

# NeuroTrac<sup>®</sup> Continenence

DUAL CHANNEL STIM UNIT

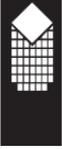
## Operators Manual

Visit our website: [www.veritymedical.co.uk](http://www.veritymedical.co.uk)  
for detailed application protocols



## 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.
	Patient's shock protection type: BF (Body Floated) Equipment. This equipment is not earthed but contains a battery within an insulated unit.
	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Manufacturer's LOT/Batch number. Present it together with SN number when you report a technical fault or claim a warranty return.
	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.
	Conformity indication with the essential health and safety requirements set out in European Directives. 0088 - Notified body identification (LRQA Ltd.)
	This product should be kept dry.
<b>IP20</b> 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.
<b>IP02</b> 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 14 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 shower or rain if used outside the carrying case.
- \* Do not use the NeuroTrac® Contenance unit in the presence of a flammable anaesthetic gas mixture.
- \* Please use 9 Volt alkaline battery (IEC code: 6LR61, size: PP3). If using rechargeable 9 Volt battery, be sure to use Nickel Metal Hydride type batteries (IEC Code 6HR61).

We advise not to use Ni-Cad rechargeable batteries.

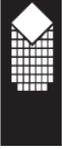
Caution: Do not use lithium batteries unless they comply with IEC60086-4.

- \* 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 to shortwave or microwave therapy equipment may produce instability in the stimulator output.
- \* Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- \* This device can deliver current densities in excess of 2mA/cm<sup>2</sup> when used at a high intensity with small electrodes.
- \* 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<sup>®</sup> Contenance 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<sup>®</sup> Contenance 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<sup>®</sup> Contenance 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.



## **Contraindications & Precautions**

Before using this equipment you must first seek the advice of your physiotherapist or doctor.

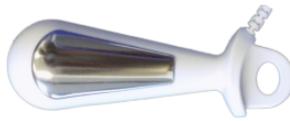
Read this operating manual before using the STIM unit.

### **STIM should not be used:**

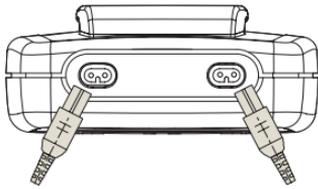
- \* By patients fitted with a demand style cardiac pacemakers unless so advised by their doctor.
- \* During pregnancy [unless medically advised].
- \* By patients with undiagnosed pain conditions.
- \* By patients with undiagnosed skin, vaginal or rectal conditions.
- \* With patients who have diminished 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



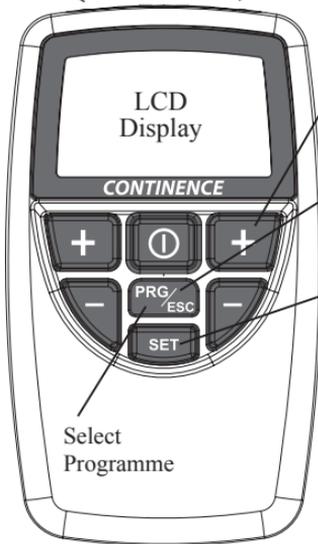
Connect the optional probe to channel A or B.



Channel A

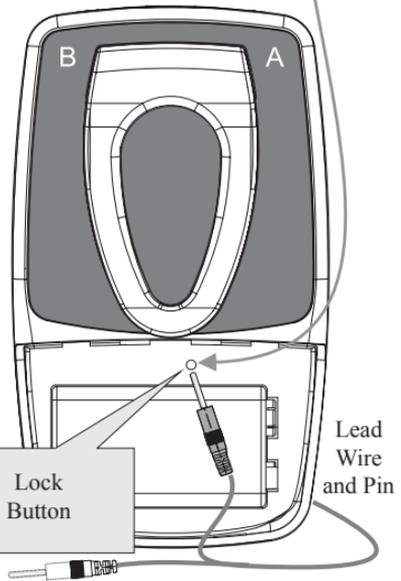
Channel B

Concealed button locks the selected programme and records the patient's home compliance. Use a metal pin of the lead wire to press the concealed button located in the battery compartment.



