NeuroTrac® PelviTone

DUAL CHANNEL STIM 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 0123	Conformity indication with the essential health and safety requirements set out in European Directives. 0123 - Notified body identification.
	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 20 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 protected from the ingress of water droplets from a shower of rain if used outside the carrying case.
* Do not use the NeuroTrac® PelviTone 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® PelviTone 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 quipment 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

Contents **Page**

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.

The NeuroTrac® PelviTone is one of a new breed of modern Neuromuscular Stimulators which Verity Medical have developed with the Therapist and Patient in mind. Our principle aim is to design products that have high levels of functional use, are sensibly priced, compact and user friendly.

The NeuroTrac® PelviTone is a dual channel device combining several treatment programmes into one unit. 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® PelviTone 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

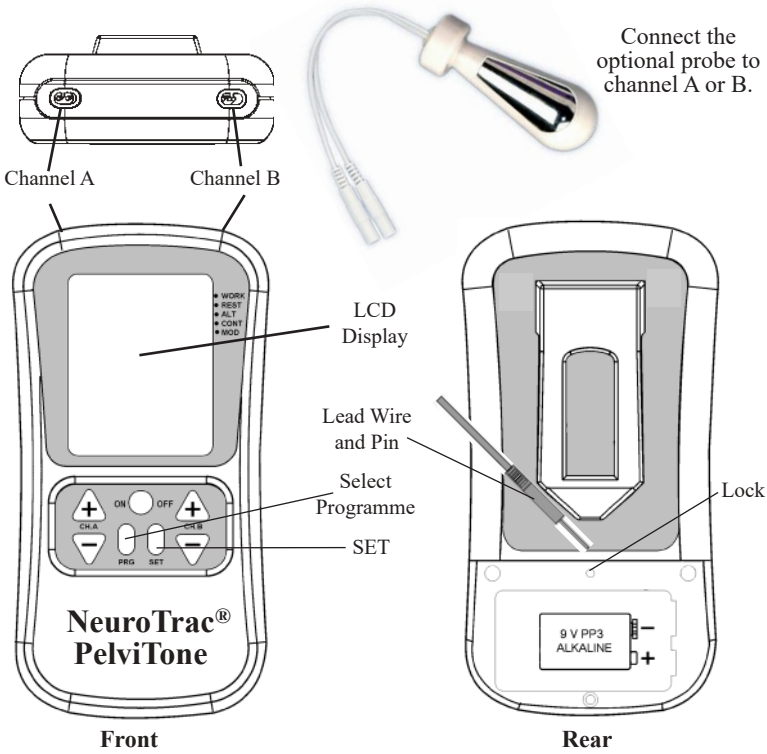
Before using this equipment you must first seek the advice of your Physiotherapist or Doctor

Read this operating manual before using the STIM unit

STIM should not be used:

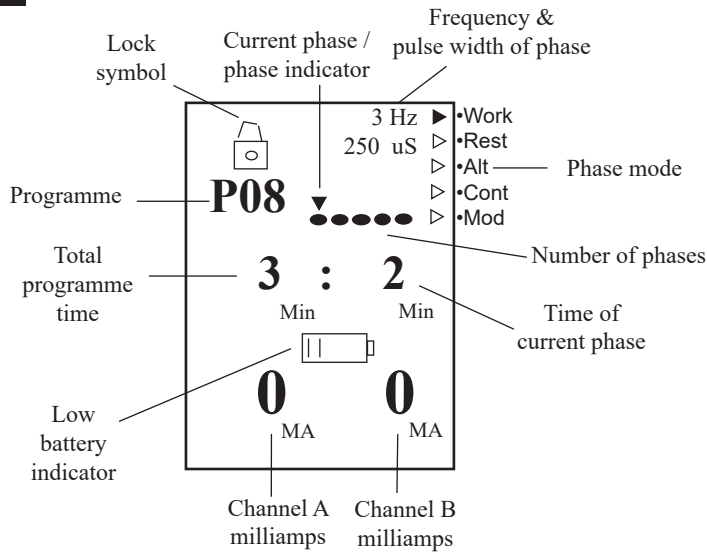
* By patients fitted with a demand style cardiac pacemakers unless so advised by their Doctor
* During pregnancy [unless medically advised]
* By patients with undiagnosed pain conditions
* By patients with undiagnosed skin, vaginal or rectal conditions
* With patients who have diminished mental capacity 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
  - > 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
* Keep unit out of reach of children
* If in doubt about the use of the STIM unit, call your Doctor, Therapist, Clinician or your distributor for advice
* Only use CE approved skin electrodes
* Only use CE approved vaginal or rectal probes

