NeuroTrac® Simplex

SINGLE CHANNEL EMG

Operators Manual

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

English

VERITY MEDICAL LTD

Symbols on the unit	
	Follow operating instructions! Failure to do so could place the patient or operator at risk.
	This product should be kept dry.
LOT	Manufacturer's LOT/Batch number. Present it together with SN number when you submit the technical fault or claim warranty return.
SN	Manufacturer's serial number of the unit. Present it together with LOT number when you submit the technical fault or claim warranty return.
	Name and address of Manufacturer.
	Date of manufacture.
CE 0088	Conformity indication with the essential health and safety requirements set out in European Directives. 0088 - Notified body identification (LRQA Ltd.)
 TYPE BF	Patient's shock protection type: BF (Body floated) Equipment. Floating isolated applied part. It is only intended for connection to patient's skin but has floating input circuits. No connections between patient and earth.
IP20 on the unit	IP -indication for protection against ingress of water and particulate matter. IP20 means: protected against solid foreign objects of 12.5mm dia and greater. Non 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).

Table of Contents

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 main power supply.
* Do not immerse in water or any other substance.
* The unit is not protect from the ingress of water droplets from a shower of rain if used outside the carrying case.
* Do not use the NeuroTrac® Simplex 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® Simplex directly to a battery charger or to any other mains powered equipment.
  We advise not to use Ni-Cad rechargeable batteries.
* To avoid the effects of electromagnetic interference never use the NeuroTrac® Simplex, within 4 metres of a cellular telephone or near any other powerful radio interference producing equipment that produces electrical sparks etc. In the EMG Mode, the NeuroTrac® Simplex may be susceptible to strong interfering radio type emissions that may lead to temporally increased EMG microvolt readings. The reading will immediately return to the correct value when the interference ceases. (Remember that a relaxed muscle should read below 3.5 µVolts).
* Patient Electrodes including all skin surface electrodes Vaginal Electrodes and rectal probe are for Single Patient Use only.
* Keep out of reach of children.
* No modification of this equipment is allowed!

Contra-Indications and Precautions

There are no precautions when using EMG other than when being used for Pelvic floor exercising or assessment. EMG should not be used:

* During menstrual period (when using vaginal probes)
* If symptoms of bladder infection are present
* With patients who have diminished mental capacity or physical competence who cannot handle the device properly
* Do not place electrodes inside mouth
* The patient should use the unit only as prescribed
* Do not immerse the unit in water or any other liquid
* If in doubt about the use of the NeuroTrac® Simplex unit, call your Doctor, Therapist, Clinician or you distributor for advice

Conditions known to respond to EMG

* Pelvic pain
* Patellofemoral pain syndrome

Introduction

The NeuroTrac® Simplex is a simple to operate low cost single channel EMG Biofeedback device. The NeuroTrac® Simplex has been developed for its ease of use, to assist the Therapist and most importantly the Patient to understand the importance of applying EMG, to enhance the understanding of muscle activity and to improve muscle conditioning. The NeuroTrac® Simplex also acts as a diagnostic tool to measure the muscle activity, which is measured in microvolts [One millionth of Volt].

The NeuroTrac® Simplex is a single channel EMG [Electromyography] device that has been designed to use with a variety of applications in particular Incontinence Assessment and Biofeedback Pelvic Floor Training, it can also be used very effectively for Sports and General Physiotherapy applications. The NeuroTrac® Simplex is an accurate and sensitive device that measures muscle activity down to as low as to 0.2 µV [Microvolts] and up to 2000 µV. The diverse range enables the device to measure very weak muscle activity for example in flaccid pelvic floor muscle.

Increasingly, EMG is being used as Therapists and Clinicians alike realise the importance of measuring muscle activity and individual patient's progress. This can be achieved by locking the device, which will record the average work/rest, onset and muscle release parameters and time in use by patients that use the NeuroTrac® Simplex at home.

The NeuroTrac® Simplex will stand upright on a flat surface enabling the user to carry out specific exercises and at the same time view the Biofeedback by way of bright LED lights on the front of the unit. At the end of a session that may entail five trials of 5 seconds work and 5 seconds rest of activity, the LCD screen will automatically display the average muscle readings for the session. The unit can be locked for a certain period so the patient cannot amend the treatment parameters such as work/rest time and number of repetitions. When the unit is then unlocked by therapist, the number of finished sessions is displayed together with the overall average readings.
In addition, the unit can be used with the optional PC Software.

