unlock the unit, press the concealed button, then PRG.1 for 10 seconds. The LOCK symbol will disappear.

You need to unlock the unit to:

- change the treatment parameters if it was locked as L:P;
- stop the statistics recording, the statistics will still be there in the memory.
- be able to delete the statistics (see next chapter for how to delete the statistics).

Deleting the statistics
The statistics are not automatically deleted when the unit is unlocked.
To delete the statistics completely, make sure the unit is unlocked, then press the concealed button. The {L:P} or {L:T} is flashing, now press the following buttons, one after another:
SET then **A+**, then **A-**, then **B+**, then **B-**
5 beeps will sound and all the records will be deleted. Now your unit can be used again for the next patient or treatment.

After you deleted the statistics, the timer and calendar is displayed and can be adjusted, please make sure it is up to date, see the next chapter of how to set it.

Timer / calendar reviewing and setting
The NeuroTrac™ Multi-TENS has a built-in real time clock to track unit usage and statistics. The time and date settings will be lost if the unit has the battery removed for more than ten minutes, so it is important to check the timer and calendar whenever you insert the new battery or lock the unit.

To review or set the real time clock, hold the PRG 1 button for ten seconds, until the LCD will start flashing the first parameter (hour).

Press A+ to select the next parameter:
Hour, Minutes, Day, Month, Year
Press B+ and B- to adjust the parameter.

Using the NeuroTrac™ Multi-TENS Unit in TENS mode

RATE [Hz or pulses per second]

The **RATE** to be selected depends primarily on the electrode placement on the patient's body. If one uses contiguous and dermatome (the electrodes alongside or over the area of pain) electrode placement, a higher rate of 80 Hz - 100 Hz is desirable. The patient should experience steady continuous stimulation. It has been found that an optimal setting of 80 or 90 Hz with a pulse width of 200 µS has good effect for most patients and is a good first choice for pain-gating. Patients using Trigger, motor or acupuncture points tend to respond to low rate stimulation 2 Hz - 10 Hz and pulse width of 200 µS. The desired effect is for the patient to feel individual pulses.

PULSE WIDTH [Duration]

The wider pulse widths will deliver stronger stimulation for any given intensity [mA] setting. By using a combination of intensity and pulse duration, it is felt that various pulse widths are capable of stimulating different groups of nerve fibres. The wider pulse duration is needed to recruit motor fibres, where as the narrow pulse duration is used more on the sensory fibres.
The selection of which pulse duration to use is dependent upon the intended treatment protocol.

Stimulating the larger nerve fibres is thought to reduce the speed and the amount at which information is transmitted along the smaller nerve fibres. Also under certain circumstances the brain is thought to produce its own analgesic pain-killing substances, known as endorphins or endogenous opiods.

Intensity [mA]

Patients respond differently to the level of intensity, this is due to differences in individual patient's skin resistance, enervation and the type and condition of electrode being used.

A good formula for setting the intensity is to increase the current so that the patient feels slight muscle contraction, but not strong enough to move a joint, and then slightly reduce the intensity so that it feels comfortable. When using low rate TENS settings, individual twitches will occur. The higher rate TENS settings will increase muscle tension. It is not advised to increase the intensity to experience strong muscle contraction.

Treatment Modes (TENS)

There are three treatment modes available on the NeuroTrac™ Multi-TENS unit:

1. C**onventional TENS or normal.** This mode enables the user to select any rate between 2 Hz - 200 Hz, and a pulse width between 50 µS - 300 µS. This is the most frequently used of the three modes. The most common selection is 80 - 90 Hz with a 200 µS pulse width.

2. **Burst Mode**. This mode is comparable to the low rate TENS technique except that each low rate pulse is substituted for by a short BURST of 9 pulses [200 µS] at 150 Hz or 185 Hz. It is a combination of conventional and low rate TENS. The burst mode is often referred to as acupuncture - like TENS.

3. **Modulation TENS** this mode was designed to help prevent nerve accommodation that some patient's experience. It is achieved by continuously cycling the pulse width and rate.

How Long Do I Use TENS For?

