ELECTRICAL STIMULATION AND BIOFEEDBACK FREQUENTLY ASKED QUESTIONS

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PRODUCT RANGE

This document covers the following products;

- NEUROTRAC CONTINENCE
- NEUROTRAC PELVITONE
- NEUROTRAC SIMPLEX
- NEUROTRAC MYOPLUS RANGE
- NEUROTRAC TENS
- NEUROTRAC OBSTETRIC TENS

ELECTRICAL STIMULATION

HOW DOES ELECTRICAL STIMULATION WORK?

Electrical stimulation, when applied to the muscles, is clinically called Neuromuscular Electrical Stimulation (NMES). This is because the electrical pulses activate the junction between the nerves and muscles being treated and produce a contraction of the muscle fibres. A stimulation induced contraction can give an effective workout for the muscle and is especially useful when the person finds it difficult to produce a contraction themselves.

HOW WILL IT HELP ME?

Using electrical stimulation can help to strengthen the pelvic floor muscles. Having stronger pelvic floor muscles can help you to 'hold on' when you feel the need to pass urine and can enable you to reach a toilet safely without leaking before you get there. They can also work more effectively to close the outlet from the bladder (urethra) and prevent urine leaking when you are active; running, coughing, sneezing, laughing or exercising. Electrical stimulation can also exercise the posterior part of the pelvic floor muscles and can help to strengthen the anal sphincter muscle. Having a strong anal sphincter can help to prevent leakage occurring from the bowel and reduce bowel urgency.

The indications for use are:

- When there is an inability to voluntarily contract the pelvic floor muscles
- When the pelvic floor muscles are very weak
- When pelvic floor muscle exercises alone are not effective
- To provide an alternative to or adjunct to other treatments
- Where there is a combination of muscle weakness and bladder urgency
- Dyspareunia, lax vagina and vulva pain

- Faecal incontinence to increase sphincter tone (limited evidence to support use in faecal incontinence)[i]
- Nice Guideline CG 171, 2013 recommends that electrical stimulation is considered in women who cannot actively contract the pelvic floor muscles in order to aid motivation and adherence to therapy

WHEN CAN'T I USE IT (CONTRAINDICATIONS)?

It is not recommended to use electrical stimulation if you have any of the following conditions:

VAGINAL

- Loss of sensation or feeling in the area where the electrode will be positioned
- Pelvic cancer that is currently being treated or is under review
- You are pregnant or trying to conceive
- Within 12 weeks of having a baby
- Within 12 weeks of having pelvic surgery
- A Pacemaker – cardiac or other
- A urinary tract infection
- A vaginal discharge or infection
- Broken skin in the area where the electrode will be positioned
- A large vaginal prolapse that prevents correct positioning of a vaginal electrode
- Fistula
- Pelvic mass
- Tissue trauma or haematoma in the last six weeks
- Inflammation of the vaginal tissues
- Abnormal smear (until patient has had one clear smear)[ii]
- Patient is unable to understand instructions or physically unable
- Combined with a ring pessary in situ – remove ring pessary before stimulation

ANAL

In addition to the contraindications above, care should be taken if you have;

- Swollen / bleeding haemorrhoids
- Anal fissure
- Rectal prolapse

PRECAUTIONS

- Recent radiotherapy
- Use of a diaphragm
- Retention of urine – this should be assessed and managed before using NMES
- Haemophilia - check with Multi-Disciplinary Team (MDT) that bleeding disorders are well managed and advise care with insertion and removal of vaginal / anal probe
- Epilepsy – need to discuss with MDT / patient regarding potential risks
- Uncontrolled hypertension
- Sexual abuse
- Contraceptive ring (e.g. NuvaRing). Ring may prevent good contact of vaginal electrode with mucus lining of the vaginal wall, may affect ability of NMES to function. Consider use of anal electrode
- Nickel allergy – need to select nickel free electrode. To purchase nickel free electrodes/probes, please visit our online shop at https://shop.desmitmedical.com and search for "nickel free"
- Diabetes – need to assess if they have pudendal nerve neuropathy and degree to which neurological function is affected

There is not a contraindication to using NeuroTrac stimulators in the presence of metal implants such as a hip replacement. The waveform produced by the NeuroTrac device is bi-phasic, with a positive phase which stimulates the muscle and a negative phase which discharges the energy, thus preventing a heating effect.

The use of the NeuroTrac device is also not contraindicated for use with an intra-uterine device in situ (including the Mirena coil).