NeuroTrac® Simplex Layout

ON / OFF Button

Pressing the Start button initiates a programme

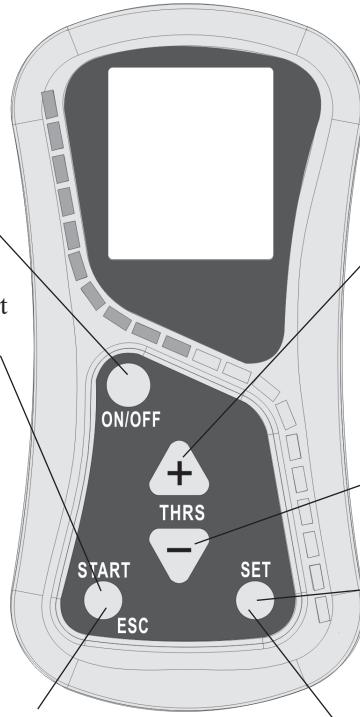
Pressing the Escape button once will bring you back to home screen.

Increases EMG threshold, or alters the parameters when setting up a programme

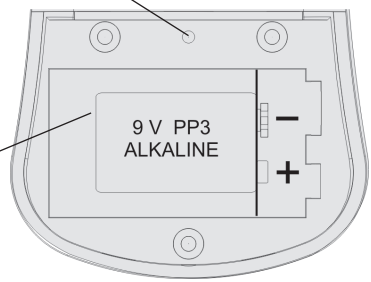
Decreases the EMG threshold, or alters the parameters when setting up a programme

Press and hold SET for 3 seconds to adjust the session parameters, such as Work/Rest time, number of trials, etc.

Press SET button to adjust the threshold automatically (contract the muscles for 3 seconds and the unit will set the most suitable bargraph scale).

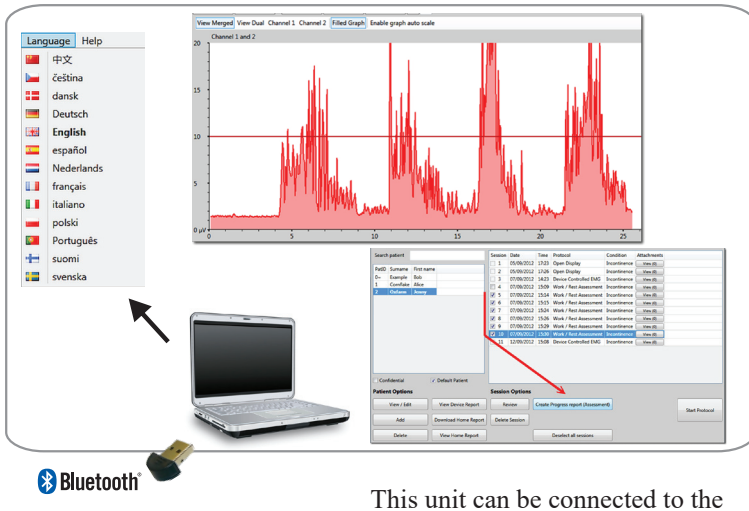


Concealed button, Locks the programme and records information. Press and hold for 5 seconds to Unlock.

