INSTRUCTION MANUAL

Microstim2 - Orthopaedic Variant

The output of this device has a physiological effect.

Read the instructions and precautions before use.

The device will only be set up by a person who has been trained in the use of FES.

…a confident choice

OML | Leading Rehabilitation Through Technology

NHS Salisbury NHS Foundation Trust

Contents

Microstim2 Orthopaedic Kit Contents

Description	Product Code	Qty
Microstim2 Orthopaedic	01-001-0040	1
Electrode Lead 1m	03-001-0008	2
Electrodes, Grey, 33x53mm	01-004-0007*	1 pack of 4 electrodes
Battery,PP3, 9V	05-001-0002	1
Instruction manual	11-003-0028	1
Warranty Card	11-003-0067	1

* This item has an expiry date. Please refer to its packaging for more detail.

Introduction

Intended Use Statement

The Microstim2 Orthopaedic variant is intended to be used for the alleviation of disability related to muscular weakness or inactivity. The weakness may be due to an upper motor neurone lesion or disuse atrophy.

The Microstim2 Orthopaedic can be used to strengthen muscles, reduce spasticity, increase range of movement, reduce pain, reduce oedema and increase local blood flow. Stimulation can also modulate the central nervous system promoting neuroplasticity.

The Microstim2 Orthopaedic is designed for use in home healthcare, residential and hospital or healthcare environments.

General Description

The Microstim2 Orthopaedic is a variant of the Microstim2. The philosophy behind the design of the stimulator is to reflect the journey of a person undergoing joint replacement surgery. As such a number of features need to be built into such a stimulator to address patient and clinician requirements at each stage of the process, from immediately after surgery through to return to normal function. These are; 'Set Up', 'Blood Flow', 'Pain', 'Muscle conditioning', 'Endurance' and 'Power', with the stimulator featuring the same easy to use 10 pre-programmed modes as the original Microstim, but with waveforms adapted specifically to the requirements of orthopaedic practice.

Warranty

The Microstim2 Orthopaedic is warrantied for a period of two years from the date of sale or fitting. Should any failure of the device occur during the warranty period, the device should be returned to Odstock Medical Limited for inspection. Should the failure be due to manufacturing or material defect the device will be repaired or a replacement supplied free of charge.

The warranty is valid providing that the failure cannot be attributed to misuse.

Important Information (Warnings)

Important Information

The clinician shall brief the patient on any known contraindications and warnings to the use of this system and any precautions to be taken. The clinician shall issue and guide the patient through the user instruction manual.

Contraindications

The Microstim2 Orthopaedic should not be used on people who have a cardiac pacemaker, implanted defibrillator, or other electronic implanted device unless investigations demonstrate that there is no interaction between the devices.

Neck Stimulation

Stimulation should not be applied over the neck, because severe spasm of the muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing. Stimulation over the neck (especially carotid sinus) could have adverse effects on heart rhythm or blood pressure.

Open or Infected Wounds

Stimulation should not be applied over open wounds or over swollen, infected, or inflamed areas or skin eruptions. Stimulation should only be applied to normal intact, clean skin. Dilated capillaries and movement caused by moving muscles may disrupt healing tissue.

Cancer

Stimulation should not be applied over, or in proximity to, cancerous tissues as increased local blood flow may increase tumour growth.

Electronic Monitoring Equipment

Stimulation should not be applied in the presence of electronic monitoring equipment, such as cardiac monitors and electrocardiogram alarms. Monitoring equipment may not operate properly when the electrical stimulation device is in use.

Transcerebral Stimulation

The effects of stimulation of the brain are unknown. Therefore, stimulation should not be applied across the head and electrodes should not be placed on opposite sides of the head, directly on the eyes or covering the mouth.

Strangulation

There is a risk of strangulation with wires of the system. Do not place leads around the neck. Use an appropriate length of lead.

Chest Stimulation

Stimulation should not be applied between the chest and upper back, crossing over the heart, because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be fatal.

Epilepsy

People with suspected or diagnosed epilepsy should follow precautions recommended by their physicians. The Microstim2 Orthopaedic should not be used by people who have poorly controlled epilepsy. Odstock Medical Limited recommend that an intended device user is fit free for 3 months before commencing treatment.

Sleeping

Do not use the stimulator whilst sleeping.

Batteries

Only use batteries recommended by Odstock Medical Limited.

Ensure you follow the instructions for installing, using, storing and disposing of the battery.

Do not short circuit the battery. Doing so may lead to excessive heat and possible burns.

When transporting batteries, cover the terminals with tape or other non-conductive material to prevent the terminals from shorting.

Flammable Cleaning Products

Do not use flammable cleaning products to clean the device.

High Frequency Surgical Equipment

Simultaneous connection to high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.

Oxygen Rich Environments

Do not use stimulation within oxygen rich environments such as a hyperbaric oxygen chamber or in close proximity to an oxygen mask.

External Orthopaedic Metal Fixation

Stimulation should not be applied in the area of exposed orthopaedic metal work.

Flammability

Do not use the stimulator near flammable fuels, fumes or chemicals.

Electromagnetic Emissions

Use of accessories and cables other than those specified or provided by Odstock Medical Limited could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Degradation of Stimulator, Consumables and Accessories

Do not use the device if the stimulator, cables or electrodes are damaged in any way. Replace the cables if they become stiff or have cracked insulation.

Handling Electrodes

Do not handle electrodes while the stimulation is on. Always make sure that the Microstim2 Orthopaedic is turned off before adjusting the electrodes. Only apply electrodes as described in this instruction manual. Ensure that the pins of the electrode wire are fully inserted into each electrode before use.

Exposed Electrode Pins

Ensure that the pins of the electrode wire are fully inserted into each electrode before use.

