NeuroTrac® TENS

DUAL CHANNEL TENS UNIT

Operators Manual

Visit our website: www.veritymedical.com



English

VERITY MEDICAL LTD

Symbols on the unit and case

	Caution! (electrical output).
	Follow operating instructions! Failure to do so could place the patient or operator at risk.
	Stimulation (STIM) and EMG Triggered Stimulation (ETS) should not be used by Patients fitted with demand style cardiac pacemakers. Please seek advice from your health supervisor.
	Patient's shock protection type: BF (Body Floated) Equipment. This equipment is not earthed but contains a battery within an insulated unit.
MD	Indicates the item is a medical device.
REF	Indicates the manufacturer's catalogue number so that the medical device can be identified.
LOT	Manufacturer's LOT/Batch number. Present it together with the SN number if you report a technical fault or claim a warranty return.
SN	Manufacturer's serial number of the unit. Present it together with the LOT number if you report a technical fault or claim a warranty return.
	Name and address of manufacturer.
	Date of manufacture.
CE 0123	This product complies with European medical device regulations 0123 - Notified body identification.
	The Australian government requires that all imported or locally produced electrical and electronic equipment comply with electromagnetic compatibility (EMC) emission requirements. A compliant product must bear the C-Tick logo.
	This product should be kept dry.
IP22	The device protected from ingress of solid foreign objects of 12.5mm dia and greater and ingress of vertically falling water drops equivalent to 3 mm rainfall/minute when the enclosure is tilted at an angle of 15° from the normal position.
	Do not dispose in normal dustbin (see page 19 for the disposal instructions).



Warnings

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

* **This unit must be used with the guidance of a clinician or therapist. This includes selection of the type of vaginal probe/skin electrodes and placement of skin electrodes.**
* 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.
* The unit is not protected from the ingress of water droplets from a shower of rain if used outside the carrying case.
* Do not use the NeuroTrac® 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® TENS directly to a battery charger or to any other mains powered equipment. We advise not to use Ni-Cad rechargeable batteries.
* Skin electrode pads are for single patient use only.
* Keep out of reach of children.
* Do not use this TENS machine on your face 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 high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
* No modification of this equipment is allowed!
* The battery cover must be closed prior to use of the device.

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Intended Purpose

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 adjunctive treatment in the management of post surgical traumatic pain problems. Mild electrical impulses are transmitted through the skin via surface electrodes to modify the body's pain perception.

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'].

Contra Indications & Precautions

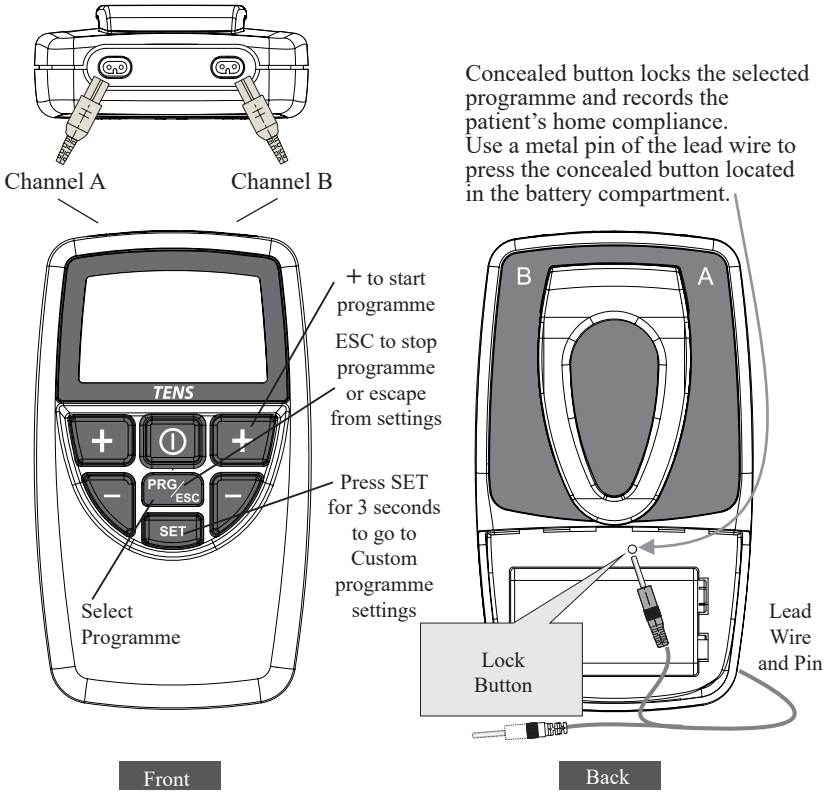
Before using this equipment you must first seek the advice of your Physiotherapist or Doctor.