There should not be any issue with the fact that the patient has had surgery using mesh unless there are changes to the vaginal wall, for example: if the mesh as eroded through the vagina as can happen in some cases – then the stimulation current may focus on the scar tissue and could be very uncomfortable.

The above contraindications / precautions are for all NMES for the pelvic floor, regardless of the type of electrode, with the exception of 'nickel allergy' which is specific to electrodes with stainless steel electrodes (you would need to select nickel free electrode).

For general contraindications (when not to use), consult the user manual.

HOW OFTEN SHOULD I USE IT?

It is recommended to use a stimulation programme building up to 30 minutes, either using it daily or alternate days. A specialist nurse or physiotherapist will be able to advise you of the best programme and frequency of use for your muscles.

WILL IT HURT?

Pelvic floor electrical stimulation should not be painful. By choosing the correct programme you should just feel a tingling sensation where the electrodes are placed and you should feel the pelvic floor muscles working – vaginal stimulation has been described like feeling a 'heartbeat' in the vagina.

HOW SOON MIGHT IT IMPROVE MY CONDITION?

This will depend upon the condition of your muscles when you start to use a muscle stimulator. Muscle strengthening can take at least 12 weeks, however in some cases using the stimulator makes you more able to connect with your muscles when you have forgotten how to use them, so improvement can happen more quickly.

Pelvic floor NMES should be used in relation to the pelvic floor muscle dysfunction rather than the severity of the symptoms. If someone has a pelvic floor dysfunction, using NMES can improve the function of the pelvic floor and this can be the case with mild or severe incontinence symptoms.

NEUROTRAC CONTINENCE AND PELVITONE

WHAT IS THE DIFFERENCE BETWEEN THESE DEVICES BESIDES PRICE?

The Pelvitone stimulator can deliver up to 5 customised phases of stimulation during one treatment session; these would normally be programmed specifically for you by your healthcare specialist practitioner. Both devices offer a customisable stimulation programme and also include a range of pre-set treatment programmes.

NEUROTRAC SIMPLEX AND MYOPLUS

WHAT IS BIOFEEDBACK?

Biofeedback is a means of using a device attached to a specific muscle to show how well that muscle is able to work. With Simplex / MyoPlus, the biofeedback is given by connecting an anal or vaginal electrode or surface electrodes near to the pelvic floor muscles. The device is then able to pick up an electrical signal (electromyography - EMG) when the muscles contract and to show this by means of lights and a microvolt (energy) reading. Or in the case of the MyoPlus when connected to the software programme, a visual graph on a computer screen.

HOW WILL IT HELP ME?

Biofeedback can help to identify the correct contraction and can greatly help you to stick to a muscle training programme.

WHEN CAN'T I USE IT (CONTRAINDICATIONS)?

EMG biofeedback is only picking up electrical energy from the body, so it has no specific contraindications. The only limitations are using the vaginal or anal probe.

For general contraindications (when not to use), consult the user manual.

HOW OFTEN SHOULD I USE IT?

Biofeedback can be used as an aid to a pelvic floor muscle exercise programme. It is a personal choice as to how often you use Biofeedback. It is helpful to connect to a biofeedback device each time you perform a pelvic floor muscle workout, however practically this is not always possible. Usage varies from one person to another, with some people using it as an aid once or twice a week and others using it three times a day - each time they exercise.

WILL IT HURT?

EMG Biofeedback should not be painful. It is picking up electrical signals from the muscles and does not deliver electrical energy to the body.

HOW SOON MIGHT IT IMPROVE MY CONDITION?

This will be dependent upon the severity of your condition when you commence using Biofeedback. Strengthening pelvic floor muscles can take at least 12 weeks.

NEUROTRAC TENS AND OBSTETRIC TENS

HOW DOES IT WORK?

TENS (Transcutaneous Electrical Nerve Stimulation) pain relief is a non-invasive drug-free method of controlling acute and principally long-term intractable pain. It can also be used as an adjunctive treatment in the management of post-surgical traumatic pain problems.

Obstetric TENS pain relief is for use during labour.

Pain relief is achieved through the device by delivering mild electrical impulses through the skin to modify the skin's pain perception, releasing natural painkillers called endorphins.

Both TENS and Obstetric TENS use surface electrodes only. It is possible to connect vaginal or anal electrodes to the leads that attach to a TENS machine. However, care should be taken in using pain relief programmes that include prolonged use of frequencies in excess of 50 Hz as this could produce pelvic floor muscle fatigue as a side effect of using prolonged higher frequencies.