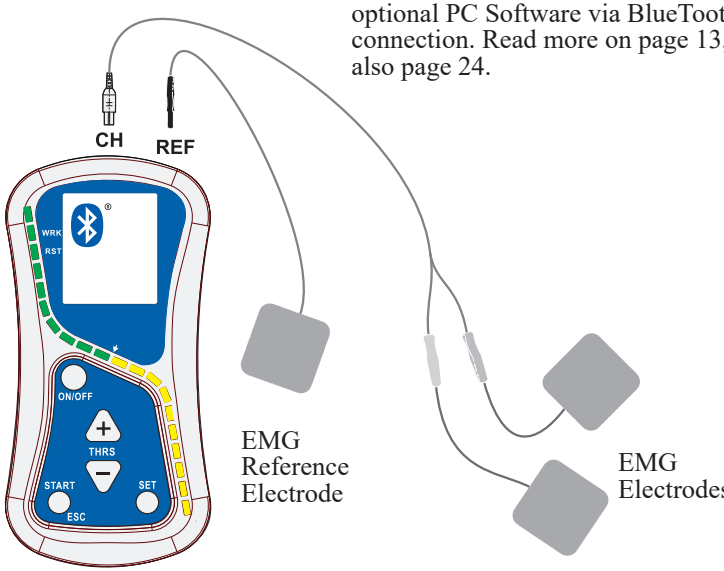


Battery Compartment

Lead / Electrode Connection Assembly

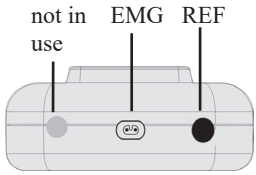


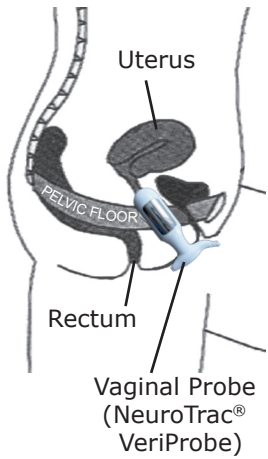
This unit can be connected to the optional PC Software via BlueTooth connection. Read more on page 13, also page 24.



Always place reference (REF) wire anywhere on your body, for example on a hip or forearm. This third electrode will allow a precise EMG measurement, if you don't use this electrode your reading will be unstable and meaningless.

Quick Start Instructions



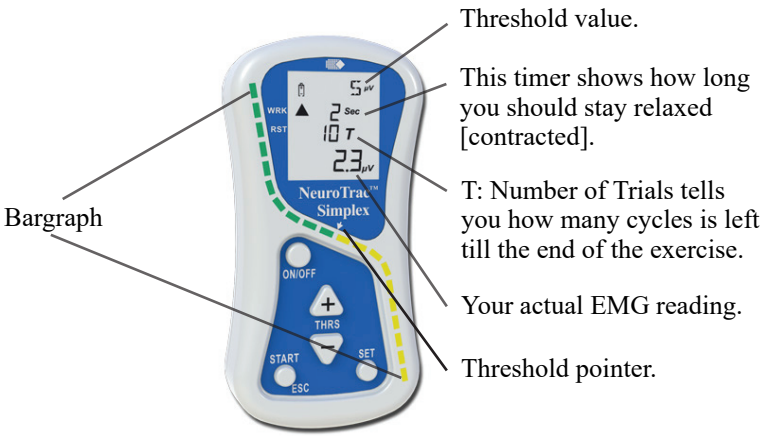


1. Remove battery cover. Insert 1 x 9 volt PP3 battery or a rechargeable Nickel Metal Hydride battery into the battery compartment. Replace the cover.
2. Insert the dual-conductor (channel) lead wire into the socket of the unit labelled as INPUT. For a precise EMG measurement, ALWAYS! use the reference wire: attach one skin electrode to a black single leadwire (reference wire) and plug the reference wire to the EMG REF socket.
3. **If you use Simplex with Vaginal or Rectal electrode probe**, remove the probe from the package and follow the probe labelling. 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 a direct socket to the unit.
   * Make sure the Vaginal or Rectal electrode is clean before use.
   * 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.
4. **For Skin electrodes placement**, make sure your skin around the treatment area is free from grease or oil. Carefully peel the electrodes from the clear plastic film. Do not throw this clear plastic film away. Attach the electrodes to your body. Place negative Black-pin near the upper insertion or top of the muscle. Positive Red-pin must be placed at the motor point of the muscle. The motor point is usually located at the centre of the muscle mass where the motor nerve enters the muscle. Find the best position by slightly moving the

positive electrode around. Your objective is to find the spot where the minimum muscle contraction will cause the greater EMG response.

5. Turn on the unit by pressing the ON/OFF button. Place the unit on a desk in its stand or hold the unit. Relax so that the microvolts reading is as low as you can manage, ideally below 1uV.
6. Press SET and contract as high as you can for 3 seconds to adjust the Threshold automatically (see next chapter for threshold automatic and manual operation). The threshold level should match your current muscle performance, so when you contract and then relax, the bargraph should go the full scale up and down in accordance with your movements.
7. To start the programme, press the **START/ESC** button.
   Follow the audio and display prompts: relax as much as you can when you hear single beep sound and the display shows arrow down. Contract as fast and as much as you can when you hear double beep sound and the display shows the arrow up.
   To end the programme before it is complete, press the **START/ESC** button again or turn the unit off.
8. When you have finished, remove and replace the electrodes onto the clear plastic film and reseal them in the plastic bag.
   If you are using a VeriProbe, clean the probe and let it dry before sealing it in its plastic bag.
9. Store the electrodes in a cool dry place, such as a fridge, which prolongs the life of your electrodes.

Threshold and bargraph scaling



Press SET for auto threshold adjustment

Relax so that the microvolts reading is as low as you can manage, ideally below 1uV.