Please read this manual before using the TENS machine.

TENS 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 cartoid sinus nerves.
  - > Over larynx or trachea.
  - > Inside the mouth.
  - > Over the area of the heart unless so advised by your Doctor.
  - > On your face unless under strict guidance from a qualified Clinician.
  - > Do not apply stimulation across or through the head, directly on the eyes, covering the mouth, on the front of the neck (especially the carotid sinus) or via electrodes placed on the chest and upper back or crossing over the heart.
* 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® TENS unit, call your Doctor, Therapist, Clinician or you distributor for advice.

Description of TENS Unit & Functions



* **PRG button** Selects the desired set programme from P01 - P11 or customised programme PC1 - PC3.

* **SET button** This button works only for programmes PC1-PC3. Press and hold SET button for 3 seconds to set parameters of your custom treatment: Pulse Rate, Pulse Width, Time, etc.

* **ESC button** Stores customised programme and returns to the home position.

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 ON/OFF button
4. Press the PRG [Programme] button to select one of the programmes as detailed in table 1 and table 2 on page 9.
5. To start press channel A + and B + button if you are using both channels.
6. Once the program is complete, you will hear five beeps.
7. To stop the programme, press the ON/OFF button which will turn the unit off.

Setting up your own continuous mode parameters for PC 1 or PC 2.

1. Select PC1 or PC2 by pressing the PRG button on the front panel.

   Press and hold the SET button for 3 seconds and the Hz symbol will flash, then press the + or – button on the front panel to adjust the Pulse Rate (frequency) from 2 - 200 Hz.
2. Press the SET button again and the µS symbol will flash, then press the + or – button to adjust the Pulse Duration from 50 - 300 µS.

Setting up your own Modulated mode parameters for PC3.

1. Select PC3 by pressing the PRG button on the front panel. Press and hold the SET button for 3 seconds until FHI is displaid. Press the + or - button on the front panel to adjust the high pulse rate (frequency) from 2 - 200 Hz.
2. Press the SET button and FLO will display. Press the + or - button on the front panel to adjust the low pulse rate (frequency) from 2 - 200 Hz.
3. Press the SET button and µS symbol will flash and WHI will display. Press the + or - button on the front panel to adjust the high pulse width from 50 - 300 µS.
4. Press the SET button and WLO will display. Press the + or - button on the front panel to adjust the low pulse width from 50 - 300 µS.
5. Press the SET button again and the Clock symbol will flash ON/OFF, then press the + or – button to adjust the time. Channel A + or – button to hours and Channel B + or – button to change minutes.
6. After setting up the customised programme parameters, press the ESC button to store the information. Simply repeating the above procedurecan reprogramme customised programmes.

Note: You must press the ESC button before locking the unit.

