Not for sale or use in the USA

Distributor:

Document revision info.:

LOT MYO220P-OM-EN00-13-03-18

NeuroTrac ®
MyoPlus2 Pro
manual (English)

NeuroTrac® MyoPlus2 Pro

THE PROFESSIONAL CHOICE

Operators Manual

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

Dual channel EMG
Dual channel ETS
Dual channel STIM

English

VERITY MEDICAL LTD

Symbols on the unit and case

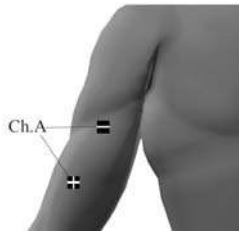
	Caution! (electrical output).
	Follow operating instructions! Failure to do so could place the patient or operator at risk.
	Neuromuscular Stimulation (STIM) and EMG Triggered Stimulation (ETS) should not be used by Patients fitted with demand style cardiac pacemakers. Please seek advice from your health supervisor.
 TYPE BF	Patient's shock protection type: BF (Body floated) Equipment. 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.
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 should you report a technical fault or claim a warranty return.
SN	Manufacturer's serial number of the unit. Present it together with LOT number should you report a technical fault or claim a 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, see page 54.
	The Australian government requires that all imported or locally produced electrical and electronic equipment comply with electromagnetic compatibility (EMC) emission requirements. A compliant product must bear the C-Tick logo.
	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 46 for the disposal instructions).

References and additional sources

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® MyoPlus2 Pro:
support@veritymedical.com

The Electrode placement manual is now available online in PDF version:
www.veritymedical.co.uk
choose:
Products ->Accessories



Store your sessions, organise your progress reports and many other useful features are available with the PC Software:
www.neurotrac.emgsoft.info

This unit can also be linked to Screen Mirror software which allows you to see on PC the very same screen you see on the unit:
www.neurotrac.emgsoft.info

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.
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

Manufactured by: Verity Medical Ltd.
Unit 7, Upper Slackstead Farm
Farley Lane, Braishfield, Romsey
Hampshire SO51 0QL, United Kingdom

Tel: +44 (0) 1794 367 110
Fax: +44 (0) 1794 367 890

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.

Table of contents

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 protected 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 4 x AA 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. Caution: Do not use lithium batteries unless they comply with IEC60086-4.
* To avoid the effects of electromagnetic interference, never use this unit in the EMG Mode, within 4 metres of a cellular telephone or near any other powerful radio interference producing equipment that causes electrical sparks etc. In the EMG mode this unit may be susceptible to strong interfering radio type emissions that may lead to temporarily 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 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 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.
* No modification of this equipment is allowed!

Returns

If you experience a continuous problem and are thinking of returning the product or getting it repaired, please read the warranty section on the next page.

1. Contact your Distributor who may be able to guide you through any issues.
2. You will need to obtain notice from the Distributor from whom you purchased the unit before returning it to them for repair or replacement. You might be charged for the postage and the device examination fee if you return the device without obtaining a return approval from your distributor (sometimes the returned products are not faulty and the fault symptoms could be fixed by yourself, therefore please call your distributor to discuss the issue).

6. **Skin electrodes condition:** Your electrodes might be too dry or too oily, which makes them fall off the skin or become less conductive. Make sure you use fresh electrodes. There are a number of improvements you can do to the way you use your skin electrodes, see page 45.

Stimulation intensity drops so I hardly feel it

There is a moment in your treatment when you suddenly feel that the mA intensity is not as high as it was. This may happen when one phase of stimulation is followed by the next phase. In this case the stimulation intensity fall is justified and is a proper function of the device: please increase the mA intensity back to the proper level.

The reason for this reduction is for your safety: the next phase is a phase with different and often higher parameters of Hz and/or µs. To balance the possible increase in power, the mA intensity is reduced automatically. This also gives you a clear indication that the new phase requires re-adjustment of the intensity in order to match new parameters.

Settings not working, cannot change programme

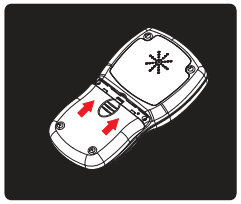
Your device might be locked and you will see the padlock symbol on your screen. When the device is locked, the programme list might be reduced and some settings become unavailable (read more on page 36). Make sure, with your treatment supervisor, that unlocking the unit is not altering your prescribed treatment. Follow steps on page 38 to unlock the unit.

Stimulation failure (STIM.F)

If you see this message on screen, please make sure you use the quality batteries which are fully charged. Your unit can still be used in EMG mode.

Battery cover

If you see the this picture, it means that unit has detected that the battery cover is missing, and for your safety the stimulation is disabled until you close the battery door.



Contra-indications and precautions

STIM: Neuromuscular Stimulation (NMS)

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

Neuromuscular Stimulation should not be used by:

* Patients fitted with demand style cardiac pacemakers
* During pregnancy (unless medically advised)
* Patients with undiagnosed pain conditions
* Do not place electrodes:
  - Over carotid sinus nerves;
  - Over larynx or trachea;
  - Inside mouth;
  - On anaesthetised or desensitised skin;
  - Do not drive a vehicle while the device is stimulating and attached to your body;
  - 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.
* Skin irritation from the treatment of NMS or EMG itself does not generally occur. However, rubber electrodes may irritate some skin types, therefore, in this case we recommend to use hypoallergenic self adhesive electrodes.
* The patient should only use the unit for what it was prescribed for.
* Do not immerse the unit in water or any other liquid substance.
* Do not use stimulation on your facial area unless you are under strict guidance from a qualified clinician.

EMG

There are no precautions when using EMG unless used for pelvic floor exercising or assessment. In this case EMG should not be used:

* During the menstrual period
* If symptoms of bladder infection are present
* With patients who have diminished mental capacity or physical competence who cannot handle the device properly

Indications for use

EMG

* pelvic pain
* patellofemoral pain syndrome
* rehabilitation after stroke, and paresis

NMES

* stress incontinence
* overactive bladder (urge incontinence)
* muscle atrophy
* upper limb rehabilitation in stroke

TENS

* general pain (including back pain)
* pelvic pain

ETS

* urinary incontinence
* rehabilitation after stroke and paresis

Also used for non medical applications:

* pelvic floor work out
* pelvic floor strength, endurance, sensitivity, vascularisation and relaxation
* muscle growth
* as a warm up prior to exercises
* active recovery
* muscle endurance
* muscle resistance
* muscle strength
* maximal strength
* explosive force
* fatigue resistance

No stimulation, mA intensity cuts off to zero

The problem you are experiencing is most likely due to poor connection. As a result you will see the “Output ...” message on screen and your mA reading will show zero. Follow the tips below and try again pressing the mA button to increase the intensity.

Using a vaginal or rectal probe

1. **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).
2. **Try to contract the pelvic floor** by lifting up the probe and increase mA at the same time. This may re-establish the connection.
3. **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.
4. **Possible probe damage:** 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 the mA and, if the probe is functioning correctly, you will feel the stimulation mildly tingling in your hand. If you do not feel anything, it might be a lead wire at fault, see next step.

Using any type of electrodes

5. **Possible broken lead wire:** Check if the dual conductor lead wire cable is broken, or it might be bent or pulled out too much exposing the 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 the lead wire, hold them firmly crossed with your fingers. Increase the 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.

   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.

Troubleshooting

Issues with EMG reading precision

1. EMG Reference: If you don't use the reference wire as described on page 9, the reading becomes unstable. Instability may cause your reading to be too high or too low. For example, when you relax your muscles and expect the EMG to drop below 4 µV but the reading is well above and does not decrease. Another example is when you try to contract your muscles but the reading seems to be too low and does not react when you contract.
2. Broken wires: 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. Skin electrodes condition: Check the electrodes. Try another pair of skin surface electrodes. Inferior surface electrodes may cause incorrect readings; we recommend you always use quality electrodes for EMG measurement.
4. Vaginal or rectal probes: If you are using vaginal or rectal probes we recommend the patient uses a conductive Gel as recommended by the Physiotherapist or Doctor. Some patient's vaginal aperture may be too large for some internal probes, causing intermittent contact with the walls of the pelvic muscle which may result in unresponsive EMG readings. In such cases one should try another larger electrode or change the body position, see more on this in the stimulation chapter overleaf.
5. Electromagnetic interference: If you are using a laptop computer and experience interference when using the charger, switch the charger off. Your EMG device is well shielded yet many electrical appliances around can cause increased or chaotic EMG reading.
   A practical approach will be to try your unit in different areas to see if any particular room is more or less noisy (from electrical point of view).

Issues with Bluetooth connection to the PC

1. **Enable Bluetooth on the device:** Make sure the Bluetooth indicator is white, not grey, see page 10. After a few minutes of no connection, the unit disables the connection to save on the battery. Please power OFF and 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.

Introduction

This unit is one of a new breed of modern EMG and Neuromuscular Stimulators which ***Verity Medical Ltd*** have developed with the Therapist and Patient in mind. Our main goal is to design products that have a high level of functional use, are sensibly priced, compact and user friendly.

The NeuroTrac® MyoPlus2 Pro unit comes with two channels of EMG combined with 2 channels of stimulation. CH.1 and CH.2 can either measure EMG or produce stimulation or stimulation only. This approach is very practical for pelvic floor using just one or two channels. Up to 2 channels can be used for sequential limbs movement or when you require larger muscle groups to be engaged.

The MyoPlus2 Pro has a colour touch screen with a lot of helpful information under the "i" touch button which helps the user to understand the use of a selected programme. This multi-channel model is a very practical choice for advanced incontinence treatment with the combination of the most effective modalities of Stimulation, ETS and Biofeedback training, all in one unit.

The MyoPlus2 Pro device can be used with or without a linkup to a PC.

The MyoPlus2 Pro is always bluetooth-ready so there is no need to switch the bluetooth on or off. Please note that the MyoPlus2Pro switches off the bluetooth automatically after 3 minutes of no connection with PC Software in order to save energy. To establish the connection, power the unit off and back on again to switch the bluetooth on. Once connected, the bluetooth stays on as long as the unit is in operation.