Skin Irritation

Some people may experience skin irritation due to electrical stimulation or the electrodes. The irritation can usually be reduced by using an alternative type of electrode, different device settings or a new electrode position. A slight reddening of the skin under the electrodes is normal and this should clear within 1 hour of stopping stimulation. If stimulation causes long term marking of the skin, the patient should discontinue use and contact their clinician.

Skin Care

Do not shave the skin under the electrodes. If long hairs require removal, cut the hairs using scissors. If skin moisturisers are required, use overnight and remove residue using warm water with a mild soap before applying electrodes in the morning.

Prevention of Pressure Sores

Patients should check the integrity of their skin that is in contact with the electrodes, lead, or stimulator each time the device is used. If pressure marking occurs, remove the cause of the pressure and recommence use once the skin marking has cleared.

Spasticity

If stimulation causes increased spasticity (involuntary, exaggerated muscle stiffness and spasms), the patient should discontinue use and consult their clinician.

Machinery Operation and Driving

Stimulation should not be used when driving, operating machinery, or during any activity in which electrical stimulation could distract or put the patient at risk of injury.

Bathing, Showering or Swimming

Do not use stimulation in the bath, shower or when swimming.

Water Ingress

Do not get the stimulator, or any part of the system or accessories wet. Water ingress may stop the stimulator or accessories working. If submerged, remove battery (if present), dry out thoroughly and return to Odstock Medical Limited for assessment. If liquid is split on the stimulator, remove battery and dry out thoroughly prior to re-use.

Shortwave and Microwave Therapy

Do not use in close proximity (e.g. 1m) to a shortwave or microwave therapy medical equipment as it may produce instability in the stimulator output.

Autonomic Dysreflexia

Patients who have high level spinal cord injuries (T6 and above), may experience symptoms of autonomic dysreflexia (increased blood pressure or sweating in response to stimulation). This may also be seen in patients with multiple sclerosis. If affected, the patient should discontinue use and consult their physician.

Cardiac/Exercise Stress

Patients with suspected or diagnosed heart disease should follow the exercise precautions recommended by their physician.

Deep vein thrombosis

Patients with suspected or diagnosed deep vein thrombosis should follow the exercise precautions recommended by their physician.

Injury, Fracture or Surgery

Electrical stimulation should not be carried out in areas of the body affected by recent injury, fracture or surgery. Movement caused by moving muscles may disrupt healing.

Pregnancy

The safety of using electrical stimulation during pregnancy has not been established.

Prescribed User

The device should only be used by the patient that the system has been prescribed for. Keep out of reach of non-intended users. Only use as instructed by the clinician.

Long-term Effects

The long-term effects of electrical stimulation are unknown. Odstock devices have been successfully used by individuals for over 20 years.

Accessories and Consumables

Only use accessories and consumables recommended by Odstock Medical Limited. Do not connect with equipment other than that intended to be used with this system as defined within this instruction manual or that of the other equipment.

Battery Change and Battery Cover

Do not operate the stimulator with the battery cover removed. Disconnect all the leads prior to opening the battery cover. The clinician / carer should not be in contact with the patient when changing the battery.

Equipment Modification

Do not tamper with, or modify the equipment.

Shelf Life

Do not use the consumables if they have passed their expiry date.

Equipment Re-use

Electrodes are single patient use only. If re-using other parts of the system ensure a thorough clean using anti-bacterial wipes.

Storage Temperature

Do not store outside of the temperature limits as detailed in the specification on page 34. If the Microstim2 Orthopaedic or accessories (excluding electrodes) have been stored at the minimum (-20°C) or maximum (70°C) storage temperatures, allow at least 10 minutes in ambient temperature before use.

Use of Small Electrodes

The use of small electrodes (less than 32mm diameter) may result in higher charge density especially when using high output settings (current, pulse width, frequency) and may lead to an increase in the likelihood of skin irritation. When possible use larger electrodes. Always monitor skin condition closely.

Adverse Reactions

The patient should report any undesirable outcomes, malfunctioning of the device, mistakes in using the device, or injury from the use of this device to the clinician who provided it to them.

The clinician is responsible for reporting all adverse events to Odstock Medical Limited or their local representative.

Residual Risk

Even though Odstock Medical Limited have taken all foreseeable steps, through design and testing, to ensure this device is safe and reliable, there remains a small risk of stimulation not being delivered when required.

Safe Disposal of Equipment

Care should be taken to dispose of parts and accessories of the device in the correct manner. In order to protect the environment, the product and its accessories should not be disposed of in household waste. Please dispose of as per local regulations. Alternatively, equipment can be returned to Odstock Medical Limited for disposal.

Symbol Definitions

Attention: device has a physiological effect

Caution (used throughout the instruction manual to identify caution item).

Applied parts of insulation type BF.

Read the instructions and precautions before use.

This product should not be disposed of with other household waste. Your Microstim2 and accessories can be returned to Odstock Medical Limited for appropriate disposal.

The CE mark indicates that the Microstim2 Orthopaedic variant complies with the European Union Medical Device Directive.

Date of manufacture.

Do not get any part of the system wet.

Expiry date (Year, Month, Day) of product (may relate to specific components, such as electrodes and batteries inside the packaging).

Manufactured by Odstock Medical Limited

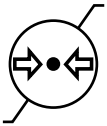
Odstock Medical Limited
National Clinical FES Centre
Salisbury District Hospital
Salisbury, Wiltshire, UK

Symbol Definitions

Do not use if the packaging is substantially damaged. Proceed with caution and check components for damage prior to use.

Do not store outside of specified temperature limits. If accompanied by <mo; for storage less than 1 month. If >mo; for storage greater than 1 month.

Do not store outside of the specified relative humidity limits.



Do not store outside of the specified atmospheric pressure limits

LOT

Batch number.

SN

Unique serial number of the stimulator.