Programmes

Table 1

Programme	P1	P2	P3	P4	P5	P6	P7	P8
Mode	CON	CON	CON	CON	CON	CON	MP/MF	MF
Pulse rate [Hz]	90	90	80	100	10	2	100/65	10/90
Pulse duration [µS]	200	175	200	200	200	200	200/100	200
Time	4hr	4hr	4hr	4hr	4hr	4hr	2hr	2hr

Table 2

Programme	P9	P10	P11	PC1	PC2	PC3
Mode	BST	A=con B=BST	MF	CON	CON	MF/MP
Pulse rate [Hz]	see below	see below	2& 100	2 to 100	2 to 100	Low:2 to100 High:2 to100
Pulse duration [µS]	200	175	200	50 to 300	50 to 300	Low:50 to300 High:50 to300
Time	2hr	2hr	35min	cust	cust	cust

Notes:

Programme 7: Pulse width modulating from 200 µS to 100 µS to 200 µS, Pulse rate modulating from 100 Hz to 65 Hz to 100 Hz over 3 seconds.

Programme 9: Burst of 9 pulses of 200 µS at 150 Hz repeated 2 times per second.

Programme 10: Channel A Constant 80 Hz and 200 µS.
Channel B Burst of 9 pulses of 200 µS at 150 Hz repeated 2 times per second.

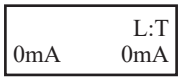
Programme 11: 2 Hz for 3 seconds, 100 Hz for 3 seconds, repeating.

Programme PC3: Pulse width modulating from high value to low value to high value, Pulse rate modulating from high value to low value to high value over 3 seconds.

Lock Mode Function

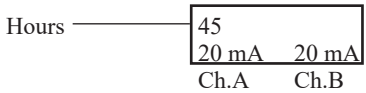
Lock Mode Function
A "concealed" Lock button is included in the NeuroTrac® TENS unit, which allows the clinician to accurately monitor the "Home Compliance" of the patient between appointments. The lock function allows the device to be locked in two ways:- One {L:T} to measure the time in use over one hour, and the average mA current used, leaving the parameters i.e. Constant, Burst, Modulation and the Rate and Pulse Width to be freely altered by the user or alternatively {L:PT} Locking the device to measure, time, mA current used and locking the parameters in place, which then cannot be changed or altered by the patient during use.

Locking the Unit
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. {L:T} Lock time and Current will appear on the LCD screen. If you want to lock the parameters as well press the +/- button until {L:PT} appears. Press the ESC button to lock parameters in place.





To Unlock the Unit
To unlock the unit and display the lock information, remove the battery cover, using the end of the 2mm dia pin press the concealed switch once and you will here a single bleep, this indicates the unit is now unlocked. The information for time in use and the average m A current used can be read on the front of the LCD display as seen on the diagram below. When you have noted the information press the ESC button to bring the unit back to the Home position.



mA Lock
For added safety, the device includes an mA lock function. After the mA is adjusted and there is no action for 60 seconds, the mA intensity will be locked and pressing the mA+ button will not have any action. This is to prevent un-wanted mA increase. To increase the mA, firstly press the mA- button, which will unlock the mA, and then press the mA+ button to adjust.

Using the NeuroTrac® TENS Unit

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 200μS 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 200μS. 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 opiates.

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

There are three treatment modes available on the NeuroTrac® 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 50μS-300μS. This is the most frequently used of the three modes. The most common selection is 80 Hz with a 200μS 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 [200μS] at 150 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

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 29-30.

Contiguous Placement

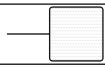
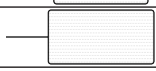
This form of electrode placement is the most common method used. It involves placing the red lead [proximal] alongside the spine where the dermatome [on which your pain lies] enters and exists. The black lead [distal] is normally placed over or near to the pain site. Your Physiotherapist or Doctor may 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, 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 your Doctor or Physiotherapist.

Electrodes Types and Tips

Compatible Electrodes and Probes

SHAPE	CODE	DESCRIPTION
	VS.4040	40 x 40 mm, square [* max 53mA]
	VS.5050	50 x50 mm, square (recommended for general use)
	VS.9040	90x40mm, rectangular
	VS.9050	90 x 50 mm, rectangular
	VS.10050	100 x 50 mm, rectangular
	VS.30	30mm diameter, round [** max 46mA]
* IMPORTANT : Don't use VS 4040 at more than 53mA and VS3030 at more than 46 mA. Using smaller electrodes may lead to current density greater than 2mA/cm^2. In such cases, special caution is to be exercised when adjusting the current level as too high values may cause skin irritation or possibly burns.		