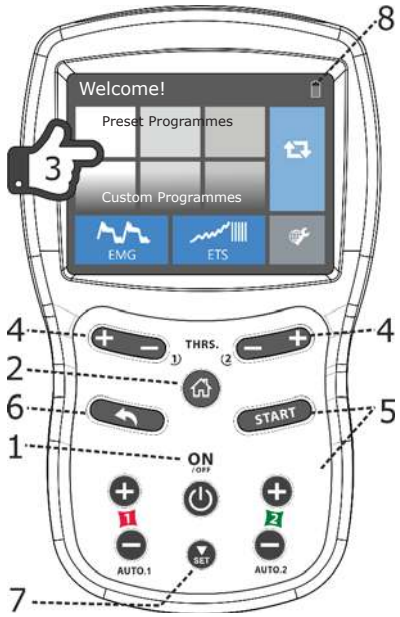
Additionally, the unit has a concealed button which enables the therapist to accurately monitor the ***Patient Daily Compliance*** with a prescribed home treatment course.

EMG helps the therapist diagnose and treat a broad variety of conditions and it enables the patient to monitor their progress with an accurate visual and audio biofeedback. Up until recently there has been little equipment available on the market for the therapist and patient to choose from at an affordable price. The NeuroTrac® MyoPlus2 Pro is the solution to this problem.
Neuromuscular Stimulation is increasingly understood by therapists and doctors. Nowadays, there is a better understanding of the mechanisms between nerves and muscles, which make it possible to stimulate the neuromuscular system with precise electrical signals.
The MyoPlus2 Pro unit offers precise signals giving full control of Pulse Widths, Rates, Ramp up times, Work / Rest cycles or cycles from the pre-defined template.

Customer care

We welcome constructive comments regarding our equipment, particularly those that might help us to improve existing features, add new ones and/or develop new products for the future.

Buttons and basic operation



1. **ON/OFF** - press to power on or switch off the unit.
2. **HOME** - press to go back to the main page. Here you can select the treatment modality or go to the device settings.
3. Please use the **touch screen** to navigate: select the desired programme, start and pause, review the settings and read more about each treatment.
4. Press **THRS +/-** buttons to adjust the EMG or ETS threshold.
5. **Press START** button to begin EMG programme. Press + on any channel (1 or 2) to adjust mA level which also starts ETS and Stimulation programme. In Home->Settings you can set the mA limit so that user cannot go above the set level of intensity.
6. Press **BACK** to go back to the previous screen.
7. Press **SET** to go to the next phase in multiphase programme.
8. Battery level indicator.

   Please note that many of the above button options are duplicated by the touch screen buttons.

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.

Table 204: Guidance and manufacturer's declaration – electromagnetic immunity

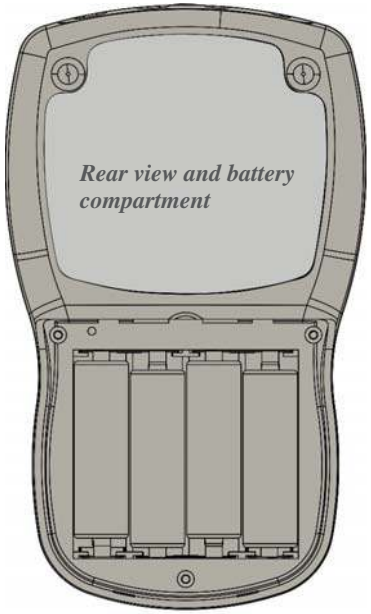
The NeuroTrac® product is intended for use in the electromagnetic environment specified below. The customer or the user of the NeuroTrac® product should ensure that it is used in such an environment.

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.

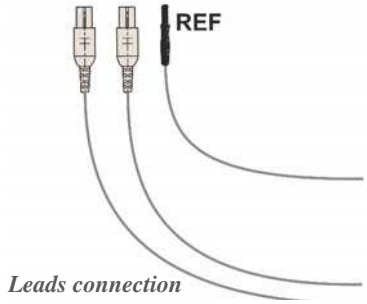
Quick start instructions



Rear view and battery compartment

1. **Insert four AA batteries**
   Remove battery cover. Insert batteries as labelled inside the battery compartment. Please mind the polarity and replace battery cover.
2. **Connect your leads to the unit.**
   The round black reference [REF] plug of the lead wire should be connected to the round black socket of the unit, marked as REF. All sockets are situated on the bottom of the unit, in one place. The reference electrode should go on your thigh or anywhere on your body. The stimulation lead wires (probe, skin electrodes) should be connected to CH1, CH2 sockets.

Top view



Leads connection

REF electrode. If you don't use the EMG reference wire (REF), your EMG and ETS results will be inaccurate. There is no need to use REF if you use stimulation only.

CH.1 and CH.2 are used for ETS, EMG and Stimulation. CH.1 is a triggering channel for ETS.

3. **Turn on the unit** by pressing the ON/OFF button once. Press the touch screen buttons to navigate. We recommend to use the supplied stylus to navigate through the screens to prevent grease from your fingers building up on the surface.
4. **Select your treatment and start the programme**

4.1 Use the on-screen buttons to select your programme.

4.2 Press + button on the keypad to begin the programme.

4.3 Follow the on-screen prompts. Use the touch buttons to review and adjust parameters, scroll the pages or go back to the previous page.

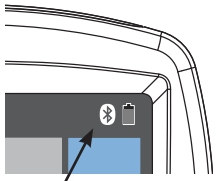
5. **For PC Software connection**, make sure Bluetooth is enabled, which is indicated by the white Bluetooth symbol on the device screen.
Please Note! The unit switches off the bluetooth transmitter after a few minutes of no connection to save battery. Tap the bluetooth icon and the icon changes color from gray to white. Alternatively, restart the device which enables bluetooth for another few minutes. Once connection is established to the PC, it remains connected.
For more information about the software, please visit:
www.neurotrac.emgsoft.info

Bluethooth connection status :

Gray logo - Bluetooth is off to save battery.
Power the unit off and back on again to switch on Bluetooth.

White logo - Bluetooth is ready, please allow connection from PC Software.

Blue logo - Connection to PC Software is established.



Bluetooth connection indicator

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.

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® MyoPlus2 Pro may be subjected to Electro-magnetic Interference (see page 4 of this operating manual).

Additionally, the power supplies of some notebook computers can give off substantial amounts of interference which the NeuroTrac® MyoPlus2 Pro 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® MyoPlus2 Pro.

Try to keep the NeuroTrac® MyoPlus2 Pro 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.

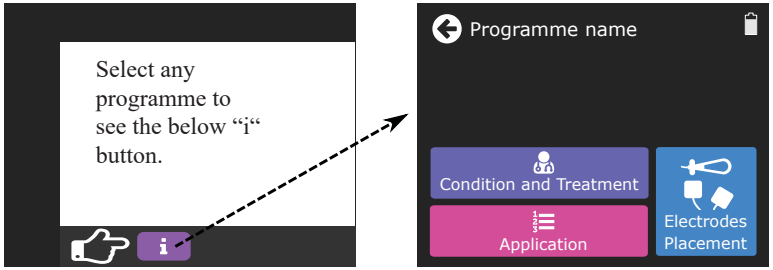
A relaxed muscle should read below 3.5 microvolts (µV). If even when the patient’s muscle is soft and relaxed to the touch, the reading is still high, try turning off the notebooks external main power supply. (The notebook will continue to run on its own internal battery). If the µV reading(s) suddenly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

6. **When you have finished,** remove and replace the skin electrodes onto the clear plastic film, reseal them in the plastic zip bag and store them in a cool place. If using a vaginal or rectal probe, thoroughly clean the probe and seal it in the plastic zip bag.

   Refer to other parts of this manual for detailed instructions on each programme.

Built-in help screens

Your unit has built-in help screens, which explain each programme and suggest the overall step-by-step use of each programme. These screens are available in the home screens of each programme, under the “i“ button.



Please Note! The suggested general use of each programme cannot cover all aspects of your treatment and some important issues may still need to be considered by specialists. Please consult the specialist or your General Practitioner to review your treatment before you start using this device.

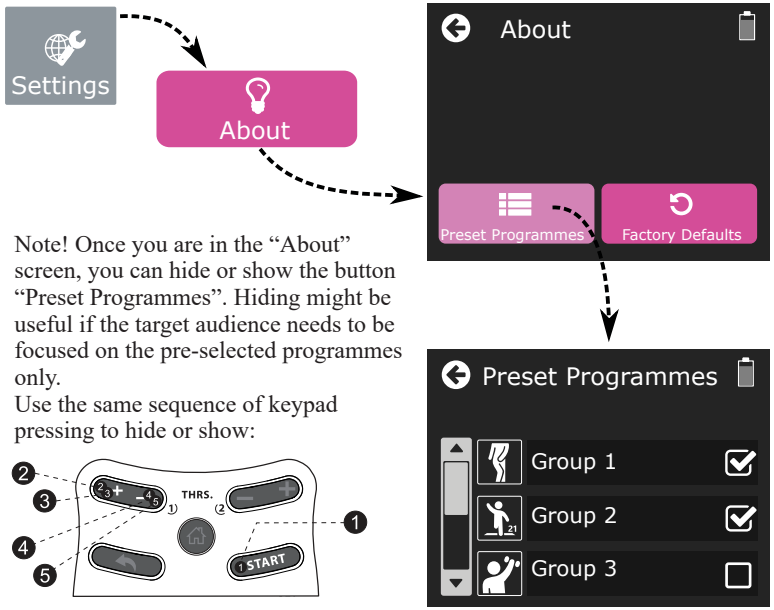
Protocols overview

There are the following protocols to choose from:

- **Up to 3 sets of preset programmes:** Pelvic Floor, Sports and Rehab
- **Up to 3 sets of custom programmes**: TENS, NMES and FES.
  Note! The above programme sets are available from the home screen, see the next chapter of how to show/hide these sets.
- **Wide range of EMG tools:** training templates, biofeedback games, relaxation protocols.
- **EMG and ETS buttons on home screen -** these two buttons allow you to set up your simple and easily accessible biofeedback or ETS training.