Press SET and contract your muscles for up to 5 seconds as high as you can. The display shows the up arrow segment flashing and the seconds are counting down 3, 2, 1 on the display. Finally the new threshold value is displayed. This value is calculated as 80% of your average contraction during the time of the above 5 seconds measurement. You can repeat the adjustment as many times as you want simply by pressing again the SET button and contracting your muscles again for up to 5 seconds.

The threshold value regulates the full bar graph scale of your Simplex. For example, for the weak or small muscle groups the bar graph should be more sensitive (threshold value 0-20µV) then for stronger muscles (threshold above 20µV). The best way to select the threshold you need is to use the auto threshold function described above.

Note! You need to be in the home screen of Simplex for SET button to initiate the automatic threshold adjustment. Turn the power OFF, then turn the power back ON to go to the home screen.

You can always adjust the threshold manually simply by pressing +/- buttons.

How to use EMG session

Your Simplex device is designed to perform a series of voluntary contraction (Work) and relaxation (Rest) exercises. The contraction/relaxation is repeated many times (Trials) and the whole procedure is called a session. Press the Start button and follow the on-screen and audio prompts which tell you when you should contract and when to relax. By the end of the session, the statistics are displayed. The session can be used as training or assessment.

EMG Biofeedback Training is used to facilitate the rehabilitation by allowing the patient a visual (bargraph and EMG µV reading) and an audio (beeps) representation of his/her actual muscular performance. Once you hear and see the muscle during the voluntary attempts to contract and then to relax, you can consciously develop the ability you need (faster relaxation, stronger hold, quicker response, etc). Typically you would use a training session intensively for several times a day or cautiously for several times a week.

EMG Biofeedback Assessment is used when the performance results (statistics) are needed to be collected for a periodic comparison. You press the START button to use the session not for a regular training but now for the examination. Upon a completed session, the statistical results are displayed (see the Statistics chapter).

Optional PC Software

Try out the latest software from **www.neurotrac.emgsoft.info**

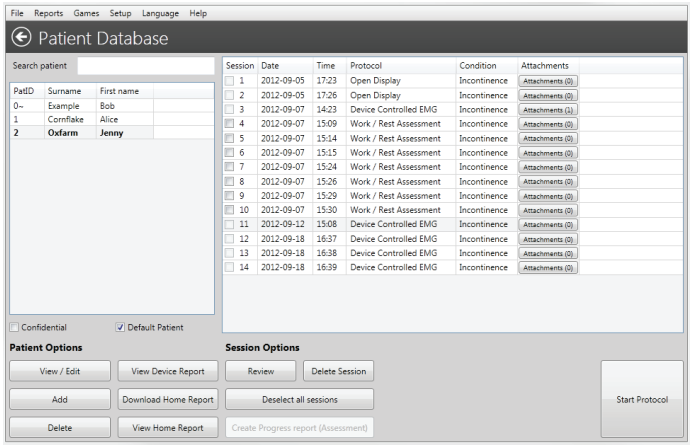
There are many useful features you can have with the PC Software, some of them are listed below:

EMG games - a range of Biofeedback Games designed for children and adults for a graphical encouragement of daily training routines.

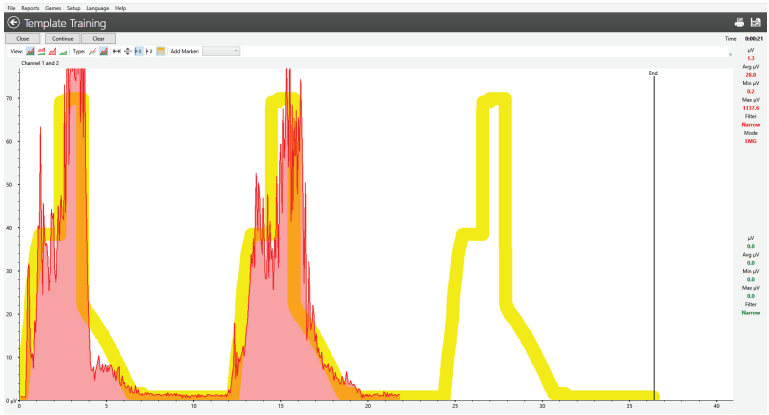
Template Training - a custom template curve can be drawn for the patient to follow, so you can create your own relaxation, rapid contraction protocols, etc.

Work/Rest Assessment - this feature allows the periodic progress records to be stored in the database and printed out to establish the results and tendencies of biofeedback or any other (additional) on-going rehabilitation protocols.