This depends on the individual patient's condition, accuracy of electrode placement, stimulation and the characteristics selected, but typically the onset of pain relief starts after 20 - 30 minutes. Generally TENS is used for longer periods of normally 1 hour 30 minutes per session. With some patients it can be much longer.

Electrode Placement (TENS)

The placement of electrodes is one of the most important parameters in achieving effective pain relief using TENS. This is best left to your Physiotherapist or Doctor to advise as to which location is most appropriate. It may transpire that various positions need to be experimented with before the user finds the most effective positioning. The positioning may be via the contiguous, dermatome, myotome, motor, trigger or acupuncture points.

Dermatomes & Myotomes
These are areas of the body enervated by a single nerve root via the spinal cord. Each nerve root serves a known area of the skin. The dermatomes are named after the nerve root which serves it. For details of dermatome sites refer to diagrams on pages 33 & 34.

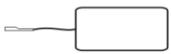
Contiguous Placement
This form of electrode placement is the most common method used. It involves placing the red lead [proximal] alongside the spine where the dermatome [on which your pain lies] enters and exists. The black lead [distal] is normally placed over or near to the pain site. Your Physiotherapist or Doctor may direct the current to cross through the pain area or using the 'bracket' system allow the current to flow on either side of the pain site through the nerve branches that supply the pain location.

Acupuncture Points
The placement of the red and black electrodes on the skin forms the electrical circuit for TENS. It is the skin itself that creates the highest electrical resistance to stimulation. The Physiotherapist or Doctor may consider using acupuncture loci (acupoints), which offer much lower resistance properties, as a more effective site for placing the electrodes.
Accurately locating an acupuncture point can be difficult, please seek advice from you doctor or physiotherapist.

Electrodes Types and Tips

* Self-Adhesive Hypoallergenic electrodes have a typical life span (if looked after) of 4/6 weeks. We recommend cleaning the skin before placing the electrodes. After use place the electrodes back onto the plastic film and in the zip-tag plastic pouch. Store in a cool environment.

Skin Electrode Types Available:

SHAPE	CODE	DESCRIPTION
	VS.4040	40 x 40 mm, square [** max 53mA]
	VS.5050	50 x 50 mm, square (recommended for general use)
	VS.9040	90 x 40 mm, rectangular
	VS.9050	90 x 50 mm, rectangular
	VS.10050	100 x 50 mm, rectangular
	VS.30	30 mm diameter, round [** max 46mA]
	VS.50	50 mm diameter, round
** IMPORTANT : Don't use VS 4040 at more than 53mA and VS3030 at more than 46 mA.		

A Few Good Tips [Self-Adhesive Electrodes]

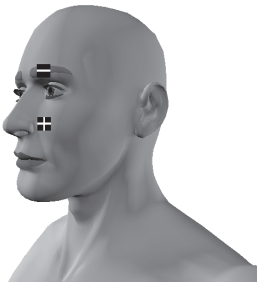
* If you find the electrodes will not stick due to oily skin, cleanse the skin with soap and water, then rinse and dry the area around the electrode site. If this does not work, try cleansing the skin with a swab impregnated with alcohol.
* Clip away hairy skin using scissors; don't use a razor to remove the hairs!
* The electrodes conductive material is water- based. If it becomes saturated (e.g. from perspiration), it will lose its adhesive qualities. After use leave the electrodes face up overnight to dry out (replace on plastic film in the morning).
  At some point the electrodes will become dry. Moisten the adhesive surface with a few drops of water, and apply onto the plastic film overnight. This procedure will increase the electrode life by few more days.