Select Programme

+ to start programme  
ESC to stop programme or escape from settings  
SET to go to custom programme settings



Lock Button

Lead Wire and Pin

Front

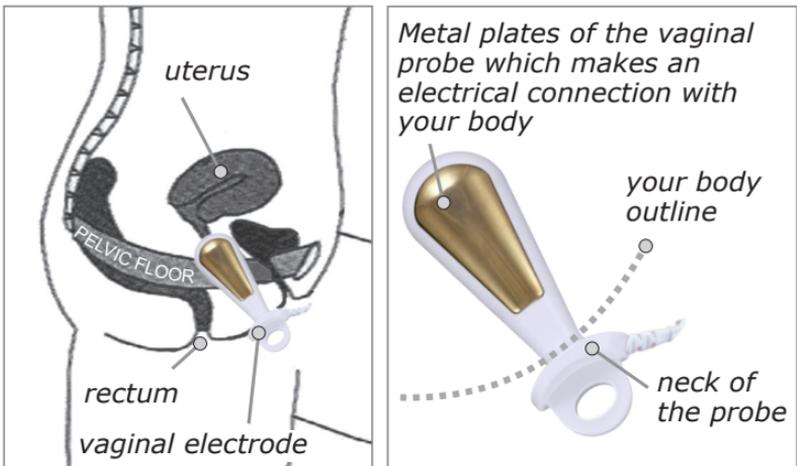
Back

- \* **PRG button** Selects the desired set programme from P01 - P09 or customised programme PC1 - PC4.
- \* **SET button** This button works only for programmes PC1-PC3. Press and hold SET button for 3 seconds to set parameters of your custom treatment: Pulse Rate, Pulse Width, Time, etc.
- \* **ESC button** Stores customised programme and returns to the home position.

## Quick Start Instructions

1. Remove battery cover. Insert 9 Volt alkaline (IEC code: 6LR61) or rechargeable Ni-MH battery (IEC code 6HR61) into the battery compartment. Replace the cover.
2. Insert the lead wire(s) into the sockets of the unit. Either red or black or red cable can be inserted. 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 connectors at the end of the lead wire. It does not matter which way the red/black cables are connected. Some probes have a long wire built-in, with the direct plug to the unit.
5. Make sure the vaginal or rectal electrode is clean before use.
6. Insert the vaginal or rectal electrode using any electrically-conductive lubricating gel or any other water-based lubricating gel (recommended for maximum performance).

A typical vaginal electrode placement diagram:



Do not insert the probe too deeply, the neck of the probe should be just inside the vagina, the metal plates of the probe should be fully inserted, metal plates facing hips.



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 12).
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 follow the troubleshooting chapter on page 21.



## Lock Button

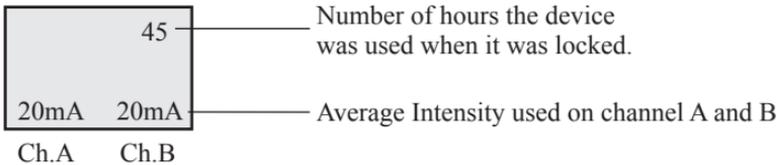
A "concealed" lock button is included in the NeuroTrac<sup>®</sup> Continenence which allows the clinician to accurately monitor "home compliance" of the patient between appointments. It also locks the customised or built in programmes.

### 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 (end of the lead wire pin meets this requirement) gently press on the lock button as shown in the diagram on page 7 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 (end of the lead wire pin meets this requirement) 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 ESC.



## Setting up the Customised Programme PC4 (Continuous)

Select PC4 by pressing the PRG button on the front panel.

1. Press and hold the SET button for 3 seconds until Hz symbol will flash on the display, then press the + or – button to adjust the pulse rate from 2-100Hz.
2. Press the SET button again and the  $\mu$ s symbol will flash on/off, then press the + or – button to adjust the pulse duration from 50 - 450 $\mu$ s.
3. Press the SET button again and the Clock [Time] symbol will flash on/off, then press the Channel A +/- button to alter the hours and Channel B +/- button to adjust minutes.[Maximum time 12 hours 59 minutes].