Description of STIM Unit & Functions

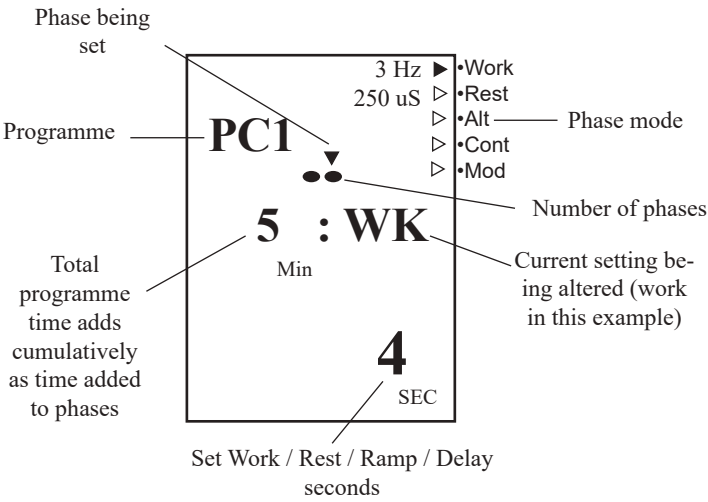


* **PRG button**	Selects the desired set programme from P01 - P11 or customised programme PC1 - PC3. Pauses (reducing the mA intensity to zero) and escapes from a running programme.
* **SET button**	Reduces the intensity (mA) to zero and pauses the programme (if a programme is running) and moves the phase one step forward. Displays the menu for programmes PC1 - PC3 and allows the parameters for Time, Work, Rest, Ramp up time, CH.A / CH.B Synchronous or Alternating and delay to be set.
* **LOCK button**	Locks the unit so the home user cannot amend the treatment parameters nor change the programme. This button must be used only by the treatment supervisor. See the details on see page 11.

Example of preset programme:



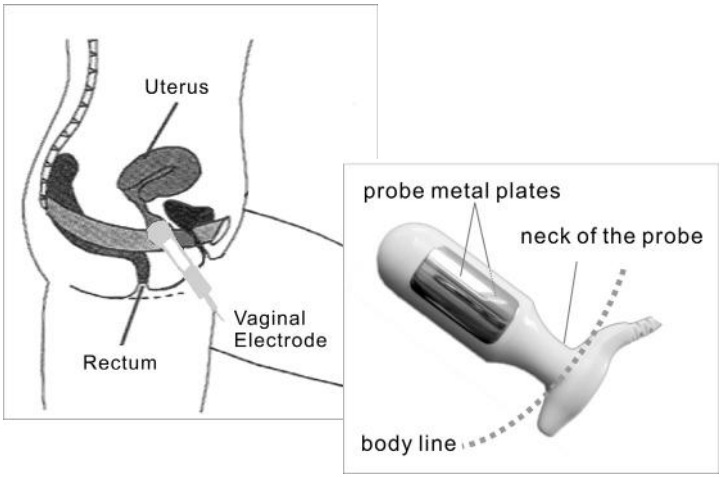
Example of custom programme:



Quick Start Instructions

1. Remove battery cover. Insert 1 x 9 volt PP3 battery or a rechargeable Nickel Metal Hydride battery into the battery compartment. Replace the cover.
2. Insert the lead wire(s) into the sockets of the unit. Lead colour is not important. You may use one lead or both leads. If you are only using one lead wire (for Channel A), insert the lead wire into the right hand socket (Channel A).
3. Remove the Vaginal or Rectal electrode from its packaging.
4. Connect the Vaginal or Rectal electrode to each of the pin connectors at the end of the lead wire. The red and black polarity are good either way. Some probes have a long wire built-in, with the direct socket to the unit.
5. Make sure the Vaginal or Rectal electrode is clean before use.
6. Insert the Vaginal or Rectal electrode using KY jelly or any other water-based lube (not mandatory).

   A typical vaginal electrode placement diagram:



Don't insert too deep, the neck of the probe should be just inside the vagina, the metal plates of the probe should be fully inserted.

7. Turn on the unit by pressing the on/off button once.
8. Select the desired programme by pressing the PRG button (please refer to the programme tables on page 11).

9. Hold down the A+ button until you feel a strong but comfortable current. The current may be decreased by pressing the A- button.
10. You may adjust the strength of the current during the treatment by pressing the A+ or A- buttons.
11. To exit the programme before it is finished, turn off the unit by pressing the on/off button once.
12. Important: Do not remove your probe / electrodes while the unit is running.
13. Carefully clean Vaginal or Rectal electrode before and after use. Wash the probe gently in mild soapy water, rinse and make sure the probe is completely dry before returning to storage in the plastic bag.