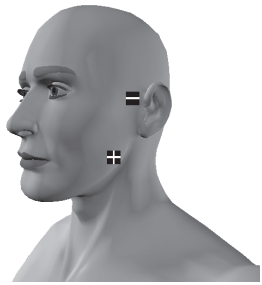
Suggested Electrode Placement (TENS)

+ = Red
- = Black

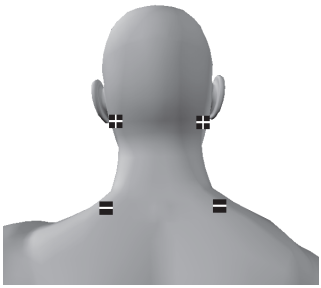
Finger Arthritis

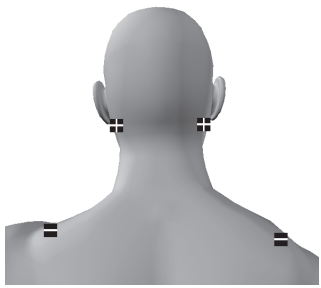
Knee Arthritis





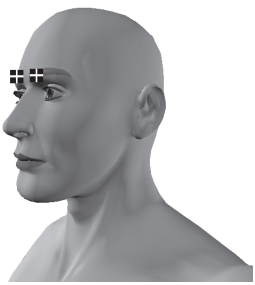
Neuralgia of Trigeninus





Cervical (2 Positions)

If you are using electrodes on your face, we recommend you contact your physiotherapist or clinician for guidance



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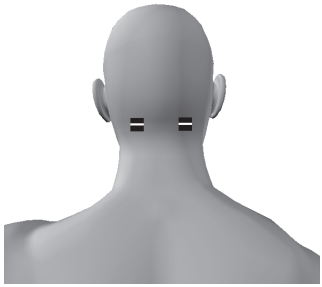
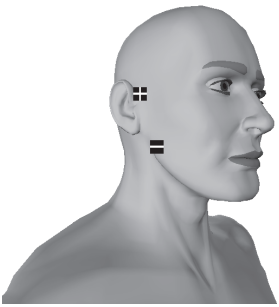
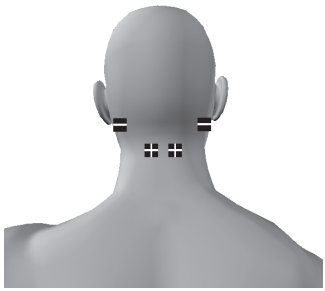
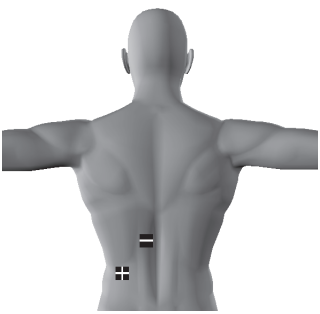


Cephalalgia Overorbital



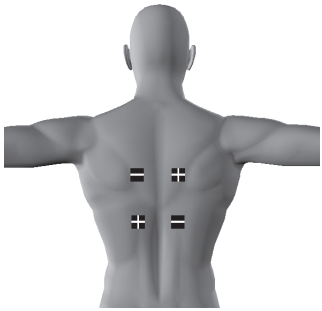


Mandibular Syndrome



Herpes Zoster

Phantom Limb



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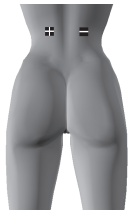
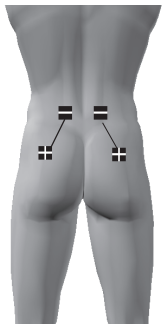
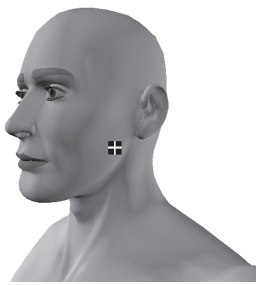


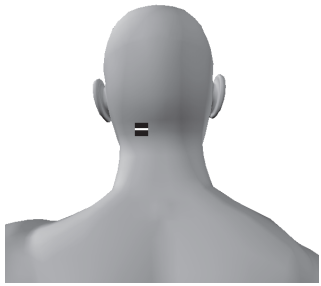
Back Pain

Menstrual Pain



Lumbar Pain (2 Positions)