## Setting up the Customised Programme PC1, PC2 or PC3 (Work/Rest)

Select PC1, PC2 or PC3 by pressing the PRG button on the front panel.

1. Press and hold the SET button for 3 seconds until Hz symbol will flash on the display, then press the + or – button to adjust the pulse rate from 2-100Hz.
2. Press the SET button again and the  $\mu\text{s}$  symbol will flash on/off, then press the + or – button to adjust the pulse duration from 50 - 450 $\mu\text{s}$ .
3. Press the SET button again and the Clock [Time] symbol will flash on/off, then press the 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 be displayed, 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 be displayed, then press the + or – button to adjust the rest period 2 – 99 seconds.
6. Press the SET button again and the RMU [Ramp up] symbol will be displayed, then press the + or - button to adjust the ramp up period from 0.1 - 9.9 seconds.
7. Press the SET button again and RMD (Ramp down) symbol will be displayed, then press the + or - button to adjust the ramp down period from 0.1-9.9 seconds.
8. Press the SET button again and SYN (Synchronous) symbol will flash on/off. This is recommended for pelvic floor disorders. If you have been advised to use ALT (Alternating) mode, press + or – button to select ALT. Otherwise leave as SYN and go to next mode.
9. Press the SET button again. If SYN is selected in point 8, the DLY (Delay) symbol will flash on/off. Press the + or – button to adjust the delay time 0-4 sec. For typical use, leave 0 seconds. If the delay is set above zero, the channel 2 will ramp up with the delay.

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.



## Contenance Treatment Programmes

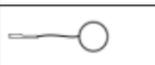
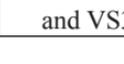
No.	Programmes	Rate [Hz]	Pulse Width [µs]	Ramp up time [s]	Work time [s]	Rest time [s]	Overall time [min]
P01	PAIN RELIEF	3	150	1	CONT		20
P02	URGE	10	250	1	5	5	20
P03	STRESS-1	40	200	1	6	15	20
P04	STRESS-2	30	200	0.8	5	8	20
P05	FREQ/URGE-1	10	200	1	5	5	20
P06	FREQ/URGE-2	10	200	1	CONT		15
P07	LACK OF SENSITIVITY [25 min]	<b>Sequential:</b> 3Hz for 3min, 10Hz for 10min, 20 Hz for 5 min, 250 µs, ramp up time 0.8 s, 30 Hz for 4 min, 40 Hz for 3 min, 200 µs ramp up time 0.7 s, work time 4 s, rest time 4 s.					
P08	PELVIC FLOOR WORK OUT [60 min]	<b>Sequential:</b> 20 Hz for 3 min, 3 Hz for 5 min, 10 Hz for 15 min, 20 Hz for 15 min: (250 µs, ramp up time: 0.8 s). 30 Hz for 5 min, 40 Hz for 5 min: (200 µs, ramp up time: 0.6 s). 10Hz for 12 min: (250µs, ramp up time: 0.8 s). Work time 4 s, Rest time 4 s.					
P09	BUILDING UP ENDURANCE P09	20	250	0.8	5	5	20
CUSTOM PC1, PC2, PC3		Customise your own Work/Rest stimulation with: 2-100Hz, 50-450µs, max 1hour 30 min, etc.					
PC4		Customise your own Continuous stimulation with: 2-100Hz, 50-450µs, max 12 hours 59 minutes, etc.					



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

### A Few Good Tips [Self- Adhesive Electrodes]

- \* If you find the electrodes will not stick due to oily skin, cleanse the skin with soap and water, then rinse and dry the area around the electrode site. If this does not work, try cleansing the skin with a swab impregnated with alcohol.
- \* Clip away hairy skin using scissors.
- \* 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 / detergent wipe.
- \* Do not use cleaning sprays or alcohol based cleaning solutions.
- \* Control unit disposal: must be disposed of in compliance with national regulatory requirements.