Note: Electrodes are not supplied with the device. They must be selected/ recommended and applied under the supervision of a clinician/ therapist**.**

Note: For skin electrodes order see our website: www.veritymedical.com

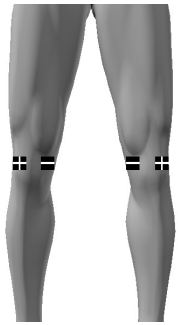
A Few Good Tips [Self- Adhesive Electrodes]:

* 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 a scissors; do not use a razor to remove the hair!
* 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 give you a few more days of electrode life.

Suggested Electrode Placement

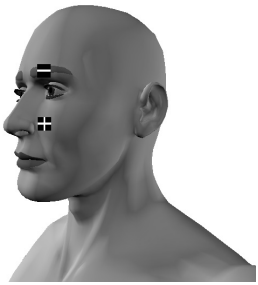


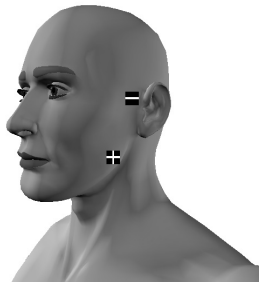
+ = Red
- = Black



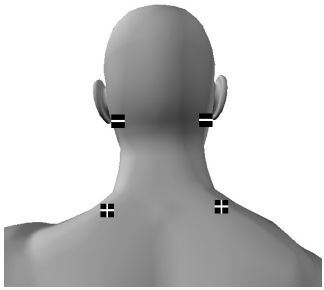
Pain caused by Finger Arthritis

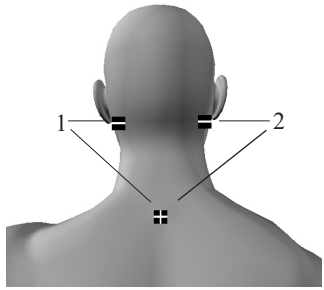
Pain caused by Knee Arthritis





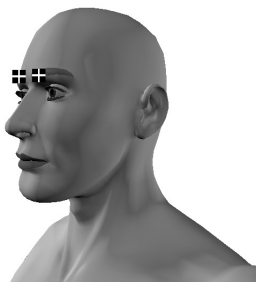
Neuralgia of Trigeninus



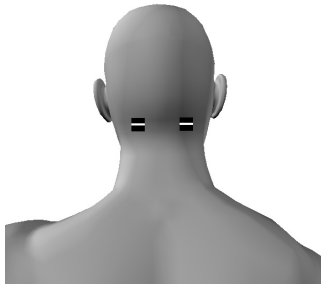


Cervical (2 Positions)

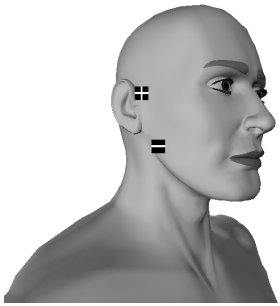
If you are using electrodes on your face, we recommend you contact your physiotherapist or clinician for guidance

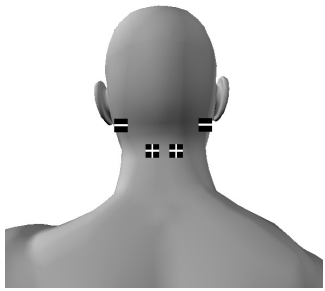


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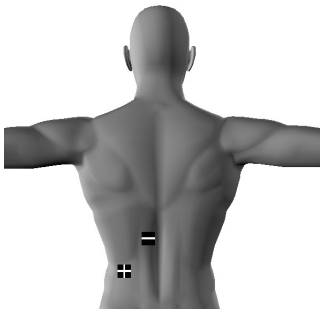