You can find more about each individual protocol by selecting the programme button and pressing the “i“ (information and help) button.

Show/Hide programme sets



Note! Once you are in the “About” screen, you can hide or show the button “Preset Programmes”. Hiding might be useful if the target audience needs to be focused on the pre-selected programmes only.
Use the same sequence of keypad pressing to hide or show:

When you are in the “Preset programmes” screen, you can select which programme set you would like to be accessible on the home screen, which can display up to 3 Preset and up to 3 custom sets.

When you lock the device (see page 36) you can further reduce the number of available programmes, which helps to narrow down the choice of treatment to the specific needs of your Patient.

Battery:
Battery set: 4 x 1.5V, AA battery.
Low battery indication at 5.4 volts +/- 0.2 volts, automatic shut off when voltage drops below the low indication. Replace the batteries immediately!
The device goes off automatically when not in use (energy saving): for example when in settings and no key pressed over 1 minute, when in stimulation mode (home screen) and all channels are 0mA.
Expected average battery set life [of standard 2800 mAh, alkaline]:
8-16 hours in STIM, 25 hours in EMG mode.

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

Calibration requirements:
No re-calibration or periodic maintenance is required for the unit.
Its characteristics do not vary under normal conditions.
NOTE: The unit was calibrated during the manufacturing process and is ready to be placed into service upon delivery.

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 160 mm, Width 95 mm, Depth 30 mm.

Weight:
MyoPlus2 Pro device: 160g (without batteries and other accessories).

Specifications

1. EMG

1.0 Dual channel EMG
1.1 EMG Range: 0.2 to 2000 µV RMS (continuous)
1.2 Sensitivity: 0.l µV RMS
1.3 Accuracy: 4% of µV reading +/-0.3 µV at 200 Hz
1.4 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%
1.5 Notch filter: 50 Hz (Canada 60Hz) - 33 dbs (0. 1% accuracy)
1.6 Common Mode Rejection Ratio: 130 dbs Minimum @ 50 Hz
1.7 Work / Rest periods: 2-99 seconds
1.8 Number of Trials: 1-99

2. STIM (Neuromuscular Stimulation)

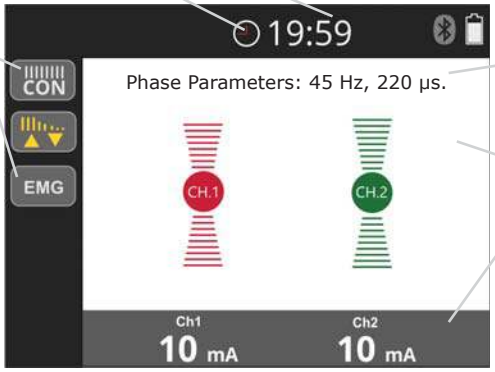
2.1 Four channel Stimulator
2.2 Amplitude: 0-90 mA into 500 Ohm load - actual mA will tend to be less than indicated due to Electrode impedance: at 1000 Ohms load (Electrodes in poor condition) the maximum will be limited to 75 mA, at 1500 Ohms load the maximum will be limited to 50 mA.
2.3 Type: Constant current, maximum output voltage 70 Volts +5 / -10 Volts
2.4 Waveform: Symmetrical, rectangular, bi-phasic with net zero DC current
2.5 Pulse width selection: 50-450 µS (10% accuracy)
2.6 Pulse rate selection: 2-100 Hz (5% accuracy)
2.7 Work / Rest periods: 2-99 seconds
2.8 Time 1 - 99 minutes
2.9 Ramp up time: 0.1 - 9.9 seconds
2.10 Preset and user programmable treatment Programs
2.11 Automatic output shut off with detection of open electrode above 0.5 mA

Preset programmes list

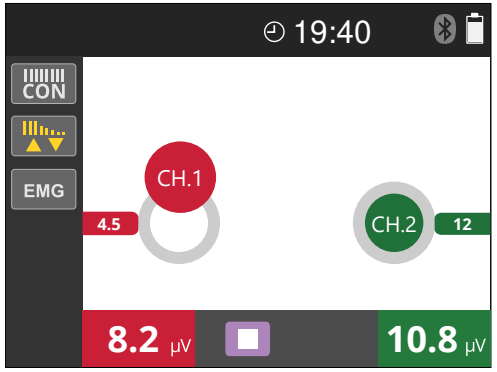
Pelvic Floor (19 programmes)	Sports (21 programmes)	Rehab (9 programmes)
1. Pelvic Floor Pain	1. Warm Up	1. Postural muscle control
2. Urge Incontinence 1	2. Active Recovery	2. Spinal Column
3. Stress Incontinence 1	3. Endurance	3. Paretic Extremities
4. Stress Incontinence 2	4. Resistance 1	4. Facial Palsy 1
5. Frequency/Urge 2	5. Resistance 2	5. Facial Palsy 2
6. Frequency/Urge 3	6. Resistance 3	6. Disuse Atrophy
7. Frequency/Urge 4	7. Resistance Strength 1	7. After Stroke 1
8. Lack of Sensitivity	8. Resistance Strength 2	8. After Stroke 2
9. Work Out	9. Resistance Strength 3	9. Multiple Sclerosis
10. Building up endurance	10. Strength 1	
11. Relaxing the Pelvic Muscle	11. Strength 2	
12. Continence after Childbirth	12. Strength 3	
13. Stress Incontinence 3	13. Max Strength 1	
14. Stress Incontinence 4	14. Max Strength 2	
15. Urge Incontinence 5	15. Max Strength 3	
16. Urge Incontinence 6	16. Max Strength 4	
17. Urge Incontinence 7 - maintenance	17. Explosive Force 1	
18. Flaccid Pelvic Floor Muscles	18. Explosive Force 2	
19. Weak Pelvic Floor Muscles	19. Resistance to muscle fatigue	
	20. Agonist strengthening	
	21. Pain relief	

Running stimulation programme

1. You can start any stimulation programme by pressing the + button on the keypad.
2. Your treatment may have one or many time phases (EMG, ETS, STIM CON, STIM SYN, STIM ALT, STIM MOD). The phase is a portion of treatment with the specific parameters. For example, one phase could be for warm up, another for the actual training, another for relaxation, etc. For preset programme, follow the programme instructions. For custom programme, ask your treatment supervisor what the phases are for and which intensity level should be used.
3. The overall programme timer [minutes] counts down.
4. The current phase timer [minutes: seconds] counts down.



5. Frequency [Hz] and Pulse Duration [µs] are the technical parameters of actual stimulation output
6. The graphical animation of stimulation.
7. When you press + or - button on the keypad, the mA intensity level is adjusted.
8. If the phase type is STIM SYN, the unit stimulates for some time and then goes to idle period (rest) where it measures your EMG [µV] . This is very useful, as you should be relaxed in between stimulation periods (work).



Try to relax as much as you can when you don't feel stimulation. The ball on the screen represents the level of your relaxation. When the ball on the screen goes down (below 4 µV) then your relaxation ability is excellent, otherwise you may be overstimulated and this is an indication to take a break.

Note! For the ball to work properly you should use the REF electrode (see page 9).

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 have purchased them.

Self-Adhesive Electrodes:

* Check that the short connectors are well connected to the electrodes
* Replace electrodes onto plastic film after use. If they drop onto the floor debris will adhere to the conductive gel making the electrodes ineffective

Electrode life can be considerably reduced by:

* The type and condition of the skin
* Deep seated moisturizers or make-up
* Storing electrodes in hot conditions

Vaginal / Rectal Probes:

* Check if the connectors have not become separated from the probe
* Cleaning: Remember! The Vaginal or Rectal probe is for single Patient only! Carefully clean the Probe after use. Wash the probe gently in mild soapy water, rinse and make sure the probe is completely dry before returnng to storage in the plastic bag. Read carefully the instruction for use included in packaging.
* Vaginal Probe Disposal: please return it to the supplier from whom you have purchased it.

<u>Caution: Static electricity may damage this product</u>

NOTE: *Only Verity Medical Ltd., or appointed distributors / importers are approved to undertake servicing*
(Please review the information on page 54 and on rear cover of this manual).

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.

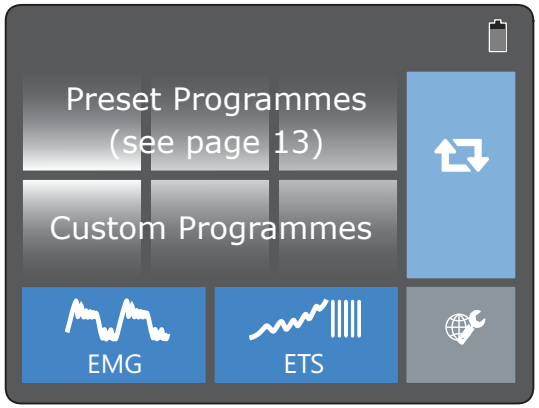
ACCESSORIES

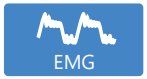
Battery and Optional Charger:

* This device is 4 x AA Batteries operated. If using rechargeable Nickel Metal Hydride batteries, be sure to use a CE approved battery charger. Never connect the MyoPlus2 Pro directly to a battery charger or to any other mains powered equipment. We advise not to use Ni-Cad rechargeable batteries. Never connect the unit directly to a battery charger or to any other mains powered equipment.
* To replace the batteries, open the battery door on the rear of the unit. To open the battery door place your finger nail under the latch and pull it towards the middle of the unit and lift. Pull the four batteries out and replace them with fresh batteries. When inserting the batteries, follow the polarity information on the bottom of the unit's battery compartment. This simple procedure can be performed by the end user and does not require specialist expertise.
* Remove the batteries completely from unit if not in use for any extended period of time (typically one week).
* Low battery indicator is shown on LCD display. When flashing, replace batteries.
* Battery and Charger disposal: please return to the supplier from whom you've purchased it.