REF

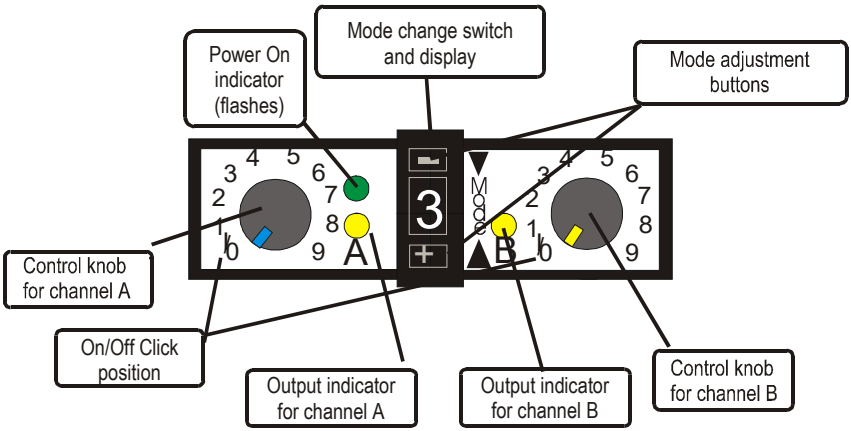
Odstock Medical Limited stimulator reference number

EC REP

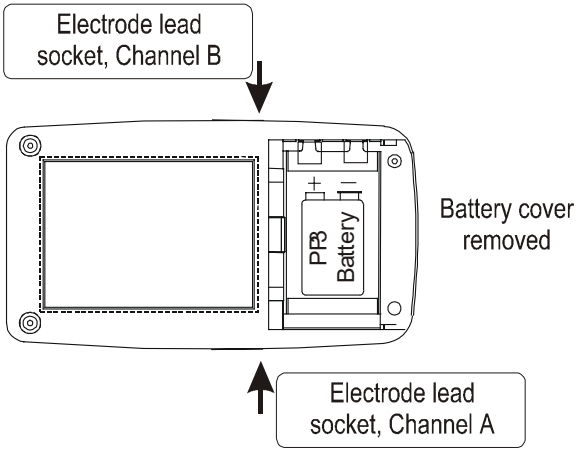
European authorised representative.

Importer

Front Cover:

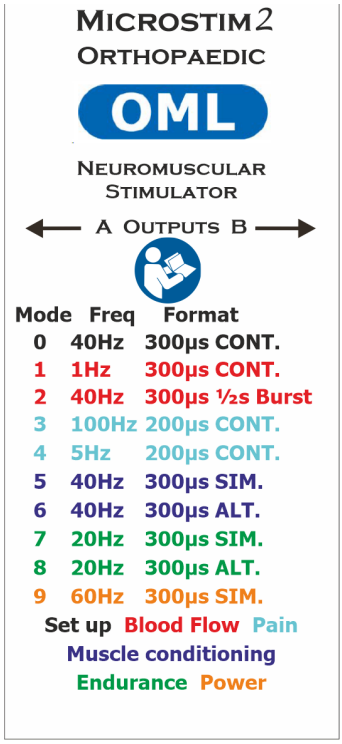


Underneath View Showing Battery Location and Electrode Sockets:



Controls & Indicators

The stimulation output level controls are the rotary knobs. To switch ON the stimulator, rotate either of the level controls clockwise from the 'I/0' position until a click is heard. The stimulator should emit a short bleep and the green power indicator will begin flashing and continue flashing while the stimulator remains on. After the initial long beep a sequence of quick beeps will signal the number of the mode selected. Note that mode 0 means there will be zero short beeps! Further clockwise rotation of the level controls increases the stimulation intensity. To switch OFF the stimulator, rotate both level controls fully anti-clockwise until a click is heard and the power indicator is extinguished.



The presence of a stimulation voltage at either of the output connectors is shown by the corresponding yellow output indicator. The 'A' output is on the left of the box and the 'B' output is on the right.

The mode select control is the central pushbutton switch. A number is displayed which indicates the mode selected. To increase the mode the lower switch is pressed and to decrease the upper switch is pressed. The mode control permits selection of the appropriate stimulation frequency and pattern for the chosen exercise.

Connectors

Two stimulation output connectors are provided. One is located in each side of the case. The stimulation lead connectors should be inserted here ensuring positive engagement in the sockets. When disconnecting the leads, remove the plugs by holding the plastic body - do not pull the wires.

Battery

A 9V PP3 alkaline non-rechargeable battery or equivalent rechargeable battery can be used. Ensure that the battery is correctly inserted. Remove the battery from the stimulator if it is not intended to be used for an extended period.

Low Battery

When the battery nears exhaustion a low battery warning will occur. During an exercise period the stimulator will automatically reduce the stimulation output to zero and then bleep and flash the power indicator for approximately thirty seconds. After this time the stimulator will enter 'sleep' mode and should be switched OFF before replacing the battery. The 'low battery' warning has been set to provide optimum usage characteristics for nickel-cadmium rechargeable batteries.

Stimulation Modes

Mode 0 is the Set up or continuous mode and is useful for determining the correct electrode positions.

Modes 1 and 2 are designed to improve blood flow in the leg by stimulating the common peroneal nerve to cause dorsiflexion of the foot to activate the calf muscle pump. Mode 1 gives a single muscle twitch every second whereas Mode 2 delivers a repetitive half second burst of stimulation followed by two seconds to replicate squeezing of the calf muscle.

N.B. It is essential that the stimulator is NOT used in either of these modes to improve blood flow in patients who already have a DVT.

Modes 3 and 4 are designed to replicate a TENS machine and as such uses the two most common stimulation patterns found in TENS machines. Mode 3 is for general pain and is thought to work on the 'Gate theory of pain', whereas Mode 4 is designed to help with muscular/chronic pain by working on the same principles as acupuncture/ endorphin release.

Modes 5 and 6 are for general muscle conditioning with mode 5 enabling antagonistic muscle pairs to be stimulated and Mode 6 designed to stimulate simultaneously so that two muscles working together can be exercised, such as two of the components of quadriceps or bilateral stimulation regimes can be employed.