Cephalalgia Overorbital





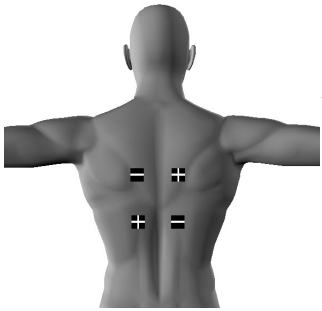
Mandibular Syndrome



Herpes Zoster

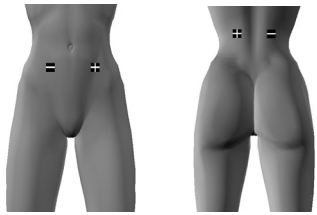


Phantom Limb



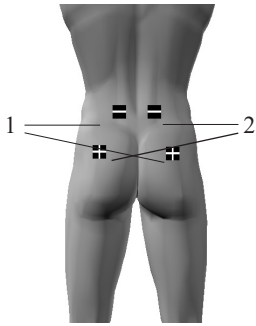
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Back Pain

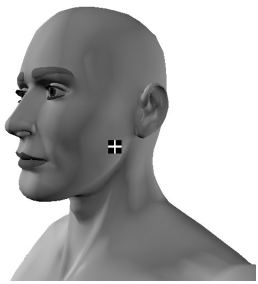


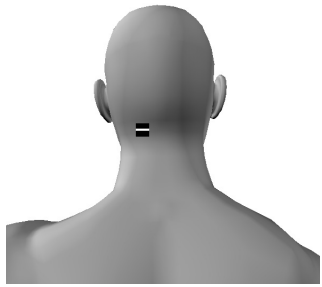
Menstrual Pain





Lumbar Pain (2 Positions)





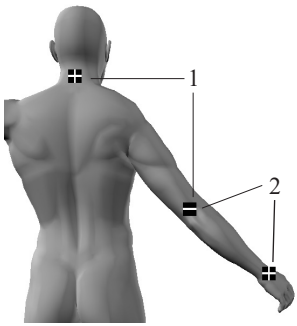
Tooth Ache



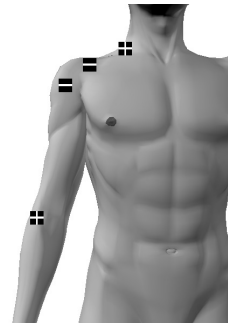
+ = Red
- = Black



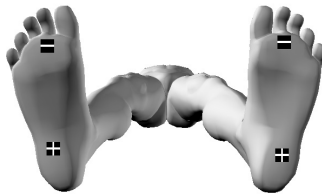
Sciatic Pain (2 Positions)



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 after each use with a damp cloth, antiseptic wipe or baby wipe.
* Do not use cleaning sprays or alcohol-based cleaning solutions.
* Control unit disposal: must be disposed of in compliance with national regulatory requirements.

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 shown on LCD display, when flashing change battery for a new one.
* Preferably use a PP3 alkaline battery.
* Battery disposal: must be disposed of in compliance with national regulatory requirements.

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: must be disposed of in compliance with national regulatory requirements.

Self-Adhesive Electrodes:

Note: Self-Adhesive Electrodes are not supplied with the device. They must be selected/recommended and applied under the supervision of a clinician/therapist.

* **Use only CE-marked skin electrodes**
* Check that the short connectors are well connected to the electrodes.
* Replace electrodes onto plastic film after use. If they drop onto the floor debris will adhere to the conductive gel making 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 /imporers are approved to undertake servicing.