Consult the user manual for appropriate surface electrodes placement examples, or your clinician.

WHEN CAN I USE IT?

- TENS pain relief as recommended by your clinician.
- Obstetric TENS from 37 weeks for common pregnancy backache and to practice for labour.

For general contraindications (when not to use), consult the user manual.

TROUBLESHOOTING

EMG biofeedback, NMES and TENS requires a circuit to be formed between the device and the muscles. In the case of pelvic floor muscle Biofeedback or NMES, this is usually achieved by using an anal or vaginal electrode (probe), in some circumstances with surface electrodes. In the case of TENS and Obstetric TENS, this is achieved by using surface electrodes.

SYMPTOMS

If you experience any of the following symptoms on your device, please follow the troubleshooting steps suggested below;

1. The device does not turn on
    a. Refer to **step 1** of the **Troubleshooting Steps** section below
2. There is no EMG signal showing on the device screen/PC
    a. Refer to **steps 2, 3, 4, 5, 6 and 7** of the **Troubleshooting Steps** section below
    b. Also refer to the **Testing Electrode Leads** section below
3. There is no stimulation output showing on the device screen/PC
    a. Refer to **steps 2, 3, 4, 5, 6 and 7** of the **Troubleshooting Steps** section below
    b. Also refer to the **Testing Electrode Leads** section below
4. The stimulation only goes up to 5 or 6 mA and cuts out
    a. Refer to **steps 2, 3, 4, 5, 6 and 7** of the **Troubleshooting Steps** section below
    b. Also refer to the **Testing Electrode Leads** section below
    c. NB – As a safety mechanism, the device automatically cuts out beyond 5mA if a high resistance is detected (i.e. a sufficient circuit has not been formed)
5. The device LCD flashes a surface electrode symbol 
    a. Refer to **steps 2, 3, 4, 5, 6 and 7** of the **Troubleshooting Steps** section below
6. The stimulation only occurs on one side of the probe (vaginal/anal probes only)
    a. Refer to **steps 5 and 6** of the **Troubleshooting Steps** section below
    b. Also refer to the **Testing Anal/Vaginal Probes** section below
7. The stimulation output is intermittent
    a. Refer to **steps 2, 3, 4, 5, 6 and 7** of the **Troubleshooting Steps** section below
    b. Also refer to the **Testing Electrode Leads** section below
    c. NB – Intermittent stimulation may be due to the work / rest (duty cycle), with periods set for the stimulation to work and periods set to allow the muscle to rest
8. The stimulation intensity drops
    a. Refer to the **Stimulation Intensity** section below

TROUBLESHOOTING STEPS

1. **Ensure that a sufficiently charged battery is securely fitted into the device battery compartment**
    a. Ensure the battery is securely in place
        i. The battery should not move/rattle
    b. Ensure the batteries are the correct polarity/orientation
        i. The device's battery compartment will indicate which way round the battery should sit
    c. Ensure the correct battery type is being used
        i. Consult the user manual for the correct battery to use
    d. The device should display a battery level indicator once powered on
    e. If you are unsure of the battery condition, replace the batteries
    f. To purchase new batteries, please visit our online shop at https://shop.desmitmedical.com and search for "batteries"
2. **Ensure the electrode leads are not physically damaged or dirty**
    a. There should be no exposed wiring or broken cable insulation
    b. The cables should not be twisted or stretched
    c. The electrode pins should be unbent, clean and free from dirt, rust and other contaminants
    d. Replace the electrode leads where necessary
    e. To purchase new electrode leads, please visit our online shop at https://shop.desmitmedical.com and search for "electrodes"

3. **Ensure the electrode lead pins are securely inserted into the electrode connectors**
    a. If you suspect the electrode leads are faulty, please follow the **Testing electrode leads** section below
4. **Ensure the electrode leads are inserted into the correct channel(s) on the device**
5. **Ensure there is a secure connection between the electrode and skin**
    a. The electrode/probe must make good contact with the skin
    b. Dry skin/internal environment can result in reduced electrical conductivity
    c. For surface electrodes only
        i. Clean the skin with an alcohol-based wipe before applying the surface electrode
        ii. Hair can cause poor contact with the surface electrode
        iii. Re-usable surface electrodes will deteriorate and have a typical life expectancy of 4-6 weeks
        iv. After use, place the surface electrodes sticky side down on to the clear plastic film they were supplied with and store in a cool place
        v. If they become dry put some drops of water on to the electrodes and store in cool place overnight – this may prolong their use by a few days

vi. To purchase new surface electrodes, please visit our online shop at https://shop.desmitmedical.com and search for “surface electrodes”

d. **For vaginal/anal probes only**

i. Apply a water-based lubricant/gel. To purchase lubricant, please visit our online shop at https://shop.desmitmedical.com and search for “lubricant”

ii. To purchase new anal/vaginal probes, please visit our online shop at https://shop.desmitmedical.com and search for “probes”

iii. If you suspect the probe is faulty, please follow the **Testing anal/vaginal probes** section below