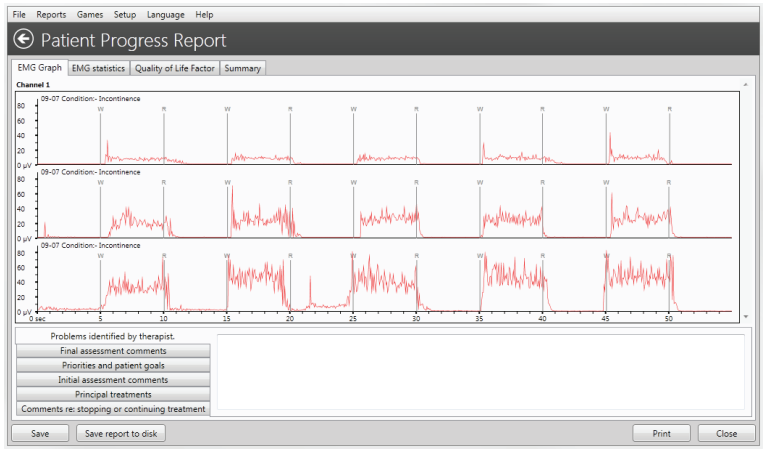
Below are some screen-shots of selected Software features:



Patient's database stores all Assessments and Trainings records if your Simplex was linked to the PC during the session. The software can handle as many patients as you need with virtually unlimited record capacity (subject to your computer limitations).



The Template Training allows you to draw the curve, adjust it's thickness, repeat it as many times as you need and this will form a pattern called "Template" which the patient follows with his/her EMG.



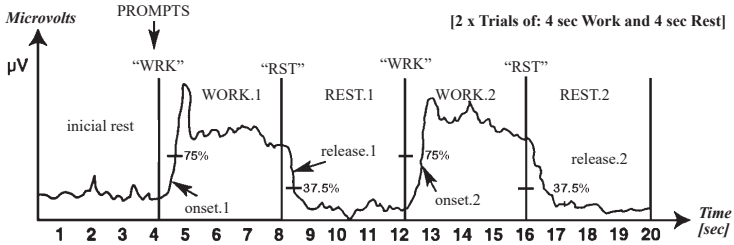
The Progress Report can be created from the records of assessment sessions previously recorded in PC Software. The graphical comparison allows the progress details to be revealed for a proper evaluation of the rehabilitation results.

EMG Session settings

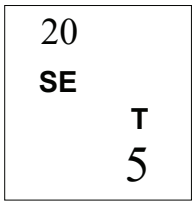
To adjust the session parameters, press and hold SET button for 3 seconds. The first parameter will be VOL (sound volume). To adjust the value, press +/- buttons. To go to the next parameter in the table below, press SET button. To save new settings, simply press ESC or OFF. The new settings will be immediately stored.

EMG parameters	Text on LCD	Available settings
Sound Volume	VOL	Value range: 0 - sound off, 1,2,3,4,5 - quiet, 5,6,7,8,9,10 - loud. Typical value: 4. This is the sound volume of beeps and prompts: Work, Rest, Lock, PC-CONNECT, Erase
Work Time	WRK	Value range: [sec]: 2,3,4, ..., 99 Typical value: 5. This is the time during which the patient is prompted to keep the measured muscles contracted above the threshold level.
Rest Time	RST	Value range: [sec]: 2,3,4, ..., 99. Typical value: 5. This is the time during which the patient is prompted to keep the measured muscles relaxed below the threshold level, ideally below 1uV.
Number of Trials	TRS	Value range: 2,3,.., 99. Typical value: 5. This parameter defines how many repetitions of Work/ Rest cycles your treatment requires.
Audio Biofeedback type	FAB FBL FCO FOF	Select from the following: FAB - the EMG beeps will be audiable only above the threshold. FBL - the EMG beeps will be audiable only below the threshold. FCO - the EMG beeps will be audiable above and below the threshold FOF - no EMG beeps. Typical setting: FAB.
PC Data output	DON DOF	Select from the following: DON: - switch ON to enable PC Software connection. DOF: - switch OFF to save batteries. Typical setting: DON.
EMG Notch Filter	WDE NRW	Select from the following: WDE (typical setting) - wide filter - your EMG reading will be more sensitive but it will also pick up heart beats. NRW - narrow filter - your EMG reading will be filtered to reduce the heart beat spikes on the EMG reading. Use narrow filter if your electrodes are in close proximity to heart (on chest, back, arms, vaginally or rectally).

