NeuroTrac® Sports

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.
	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 19 for the disposal instructions).

Warnings

* This unit must be used with the guidance of a clinician or therapist.
* 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 this unit in the presence of a flammable anaesthetic gas mixture and air or with Oxygen or Nitrous Oxide.
* This device is 1 x 9V PP3 Batteries operated. If using rechargeable Nickel Metal Hydride batteries, be sure to use a CE approved battery charger. Never connect this unit directly to a battery charger or to any other mains powered equipment. We advise not to use Ni-Cad rechargeable batteries.
* Patient Electrodes including all skin surface electrodes, vaginal and rectal probes are for single patient use only!
* Keep out of reach of children.
* Do not use stimulation on your facial area unless you are under strict guidance from a qualified clinician.
* Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
* Operation in close proximity (e.g. 1m) to a shortwave or microwave therapy equipment may produce instability in the stimulator output.
* Simultaneous connection of a patient to a high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
* No modification of this equipment is allowed!

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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® Sports 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® Sports 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 Sports 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.

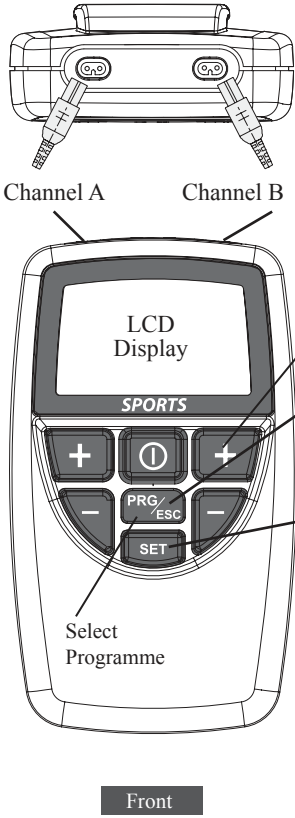
Contra Indications & Precautions

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
* 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

Description of STIM Unit & Functions



* **PRG button** — Selects the desired set programme from P01 - P15 or customised programme PC1 - PC3.

* **SET button** — Displays the menu and changes the parameters for Pulse Rate, Pulse Width, Time, Work, Rest, Ramp up time, ChA / ChB Synchronous or Alternating and delay for custom programmes.

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

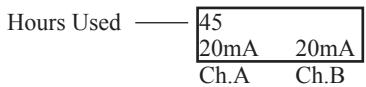
Quick Start Instructions

1. Insert a 9 volt PP3 Alkaline battery. Alternatively insert a rechargeable Nickel Metal 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 you are using two channels.
3. Switch on the unit by pressing the on/off button on the front of the unit.
4. Press the PRG button to select one of the pre-set programmes P01 - P15 or PC1 - PC3 for the customised programmes (see page 8 for customised programmes).
5. When you have selected one of the programmes, (P01 - P15, PC1 - PC3) press the + button/s to start the programme and to increase the mA intensity.
6. To stop the programme press the on/off button which will turn the unit off.

Lock Button
A "concealed" Lock button is included in the NeuroTrac® Sports which allows the clinician to accurately monitor "Home Compliance" of the patent between appointments. It also locks the customised or built in programmes.

To Lock the Unit
1. Select the built in 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".

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 the unit has been in use as shown in the diagram. To return to normal "unlocked" operation, simply press the ESC button.



Setting up the Customised Programme PC1, PC2 or PC3

First press the ESC button to return to the home screen

1. Press the SET button and the Hz symbol will flash on/off, then press the + or – button to adjust the Pulse Rate.

2. Press the SET button again and the µS symbol will flash on/off, then press the + or – button to adjust the Pulse Duration from 50 to 450 µS

3. Press the SET button again and the Clock [Time] symbol will flash on/off, then press the+ or – button to adjust the time Channel A +/- button to alter the hours and Channel B +/- button to adjust minutes. [Maximum time 1 hour 30 minutes].

4. Press the SET button again and the WRK [Work] symbol will flash on/off, then press the + or – button to adjust the work period from 2 –99 seconds.

5. Press the SET button again and the RST [Rest] symbol will flash on/off, then press the + or – button to adjust the rest period 2 – 99 seconds.