Modes 7 and 8 are designed to improve endurance using a low frequency to minimise fatigue, but with long on times and short off times to activate the slow, fatigue resistant muscle fibres and hence increase endurance.

Mode 9 is designed to improve power using a higher frequency with short bursts of high intensity stimulation in order to induce muscle fatigue. It should be used 3 or 4 times a week at a sufficient intensity to induce muscle fatigue

Changing Modes

Do not change the Mode while the stimulator is operating. In order to change the Mode, turn the stimulator off, change the Mode and turn the stimulator on again, gradually increasing the output. If you do attempt to change the Mode while the stimulator is operating, the original Mode will continue to operate until the stimulator is turned off and on again.

Stimulation Modes

Function	Mode	Waveform	Comments
Set-up	0	300us 40Hz continuous	• Useful for finding the correct electrode positions and testing response.
Blood Flow	1	300us 1Hz continuous	• This gives a single impulse to cause a twitch of the foot
	2	300us pulse width, 40 Hz, 0.5 sec burst then rest for 2 seconds and then repeat. Continuous	• This causes a more sustained contraction and movement of the foot to replicate squeezing the calf.
Pain	3	100Hz, 200us pulses CONT	• General pain relief Works like massage/ rubbing Gate theory
	4	5 Hz 200us pulses CONT	• Muscle/ chronic pain. Works like acupuncture Endorphin release
General Muscle Conditioning	5	40Hz 5 sec on 10 sec off, 0.5 sec ramps 300us pulses SIM	• Both come on and go off together 0.5 sec ramp up, 5 secs at set level. 0.5 sec ramp down. Off for 10 secs.
	6	40Hz 5 sec on 10 sec off, 0.5 sec ramps 300us pulses ALT	• Channel 1 comes on 0.5s ramp stays on for 5 secs at set level. Ramps down in 0.5 sec. After 2 secs Channel 2 comes on 0.5 sec ramp, stays on at set level for 5 secs, ramps down 0.5 secs. Two secs later Channel 1 comes back on.
Endurance	7	20 Hz 300s pulses 10 secs on, 0.5 sec ramps. SIM	• Both come on and go off together 1s ramp up, 10 secs at set level. 1sec ramp down. Off for 3sec
	8	20 Hz 300s pulses 10 secs on, 0.5 sec ramps. ALT	• Channel 1 comes on 1s ramp stays on for 10 secs at set level. Ramps down in 1 sec. Channel 2 comes on 1 sec ramp, stays on at set level for 10 secs, ramps down 1 secs. Channel 1 comes back on.
Power/ Strength	9	60Hz 300us 200ms ramps, 3.5s on 4.5 sec off SIM	• To be used at high intensity 3/4 times a week to induce muscle fatigue.

Stimulation Formats

The formats continuous, alternate and simultaneous describe the manner in which the intensity of the stimulation output of channels A & B change relative to each other.

Continuous (CONT)

The intensity of both outputs is manually increased from zero to the maximum set by each channel level control and remains at this level until the stimulator is switched off. This format is normally used before an exercise period to allow location of optimum electrodes positions and to determine appropriate stimulation levels.

Simultaneous Modes (SIM)

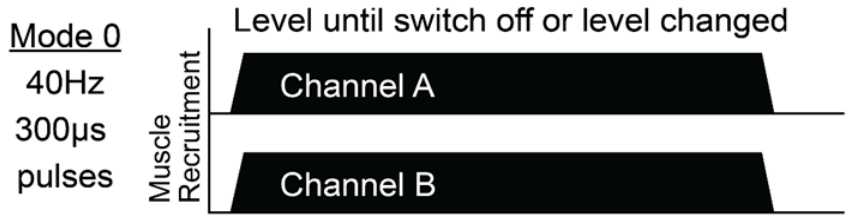
The intensity of both outputs ramps up from zero to the maximum set by each channel level control, remain at this level for a set time and ramps down to zero. After a set time this cycle is repeated. Both outputs are active simultaneously, with stimulation intensity changes in phase. This format is the normal exercise mode for related muscle groups requiring stimulation at the same time e.g. finger and elbow extensors

Alternate Modes (ALT)

The intensity of each output ramps up from zero to the maximum set by the channel level control, remains at this level for a set time and ramps down from this level back to zero. After a set time this cycle is repeated. Only one of the two outputs is on at any time. This format is the normal exercise mode for independent muscle groups such as bilateral quadriceps or agonist / antagonist muscle pairs

Mode 0 - Set Up

Mode 0 is the Set up or continuous mode and is useful for determining the correct electrode positions or when using the stimulation probe.

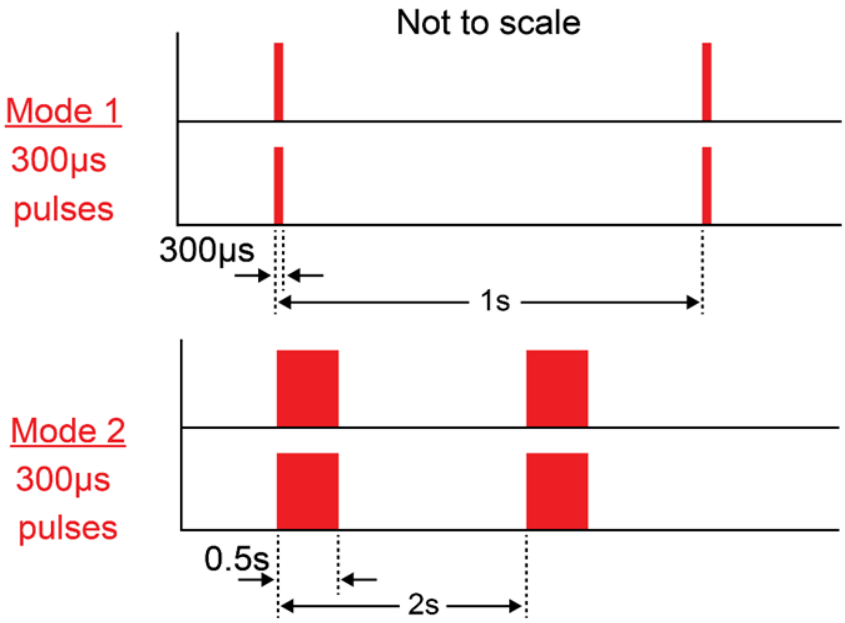


Justification

When setting up a stimulator in order to find the correct electrode position and stimulation intensity, a steady controlled response is required. This mode provides a continuous output, controlled by the intensity control in order to achieve this.