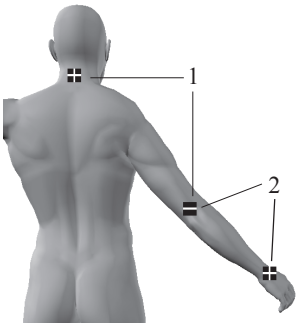




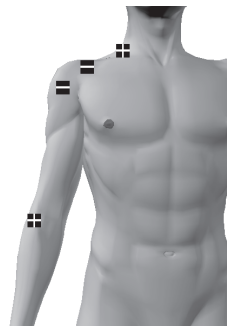
Tooth Ache

+ = Red
- = Black

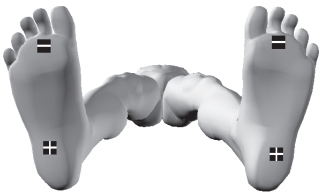
Sciatic Pain (2 Positions)



Epicondylitis



Shoulder Pain



Feet Pain

Ankle Pain

Care, Maintenance, Accessories and Disposal

WARNING! Only medically approved accessories should be used!

CONTROL UNIT

* Wipe the surface once a week with a damp cloth or antiseptic wipe.
* Do not use cleaning sprays or alcohol based cleaning solutions.
* Control unit disposal: please return to Verity Medical LTD or to the appointed distributor.

ACCESSORIES

Battery:

* To change the battery, open the battery door on the rear of the control unit by pressing down on the raised rib pattern just below the belt clip. Lift the battery out of the compartment. This is very easy and can be done by the user.
* Check periodically for any discharge from the battery.
* Remove battery completely from unit if not in use for any extended period of time (typically one week).
* Low battery indicator of 6.9 volts shown on LCD display, when flashing change battery for a new one.
* Preferably use a PP3 alkaline battery.
* Battery disposal: please return to the supplier from whom you've purchased it.

Lead Wires:

* The lead wires should be handled carefully and never stretched, as this can cause the stimulation to function below normal standards or not at all.
* Examine lead wires before each treatment for loose connections or damage.
* Avoid stretching and twisting the lead wires.
* Store the lead wires carefully after each use.
* Lead wires Disposal: please return to the supplier from whom you've purchased them.

Self-Adhesive Electrodes:

* Check the short connectors have not become separated from the electrodes.
* Replace electrodes onto plastic film after use. If they drop onto the floor debris will adhere to conductive gel rendering the electrodes ineffective.

Electrode life can be considerably reduced by:

* The type and condition of the skin.
* Deep seated moisturisers or make-up.

For the Best Results:

* Before each use cleanse the skin.
* After each use stick the pads on the shiny insert card and store in a cool and dry place, such as the fridge. (not freezer).

Caution: Static electricity may damage this product

NOTE: Only Verity Medical Ltd or appointed distributors / importers are approved to undertake servicing.

Conditions that respond to TENS

* Pain associated with Arthritis
* Post Operative Pain
* Lumbago
* Pain due to Sports injury
* Phantom Limb Pain following Amputation
* Skeletal Pains
* Neuralgia
* Whiplash
* Pain associated with Rheumatoid and Osteo Arthritis
* Period Pain
* Cancer Pain
* Back Pain
* General Pain
* Sciatica
* Muscular Shoulder Aches
* Tension

Conditions that respond to STIM

* Sports Injuries
* Continence
* Prevents disuse atrophy
* Odema
* Stroke
* Increases muscle strength
* As a warm up prior to exercise
* Maintains and improves movement
* Increases and improves the blood supply to the muscle in cases of intermittent claudication

Information regarding Electromagnetic compatibility and interference (EMC)

NeuroTrac™ products are designed to produce very low levels of radio frequency (RF) emissions (interference), to be immune from effects of interference produced by other equipment operating in their vicinity and damage due to electrostatic discharge all when operating in a typical domestic and or clinical environment. They are certified to meet the international EMC standard EN60601-1-2. For more information please refer to the tables 201, 202, 204 and 206 overleaf.

Table 201: Guidance and manufacturer's declaration – electromagnetic emissions

The NeuroTrac™ product is intended for use in the electromagnetic environment specified below. The customer or the user of the NeuroTrac™ product should ensure that it is used in such an environment.