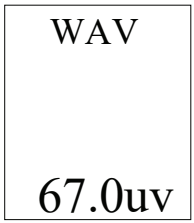
EMG Session Statistics



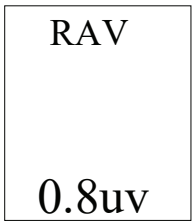
The EMG session statistics are used for assessment of muscular activities. Start the session, follow the on-screen prompts, by the end of the session the following statistics will be displayed. Press SET to scroll down the list of statistics.



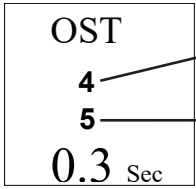
SE and T are displayed only when the unit is locked.
SE - the number of completed sessions when the unit was locked. If no sessions were completed and you unlock the unit, SE will read zero and it will be the only statistics screen you would see, as nothing else to be presented.
T - number of trials set for a session.



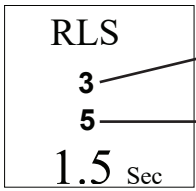
Work Average [µV] - the overall average microvolts achieved during all work periods of the session. Generally the higher the Work average is, the better the muscle performance.
Assessment: the good progress is when Work average is getting higher and higher each day.



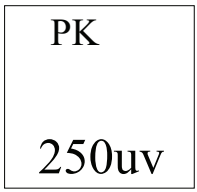
Rest Average [µV] - the overall average microvolts during all rest periods of the session.
Generally the lower the Rest average is, the better the muscle performance. It is very important how low you can relax your muscles in terms of microvolts. Below 4µV a muscle is beginning to rest. If the Rest average is above 4µV make sure you use the EMG reference lead wire! The reading above 4µV commonly means the muscle is overstimulated or tired after a longer EMG training session.
Assessment: a good progress is when the Rest average is getting lower and lower each day.



Onset Average [sec] - This is the average time taken in seconds to achieve 75% of the work average of all work segments, any values over 2 seconds are ignored.
Generally this parameter measures how fast you can contract a muscle, the shorter the Onset average time is, the better the muscle performance. Reading below 1 second can be considered normal. The time it takes to contract a muscle gives an indication on the recruitment of the fast twitch fibres. If the onset time was slow, the recruitment percentage of the fast twitch fibres would be less than if the onset time was faster.
Assessment: the good progress is when Onset average time is getting shorter and shorter each day.

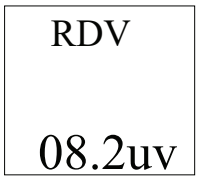


Release Average [sec] - This is the average time taken in seconds to relax below 37.5% of the work average of all work segments, any values over 2 seconds are ignored.
Generally this parameter measures how fast you can relax a muscle, the shorter the Release average time is, the better the muscle performance.
Healthy muscle normally reverts back to a low resting EMG value in less than one second. If the muscle takes longer to revert back to rest then there will be a reason, such as muscle or nerve damage or some other underlying problem.
Assessment: the good progress is when Release average time getting shorter and shorter each day.



Peak value [µV] - This is the maximal muscle contraction over the session. This information is less important for the overall analysis.

Work Average deviation [µV] - The average deviation in microvolts of the work periods of the session, it excludes the first second of each work portion. Generally the deviation means the average differences between EMG readings.
If a muscle shakes and contracts spasmodically, the EMG graph is sharp and wavy (high EMG deviation). If the muscle is not tired and in good shape, it doesn't tremble and stays firm in contraction, the EMG graph will be smother (low EMG deviation).
Assessment: the good progress is when Work Deviation % value is getting smaller and smaller each day.



Rest Average deviation [µV] - The average deviation in microvolts of the rest periods of the session, it excludes the first second of each rest portion. Generally the high Rest average deviation means overstimulated or overtrained muscle or the body has difficulties in controlling the muscle because of the damage of the motor neurons.

Assessment: the good progress is when Rest Deviation % value is getting smaller and smaller each day.

Warning! All suggested assessment criteria on page 14-16 is not necessarily the case for every imaginable treatment. Given examples of how you should analise the statistical results cannot be considered as complete or always true, the aim is to give the initial idea and a point of reference for the beginners in EMG analysis. Please seek the advice among specialists.

Lock Function for compliance record

The LOCK function locks the treatment for home or in-clinic use. When the unit is locked, user cannot amend any crucial treatment settings such as Work time, Rest time, number of trials and EMG notch filter. However user at home can still adjust threshold, sound volume, change the audio biofeedback type, or switch ON/OFF the link to PC. When the unit is locked, the statistics are gathered and averaged to cover the whole treatment. Simplex has no ability to show the statistics day by day, it averages all the statistics of up to 1999 sessions. The sessions over 2000 will not be included (ignored) in the overall statistics record.