Modes 1&2 - Blood Flow

Modes 1 and 2 are designed to improve blood flow in the leg by stimulating the common peroneal nerve to cause dorsiflexion of the foot by stimulation of the common peroneal nerve to activate the calf muscle pump. The active electrode is placed over the nerve where it is most superficial, just distal to the head of fibula. Mode 1 gives a single muscle twitch every second, whereas Mode 2 delivers a repetitive half second burst of stimulation followed by two seconds rest to replicate squeezing of the calf muscle.

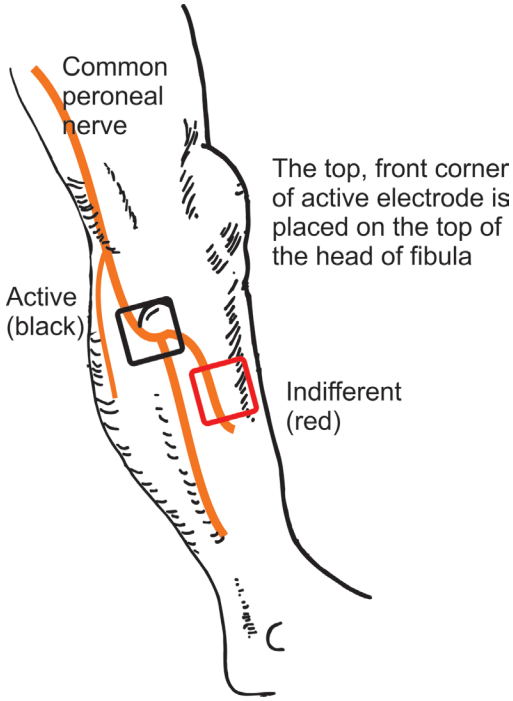


Justification

The basic concept of both waveforms to improve venous return in the leg is to facilitate the normal 'calf muscle pump' in which when the foot is dorsiflexed, the calf muscles are squashed against the back of the tibia hence pushing blood out of the calf in a proximal flow. Mode 1 gives a single impulse to cause the foot to twitch and has been shown to improve venous return in a number of trials (1-5). Mode 2 causes a more sustained movement of the foot to replicate squeezing the calf and has also been show to improve blood flow (6). In order to achieve

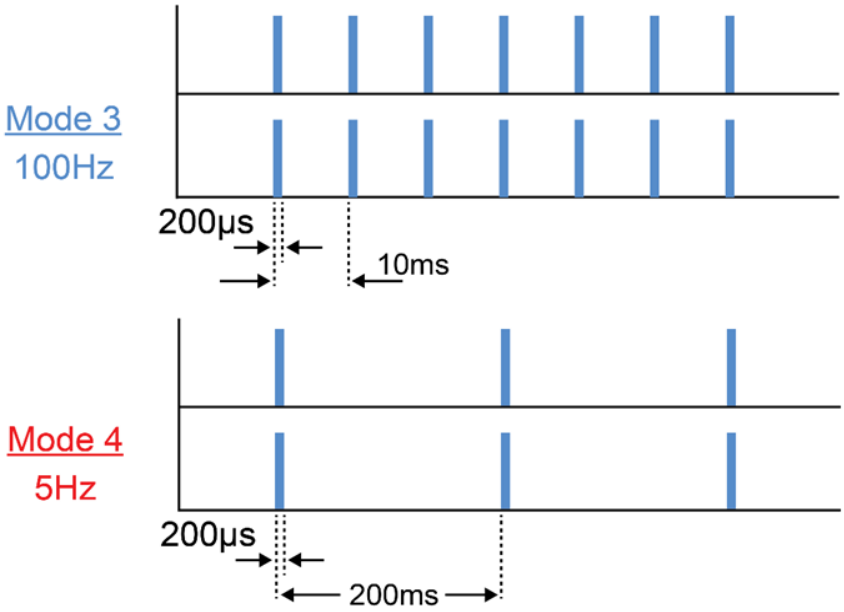
an increase in blood flow it is necessary to have sufficient stimulation intensity to achieve dorsiflexion at the ankle. The increase in blood flow can be quantified by Doppler examination of the femoral veins.

N.B. It is essential that the stimulator is NOT used in either of these modes to improve blood flow in patients who already have a DVT in the leg being stimulated as this could cause any existing DVT to move proximally. If in doubt seek expert medical advice.



Modes 3&4 - Pain

Modes 3 and 4 are designed to replicate a TENS machine and as such uses the two most commonly found stimulation patterns found in TENS machines. Mode 3 is for general pain, whereas Mode 4 is designed to help with muscular/chronic pain.