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

Table 202: Guidance and manufacturers declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment– guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at characteristic levels of a typical location in a typical commercial or hospital environment.

Table 204: Guidance and manufacturer's declaration – electromagnetic immunity

The NeuroTrac™ productis intended for use in the electromagnetic environment specified below. The customer or the user of the NeuroTrac™ product should ensure that it is used in such an environment.

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

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which NeuroTrac ™ product is used exceeds the applicable RF compliance level above, the NeuroTrac ™ product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the NeuroTrac ™ product.
(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 206: Recommended separation distances between portable and mobile RF communications equipment and NeuroTrac™ product

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance "d" in meters [m] can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Specifications

TENS and STIM

1. Dual channel: individually isolated circuits.
2. Amplitude: 0-90 mA into 500 Ohm load ; indication only. Actual mA will tend to be less than indicated due to electrode impedance: at 1000 Ohms load (Electrodes in poor condition) the maximum will be limited to 70 mA, at 1500 Ohms load the maximum will be limited to 65 mA.
3. Type: Constant Current, maximum output voltage 180 Volts +10 / -30 Volts.
4. Waveform: Asymmetrical, rectangular bi-phasic with zero DC current.
5. Selectable pulse width: 50 µS - 450 µS [2% accuracy].
6. Pulse Rate selection: in the continuous mode 2 – 200 Hz [2% accuracy].
7. Mode: Continuous, Burst or Modulated.
8. Burst mode: Bursts of 9 pulses [200 µS] at 150 Hz or 185 Hz, over 2 seconds.
9. Modulation mode: 6-second cycle of concurrent width modulation and pulse repetition rate modulation.
11. Low Battery Indicator: If the battery goes below 6.9 volts +/- 0.2 volts the battery symbol will flash on/off once every second.
12. If the battery voltage is below 6.6 (+/- 0.2) volts the unit will not turn on.
13. **Open Electrode Detect: If an open circuit is detected at the output of channel A or B the output current will be reset at zero.**

Physical dimensions: 119.2 x 69 x 28.7 mm.

Weight: 106g without battery, 152g with battery.

Environmental Conditions for use:
+10 to +30 degrees Centigrade. 0-90% Humidity.

Environmental conditions for storage & transport:
-10 to +50 degrees Centigrade. 0-90% Humidity.

Warranty

Verity Medical Ltd., provides a warranty to the original purchaser that this product will be free from defects in the material, components and workmanship for a period of 2 years from the date of purchase by the Distributor [invoice date from Verity Medical to the appointed Distributor].
If the distributor - from whom the product was purchased by the user - is satisfied that the product is defective, the user may return the unit directly to this Distributor who will forward it to Verity Medical Ltd. All such returns from the Distributor to Verity Medical must be authorised by Verity Medical Ltd., in advance. The liability of Verity Medical Ltd., under this limited product warranty does not extend to any misuse or abuse such as dropping or immersing the unit in water or other liquid substance or tampering with the unit or normal wear and tear. Any evidence of tampering will nullify this warranty.

Customer Service

Any queries should be addressed to:

Verity Medical Ltd.,
Unit 7, Upper Slackstead Farm
Farley Lane, Braishfield
Romsey
Hampshire SO51 0QL
United Kingdom

Tel.: +44 (0) 1794 367 110
+44 (0) 1794 367 451

Fax: +44 (0) 1794 367 890

E-mail: sales@veritymedical.co.uk
Web: www.veritymedical.co.uk

This product is manufactured by Verity Medical Ltd.,
in compliance with the European Union Medical Device Directive
MDD93/42/EEC under the supervision of SGS,
Notified Body number 0120.