Locking instructions:

1-Lock (double beep)

Please programme the treatment you want and press the concealed button to lock the unit. The lock symbol will appear on the display. From this moment the overall statistics are gathered. For example, if you lock and complete 10 sessions during a couple of weeks, the unit displays the number of completed sessions [SE], the overall average work of these 10 sessions, the overall average rest, the overall average onset and release, the overall average work and rest deviation.

2-Statistics review (single beep)

Press the concealed button one more time to review the overall statistics. Press SET to scroll down the list of available statistics.

You can connect the unit to PC Software to download the statistical information you see on LCD screen. You can press ESC or OFF and the unit will remain locked and statistics not erased

Concealed Button to Lock and Record a Patients Compliance

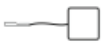
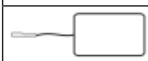
3- Unlock and clear
(5 beeps, the last one is longer)

When in Statistics review, press and hold the concealed button for 5 seconds to unlock the unit and erase the statistics. The unit is now ready to be programmed for another treatment.

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; don't use a razor to remove the hairs!
* The electrodes conductive material is water- based. If it becomes saturated (e.g. from perspiration), it will lose its adhesive qualities. After use leave the electrodes face up overnight to dry out (replace on plastic film in the morning).
  At some point the electrodes will become dry. Moisten the adhesive surface with a few drops of water, and apply onto the plastic film overnight. This procedure will increase the electrode life by few more days.

Care, Maintenance, Accessories and Disposal

WARNING! Only medically approved accessories should be used!

CONTROL UNIT

* Wipe the surface after each use with a damp cloth or antiseptic wipe or baby wipe.
* Do not use cleaning sprays or alcohol based cleaning solutions
* Control unit disposal: please return to Verity Medical LTD or to the appointed distributor.

ACCESSORIES

Battery:

* To change the battery, open the battery door on the rear of the control unit by pressing down on the raised rib pattern just below the belt clip. Lift the battery out of the compartment. This is very easy and can be done by the user.
* Check periodically for any discharge from the battery.
* Remove battery completely from unit if not in use for any extended period of time (typically one week).
* Low battery indicator of 6.9 volts shown on LCD display. When flashing change battery for a new one.
* Preferably use a PP3 alkaline battery.
* Battery disposal: please return to the supplier from whom you've purchased it.

Lead Wires:

* 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:

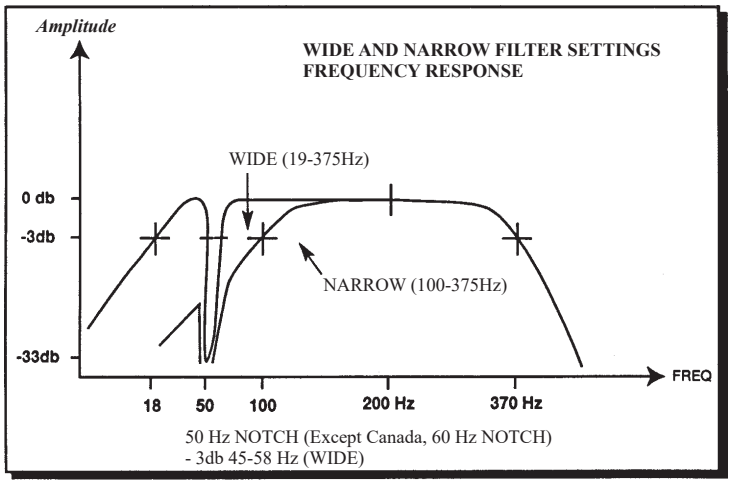
* The type and condition of the skin
* Deep seated moisturisers or make-up

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.



The picture above shows the EMG notch filter characteristics. For the frequencies which correspond to heart beats (Narrow option only) and mains interference (Wide and Narrow option), the filter reduces the amplitude of reading, effectively it filters out the two major EMG interference sources. See page 15 for how to select Wide or Narrow option.