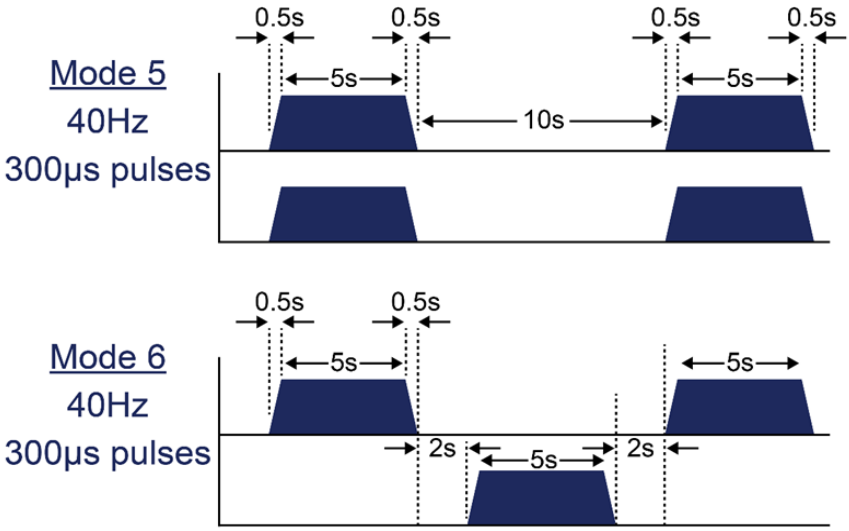


Justification

There are two ways in which TENS can be used to reduce pain. Many settings have been used and the two chosen here are the more commonly used. They work by different mechanisms. The first works on the gate theory of pain, which postulates that activity in sensory nerves from the same part of the body as the nociceptive nerves carrying pain signals will block the transmission of the pain signals via an inhibitory interneuron. The second mode is designed to promote the release of endorphins, the body's own natural pain relief agent and it is suggested that this is a similar mechanism to acupuncture. (7,8) see also http://patient.info/health/tens-machines-leaflet

Modes 5&6 - General Muscle Conditioning

Modes 5 and 6 are for general muscle conditioning. Mode 5 is designed to stimulate pairs of muscles that contract synergistically for example pairs of extensors used for reaching or weight support. Mode 6 is intended for antagonistic muscle pairs, for example flexor and extensor pairs.

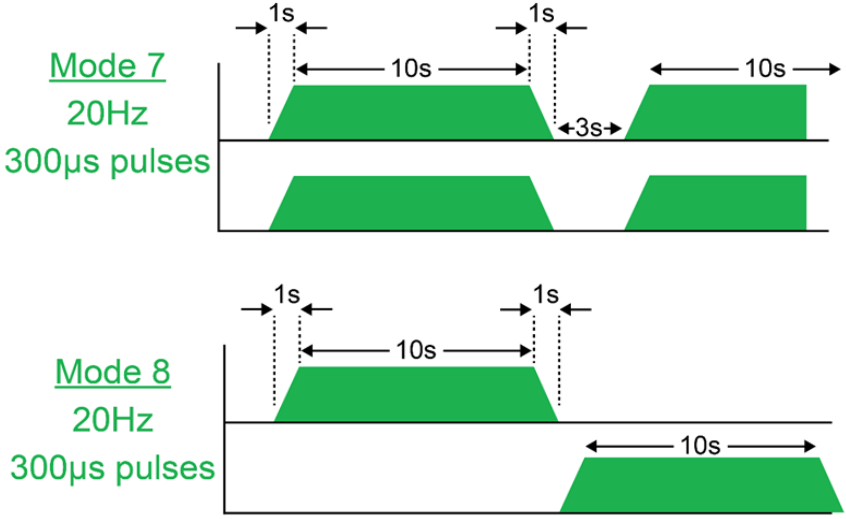


Justification

These two settings give a general muscle conditioning effect. There is a 1:3 duty cycle with simulation being on for 5 seconds and then off for 10 seconds at a frequency of 40Hz. This is to give a smooth, fused muscle contraction but with a longer rest period in order to minimise fatigue (9). It is recommended that this mode is used initially to get people and their muscles used to stimulation and then go to one of the specialised Modes to improve either fatigue resistance or strength.

Modes 7&8 - Endurance

Modes 7 and 8 are designed to improve endurance using a low frequency to minimise fatigue, but with long on times and short off times to allow a longer stimulation time. Over time this can lead to fibre type change to slow fatigue resistant fibres which will hence increase endurance.

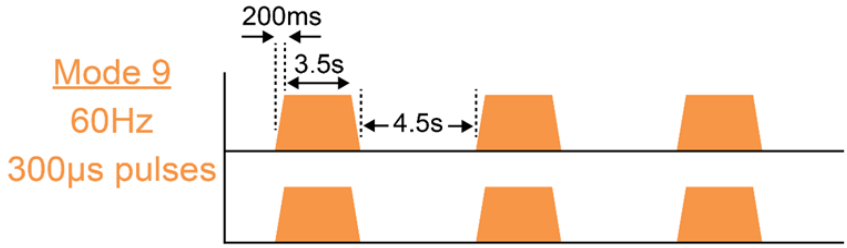


Justification

Muscles respond to the pattern of stimulation based upon normal muscle physiology. Slow muscles which are used for postural control and endurance develop a tetanic contraction at a lower frequency, whereas fast muscle fibres develop more power but fuse at a higher frequency. Fast muscle fibres fatigue far faster than slow. Therefore in order to build fatigue resistance a slow frequency stimulation with long stimulation envelopes and short rest times is required. As in order to achieve fatigue resistance long periods of stimulation are required the length of time the stimulator is used should be increased. It is recommended that stimulation is undertaken twice a day, starting for at least 15mins per session and then increasing the session length, ideally to two periods of at least an hour per day, at least 5 days per week. The rate at which this can be increased will depend on the individual subject. The level should not be at the maximum a given person can tolerate, but at a level to cause a sustained contraction over the exercise period. The level might need to be increased slightly as the session progresses (9).

Mode 9 - Power/ Strength

Mode 9 is designed to improve power using a higher frequency with short bursts of high intensity stimulation in order to induce muscle fatigue. It should be used 3 or 4 times a week at a sufficient intensity to induce muscle fatigue.



Justification.