Indications for use

* back pain
* phantom limb pain
* postoperative pain
* pain associated with knee arthritis

Specifications

TENS

1. Dual channel: individually isolated circuits.
2. Amplitude: 0 - 80 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: 50μS -300μS [10% accuracy].
6. Pulse Rate selection: in the continuous mode 2 – 200 Hz [5% accuracy].
7. Mode: Continuous, Burst or Modulated.
8. Burst mode: Bursts of up to 9 pulses [200 μS] at 150 Hz repeating twice per second.
9. Modulation mode: 6-second cycle of concurrent width modulation and pulse repetition rate modulation. Width starting at 200 μS and decreasing exponentially to 100 μS in three seconds and then returning back to 200 μS in the next three seconds. Rate starting at 100 Hz, decreasing exponentially to 65 Hz and then returning to 100 Hz.
10. Selectable treatment time duration: 1 second to 12 hours 59 minutes.
11. Battery: PP3 Alkaline, 9V. Expected average battery life: 34 h.
12. Low battery indication at 6.9 V (+/- 0.2 V), automatic shut off when voltage drops below 6.2 V (+/- 0.2 V). Replace the batteries immediately!
13. If the battery voltage is below 6.6 V +/- 0.2 V the unit will not turn on.
14. **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**.

Expected service life: 5 years. Careful use and maintenance extend the life of the unit over the service life limit.

Environmental Conditions for use: +5 to +40 degrees Centigrade. 15-90% Humidity. Atmospheric pressure: 700 hPa to 1 060 hPa.

Environmental conditions for storage & transport: -25 to +70 degrees Centigrade. 15-90% Humidity. Atmospheric pressure: 700 hPa to 1 060 hPa.

Additional requirements for device use.
1 hour required to warm from the minimum storage temperature between uses until it is ready for intended use.
1 hour required to cool from the maximum storage temperature between uses until it is ready for intended use.

Physical dimensions: 119.2mm x 69mm x 28.7mm

Weight: 104 g without battery

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.

Table 201: Guidance and manufacturer's declaration - electromagnetic emission

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

Emission test	Compliance	Electromagnetic environment guidance
RF emission 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 emission 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	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	



Table 202: Guidance and manufacturer's declaration – electromagnetic immunity

The NeuroTrac® product is intended for use in the electromagnetic environment specified below. The customer or the user of theNeuroTrac® product should assure 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 levels characteristic of a typical location in a typical commercial or hospital environment.

Table 204: Guidance and manufacturer's 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 assure 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	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the NeuroTrac® 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m 80 MHz to 2,5 GHz	

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 d =1.2 √P	**80 MHz to 800 MHz** d =√1.2 P	**800 MHz to 2,5 GHz** d = √2.3 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.

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 guidance 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.

Frequently 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?***
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 6.

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.

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:
Please contact your distributor for any customer service enquiries, including the warranty returns.
Your invoice of purchase and/or the rear cover of this manual should state the name and the contact details of your distributor.
For assistance, if needed, in setting up, using or maintaining the unit, or report unexpected operation or events, please visit the manufacturer's website for further details: www.veritymedical.com.

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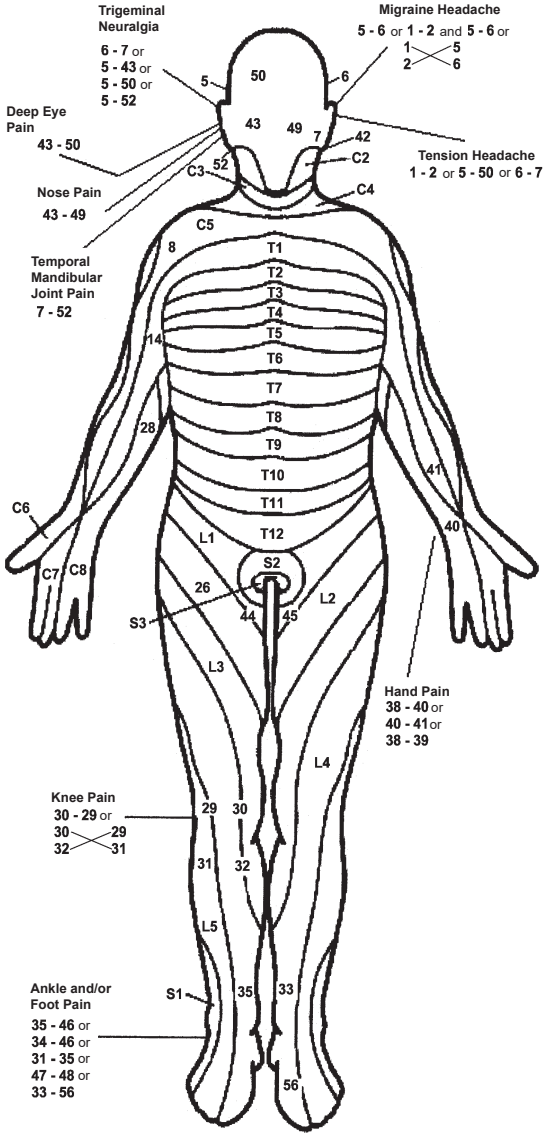
This product is manufactured by Verity Medical Ltd.