6. Press the SET button again and the RMP [Ramp up] symbol will flash on/off, then press the + or - button to adjust the ramp up period from 0.1 - 9.9 seconds.

7. Press the SET button again and ALT [Alternating] or SYN [Synchronous] symbol will flash on/off, then press the + or – button to select ALT or SYN.

8. If SYN [Synchronous] has been selected, press the SET button again to set the required delay time of Ch. B stimulation after Ch. A one. DLY will flash on the LCD display. Select the delay by pressing the Ch. B +/- buttons to read the appropriate delay value (between 0.1 sec. and 4 sec).

After setting up the programme, press the ESC button to install and store the customised programme. Repeat the above procedure to re-programme.

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

Sports Treatment Programmes

Programme: P01	**Warm up**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	6				
Mode		Cont				
Frequency work	Hz	5				
Frequency rest	Hz					
Pulse duration	µS	300				
Modulation time	secs					
Ramp up time	secs					
Ramp down time	secs					
Work time	secs					
Rest time	secs					
Alternating						
Synchronous		*				
Overall time	6 min					

Used before starting strenuous physical activity. It activates the metabolism, increases the muscles temperature and oxygenates the muscle by speeding up blood blow.

Programme: P02	**Capillary**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	20				
Mode		Cont				
Frequency work	Hz	10				
Frequency rest	Hz					
Pulse duration	µS	250				
Modulation time	secs					
Ramp up time	secs					
Ramp down time	secs					
Work time	secs					
Rest time	secs					
Alternating						
Synchronous		*				
Overall time	20 min					

Developing the capillary bed density system surrounding the muscle fibers to improve the resistance qualities of the fast glycolytic muscle twitch fibres and its recovery. Used for all type of sports activities.

Programme: P03	**Endurance**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	50				
Mode		W/R				
Frequency work	Hz	20				
Frequency rest	Hz	3				
Pulse duration	µS	300				
Modulation time	secs					
Ramp up time	secs	2				
Ramp down time	secs	1.5				
Work time	secs	10				
Rest time	secs	10				
Alternating						
Synchronous		*				
Overall time	50 min					
Improving the capacity to sustain long periods of aerobic muscle activity. Developing the efficacy of oxygen muscle consumption and storage of oxygen in the fast twitch fibre white muscle.						

Programme: P04	**Resistance force output 1**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	5	12	7	10	16
Mode		Cont	W/R	Cont	W/R	Cont
Frequency work	Hz	5	50	5	50	5
Frequency rest	Hz		5		5	
Pulse duration	µS	300	300	300	300	300
Modulation time	secs					
Ramp up time	secs		2		2	
Ramp down time	secs		2		2	
Work time	secs		8		8	
Rest time	secs		8		8	
Alternating						
Synchronous		*	*	*	*	*
Overall time	50 min					
Increasing the capacity to habitually develop a high level of muscle force. Improving oxygen consumption at muscular level and to increase the capacity to withstand toxin amassing. Used on sports activities requiring prolonged and high levels of muscle force: Cycling, Rowing, Middle distance running						

Programme: P05	**Resistance force output 2**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	5	12	5	12	6
Mode		Cont	MF	Cont	MF	Cont
Frequency work	Hz	5	50-75	5	40-75	3
Frequency rest	Hz		3		3	
Pulse duration	µS	300	300	300	300	300
Modulation time	secs		10		10	
Ramp up time	secs		2		2	
Ramp down time	secs		1		1	
Work time	secs		10		10	
Rest time	secs		8		8	
Alternating						
Synchronous		*	*	*	*	*
Overall time	40 min					
Improving and increasing the capacity to develop very high level of muscle force over a long period of time. Improving the efficacy of the oxygen consumption at the muscle level and the capacity to with stand toxin accretion, such as lactic acid. For sports activities that require very high levels of prolonged muscle activity: Rowing, Cycling, Middle Distance Running.						

Programme: P06	**Resistance force output 3**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	5	10	10	12	
Mode		Cont	MF	MF	Cont	
Frequency work	Hz	5	40-60	45-75	5	
Frequency rest	Hz		3	3		
Pulse duration	µS	300	300	300	300	
Modulation time	secs		10	10		
Ramp up time	secs		2	2		
Ramp down time	secs		1.2	1.2		
Work time	secs		10	10		
Rest time	secs		4	4		
Alternating						
Synchronous		*	*	*	*	
Overall time	37 min					
The same as Programme 5.						