Higher frequencies generate a more tetanic contraction, but do cause greater muscle fatigue. However if strength training rather than endurance is required, fatigue is an essential component. The protocol used here is based on the work of Kern et al in Vienna and the advice of Prof Jarvis in Liverpool. It is recommended that a typical training programme is 3x10 min sessions, with at least 5 mins rest in between. Initially use twice per week, building up to three or four times per week. Participants are asked to adjust the level to the highest level they can tolerate. The idea behind this mode is to cause muscle fatigue in order to increase strength (10, 11).

References

1.Tucker AT, Maass, A, Bain DS et al. Augmentation of venous, arterial and microvascular blood supply in the leg by isometric neuromuscular stimulation via the peroneal nerve. Int J Angiol. 2010 Spring; 19(1): e31–e37.

2. Izumi M, Ikeuchi M, Mitani T et al. Prevention of venous stasis in the lower limb by transcutaneous electrical nerve stimualtion. European Journal of Vascular and Endovascular Surgery; 2010 May; 39 (5): 642-645.

3. Warwick DJ, Shaikh A, Gadola S et al. Neuromuscular electrostimulation via the common peroneal nerve promotes lower limb blood flow in a below knee cast. A potential for thromboprophylaxis. Bone Joint Res. Sep 2013; 2(9): 179–185.

4. Jawad H, Bain DS, Dawson H et al. A Comparative Study Investigating the Effectiveness of the geko™ Medical Device versus Intermittent Pneumatic Compression in Enhancing Lower Limb Blood Flow in Healthy Subjects.

5. The geko device for reducing the risk of venous thromboembolism. NICE medical technologies guidance [MTG19] Published June 2014

6. Papworth NJ.; Harris L, Swain ID Functional Electrical Stimulation (FES): a potential method of Deep Vein Thrombosis (DVT) prevention acute stroke patients? UKIFESS May 2015.

7. De Santana PT et al Effectiveness of Transcutaneous Electrical Nerve Stimulation for Treatment of Hyperalgesia and Pain. Curr Rheumatol Rep Dec 2008; 10(6):492-49

8. Nizard J, Lefaucheur JP, Helbert M, de Chauvigny E, Nguyen JP. Non-invasive stimulation therapies for the treatment of refractory pain. Discov Med. 2012 Jul;14(74):21-31.

9. Swain ID 'Conditioning of Skeletal Muscle by Long Term Functional Stimulation - Implication for the Development of Practical Systems in Spinal Cord Dysfunction Vol. 3 Ed. Illis L., Oxford Medical Publications - 1992.

10. Kern H, Barberi L, Löfler S, Sbardella S, Burggraf S, Fruhmann H, Carraro U, Mosole S, Sarabon N, Vogelauer M, Mayr W, Krenn M, Cvecka J,Romanello V, Pietrangelo L, Protasi F, Sandri M, Zampieri S, Musaro A Electrical stimulation counteracts muscle decline in seniors. Front Aging Neurosci. 2014 Jul 24;6:189. doi: 10.3389/fnagi.2014.00189. eCollection 2014.

11. Personal communication Prof. J.Jarvis, Professor of Sports and Exercise Science, Liverpool John Moores University.

Electrodes

Two types of electrodes are available;

- self-adhesive electrodes.
- conductive silicone rubber electrodes used with adhesive gel.

The therapist will explain which type you have and how to use them.

Self-Adhesive Electrodes

1. Connect the electrodes to the leads by inserting the pin into the connector on the flying leads of the electrodes.
2. Peel the electrode away from the plastic sheet by lifting at the electrode edge. Do not pull the flying lead.
3. Place the electrodes on the skin in the desired positions. The electrode with the black plug is the active electrode. The electrode with the red plug is the indifferent electrode. Care should be taken when pulling clothing on over the electrodes and wires.
4. After use, peel the electrode away from the skin by lifting its edge. Do not pull the flying lead. Replace the electrodes on their plastic sheet and remove the electrode lead by pulling the plug from the flying lead connector. Do not pull on the electrode lead.
5. Replace the electrodes in their plastic bag and reseal the bag to prevent evaporation of moisture from the electrode gel.
6. If after repeated use the electrodes loose their stickiness, dampen the surface of the electrodes with water and leave to dry for a few minutes, gel side uppermost. If this is unsuccessful, contact your therapist and ask for a new set of electrodes.

Conductive Rubber & Gel Electrodes

1. Connect the electrodes to the leads by inserting the pin into the moulded hole in the electrode.
2. Squeeze a little gel on to one electrode and rub the two electrodes together to spread the gel evenly over both surfaces. Use the gel sparingly for good

adhesion to the skin.

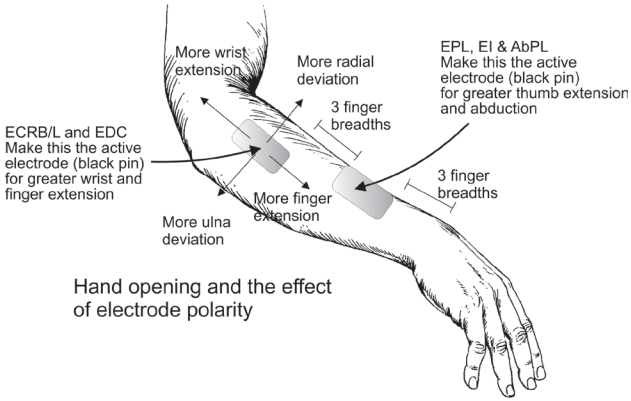
3. Place the electrodes on the skin in the desired positions. The electrode with the black plug is the active electrode. The electrode with the red plug is the indifferent electrode. Adhesive tape will be required to hold the electrodes in place. Care should be taken when putting on clothing over the electrodes and wires.

4. After use, remove the leads from the electrodes by gently pulling the plug. Do not pull on the wires. Wash the gel from the electrode using warm water after each use. Do not use soap or spirit based cleaner.

