NeuroTrac® Obstetric TENS

DUAL CHANNEL OBSTETRIC TENS UNIT

Operators Manual

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

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. afgafadf
	Neuromuscular 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.
 TYPE BF	Patient's shock protection type: BF (Body Floated) Equipment. This equipment is not earthed but contains a battery within an insulated unit.
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 SN number when you report a technical fault or claim a warranty return.
SN	Manufacturer's serial number of the unit. Present it together with LOT number when you report a technical fault or claim a warranty return.
	Name and address of Manufacturer.
	Date of manufacture.
CE 0120	Conformity indication with the essential health and safety requirements set out in European Directives. 0120 - notified body identification (SGS).
	This product should be kept dry.
IP20 on the unit	This is an indication for protection against ingress of water and particulate matter. The mark IP20 on your unit means: your unit is protected against solid foreign objects of 12.5mm dia and greater. Not protected against water.
IP02 on the case	IP02 on the carrying case means: Protected from the ingress of water droplets from a shower of rain.
	Do not dispose in normal dustbin (see page 10 for the disposal instructions).

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.
* The unit is not protect from the ingress of water droplets from a shower of rain if used outside the carrying case.
* Do not use the NeuroTrac® Obstetric 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® Obstetric 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.
* This unit is not suitable for use during water birth.
* 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.
* No modification of this equipment is allowed!

Contents

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'].

Methodes of operation for Obstetric (Labour) Pain

The Obstetric TENS stimulator uses four long skin electrodes on the skin close to the spine and connected to the device via lead wires. The stimulation intensity is adjusted until a mild tingling sensation is felt. The NeuroTrac® Obstetric TENS unit has a hand held push button control to switch between high frequency **Boost** and low frequency **Burst**. The low frequency Burst is used during rest periods [Between contractions]. As soon as labour contraction is felt strongly the mode is changed to high frequency Boost stimulation, once the contractions have subsided the mode is reverted back to low frequency Burst mode.

Clinical evidence suggests that to achieve the best pain relief, the stimulator should be used from the first onset of labour pain and for two to three hours after birth. If it is found that insufficient pain relief is achieved with the Obstetric TENS unit then, improved relief can be achieved by using smaller amounts of alternative analgesia to compliment the TENS unit.

Contra Indications & Precautions

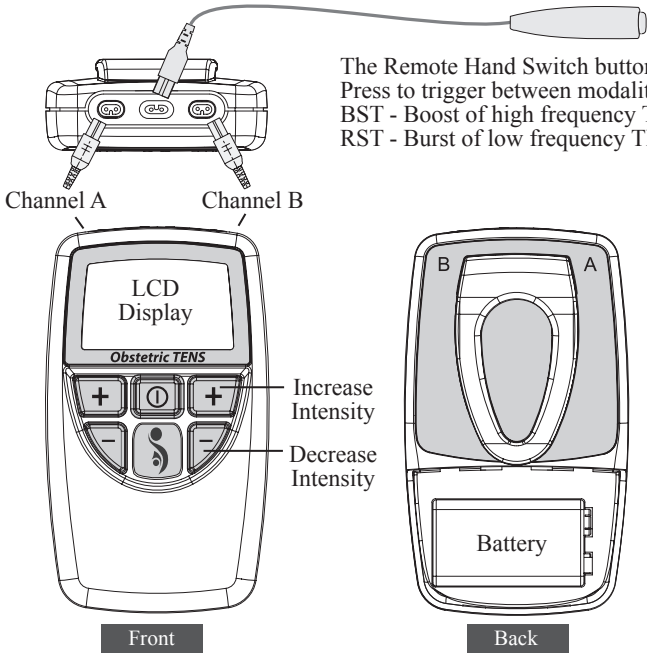
Before using this equipment you must first seek the advice of your Physiotherapist or Doctor.

Read this operating manual before using the TENS unit:

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 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® Obstetric TENS unit, call your Doctor, Therapist, Clinician or you distributor for advice
* **Used only in the course of labour pain and not during pregnancy!**

Description of Obstetric TENS Unit & Functions.