Programme: P07	**Maximum force output**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	5	20	10		
Mode		Cont	W/R	Cont		
Frequency work	Hz	5	75	2		
Frequency rest	Hz		3			
Pulse duration	µS	300	300	250		
Modulation time	secs					
Ramp up time	secs		1.5			
Ramp down time	secs		1			
Work time	secs		5			
Rest time	secs		12			
Alternating						
Synchronous		*	*	*		
Overall time	35 min					
Developing the muscle to cope with and produce maximum muscle force output, and to develop muscle bulk. Used in activities of anaerobic activity. Used in sports such as: Weight Lifting, Judo, Ball Games, Sprint Running and Cycling.						

Programme: P08	**Explosive force output**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	5	15	15		
Mode		Cont	W/R	Cont		
Frequency work	Hz	5	90	10		
Frequency rest	Hz		3			
Pulse duration	µS	300	250	250		
Modulation time	secs					
Ramp up time	secs		2			
Ramp down time	secs		1.5			
Work time	secs		6			
Rest time	secs		6			
Alternating						
Synchronous		*	*	*		
Overall time	35 min					
Anaerobic activity- increasing the muscle capacity to a level of instantaneous maximum muscle force, changing muscle force into explosive action. Used for all activities requiring maximum muscle output in a very short space of time, such as Judo, Short Distance Sprinting, Throwing the Discuss or Shot Put.						

Programme: P09	**Lipocytes Metabolism**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	5	5	5	5	5
Mode		Cont	W/R	Cont	W/R	Cont
Frequency work	Hz	2	30	50	30	50
Frequency rest	Hz		3		3	
Pulse duration	µS	250	250	150-250	250	150-250
Modulation time	secs			3		3
Ramp up time	secs		1.5		1.5	
Ramp down time	secs		1.2		1.2	
Work time	secs		7		7	
Rest time	secs		7		7	
Alternating						
Synchronous		*	*	*	*	*
Overall time	25 min					
Increasing the flow of blood circulation, and modifying the metabolism of the lipocytes. To help stimulate the subcutaneous deposits of fat. To assist reduce or eliminate the Orange Peel effect on the skin surface.						

Programme: P10	**Muscle at Rest**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	20	20	10		
Mode		MF	MF	W/R		
Frequency work	Hz	2-5	5-10	10		
Frequency rest	Hz			3		
Pulse duration	µS	150-250	150-250	200		
Modulation time	secs	10	10			
Ramp up time	secs			2		
Ramp down time	secs			2		
Work time	secs			10		
Rest time	secs			10		
Alternating						
Synchronous		*	*	*		
Overall time	50 min					
To help improve recovery after high levels of training and to reduce the possibilities of muscle contraction commonly know as Cramp. Used after intense levels of sporting activity and completions in particular.						

Programme: P11	**Mass Muscle Contraction**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	5	15	10		
Mode		Cont	W/R	Cont		
Frequency work	Hz	5	60	2		
Frequency rest	Hz		3			
Pulse duration	µS	300	350	250		
Modulation time	secs					
Ramp up time	secs		2			
Ramp down time	secs		1.5			
Work time	secs		7			
Rest time	secs		14			
Alternating						
Synchronous		*	*	*		
Overall time	30 min					
To increase muscle bulk and volume and to improve muscle force. Searching for muscular hypertrophy.						

Programme: P12	**Active Recovery**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	10	25			
Mode		Cont	Cont			
Frequency work	Hz	2	2-10			
Frequency rest	Hz					
Pulse duration	µS	250	150-250			
Modulation time	secs		10			
Ramp up time	secs					
Ramp down time	secs					
Work time	secs					
Rest time	secs					
Alternating						
Synchronous		*	*			
Overall time	35 min					
To help improve muscle recovery after prolonged activity, helps to rid the system of toxin waste. Used 10 to 24 hours after prolonged activity.						