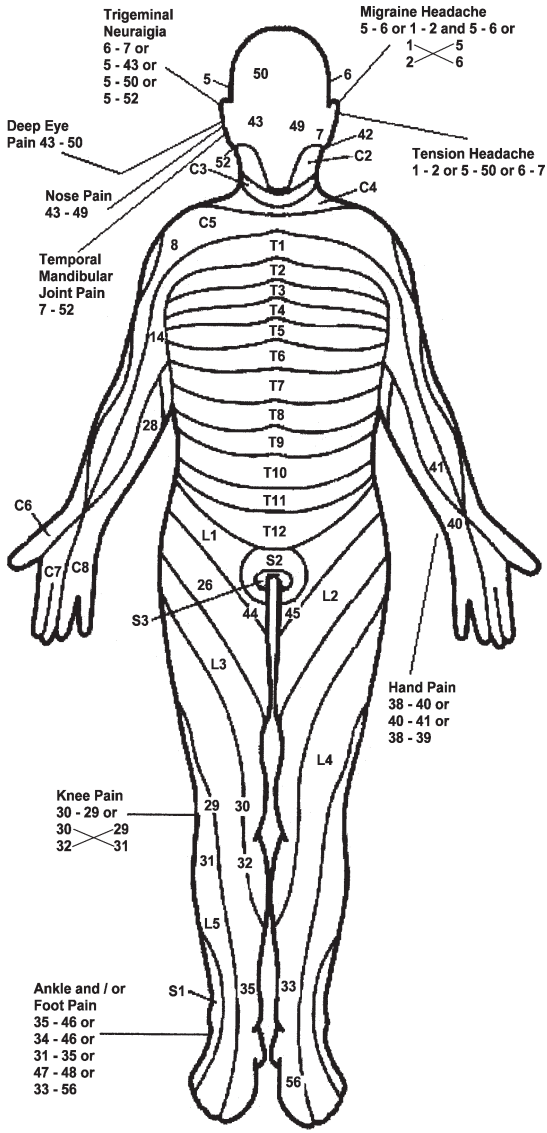
CE 0120

Verity Medical Ltd., is certified by SGS to the following
Quality Standards:

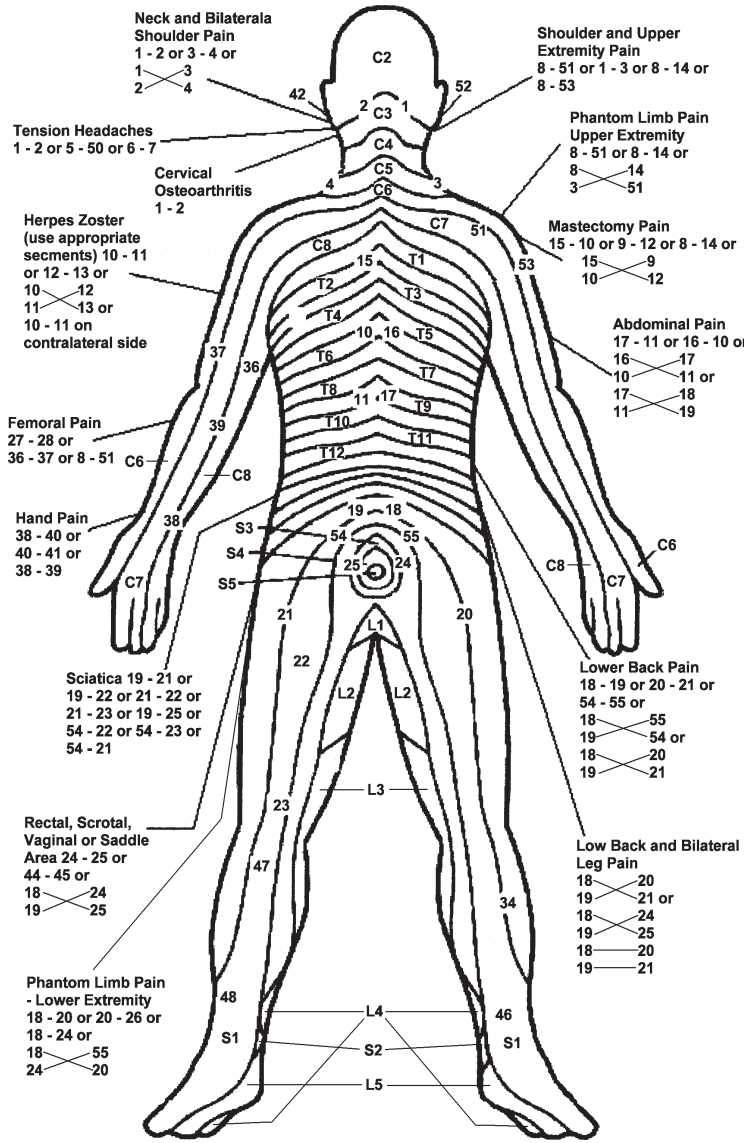
ISO 9001:2008, ISO13485:2003.