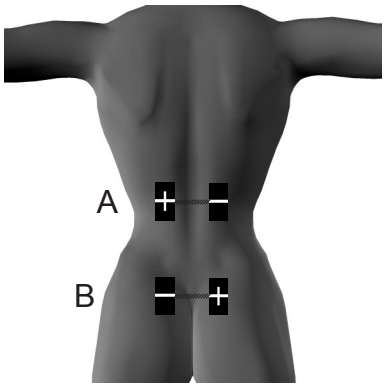


1. Insert a 9 volt PP3 Alkaline battery. Alternatively insert a recharge able Nickel Hydride battery [Which has a much longer life than the Ni-Cad rechargeable batteries] into the battery compartment.
2. Insert lead wire/s to channel A and B if both channels are to be used.
3. Insert Remote hand switch to centre connector as shown on page 8.
4. Switch on the unit by pressing the ON/OFF button
5. Press the remote hand switch to initially select high frequency Boost mode (BST).
6. To start press channel A + and B + button if you are using both channels.
7. Increase the intensity using channel A+ or B+ until you feel a slight muscle contraction, then press the button on the remote hand switch to revert back to the rest mode (RST).
8. When you feel labour pain, press the button on the remote hand switch which will select Boost mode (BST). When switching from Boost to Rest mode the intensity will reduce by 20%.
9. To decrease the intensity, select Boost mode and press the channel A- or B- button.
10. **Familiarise** yourself with the unit **before** using it during **labour**
11. To stop the programme, press the ON/OFF button which will turn the unit off.

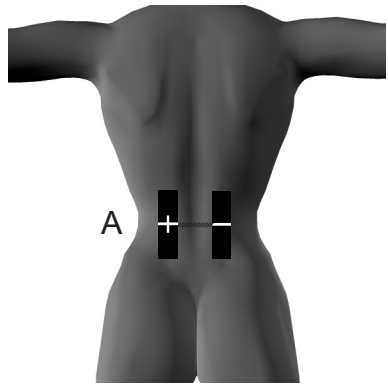
Electrode Placement

Skin pad with the **red** connector

Skin pad with the **black** connector



4 electrodes placement



2 electrodes placement

Recommended Types:
100 x 50 mm (rectangular) for 4 or 2 electrodes placement.

Place the electrode approximately 2 inches either side of you spine in the positions indicated by the drawings.

2 channels A and B - recommended:
When using two pairs of 100 x 50 mm electrodes, place the upper pair of electrodes between T10 & L1 and the lower pair of electrodes between S2 & S4 as shown on the left diagram.

Channel A only:
For 1 pair of 100 x 50 mm (or larger) electrodes, place them halfway between T10 and S2 as shown on the right diagram.

Please refer to the Dermatome chart on page 14 or ask your mid wife, physiotherapist or Doctor for more information.

Electrodes Types and Tips

* Self-Adhesive reusable long-term electrodes (if looked after) have a typical life span of 4/6 weeks. We recommend cleaning the skin with an alcohol-based wipe before placing the electrodes. The wipe should not contain fat as any grease will degrade the electrode stickiness. After use, place the electrodes back onto the plastic film and in the zip-tag plastic pouch. Store in a cool environment which is not too dry.

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.

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 or antiseptic wipe or baby 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 and Remote Control:

* The lead wires and remote control 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 and remote control before each treatment for loose connections or damage.
* Avoid stretching and twisting the lead wires and remote control.
* Store the lead wires and remote control carefully after each use.
* Lead wires and remote control 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.*

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 and up to 80% when used for reducing labour pain.

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; please see page 6 for further information.

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.

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.
* Finally, 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.