Programme: P13	**Resume Training**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	5	15	10	15	5
Mode		Cont	W/R	W/R	W/R	Cont
Frequency work	Hz	10	20	30	20	5
Frequency rest	Hz		3	3	3	
Pulse duration	µS	250	300	300	300	250
Modulation time	secs					
Ramp up time	secs		2	2	2.5	
Ramp down time	secs		1.8	1.8	1.8	
Work time	secs		6	10	6	
Rest time	secs		10	10	10	
Alternating						
Synchronous		*	*	*	*	*
Overall time	50 min					
To promote the slow twitch fibres to build muscle strength to help reduce muscle atrophy ready for resuming training activities. Used for all type of sports.						

Programme: P14	**Muscle Toning**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	5	3	3	2	2
Mode		Cont	W/R	W/R	W/R	W/R
Frequency work	Hz	5	75	50	75	50
Frequency rest	Hz		3	3	3	3
Pulse duration	µS	250	250	300	300	250
Modulation time	secs					
Ramp up time	secs		3	2	3	2
Ramp down time	secs		2	1.5	2	1.5
Work time	secs		4	6	4	6
Rest time	secs		10	10	10	10
Alternating						
Synchronous		*	*	*	*	*
Overall time	15 min					
Strengthening the muscles, improving blood circulation and capillary bed density. Ideal for applying to the Thigh, Legs, Bottom and Abdomen.						

Programme: P15	**Calming the Muscle**	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	25	20	10		
Mode		Cont	Cont	W/R		
Frequency work	Hz	2-10	5-15	10		
Frequency rest	Hz			3		
Pulse duration	µS	150-250	150-250	150		
Modulation time	secs	10	10			
Ramp up time	secs			2		
Ramp down time	secs			2		
Work time	secs			10		
Rest time	secs			10		
Alternating						
Synchronous		*	*	*		
Overall time	55 min					
Relaxing the muscles as much as possible and to promote the bodies natural endorphins to promote pain relief and to improve the blood circulation and provide oxygen into the muscle. Used on the Trapezius, Deltoid area of the shoulder, upper and lower Trapezius and Neck area.						

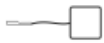
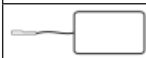
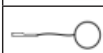
MF = MODULATED FREQUENCY IN LINEAR STEPS
W/R = INTERMITTENT WORK/REST
CONT = CONTINUOUS

MODULATION TIME = EXPONENTIALLY
Example: Modulation time 10 seconds 150µS-250µS:- means starting at 150µS increasing exponentially (fast then slow) to 250µS in five seconds and returning (fast then slow) back to 150µS to complete the cycle in 10 seconds.

Electrode Types & 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]
	VS.50	50 mm diameter, round
** IMPORTANT : Don't use VS 4040 at more than 53mA and VS3030 at more than 46 mA.		

A Few Good Tips [Self- Adhesive Electrodes]

* If you find the electrodes will not stick due to oily skin, cleanse the skin with soap and water, then rinse and dry the area around the electrode site. If this does not work, try cleansing the skin with a swab impregnated with alcohol.
* Clip away hairy skin using a 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 give you a few more days of electrode life.

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:

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

Self-Adhesive Electrodes:

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

Electrode life can be considerably reduced by:

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

For the Best Results:

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

Caution: Static electricity may damage this product

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

Applications

* Increases muscle strength
* Maintains or improves range of movement
* Increases and improves the blood supply to the muscle in cases of intermittent caudication
* As a warm up prior to exercise
* Prevents disuse atrophy (e.g. rheumatoid arthritis)

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 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 – 450µS [2% accuracy].
6. Pulse Rate selection: in the continuous mode 2 – 100 Hz [2% accuracy].
7. Time duration of the treatment selectable: 1 minute to 90 minutes.
8. Ramp up time 0.3 - 9.9 seconds.
9. Battery: PP3 Alkaline, 9V. Expected average battery life [of standard 800 mAh, alkaline]: 26 hours.
10. Low Battery Indicator: If the battery goes below 6.9 volts +/- 0.2 volts the battery symbol will flash on/off once every second.
11. If the battery voltage is below 6.6 (+/- 0.2) volts the unit will not turn on.
12. **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:
70g without battery, 100g 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.

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.

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.

Clinical References

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