Specifications

EMG Electrical Specification

1. Single Channel
2. EMG Range: 0.2 to 2000 µV RMS (continuous)
3. Sensitivity: 0.l µV RMS
4. Accuracy: 4% of µV reading +/-0.3 µV at 200 Hz
5. Selectable Bandpass filter - 3db Bandwidth,
   a. Wide: 18 Hz +/- 4 Hz to 370 Hz +/- 10%
   - Reading below 235 microvolts
   10 Hz +/-3 Hz to 370 Hz +/- 10%
   - Reading above 235 microvolts
   b. Narrow: 100 Hz +/- 5% to 370 Hz +/- 10%
6. Notch filter: 50 Hz (Canada 60Hz) - 33 dbs (0. 1% accuracy)
7. Common Mode Rejection Ratio: 130 dbs Minimum @ 50 Hz
8. Work / Rest periods: 2-99 seconds
9. Number of Trials: 1-99
10. Battery: PP3 Alkaline, 9V.
    Expected average battery life [of standard 800 mAh, alkaline]:
    40 hours.
11. Low battery indication at 7.4 volts +/- 0.2 volts and automatic shut off 10 minutes after last key pressed, unless infra-red is turned on.

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.

Physical Dimensions:
Length 128.5mm, Width 64mm, Depth 28.3 mm excluding belt clip

Weight: 150g.

Trouble Shooting

If you experience problems with EMG readings we recommend you make the following checks.

1. The EMG biofeedback reading becomes unstable, when the reference REF wire is not used (read on page 8).

2. Check the lead wires for splits or breaks in the wire or at the end, where the connectors are attached to the wire. Try another lead wire.

3. Check the electrodes. Try another pair of skin surface electrodes or another probe. Inferior surface electrodes may cause incorrect readings, we recommend you always use quality electrodes for EMG measurement.

4. If you are using a laptop computer and experience interference when using the charger, switch the charger off, if you still experience interference move to another area.

5. If you are using Vaginal or Rectal probes we recommend the patient uses conductive Gel as recommended by the Physiotherapist or Doctor.

6. Some patients vaginal aperture may be too large for some internal probes, causing intermittent contact with the walls of the pelvic muscle. In such cases one should try another larger electrode.

Other possible issues:

1. PC Software connection: Make sure your unit has DON - data ON in settings (see page 15). When DON is enabled, the unit enables the BlueTooth connection. In few minutes of no connection, the unit disables the connection to save battery. Please power off Simplex then power back on again to enable the BlueTooth, so you can connect to the PC Software. For more PC Software troubleshooting, or to get the most up to date version, review the licence options, etc., please visit: www.neurotrac.emgsoft.info.

2. If the SET or Concealed button is not working, it is possible that the function you require will work after you press and hold this button for 5 seconds. Please read on page 7 how these buttons are operated.

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.

In the EMG mode the Neurotrac® device may be subjected to Electromagnetic Interference. (see page 2 of this operating manual).

Additionally, the power supplies of some notebook computers can give off substantial amounts of interference which the NeuroTrac® device is susceptible. This can happen when the power supply "block" has only a two pin connector connecting it to the mains with no earth.

As a precaution, make sure that the power cable from the notebook is placed as far away as possible from the connection wires of the NeuroTrac® device.

Try to keep the NeuroTrac® device close to the patient's body (in the "field" of the patient) either on their lap, in their pocket or clipped to their belt. Keep the electrode wires as close as possible to the patients' body and not dangling freely.

A relaxed muscle should read below 3.5 microvolts (µV). If even when the patient's muscle is soft and relaxed to the touch, the reading is still high, try turning off the notebooks external main power supply. (The notebook will continue to run on its own internal battery). If the µV reading(s) suddenly reduce(s) and then go back up after turning on the notebook power supply, it means that an interference has occurred.

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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	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: 

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 $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = \sqrt{1.2}\,P$	**800 MHz to 2,5 GHz** $d = \sqrt{2.3}\,P$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Warranty

Verity Medical Ltd., provides a warranty to the original purchaser, that this product will be free from defects in the material, components and workmanship, for a period of 2 years from the date of purchase by the distributor [invoice date from Verity Medical to the appointed distributor].
If the distributor - from whom the product was purchased by the user - is satisfied that the product is defective, the user may return the unit directly to this distributor who will forward it to Verity Medical Ltd. All such returns from the distributor to Verity Medical must be authorised by Verity Medical Ltd., in advance. The liability of Verity Medical Ltd., under this limited product warranty does not extend to any misuse or abuse such as dropping or immersing the unit in water or other liquid substance or tampering with the unit or normal wear and tear. Any evidence of tampering will nullify this warranty.

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

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This product is manufactured by Verity Medical Ltd.,
in compliance with the European Union Medical Device Directive
MDD93/42/EEC under the supervision of 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® Simplex:
enquiries@veritymedical.com

Notes

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