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. Pulse width: 220µS [2% accuracy].
6. Pulse Rate: 90Hz (Continuous mode) [2% accuracy].
7. Mode: Continuous (Boost mode).
8. Burst mode: Bursts of 9 pulses [200 µS] at 150 Hz, repeating twice every second (Rest mode).
9. Ramp up Time: 0.8 seconds from Rest to Boost.
10. Time duration: continuous until switched off.
11. Battery: PP3 Alkaline, 9V.
    Expected average battery life [of standard 800 mAh, alkaline]:
    17 hours.
12. Low Battery Indicator: If the battery goes below 6.9 volts +/- 0.2 volts the battery symbol will flash on/off once every second.
13. If the battery voltage is below 6.6 (+/- 0.2) volts 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 extends the life of the unit over the service life limit.

Physical dimensions: 119.2 x 69 x 28.7 mm

Weight: 90g without battery, 140g with battery.

Environmental Conditions for use:
+5 to +40 degrees Centigrade. 15-93% Humidity.

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

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.

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.co.uk

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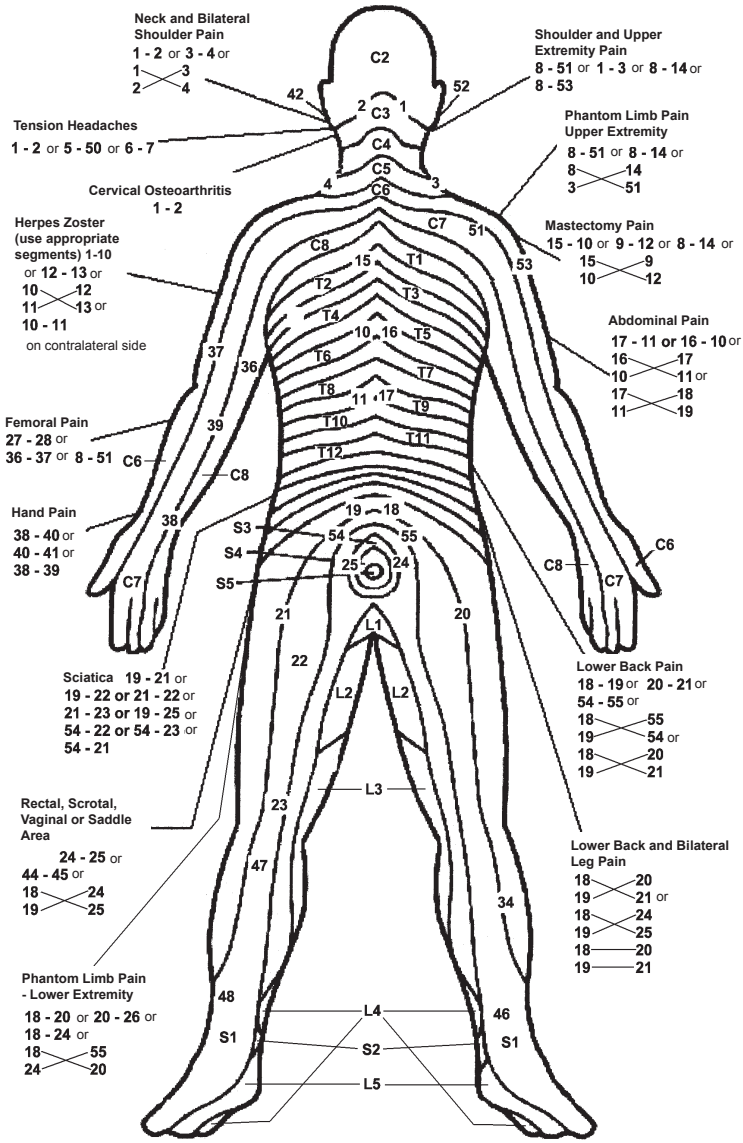
This product is manufactured by Verity Medical Ltd.,
in compliance with the European Union Medical Device Directive
MDD93/42/EEC under the supervision of SGS,
Notified Body number 0120.

CE 0120

Verity Medical Ltd., is certified by SGS to the following
Quality Standards:
ISO 9001:2008, ISO13485:2003.

Dermatome Charts

Posterior View



Clinical References

Conventional TENS:

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Not for sale or use in the USA

Distributor:

NeuroTrac Obstetric TENS

Accessory control information:

LOT ECS310A-OM-EN11-17-10-14

NeuroTrac ObstetricTENS manual (English)