Electrodes Placement

Muscles are most sensitive to stimulation at the motor point, the point at which the nerve enters the muscle. Motor points are generally situated about 1/3rd from the proximal end of the muscle. Muscles can also be activated by stimulating the motor nerve before it enters the muscle, for example, stimulating the common peroneal nerve as it crosses the head of the fibula bone will recruit all the muscles that dorsiflex and evert the foot, and extend the toes.

Generally speaking the active electrode (black pin) has a stronger stimulating effect than the indifferent electrode (red pin). For this reason, place the active electrode over the muscle or nerve from which you wish to achieve the biggest effect. Place the indifferent electrode over a “neutral” position such as the back of the wrist, elbow or knee, at the distal end of a muscle or over another muscle or nerve you also wish to recruit. The indifferent electrode will give a slightly weaker effect. For example, if stimulating for hand opening, place the indifferent over the thumb and index finger motor points (centre of the forearm about 3 finger breadths above the wrist) and active electrode over the wrist and finger extensors (posterior interosseous nerve – about 3 finger breadths proximal from the indifferent electrode) will give strong finger and wrist extension but less thumb extension. Swapping the active and indifferent electrodes will give stronger thumb extension but less wrist extension.



Hand opening and the effect of electrode polarity

Choosing the electrode size is important to achieve the best effect. Larger electrodes may be more comfortable to use as the current is spread over a larger area but may give undesirable effects because current may spread to more muscles and nerves than is required. The best electrode size is usually the biggest one that does not lead to overflow to unwanted muscles.

Always turn off the stimulation when moving or handling the electrodes. Only increase the intensity when the indicator light next to the control being adjusted is lit.

Fault Finding

To assist you with solving any problems you may have with your stimulator, we have included a list of possible problems with likely solutions;

No output and no indicator lights:

a. Exhausted battery - replace battery.

b. Battery incorrectly installed - reconnect battery.

c. Faulty stimulator - return to Odstock Medical.

No output but the indicator lights operate:

a. Broken stimulation lead - replace lead.

b. Faulty stimulator - return to Odstock Medical.

The stimulator's output produces the wrong movement:

a. Incorrect electrode positions - refer to therapist's diagrams or contact your therapist.

b. Incorrect level of stimulation - the level may be too high or low.

c. Incorrect electrode polarity may have been used - refer to therapist's diagrams or contact your therapist.

d. Poor electrode contact - re-apply or replace electrodes.

The movement produced is weaker than normal:

a. Insufficient stimulation - increase the stimulation level.

b. The muscles may be fatigued - rest before restarting exercising.

c. Electrode condition may be poor. Replace electrodes.

The stimulation is painful:

a. Incorrect electrode positions - refer to therapist's diagrams or contact your therapist.

b. Poor electrode contact - clean & re-apply electrodes.

c. Excessively high stimulation intensity - adjust appropriate level control.

The stimulator bleeps for 30 seconds then switches off:

a. Low battery - replace battery if a non-rechargeable PP3 is used, recharge battery if a rechargeable battery is used.

Specifications

Output amplitude:	Maximum 100mA with 1KOhm output load.
Stimulation frequency:	Programmable (normally 1-100Hz).
Stimulation wave form:	Nominally square with passive charge balancing.
Stimulation pulse width:	330µs maximum .

The Microstim2 Orthopaedic variant is a Class IIa Medical Device within the definition of the European Medical Devices Directive.

Expected Service Life and Shelf life

This is an indication of the life span of the parts (figures based upon daily use). Life span will depend on usage.

Item	Expected service life	Shelf life
Microstim2 Orthopaedic variant	5 Years	N/A
Electrode socket	2 Years	N/A
Electrode lead	6-12 Months	N/A
Neurostimulation electrodes	3-4 Weeks	See expiry date
PP3 Battery (9V) (non-rechargeable)	6-12 Weeks	See expiry date

Medical Device Classification:	**Class IIa, internally powered, continuous operation. Type BF applied part(s)**	
Ingress protection rating	No protection against liquid ingress. Do not get the device wet! Protected against objects entering the stimulator of 12.5mm and above.	
	Operational	Storage & Transport
Temperature:	**Electrodes:** 5°C to 27°C **Alkaline Battery:** -20°C to 54°C **System (excluding above items):** 5°C to 40°C	**Electrodes:** 5°C to 27°C >1 month **Electrodes:** 0°C to 40°C <1 month **Alkaline Battery:** 5°C to 30°C **System (excluding above items):** -20°C to 70°C
Relative humidity:	Electrodes: 35% to 50% System & Batteries: 15% to 90%	Electrodes: 35% to 50% System & Batteries: 15% to 90%
Atmospheric pressure:	700hPa to 1060hPa	700hPa to 1060hPa
Stimulator size:	125 x 70 x 26 mm	
Battery:	PP3, 9V	
Battery life of average use:	Alkaline battery: 6 to 12 weeks	
Stimulator weight:	165g with battery	

Feedback

We are looking to improve our products and make them more suitable for the needs of patients and therapists. Please contact us with your ideas for improvements. Whilst we may not be able to change products that are in production we welcome ideas that we can incorporate into future developments.

Special Requirements

The Microstim2 may be supplied with different parameters if required. Please address any such requests to sales@odstockmedical.com

EC REP
Emergo Europe
WestervoortSedijk 60
6827 AT Arnhem
The Netherlands

Odstock Medical Limited
The National Clinical FES Centre
Salisbury District Hospital,
Salisbury, Wiltshire SP2 8BJ
United Kingdom

+44 (0) 1722 439540

www.odstockmedical.com

enquiries@odstockmedical.com

Registered Company No. 5532620

Revision: 3.0
Manual Product Code: 11-003-0028
QF/018

OML
Leading Rehabilitation Through Technology

CE 2797

NHS Salisbury NHS Foundation Trust