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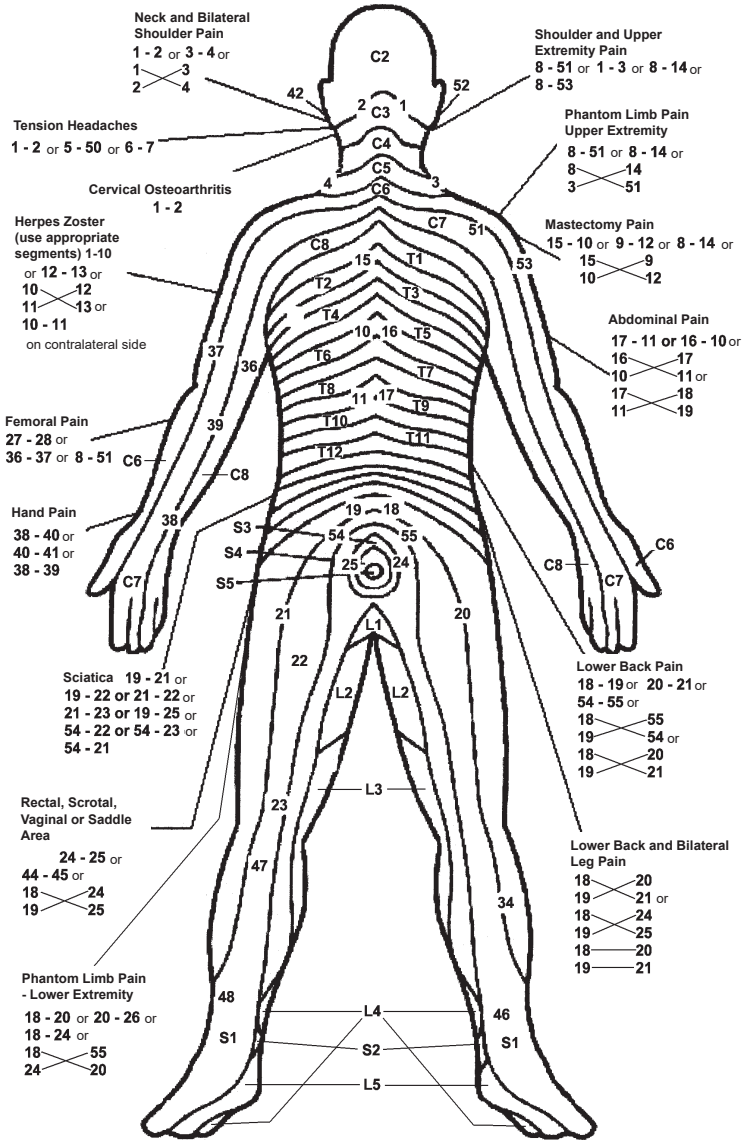
Verity Medical Ltd. is certified to the ISO13485:2016 Quality Standard.

Dermatome Charts

Anterior View



Posterior View.



Notes

Not for sale or use in the USA

Distributor:

NeuroTrac® TENS

Accessory control information:

LOT ECS300A-OM-EN32-06-08-24

NeuroTrac®
TENS manual
(English)