### ACCESSORIES

#### Battery:

- \* To change the battery, open the battery door on the rear of the control unit by pressing down on the raised rib pattern just below the belt clip. Lift the battery out of the compartment. This is very easy and can be done by the user.
- \* Check periodically for any discharge from the battery
- \* Remove battery completely from unit if not in use for any extended period of time.
- \* Low battery indicator of 6.9 volts shown on LCD display. When flashing change battery for a new one
- \* Please use 9 Volt alkaline battery (IEC code: 6LR61, size: PP3).
- \* Battery disposal: must be disposed of in compliance with national regulatory requirements.



#### Lead Wires:

- \* The lead wires should be handled carefully and never stretched, as this can cause the stimulation to function below normal standards or not at all
- \* Examine lead wires before each treatment for loose connections or damage
- \* Avoid stretching and twisting the lead wires
- \* Store the lead wires carefully after each use
- \* Lead wires Disposal: must be disposed of in compliance with national regulatory requirements.





**Self-Adhesive Electrodes:**

- \* 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.

For troubleshooting - see page 17.

**Caution: Static electricity may damage this product**

*NOTE: Only Verity Medical Ltd is approved to undertake servicing.*

## Indications for use

- \* Pelvic pain
- \* Stress incontinence
- \* Overactive bladder (urge incontinence)

## Also used for non medical purposes:

- \* Pelvic floor strength, endurance, vascularisation and relaxation



## Technical 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 the maximum will be limited to 70 mA, at 1500 Ohms load the maximum will be limited to 65 mA.
3. Type: Constant current, maximum output voltage 180 Volts +10 / -30 Volts.
4. Waveform: Asymmetrical, rectangular bi-phasic with zero DC current.
5. Selectable pulse width: 50 $\mu$ s – 450 $\mu$ s [10% accuracy].
6. Pulse rate selection: in the continuous mode from 2 – 100 Hz [5% accuracy].
7. Time duration: Preset programmes have fixed times (see the table on page 12). In custom programme PC4 the timer can be set up to 12 h. 59 min. In PC1-PC3 the max. time is 1h 30 min.
8. Ramp up time 0.3 - 9.9 seconds.
9. Battery: 9 Volt alkaline battery (IEC code: 6LR61, size: PP3). Expected average battery life [of standard 800 mAh, alkaline]: 32 hours. It is recommended to use battery type 6LR61.
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 to 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:

100g with battery.

### Environmental Conditions for use:

+5 °C to +40 °C. 15-93% Humidity.

### Environmental conditions for storage & transport:

-25°C to +70°C. 15-93% Humidity.



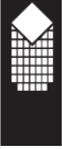
## Troubleshooting

**If the programme cannot be changed** - remove the battery cover and unlock the unit by pressing the unlock button - see page 7 and 8.

**If mA intensity cuts out and zero mA and  symbol is flashing on LCD screen:**

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 contract 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 probe may fall out. We recommend that the next best position is to sit down and lean back slightly, or lie down.
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 tingling in your hand (or elbow crook). This proves the unit works when the connection is established, try again the above instructions. If you don't feel any tingling in your hand, try another lead wire to compare (see next point), or try with a different probe (malfunctioning probe?).
6. Broken lead wire. Check if the dual conductor lead wire cable is broken, or it might be bent or pulled out too much exposing pins, etc. This can result in no conductivity, please 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. Now, check with the probe: follow point 5 from above.

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](http://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 LRQA Ltd., (Lloyd's Register Quality Assurance Ltd), Notified Body number 0088.

**CE 0088**

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



## **Clinical References**

Please go to our website for the latest clinical protocols:

<http://www.veritymedical.co.uk/Protocols>

Please contact us for any clinical references of NeuroTrac® Continance:

[enquiries@veritymedical.com](mailto:enquiries@veritymedical.com)

Not for sale or use in the USA

Distributor:

# NeuroTrac® Continance

**Accessory control information:**

<b>LOT</b>	ECS400A-OM-EN21-15-09-17
NeuroTrac® Continance manual (English)	