Custom programmes

There are a number of programmes which you can fully customize:



Icon	Custom programme explained
	This is a simple **EMG** programme, where you can customise your Work, Rest time and a number of trials. (page 16)
	This is a simple **ETS** programme, where you can customise your Work, Rest time, number of trials and stimulation parameters (page 17).
	This is a set of up to 10 Programmes which you can customise for **Pain relief** (TENS). Each programme can have up to 5 phases of the following phase types: CON, MOD.
	This is a set of up to 10 Programmes which you can customise for **Muscle Stimulation** (NMES). Each programme can have up to 5 phases of the following phase types: CON, MOD, SYN, ALT.
	This is a set of up to 10 Programmes which you can customise for **Functional electro-stimulation** (FES). Each programme can have up to 5 phases of the following phase types: CON, MOD, SYN, ALT, EMG, ETS.

Phase types

Each Preset or custom programme consists of 1 or up to 5 phases of different kind. The phase is the specific type of treatment (EMG, ETS, STIM: CON/SYN/ALT/MOD), below there is an explanation of purpose of each phase type.

EMG	EMG is available as a stand-alone button (Home ►EMG ►Work/Rest), or you may select EMG as one of the phases in your custom programme. For example, by placing your Biofeedback EMG phase at the very end of the programme, to test your muscle performance after stimulation. When in EMG phase, the unit measures the muscular activity when you contract muscles voluntarily. You can use Biofeedback EMG for assessment or training. You can use EMG just for neuromuscular training. When you see or hear the Work prompt, contract and hold your muscles until you see the Rest prompt. Relax your muscles when you see the Rest prompt. This visualized biofeedback training allows you to see and hear and measure your performance and progress. To assess neuromuscular activity, follow the Work and Rest prompts with your voluntary contraction and relaxation. The unit measures your muscular performance and the result is displayed as a set of EMG statistics by the end of the programme.
ETS	ETS (EMG Triggered Stimulation) is a highly effective training technique, available as a stand-alone button on your home screen, or you may select ETS as one of the phase in any custom programme. ETS combines voluntary contractions with neuromuscular stimulation. This combination is regarded as the best approach for muscle rehabilitation, the results are achieved faster than EMG on its own or using stimulation only. **In Classic ETS**, the user is prompted to contract muscles during work period of time and relax during Rest period of time. As soon as the certain threshold of effort is reached, stimulation is triggered to help sustain the contraction. If you set auto-threshold in general settings (see page 34), the unit will rise or drop the target threshold depending on actual performance. This way, auto-threshold encourages better, stronger contractions, but keeps the threshold within the limits of possibilities. If you set **nETS** type of the phase, your stimulation will be triggered by the end of Work period, regardless of voluntary effort or can be triggered earlier if you reach the target threshold sooner. nETS is a good start up in case of very weak muscles.

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

2. Set AUTO (ETS target) Threshold on MyoPlus2 PRO, the threshold will be adjusted automatically by the device, the better the muscle performance, the higher the threshold that will be set automatically by the MyoPlus2 Pro. After Home Compliance Download (page 37) - analyse the ETS Target Threshold (ignore ETS Score).

ETS Stim mA [mA] - This is the average stimulation level used during ETS sessions.
Home Compliance: You need to consider the Patient's situation to be able to judge the ETS Stim mA properly. For some Incontinence, Stroke and similar rehabilitation the Patient normally feels lack of Pain due to the damaged sensory neurons for higher mA. In this situation progress can be considered to have been made when mA level was lower and lower due to sensation ability improvements. For muscle growth, reeducation or improvement treatment, the higher mA used the better the achievements.

ETS Stim Time [mm:ss] - total time of Stimulation during ETS. Compare this time with the ETS overall Time and you will have an idea whether the EMG or STIM was used more often during the ETS sessions.
Home Compliance: These statistics are supplementary and the analysis depends on the Clinician's point of view which depends on the way the ETS treatment was performed. In some cases the ETS treatment is used to encourage reaching the threshold by voluntary contractions and the Stimulation helps to keep the muscle contracted. Sometimes ETS is used to help voluntary contractions when a Patient tries to contract muscles during the stimulation.

ETS Time [mm:ss] - the accumulated time of all finished ETS phases.
In the Home Compliance report this is the accumulated time of all ETS phases for the selected time period.

STIM CON	Continuous stimulation is typically used for TENS pain relief, blood flow improvement or as a warm up before Work/Rest stimulation. Please seek the advice of specialists when selecting the parameters. This type of stimulation produces a constant output intensity (mA) level during the whole programme.
STIM SYN	This is a typical Work/Rest stimulation which is used most of for muscular stimulation. SYN means Synchronous output of both channels at the same time, as opposed to ALT (see next phase). The Work time is when the stimulation provokes the muscular contractions, typically for 4-8 seconds, followed by Rest time during which there is no stimulation and the patient should relax. The rest time is typically twice the Work time to allow proper resting in between efforts. During the Rest periods the EMG is enabled in a form of a simple animation (page 14), which is useful for muscle fatigue observations. The STIM SYN phase has a function of channel Delay, which makes it possible to set up the sequential stimulation to perform complex movements, such as arm lifting, standing up from a chair, etc. To use a simple Work/Rest stimulation, set Delay=0. (this is a delay time after which the next channel will start up). Please seek the advice of specialists when selecting the parameters.
STIM ALT	This is a specific Work/Rest stimulation which is used for antagonist training or when you need to contract muscles in alternation. During the "odd" Channel 1 Work period only the "odd" Channel 1 stimulates while the "even" Channel 2 has zero mA. During the "even" Channel 2 Work period the stimulation alternates: Channel 1 has zero mA and Channel 2 timulates. An example of use will be to place Channel 1 on flexor muscles and Channel 2 on extensors. During the Rest period the EMG is enabled in the form of a simple animation (page 14), which is useful for muscle fatigue observations. Please seek the advice of specialists when selecting the parameters.
STIM MOD	The modulated stimulation. It works similarly to the above Work/Rest type. The difference is on the Rest period of time where the unit stimulates with lower frequency and higher pulse width. This is particularly useful for pelvic strength exercises where during the rest time you want a lower frequency stimulation to improve the relaxation. The MOD phase can also be easily adjusted as modulated TENS used for pain relief and a variety of other applications. Please seek the advice of specialists when selecting the parameters.

Setting up your custom treatment

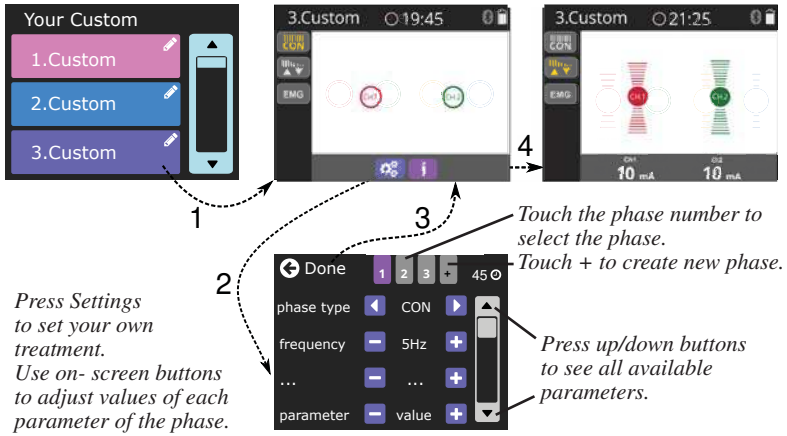
See on page 15 how to find the list of available custom programmes.

1. Select your custom programme. When you see the list of custom programmes, you can re-name any programme by typing the name which will suit the functionality you are about to set. Press and hold 3 seconds to start renaming, a keypad will appear on screen. Type the new name and press OK. Programme re-naming will not alter any programme settings.

2. To change custom programme settings, press Settings button (step 2 - see the picture below). Use the on-screen buttons to set up your multi-phase treatment. See on page 16-17 which types of phases are available. See on page 19-21 the parameters available for each phase.

3. When all parameters are set, go back to the home screen of the programme by pressing DONE button (step 3 - see the picture below).

4. Follow the on-screen messages to begin your programme.



Deleting the phase

There are upto 5 phases to be set in your treatment, but you can reduce the number of phases. To delete the selected phase and all the following phases, set the phase type to the value "--".

ETS statistics

ETS Target [µV] - the average Target threshold used during ETS phase.
The ETS Target is defined by EMG threshold, which the Patient needs to achieve by voluntary muscle contraction to trigger EMG to STIM.
Generally the higher the Target is, the better the muscle performance.
When analysing the Target progress, compare the reading with the ETS Score for the same day. Normally, the higher the Target, the smaller the Score is.
Home Compliance: good progress is when the Target is getting higher and higher each day.

ETS Score [%] - how successful the Patient was in reaching the threshold. If on average the Patient reached the threshold immediately after Work prompt - the score is high (60-90%). If the Patient has difficulties reaching the target and it takes them several seconds to trigger from EMG to Stimulation, their ETS Score will be low (10-50%).
Home Compliance: good progress is when the Score is getting higher and higher each day.

ETS Target setting will influence the ETS Score result, for example for lower Targets it will be higher scores, if the Target threshold is variable (not stable) during the treatment, the Score result should be ignored. If you want to concentrate purely on ETS Score statistics - make the Target threshold the same for the period of time you do the treatment.

Please consider one of suggested ETS treatments:
1. Set MANUAL (ETS target) Threshold on MyoPlus2 PRO, do not change the threshold during the home treatment. On the Home Compliance Report the Target Threshold result should be the same or almost the same for each day.
After the Home Compliance Download - analyse the ETS Score (ignore ETS Target threshold).

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.
Home Compliance: good progress is when the Release average time getting shorter and shorter each day.

Average peak/minimum value [µV] - These are the (extreme) maximal/minimal recorded values of EMG. If you see it on the Progress Report, these represent maximal/minimal values averaged for all peaks/minimums for the selected time period.

EMG Time [mm:ss] - the accumulated time of all finished EMG phases.
In the Home Compliance report this is the accumulated time of all EMG phases for the selected time period.