Low Battery Indicator
When the battery power is low, the low battery indicator will appear on the screen (shown in the diagram on page 7). When the battery indicator shows one bar, replace the battery.

Disconnection Indicator
When the probe becomes disconnected or when the lead wires do not conduct the electrical current, the milliamp level will return to zero and the effected channel will flash on and off.

> ***Common Issue:***
> If you press + button but the intensity stops at 6-9 mA and cuts off to zero and you see 0 mA flashing on the screen:
> - This is a typical situation for any muscle stimulator. You are experiencing the safety cut off due to no electrical load on the output. You should be able to resolve this issue yourself, please folow the troubleshooting chapter on page 25.

Setting up your Customized Programme

First, if a programme is running, press the PRG button twice to return to the home screen.

Refer to the example of custom programme diagram on page 7.

1. Press the PRG button until PC1, PC2 or PC3 is selected.
2. Press and hold the SET button for three seconds, the phase indicator arrow and Hz symbol will flash on and off.

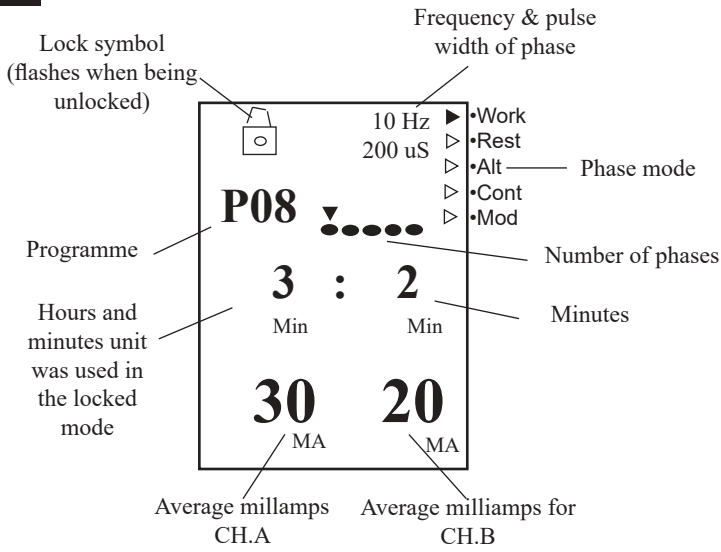
NB: CHA buttons select the parametres, CHB buttons change the values of the parametres.

3. Press CH.B +/- to set the fequency between 2 Hz and 100 Hz.
4. Press CH.A -, the µS symbol will flash, press CH.B +/- to set the pulse duration between 50 µS and 330 µS.
5. Press CH.A -, the MIN symbol will flash, press CH.B +/- to set the length of the phase time between 1 and 99 minutes.
   Set the time to zero to end the programme on this phase.
6. Press CH.A -, the WORK / REST or the CONT symbols will flash, Press the CH.B +/- to select WORK / REST or CONT (continuous).
   Note: if continuous is selected, the menu will loop back to step 2.
7. Press CH.A -, WK will appear and flash, press CH.B +/- to set the work seconds between 2 and 99 seconds.
8. Press CH.A -, RT will appear and flash, press CH.B +/- to set the rest seconds between 2 and 99 seconds.
9. Press CH.A -, RP will appear and flash, press CH.B +/- to set the ramp seconds between 0.1 and 9.9 seconds.
10. Press CH.A -, AL or SY will appear and flash, press CH.B +/- to select alternating or synchronous current.
    Note: if alternating is selected, the menu will loop back to step 2.
11. Press CH.A -, DY will appear and flash, press CH.B +/- to set the delay of channel B starting between 0 and 4 seconds after channel A.
12. The menu will now loop back to step 2 and the Hz symbol will flash.
13. To set the next phase, press the set button. The phase symbol will flash over the next phase, continue with step 2 to set this phase.
14. When finished setting the phases, press the PRG button to save the settings and return to the home screen.
    The programme will be saved permanently.

Setting the phase time of phase 2,3,4 or 5 to zero will cause the programme to end at that phase.

Following procedures 1 to 12 you can reprogramme a customised programme. If for example there are 5 pre-set phases in one overall programme and only 4 phases are now required, input 0 (zero) into the phase time that is no longer required and press the PRG key to store the new information.

Lock Button



A "concealed" lock button is included in the NeuroTrac® PelviTone which allows the clinician to accurately monitor "Home Compliance" of the patent between appointments. It records the time in use and the average intensity (MA). It also locks the customised programmes, stopping them from being altered. You can lock the unit to start measuring the statistics of use and make sure the programme parameters stays the same. To change or modify the programme, first unlock the unit. Unlocking will clear the statistics.