Dermatome Charts

Anterior View



Posterior View.



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Conventional TENS:

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Ellis B [1995] Transcutaneous electrical nerve stimulators: outpatient response to a temporary home loan programme Br J The Rehabil 2 [8]: 419-23

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Neuromuscular Stimulation:

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Osterber A, Graf W, Eeg-Olofsson K, Hallden M, Pahlman L. [1999]; Is electrostimulation of the pelvic floor an effective treatment for neurogenic faecal incontinence?

Troubleshooting

Problem:

- Cannot reach maximum mA level; or
- The unit cuts off stimulation at certain level; or
- When increase the intensity, zero mA is flashing; or
- Power is cutting off when using

Solution:

It is normal behaviour in our and any other quality muscle stimulators (and TENS machines), and in most cases resolves itself - please read the guideance below.

The stimulation intensity will drop to zero if you simply press the mA+ button and no electrodes are connected to the channel on which you increase the intensity. You should attach a pair of electrodes to the lead wire and the lead should be connected to the channel on which you increase the stimulation intensity (mA).

Our unit is designed to detect any poor or intermittent connection across the electrodes and to cut off the stimulation output (mA) when it does so. This is a safety precaution. It is designed to prevent the user from inadvertently turning up the output stimulation current in the presence of a poor or intermittent connection and then experiencing a large unexpected powerful surge in the stimulation, if and when the connection is re-established.

Reasons for no connection if you use surface skin electrodes:

* Check if both electrodes are connected to the same dual conductor lead wire, one electrode to the black connector (-) and another to red connector (+).
* Check if both electrodes are making a sticky contact on your skin, some electrode edges could not be stuck due to electrode wear & tear, but the electrode should be sticking with at least 80% of it's field. You may have lots of grease after long term use, try new electrodes. You may have dry gel on electrodes, try to make it more sticky by dropping a small amount of water on the black (conductive) side of the electrode and leave for an hour for the gel to absorb. Don't use wet electrodes! Try some fresh electrodes as electrodes loose conductivity proportionally to the use time due to grease and gel getting drier.
* This is the most frequent reason: check if the dual conductor leadwire cable is not broken, as it might be bent or pulled out too much which results in no conductivity: try another cable. To check if the cable is good, cross the red and black pin and increase mA on the unit. If the cable conducts the electricity, the mA will go above 10mA and you would feel the stimulation mild tickling in your fingers which holds the crossed pins. If you feel a mild electrical current, this means the problem is with surface skin electrodes.

Commonly Asked Questions

Q - ***Does TENS work for all pain conditions and on all patients?***
A - There is significant variation between patients with similar pain conditions. However, it is known that TENS does work in up to 70% of cases.

Q - ***How can I have a better chance of success using TENS?***
A - Seeking professional advice from your Physiotherapist or Doctor on how to best apply TENS is the best answer we can give to this question.

Q - ***Are there circumstances in which TENS should not be used?***
A - Yes. For undiagnosed pain; When using a cardiac pace maker; During pregnancy and other instances as fully detailed in this manual on page 5.

Q - ***How long will I have to use the TENS stimulator?***
A - Some long term chronic pain sufferers may have to use a stimulator for extended periods of time, even years. Other conditions may only need a short period of treatment lasting weeks.

Q - ***If I have any medical or product queries how can I get help?***
A - Any clinical advice on the TENS stimulator should be provided by your Physiotherapist or Doctor.

Notes

Not for sale or use in the USA

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E-mail: info@win-health.co.uk

Website: www.win-health.co.uk

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