STIM statistics

Average Stim mA [mA] - This is the average stimulation level used during STIM session. If you see it on the Progress Report, it represents the average stimulation level for the selected time period.

STIM Time [mm:ss] - the accumulated time of all finished STIM phases.
In the Home Compliance report this is the accumulated time of all STIM phases for the selected time period.

Phase settings for EMG (Work/Rest)

Parameter	Value
Phase type	**EMG**
Work Time	Press +/- buttons on screen to select the value: 2-99 sec.
Rest Time	Press +/- buttons on screen to select the value: 2-99 sec.
Trials	Press +/- buttons on screen to select the value: 2-99.

Touch Up / Down buttons to see all available parameters.
When finished, either select the next phase to be set up or escape from settings by touching the Done button.

Phase settings for ETS

Parameter	Value
Phase type	**ETS (Classic or nETS)** - see page 16
Work Time	Press +/- buttons on screen to select the value: 2-99 sec.
Rest Time	Press +/- buttons on screen to select the value: 2-99 sec.
Trials	Press +/- buttons on screen to select the value: 2-99.
ETS Stim time	Press +/- buttons on screen to select the value: 1-99 sec.
Pulse width	Press +/- buttons on screen to select the value: 50-330 µS.
Frequency	Press +/- buttons on screen to select the value: 2-100 Hz.
Ramp Up	Press +/- buttons on screen to select the value: 0.1-9.9 sec.
Ramp Down	Press +/- buttons on screen to select the value: 0.1-9.9 sec.

Touch Up / Down buttons to see all available parameters.
When finished, either select the next phase to be set up or escape from settings by touching the Done button.

Phase settings for CON

Parameter	Value
Phase type	**STIM CON**
Frequency	Press +/- buttons on screen to select the value: 2-100 Hz.
Pulse width	Press +/- buttons on screen to select the value: 50-330 µS.
Phase time	Press +/- buttons on screen to select the value: 1-99 min

Touch Up / Down buttons to see all available parameters.
When finished, either select the next phase to be set up or escape from settings by touching the Done button.

Phase settings for STIM SYN

Parameter	Value
Phase type	**STIM SYN**
Frequency	Press +/- buttons on screen to select the value: 2-100 Hz.
Pulse width	Press +/- buttons on screen to select the value: 50-330 µS.
Phase time	Press +/- buttons on screen to select the value: 1-99 min
Work Time	Press +/- buttons on screen to select the value: 1-99 sec.
Rest Time	Press +/- buttons on screen to select the value: 1-99 sec.
Ramp Up	Press +/- buttons on screen to select the value: 0.1-9.9 sec.
Ramp Down	Press +/- buttons on screen to select the value: 0.1-9.9 sec.
Delay	Press +/- buttons on screen to select the value: 0.0-9.9 sec.

Touch Up / Down buttons to see all available parameters.
When finished, either select the next phase to be set up or escape from settings by touching the Done button.

Phase settings for STIM ALT

Parameter	Value
Phase type	**STIM ALT**
Frequency	Press +/- buttons on screen to select the value: 2-100 Hz.
Pulse width	Press +/- buttons on screen to select the value: 50-330 µS.
Phase time	Press +/- buttons on screen to select the value: 1-99 min
Work Time	Press +/- buttons on screen to select the value: 1-99 sec.
Rest Time	Press +/- buttons on screen to select the value: 1-99 sec.
Ramp Up	Press +/- buttons on screen to select the value: 0.1-9.9 sec.
Ramp Down	Press +/- buttons on screen to select the value: 0.1-9.9 sec.

Touch Up / Down buttons to see all available parameters.
When finished, either select the next phase to be set up or escape from settings by touching the Done button.

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 does not tremble and stays firm in contraction, the EMG graph will be smoother (low EMG deviation).

$$\text{Work Deviation \%} = \frac{\text{Work average deviation [µV] x 100 \%}}{\text{Work Average [µV]}}$$

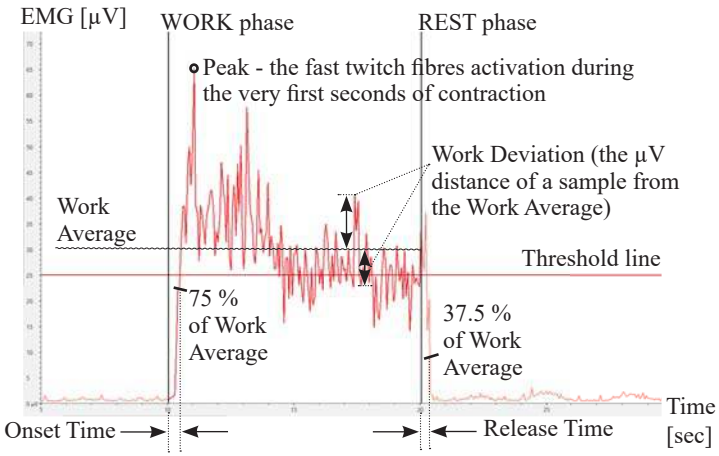
If the deviation in the work phase were more than 20% then it would be considered that the muscle is becoming unstable.
Home Compliance: good progress is when the Work Deviation % value is getting smaller and smaller each day.

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 damage to the motor neurons.

$$\text{Rest Deviation \%} = \frac{\text{Rest average deviation [µV] x 100 \%}}{\text{Rest Average [µV]}}$$

This percentage is called the coefficient of variability. Deviations of over 20% normally indicate lack of muscle control and stability.
Home Compliance: good progress is when the Rest Deviation % value is getting smaller and smaller 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, a 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.
Home Compliance: good progress is when the Onset average time is getting shorter and shorter each day.



EMG statistics

Work Average [µV] - the overall average microvolts achieved during all work periods of the session. The calculation excludes the first second of each work period to remove the initial spikes of the first contraction attempt.
Generally the higher the Work average is, the better the muscle performance.
Home Compliance: good progress is when the Work average is getting higher and higher each day.

Rest Average [µV] - the overall average microvolts during all rest periods of the session. The calculation excludes the first second of each rest period to remove the initial instability of relaxation.
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.
Home Compliance: good progress is when the Rest average is getting lower and lower each day.

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.

Phase settings for MOD

Parameter	Value
Phase type	**STIM MOD**
Frequency High	Press +/- buttons on screen to select the value: from Frequency Low value set below to 100 Hz.
Frequency Low	Press +/- buttons on screen to select the value: from 2 Hz to Frequency High value set above.
Pulse width Low	Press +/- buttons on screen to select the value: from 50 µS to Pulse width High value set below.
Pulse Width High	Press +/- buttons on screen to select the value: from Pulse width Low value set above to 450µS.
Phase time	Press +/- buttons on screen to select the value: 1-99 min
Work Time	Press +/- buttons on screen to select the value: 1-99 sec.
Rest Time	Press +/- buttons on screen to select the value: 1-99 sec.
Ramp Up	Press +/- buttons on screen to select the value: 0.1-9.9 sec.
Ramp Down	Press +/- buttons on screen to select the value: 0.1-9.9 sec.

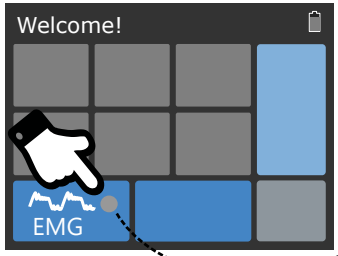
Note! Work period has High Hz, Low µS, Rest period has Low Hz, High µS.

Touch Up / Down buttons to see all available parameters.
When finished, either select the next phase to be set up or escape from settings by touching the Done button.

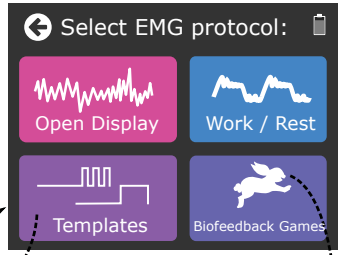
EMG programmes overview

You can find all EMG Programmes by pressing the HOME button, then select from the touch screen: “EMG”.

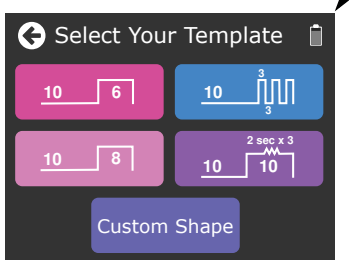
These programmes will not produce any stimulation as they function as EMG biofeedback training or assessment. You will be prompted to contract or relax voluntarily. EMG is found to be a very useful tool to facilitate muscular control when the unit encourages your own neurological system to work better, more efficiently and in a controlled manner so you can watch, measure and trace your performance and progress.



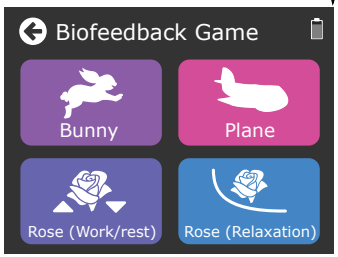
1. ON ► Home screen



2. Selection of EMG protocols



3. Selection of EMG Templates

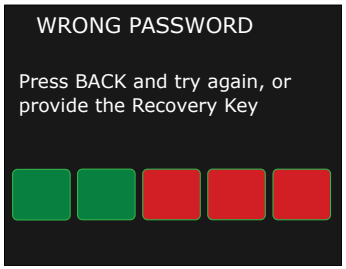


4. Selection of EMG biofeedback games

Recovery Key

You may see the recovery key screen if you mistyped your password when trying to see your history or trying to unlock the device. The recovery key is known by your distributor and this key is used to create new password (if you try to get access to History) or to remove the password (if you try to unlock the unit).