To Lock the Unit

1. Select the pre-set or customised programme required. In the case of a customised programme, make sure that the pulse width, frequency, time etc. are set-up correctly.
2. Remove the battery cover and, using a thin rod gently press on the lock button as shown in the diagram on page 6 until you hear a double beep. The unit is now "locked" and cannot be altered until "unlocked". Note: The lock symbol will appear on the LCD when the unit is "locked".

To Unlock the Unit

Remove the battery cover and press the concealed switch with a thin rod until a single beep is heard. Now the LCD will display the average mA used on each channel and the total hours and minutes the unit has been in use as shown in the diagram. To return to normal "unlocked" operation, simply press SET.

Continence Treatment Programmes

Programme: P01	**Pelvic Floor Pain**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	20				
Mode		Cont				
Frequency work	Hz	3				
Pulse duration	µS	150				
Ramp up time	secs	1.0				
Ramp down time	secs	0				
Work time	secs	Cont				
Rest time	secs	0				
Alternating						
Synchronous		*				
Overall time	20 min					

Programme: P02	**Urge Incontinence**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	20				
Mode		W/R				
Frequency work	Hz	10				
Pulse duration	µS	250				
Ramp up time	secs	1.0				
Ramp down time	secs	0				
Work time	secs	5				
Rest time	secs	5				
Alternating						
Synchronous		*				
Overall time	20 min					

Programme: P03	**Stress Incontinence 1**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	20				
Mode		W/R				
Frequency work	Hz	40				
Pulse duration	µS	200				
Ramp up time	secs	1.0				
Ramp down time	secs	0				
Work time	secs	6				
Rest time	secs	15				
Alternating						
Synchronous		*				
Overall time	20 min					

Programme: P04	**Stress Incontinence 2**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	20				
Mode		W/R				
Frequency work	Hz	30				
Pulse duration	µS	200				
Ramp up time	secs	0.8				
Ramp down time	secs	0				
Work time	secs	5				
Rest time	secs	8				
Alternating						
Synchronous		*				
Overall time	20 min					

Programme: P05	**Frequency / Urge 1**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	20				
Mode		W/R				
Frequency work	Hz	10				
Pulse duration	µS	200				
Ramp up time	secs	1.0				
Ramp down time	secs	0				
Work time	secs	5				
Rest time	secs	5				
Alternating						
Synchronous		*				
Overall time	20 min					

Programme: P06	**Frequency / Urge 2**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	15				
Mode		Cont				
Frequency work	Hz	10				
Pulse duration	µS	200				
Ramp up time	secs	1.0				
Ramp down time	secs	0				
Work time	secs	Cont				
Rest time	secs	0				
Alternating						
Synchronous		*				
Overall time	15 min					

Programme: P07	**Frequency / Urge 3**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	20				
Mode		Cont				
Frequency work	Hz	10				
Pulse duration	µS	220				
Ramp up time	secs					
Ramp down time	secs					
Work time	secs					
Rest time	secs					
Alternating						
Synchronous		*				
Overall time	20 min					
This programme works continuously with no rest period. It is used in some countries where they have found continuous stimulation can work effectively.						

Programme: P08	**Lack of Sensitivity**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	3	10	5	4	3
Mode		W/R	W/R	W/R	W/R	W/R
Frequency work	Hz	3	10	20	30	40
Frequency rest	Hz					
Pulse duration	µS	250	250	250	200	200
Modulation time	secs					
Ramp up time	secs	0.8	0.8	0.8	0.7	0.7
Ramp down time	secs	0	0	0	0	0
Work time	secs	4	4	4	4	4
Rest time	secs	4	4	4	6	6
Alternating						
Synchronous		*	*	*	*	*
Overall time	25 min					

Programme: P09	**Pelvic Floor Work Out**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	4	15	8	8	10
Mode		W/R	W/R	W/R	W/R	W/R
Frequency work	Hz	20	10	20	30	10
Pulse duration	µS	250	250	250	200	250
Ramp up time	secs	0.8	0.8	0.8	0.6	0.8
Ramp down time	secs	0	0	0	0	0
Work time	secs	5	5	5	5	5
Rest time	secs	5	5	5	6	7
Alternating						
Synchronous		*	*	*	*	*
Overall time	45 min					

Programme: P10	**Building Up Endurance**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	20				
Mode		W/R				
Frequency work	Hz	20				
Pulse duration	µS	250				
Ramp up time	secs	0.8				
Ramp down time	secs	0				
Work time	secs	5				
Rest time	secs	5				
Alternating						
Synchronous		*				
Overall time	20 min					