6. **For vaginal probes only**

a. Ensure you have used a water-based lubricant. To purchase lubricant, please visit our online shop at https://shop.desmitmedical.com and search for “lubricant”

b. Try changing your body position – sit down and lean back slightly, or lie down

c. Ensure the probe metal plates are pointing hips outward

d. Some women experience stimulation only on one side

i. This could be a result of sensory nerve damage

ii. If you can feel some stimulation, even if only on one side, this means that the device is working

iii. If the electrode plates run along the length of the probe, rather than around the electrode (such as the Periform or Anuform), stimulation may only be felt on the positive (+) side of the electrode
If this is the case, rotate the probe or reverse the electrode leads
The stimulation should be felt on the opposite side

e. To purchase new vaginal probes, please visit our online shop at https://shop.desmitmedical.com and search for “vaginal probes”

f. If the device/electrode has been tested and felt to be working but the user is unable to feel any stimulation when the electrode is in situ in the vagina, please seek a health professional assessment.

7. **For surface electrodes only**

a. Place on the skin according to recommendation

b. Check that the electrode surface has not ‘dried out’

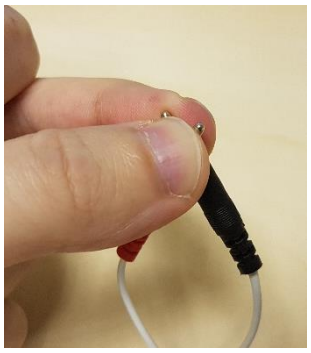
c. To purchase new surface electrodes, please visit our online shop at https://shop.desmitmedical.com and search for “surface electrodes”

TESTING ELECTRODE LEADS

If you have a stimulation device, you can perform the following test to ensure the electrode leads are functioning correctly. This does not apply to non-stimulation devices, such as the NeuroTrac Simplex.

1. Power on your device
2. Insert an electrode lead into channel **A** or **B** on the device

3. Cross over the metal pins at the end of the electrode lead and firmly hold them together, thereby creating a circuit



4. Start a stimulation session on the device
5. Hold down the plus (+) button relating to the relevant channel to increase the mA output
    a. It may pause at 20 mA – This is normal
    b. Press and hold the plus (+) button again to continue beyond 20 mA
6. If the device goes up to the maximum mA
    a. The device and electrode leads are working and setup correctly
    b. The maximum value varies depending on the device but should range from 80-90 mA, consult the user manual for the maximum mA value for your model.
7. If the device does not go beyond 20mA when following 5 b. above: -
    a. Try another electrode lead and repeat this test procedure
    b. If a replacement electrode lead does not resolve the problem, please contact de Smit Medical for further support

TESTING ANAL/VAGINAL PROBES

You can perform the following test to ensure the probe is functioning correctly.

1. Power on the device
2. Wash the probe and hold between your first finger and thumb, or elbow crook, to make a connection across the electrode plates
3. Insert the probe electrode lead into either channel **A** or **B** on the device
4. Hold down the plus (+) button relating to the relevant channel to increase the mA output
5. If the probe is functioning correctly, you should feel the stimulation as the current passes through your hand
    a. This proves the device works when the connection is established
6. If you don't feel any stimulation in your hand/elbow crook, try another electrode lead or probe and repeat this test procedure

EMG READING PRECISION

1. **EMG Reference**: If you don't use the reference wire, the reading becomes unstable. Instability may cause your reading to be too high or too low. An 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. **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 the increased or chaotic EMG reading. A practical approach will be to try your device in a different area to see if another room has less electrical interference.

STIMULATION INTENSITY

- 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 new phase requires re-adjustment of the intensity in order to match new parameters.

Should you require further help or information please refer to the user manual supplied or contact de Smit Medical on 0845 345 4226 or sales@desmitmedical.com

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[i] NICE Guidelines CG171 2013
[ii] POGP Guidance 2016
Further reading: Good Practice Statement (GPS) POGP 2019