Press secret 5 keys to successfully apply the recovery key:



Statistics

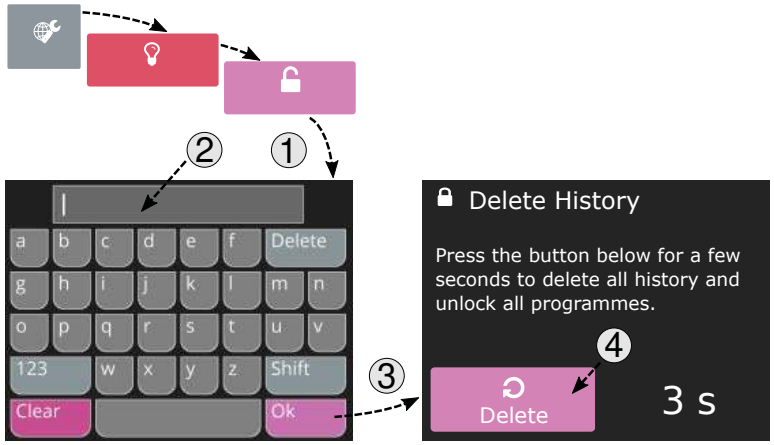
This chapter explains the statistics which you may see after completing the session or when the device is locked and you go to Home ► History.

It is important to clarify that the statistical result of one session (the screen you see after a completion of preset or custom programme) represents the result of this session only. If you want to store the session statistics result, you can do it by connecting to the PC Software and saving the session record. Alternatively you can copy the result by any other means. After you escape from the session statistics screen, you can go back to satistics screen by pressing the Last Used button for 5 seconds. Once you have started the new programme, the previous statistics are removed from the device memory.

If you want your unit to keep collecting day-to-day statistics in memory, the only option is to lock the device (see page 36) so the unit starts to organise all statistical results by date. You can find your daily statistics by going to Home ► History. For each day, you can see the overall average mA of this day, overall average EMG work of this day, etc (not the statistics per session).

Unlock

You need to unlock your unit if you would like to clear the History and get your unit ready for the next treatment.



1. Unlocking the unit is easy: go to Home ► Settings ► About: press the Unlock button.

2. Type your password which you have created in locking procedure.

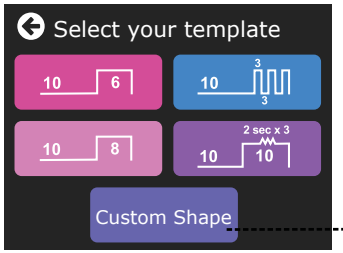
3. Press OK. If the password is forgotten, please use the Recovery Key, see the next chapter.

4. Press and hold the Delete button for 3 seconds to delete the history records and unlock the unit. If you don't wish to remove the history, or perhaps you wish to record the history to PC Software, simply press Home button on your keypad to go back to the locked state.

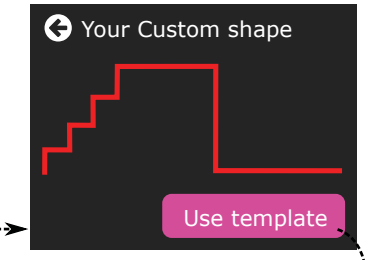
EMG templates

The Template training is designed for a wide range of neuromuscular disorders and is particularly useful for pelvic floor workout training.

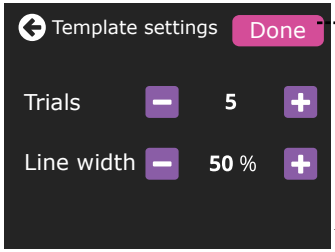
Tap on screen to select one of the template.



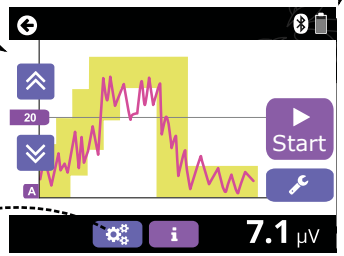
1. Select one of the Templates.



2. Use touch-screen to draw your own shape.



3. Review or adjust template settings



4. Touch Start to begin.

When you see your EMG graph, do not press the Start button yet.

Make sure your graph is properly calibrated: It is important to make sure your graph is adjusted to your personal level of EMG performance, Use the THRS buttons to adjust the threshold level. See page 28 for details.

Use your template: Press the Start button. The yellow template line can be used in an arbitrary way, depending on the training strategy. The most popular way is to try and keep your EMG graph (red) always inside or as close as possible to the yellow template line. Your training result will show the score and the time of training.

EMG games

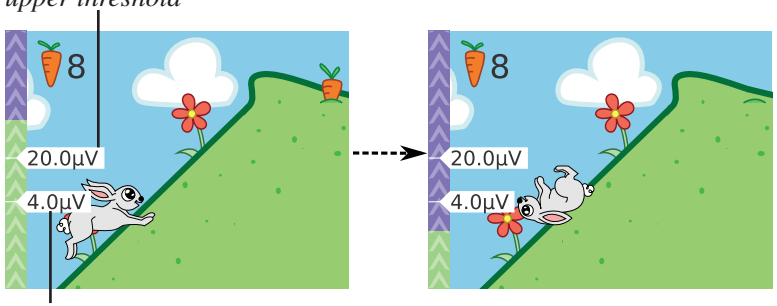
The Biofeedback EMG games are designed for biofeedback training. Games encourage to exercise consistently and appeal to the imagination. Games give users a positive association with the training, which is particularly important for children to get them focused. The biofeedback training in a form of a game is more pleasant, the results and tendencies are more obvious (you gather stars, try to finish the task on time, etc.).

You can find EMG games by pressing the HOME button, then select from the touch screen: EMG ► EMG Games.

There are 4 built-in EMG Games to choose from:

Bunny

upper threshold



lower threshold

How to play:

The Bunny Game is a Work/Rest type of EMG training when the user (Bunny) collects carrots and the aim is to collect as many carrots as possible and overcome all the hills in the shortest time possible. The user should contract above the upper threshold for bunny to go up the hill. When at the top of the hill, the wind blows stronger and the user should relax as quickly as possible to get the carrot, otherwise the wind blows bunny back down to the foot of the hill.
As a result, the user performs a series of effective physical efforts with an emphasis on proper relaxation.

7. Press OK to lock the unit.

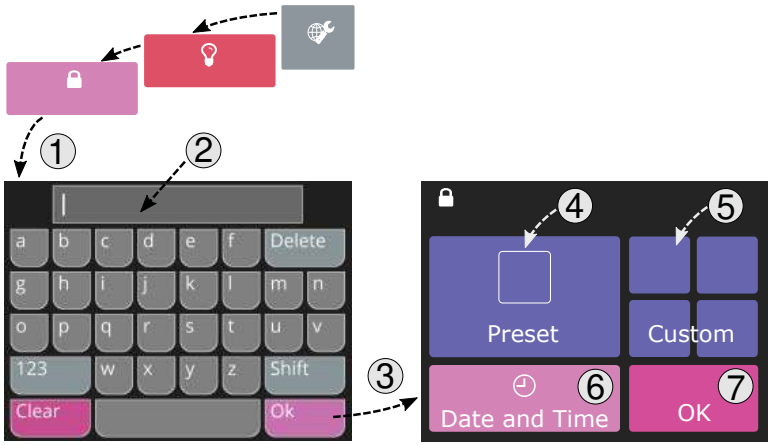
The unit displays the home screen with the padlock symbol in upper right corner, which indicates that the unit is locked:

History and home compliance download

The “Last used“ button is now changed into “History“ button which always shows the gathered daily statistics of use. For the data protection, the History is password-protected with the same password created in locking process(step 2). You can store your compliance data (History) on your PC Software, this will allow you to print the reports and organise your patient records. To download your History record, connect your unit to to PC Software, go to History on your device, your unit will start to send the History data automatically to PC. On PC, please press “Save Home Report“ button to download the data:

Lock (create password)

The lock function allows the user to lock the unit and gather the daily statistics of use. Locking the unit reduces the ability of the end user to alter the treatment, thus it is useful for organising a personal therapy at home. As a result of locking, many features sensitive to the treatment will be locked (grayed out), such as changing the date and time, updating the custom parameters, etc. Below is the locking procedure:



1. To lock the unit, go to Home ► Settings ►About : press the Lock button.

2. You will be prompted to create and confirm the password (see point 2 in the picture above). Please make sure you remember this password, as you will need it to review the History or to unlock the unit. While the unit is locked, all the stored patient's data (Home ► History) is password protected, this is for data protection.

3. Press OK to confirm new password.

4. The new window appears, here in upper left corner (see point 4 in the picture above) you can find the preset programmes which could be further reduced so that your user will access only the programmes which are ticked. Select each preset programme set and tick the programmes you would like to be accessible. All un-ticked programmes will become unavailable.

5. Repeat the above procedure for the remaining custom programmes (upper right part of the screen).

6. Please make sure the Date and Time is actual, correct if necessary. Making it right is very important for the accuracy of Home Compliance records.

Settings:

Trials - Number of hills. 5 is a typical value. You can do a "sprint" settings with less hills higher threshold, this is good for a quick assessment. For a quality training please select 10 hills or over and set the comfortable threshold levels.

Upper - Upper threshold above which the user should contract for the bunny to jump up a hill, 20uV is a typical value, but it may be adjust to suit meet the users ability.

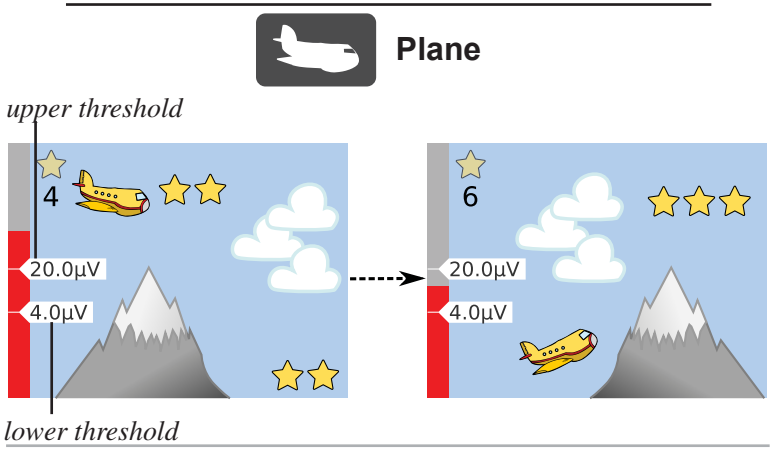
Lower - Lower threshold below which the user should relax as soon as possible when the bunny is at the top of the hill, 10µV is a typical value, but it may be adjust to suit meet the users ability.