Programme: P11	**Relaxing the Pelvic Muscle**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	20				
Mode		W/R				
Frequency work	Hz	2				
Pulse duration	µS	220				
Ramp up time	secs	1.2				
Ramp down time	secs	1.2				
Work time	secs	6				
Rest time	secs	10				
Alternating						
Synchronous		*				
Overall time	20 min					

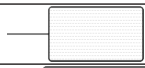
This programme helps to relax the pelvic muscle. It may be used where the EMG readings are high, in the region of 8 microvolts or more or when the pelvic muscle has been working hard and some fatigue may have occured. The very low frequency (2 Hz) will help to relax the muscle.

W/R = INTERMITTENT WORK/REST
CONT = CONTINUOUS

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.

Skin Electrode Types Available:

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.		

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 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 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 once a week 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:

* 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

Vaginal / Rectal Probes:

* Check the connectors have not become separated from the probe
* We advice you to use Verity Medical's VeriProbe.
* Vaginal Probe Disposal: please return it to the supplier from whom you've purchased it.

Caution: Static electricity may damage this product

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

Indications for use

* Pelvic/ prostatis pain
* Stress incontinence
* Overactive bladder (urge incontinence)

Also used for non medical purposes

* Pelvic floor strength, endurance, vascularisation and relaxation

Specifications

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 86 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: Symmetrical, rectangular bi-phasic with zero DC current.
5. Selectable pulse width: 50 µS – 330 µS [10% accuracy].
6. Pulse Rate selection: in the continuous mode 2 – 100 Hz [5% accuracy].
7. Time duration of the treatment selectable: 1 minute to 90 minutes.
8. Low Battery Indicator: If the battery goes below 6.9 volts +/- 0.2 volts the battery symbol will flash on/off once every second.
9. 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.
10. Ramp up time 0.1 - 9.9 seconds.
11. If the battery voltage is below 6.6 (+/- 0.2) volts the unit will not turn on.
    Expected average battery set life [of standard 800 mAh, alkaline]: 19h.

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

Environmental conditions for use:
+5 to +40 degrees Centigrade, 15-93% humidity.

Environmental conditions for storage & transport:
-25 to +70 degrees Centigrade. 15-93% humidity.

Weight: 180g with 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 overleaf.

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

If the programme cannot be changed - remove the battery cover and unlock the unit by pressing the unlock button - see page 6 and 11.

If mA intensity cuts out above 8 milliamps and zero mA is flashing on LCD:

1. The problem you are experiencing is most likely due to a poor connection of the two stainless steel electrode plates on the shaft of the probe in your body. If the probe is not fitting well or momentarily becomes disconnected, for example, when you shift position, you will see the "0" mA symbol flashing on and off and the current will have been cut off. Follow the tips below and try again mA button to increase the intensity.

2. If the internal environment is dry, it may lead to reduced electrical conductivity. Use a suitable, approved water based lubricant such as KY (don't use standard creams or grease as the lubricant must be electrically conductive).

3.Try to pull up the pelvic floor by lifting up the probe and increase mA at the same time. This may re-establish the connection.

4. The body position which leads to lack of conductivity: The best position to conduct electrical stimulation using the vaginal probe is to stand up. However, with the shape of vaginal probes on the market, it is not ideal to stand up as the probes tend to fall out. We recommend that the next best position is to sit down and lean back slightly.

5. If you think the probe itself is not working, wash it and hold it, using your first finger and thumb (or elbow crook) to make a connection across the electrode plates. Connect it to the stimulator as normal. Increase mA and, if the probe is functioning correctly, you will feel the stimulation mildly tickling in your hand (elbow crook). This proves the unit works when the connection is established, try again the above instructions. If you don't feel any tickling in your hand, try another lead wire to compare (see next point), try with a different probe (malfunctioning probe?).

6. Broken lead wire. Check if the dual conductor lead wire 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, disconnect the probe and cross the red and black metal pins of a lead wire, hold them firmly crossed with your fingers. Increase mA on the unit. If the cable conducts the electricity, the mA will go above 10 mA and you will feel a mild tingling sensation in your fingers which are holding the crossed pins. If you feel a mild electrical current in your fingers when the unit stimulates above 10mA, this proves the unit and lead wire are not causing the mA intensity cut-off. Check with the probe: above point 5.

You may need to obtain another lead wire or /and a probe, please contact your distributor. It is a good idea to have some spare wires and probes for one user.

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 TÜV SÜD Product Service GmbH Zertifizierstellen,
Notified Body number 0123.

CE 0123

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