Constant/Adaptive - type of real-time threshold adjustment. Constant is used by default and it keeps Upper and Lower threshold unchanged throughout the game. Use Adaptive to allow the game to analyse the actual user's performance and ease the levels when necessary for better training encouragement.

Work - Work time during which the user should contract above Upper threshold, 4 sec is a typical value, use longer work time for longer contractions.

Rest - Rest time is a time of relaxation given to relax before the next hill, 4 sec is a typical value. Use at least the same time for relaxation as you set for contraction to allow a proper muscle resting and avoid muscle fatigue.

Release - a delay time given for the bunny to relax below the lower threshold, once the bunny is at the top of the hill. 2 seconds is a typical value. It is recommended that this setting is extended to encourage the ability to relax.



How to play:

The Plane Game is a Work/Rest type of EMG training when the user (Plane) collects stars and the aim is to collect as many stars as possible by coordinated contractions and relaxations. The user should contract above the upper threshold for the aeroplane to go up and relax below the lower threshold for the aeroplane to descend.
As a result, the user performs a series of effective physical efforts with an emphasis on proper relaxation.

Settings:

Trials - Number of mountains, 5 is a typical value. The number of mountains defines the length of the game .

Upper - Upper threshold above which the user should contract to be able to collect the stars above the mountains, 20µV is a typical value, but it may be adjust to suit meet the users ability.

Lower - Lower threshold below which the user should relax to be able to collect the stars from below, 10µV is a typical value, but it may be adjust to suit meet the users ability.

Constant/Adaptive - type of real-time threshold adjustment. Constant is used by default and it keeps Upper and Lower threshold unchanged through a game. Use Adaptive to allow the game to analyse the actual user's performance and ease the levels when necessary for better training encouragement.

Work - Number of stars on top of the mountain, also the number of seconds the user should contract, 5 sec is a typical value, use longer work time for longer contractions.

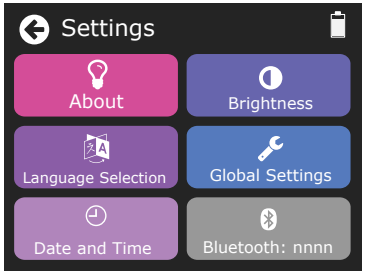
Rest - Number of stars on the foot of the mountain, also the number of seconds the user should relax. 5 sec is a typical value. Use at least the same time for relaxation as you set for contraction to allow a proper muscle resting and avoid muscle fatigue.

Parameter	Description
Threshold mode	AUTO option will adjust the threshold automatically whenever you see the running EMG or ETS session. In EMG the next threshold is set 80% of the previous average contraction. In ETS the next threshold increases or decreases depending how quick the user reached the previous target and goes +/- 12.5%. MANUAL option switches off automatic function. With any of the above options, you can always adjust the threshold manually by pressing THRS buttons.
Biofeedback Sound	ABOVE - the beeps appear only when the user's EMG reading goes above the threshold. Useful for hearing when the sufficient contraction is achieved. BELOW - you will hear beeps only when the user's EMG reading goes below the threshold. Useful for hearing when a proper relaxation is achieved. CONT. - continuous beeps above or below the threshold. useful in most of the cases. OFF - no beeps in EMG or ETS.
mA upper limit	This setting allows the user to limit the maximum mA output from 90mA to any desirable value in the range of 20 - 90 mA. This is particularly useful when it is necessary to limit the user and make sure she/he does not use too high output levels.
Click sound	You can switch ON or OFF the click sound which you hear while pressing any touch buttons.
EMG.1 filter EMG.2 filter	This is EMG filter parameter NARROW filter setting will filter out the heart beats on your EMG/ETS graph. WIDE settings does not remove the typical frequencies for heart beat, so if your electrodes are close to your heart, your EMG/ETS will pick up every beat as a small spike on the graph. You can completely disable the channel 2 EMG by selecting EMG.2 (filter) = OFF.

Bluetooth button displays four last numbers of the device Bluetooth address. When you want your unit to connect to any available software on the PC, you will see this number on the list of available devices. This is to make sure you connect your PC to the desired device.

Device settings

The device Settings button is available from the Home screen of the unit. Here you can adjust all the system controls, such as language, date and time, brightness, etc.



About - here you can see the device software version and if necessary, you can restore all the **factory defaults**: programme settings, games settings, device settings and global settings. The **Lock** function is explained on page 36.

Language Selection - here you can select the language for screen text and voice prompts.

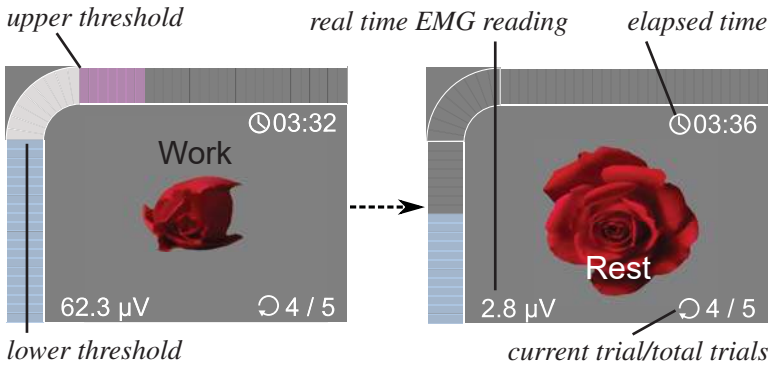
Date and Time - here you can set date and then time, which is very important if you use the lock function for daily statistics.

Brightness - here you can set the **screen brightness**, 100% is a default value, you can decrease it to 50% to save on battery, or increase to 150% for presentation or very bright room environment. In addition, the **dimming delay** can be set to 15 sec, 30 sec, 1min. (default), 2min., 5min., or CON for continuous (no dimming). The delay defines the time after which the unit display will get slightly darker to further reduce battery consumption. It will get darker on screens where the display is not typically observed, such as stimulation session. Wherever the display is critical, (EMG graph, Game, etc) the display will get slightly darker or not dim at all. If you want your dimmed display to be brighter on demand, simply touch the screen.

Global Settings - here you can set the overall EMG, STIM and ETS settings. All the settings in here are global, which means the value is identical in all the programmes: sound volume, auto/manual threshold, biofeedback sound and filter, mA limit and touch screen click sound.

Parameter	Description
Volume	The sound volume for the EMG beeps can be set separately from the general volume, which is applicable for the rest of the sounds in system. Note that the sound volume of beeps can be the same or quieter than general level. This allows the user to reduce the noise of the beeps, if they are not helpful for your purpose. The volume can be set from 100% (loudest) to 0 % (no sound).

Rose for training



How to play:

The Rose Game is a Work/Rest type of EMG training when the user (Rose) opens when relaxation is detected and closes when the user contracts. The user should contract above the upper threshold for the rose to start closing. Keep contracting until the Relax prompt appears, then relax below the lower threshold and the rose will open.
As a result, the user performs a series of effective physical efforts followed by relaxation. The rose's opening and closure helps to visualise the actual muscle activity.

Settings:

Trials - Number of repetitions, 5 is a typical value. For a quality training please select 10 repetitions or over and set the comfortable threshold levels.

Upper - Upper threshold above which user should contract for the rose to begin to close, 20uV is a typical value, but it may be adjust to suit meet the users ability.

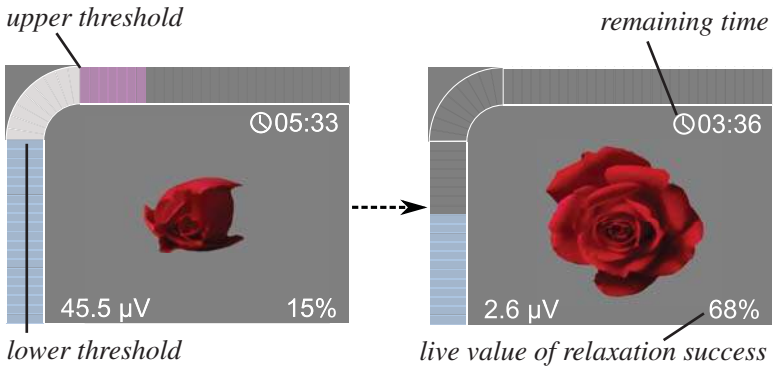
Lower - Lower threshold below which user should relax for the rose to begin to open, 10µV is a typical value, but it may be adjust to suit meet the users ability.

Constant/Adaptive - type of real-time threshold adjustment. Constant is used by default and it keeps Upper and Lower threshold unchanged throughout the game. Use Adaptive to allow the game to analyse the actual user's performance and ease the levels when necessary for better training encouragement.

Work - Work time during which user should contract above Upper threshold, 4 sec is a typical value, use longer work time for longer contractions.

Rest - Rest time is a time of relaxation, 4 sec is a typical value. Use at least the same time for relaxation as you set for contraction to allow a proper muscle resting and avoid muscle fatigue.

Rose for relaxation



How to play:

The Rose Game for relaxation is an EMG biofeedback training when the user (Rose) opens when relaxation is detected and the aim is to relax completely and stay relaxed. The success of relaxation is measured in percentage of time when the user was relaxed below the lower threshold of EMG.
As a result, the user is prompted visually to relax which might be very helpful for any sort of relaxation disorder treatments.

Settings:

Time - Given time of relaxation session, 5 minute is a typical value.

Upper - Upper threshold - used graphically to control the rose and the bargraph.

Lower - Lower threshold is the most important value to be considered, below which the user should relax for the rose to begin to open. 4µV is the default value, however please adjust it to a higher value if the user cannot relax successfully. You can always lower the target relaxation later, this way you gradually build up relaxation ability.

ETS (EMG Triggered Stimulation) is primarily used for the training of weak skeletal muscles, but is also found to be very effective in pelvic floor strengthening.

nETS is a modification of classical ETS, see page 16 for details.

ETS is a combination of voluntary contractions with stimulation. A single ETS session typically lasts 5-15 minutes. The treatment is similar to EMG work/rest with only one difference: as soon as you reach the target threshold during the Work period, stimulation occurs which helps to support the contracted muscle.

First, adjust the threshold level automatically (see page 30) or manually by pressing the THRS buttons.
Press Start button on screen, then press mA + button, keep pressing + and - to set the desired level of intensity. Typically it is at a level not higher then 55mA, you should already feel a muscular contraction but it should not cause pain.

When the stimulation level is set, follow the online prompts: when you see the Work Prompt, try to contract above the threshold, if you reach it - stimulation occurs. The stimulation helps you to sustain longer contractions. You may keep contracting the pelvic floor voluntarily while you feel the stimulation, remember to relax during the rest time.

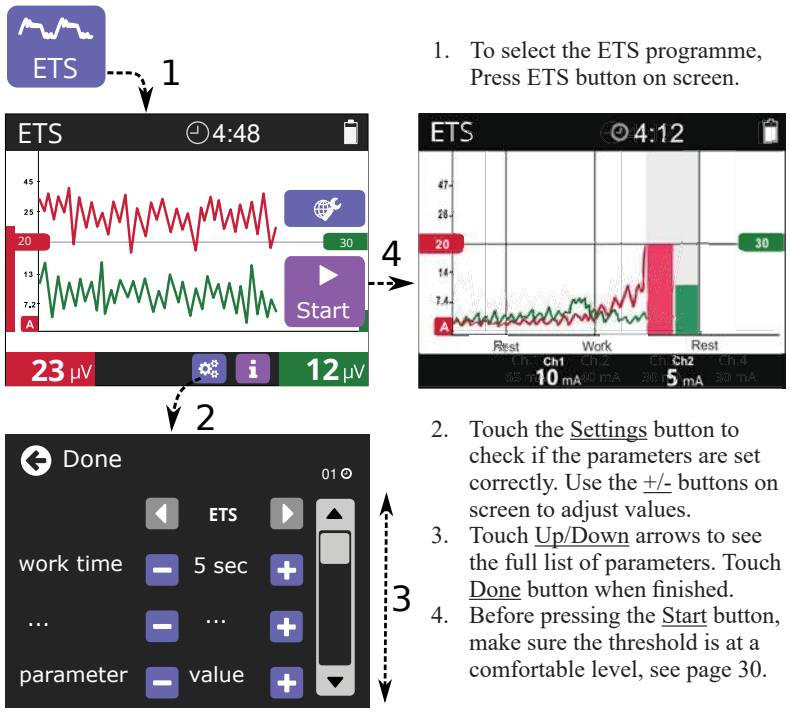
Stop when you feel tired, avoid becoming exhausted. It is better to exercise more regularly keeping the mA level reasonably low (not exceeding 55mA). There are many strategies for ETS, one of them is to contract voluntarily when you feel stimulation, in time use lower levels of stimulation so you gradually substitute stimulation with your own pelvic floor contractions. All the above instructions are for reference only, please seek professional advice before you decide about your own treatment.

EMG Work/Rest function can either be used for training as well as for periodic assessment of muscular performance.

Work/Rest Training facilitates daily trainings when the user performs the biofeedback session of contractions followed by relaxations and the goal is to make better contractions, followed by proper relaxations.

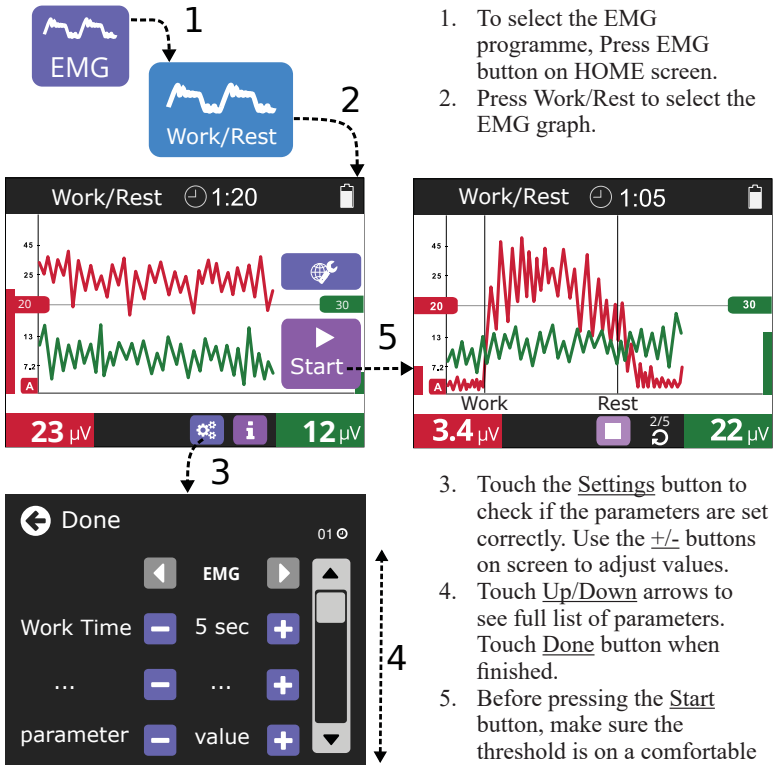
Work/Rest Assessment helps to check and quantify the actual muscular performance to observe any improvements or progress in muscular control. User should perform a session of work/rest periodically, for example, once a week.

ETS Training



1. To select the ETS programme, Press ETS button on screen.
2. Touch the Settings button to check if the parameters are set correctly. Use the +/- buttons on screen to adjust values.
3. Touch Up/Down arrows to see the full list of parameters. Touch Done button when finished.
4. Before pressing the Start button, make sure the threshold is at a comfortable level, see page 30.

EMG Work/Rest
for Training or Assessment



1. To select the EMG programme, Press EMG button on HOME screen.
2. Press Work/Rest to select the EMG graph.
3. Touch the Settings button to check if the parameters are set correctly. Use the +/- buttons on screen to adjust values.
4. Touch Up/Down arrows to see full list of parameters. Touch Done button when finished.
5. Before pressing the Start button, make sure the threshold is on a comfortable level, see next page for details.

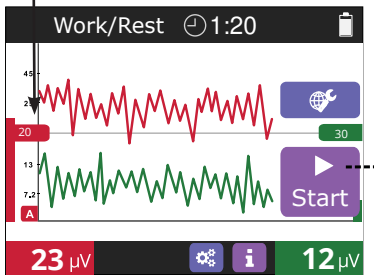
Work/Rest session

1. Automatic threshold adjustment.

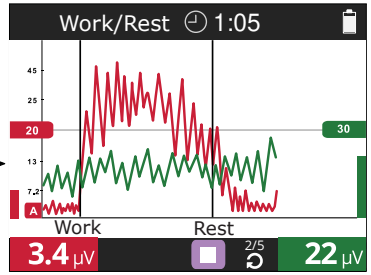
It is important to make sure your graph is adjusted to your personal level of EMG performance. Use the THRS buttons to adjust the threshold level. The threshold is shown as a horizontal line along your graph. Threshold level will adjust the sensitivity of the graph as well. Good calibration is when your running EMG graph can reach the top of the white area of the display when you contract, and fall well below the threshold line when you relax.

You can adjust the threshold automatically, just before you start your session:

Auto-threshold: Press AUTO button on the bottom of keypad and at the same time contract your muscles as much as you can for a few seconds, the threshold value will flash on screen, then the new threshold will be set as 80% of the average of your maximum contraction. You can repeat the above procedure until the threshold is on a comfortable level.



1. Adjust the threshold and touch Start.



2. Follow the on-screen prompts with your contractions and relaxations.

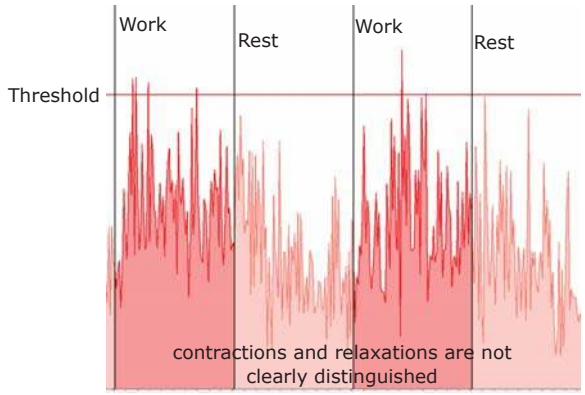
2. Following the prompts with contractions and relaxations.

Press Start button. The Work and Rest prompts appears as vertical bars on screen. As soon as you see the Work prompt, contract as quick and as much as you can for the remaining time or Work period. Manage your efforts properly, so you don't exhaust yourself before the session is finished. As soon as you see the Rest prompt, relax as quickly as possible and try to stay relaxed, watch your resting EMG and make sure it is as smooth and as low as possible.

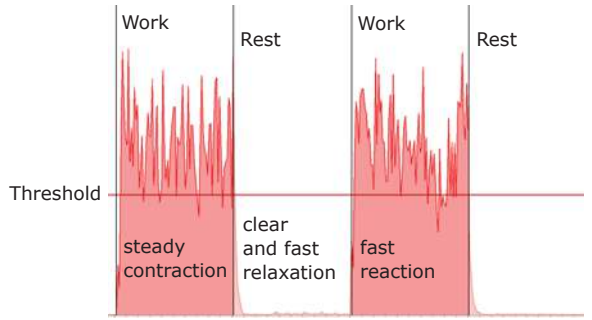
Muscular performance and how to read it on EMG graph

EMG is a very powerful tool which helps to determine the muscular performance, such as speed of response, power of contraction, ability to relax properly, etc.

Below are the examples of two different EMG readings and the story they tell about muscular performance:



Example 1: Weak muscular performance: very weak control of contraction and relaxation.



Example 2: Improved muscular performance: strong contraction followed by a proper relaxation