INSTRUCTION MANUAL

Microstim2

The output of this device has a physiological effect.

Read the instructions and precautions before use.

The device should only be supplied and set-up by a trained clinician.

…a confident choice

OML | Leading Rehabilitation Through Technology

NHS Salisbury NHS Foundation Trust

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Microstim2 Kit Contents

Description	Product Code	Qty
Microstim 2V2	01-001-0015	1
Electrode Lead 1m	03-001-0008	2
Electrodes, Grey, 30x50mm	01-004-008	1 pack of 4 electrodes
Battery,PP3, 9V	05-001-0002	1
Instruction manual	11-003-0008	1
Warranty Card	11-003-0067	1

Introduction

Intended Use Statement

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

General Description

The Microstim2 neuromuscular stimulator is intended for the exercise of weak or paralysed muscle. It is designed to be simple to use with the minimum necessary user controls. The output stimulation intensity is ramped at the beginning and end of each cycle by pulse width modulation to produce a comfortable sensation. Powered by a standard 9V battery, this makes it ideal for use at home for regular exercise.

Warranty

The Microstim2 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 and the warranty registration card has been completed and returned to Odstock Medical Limited as soon as possible. Alternatively, this information can be completed online at: www.odstockmedical.com

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 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 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 is turned off before adjusting the electrodes. Only apply electrodes as described in this instruction manual.

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 27 If the Microstim2 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, 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 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

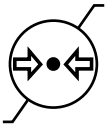
Odstock Medical Limited
National Clinical FES Centre
Salisbury District Hospital
Salisbury, Wiltshire, UK

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.

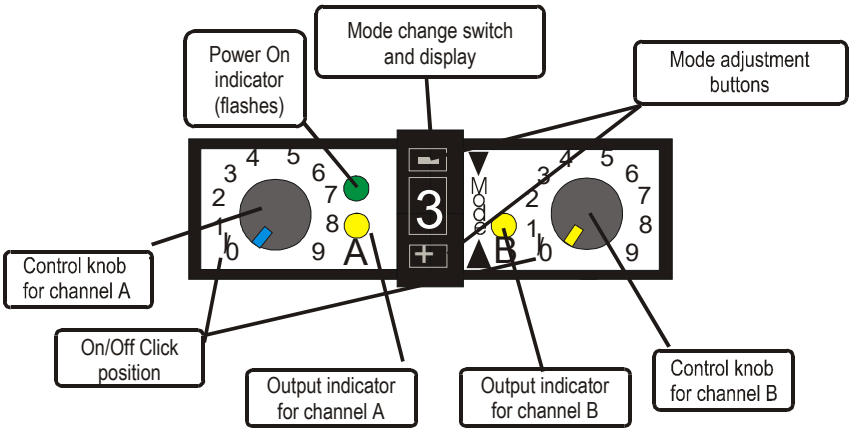
REF

Odstock Medical Limited stimulator reference number

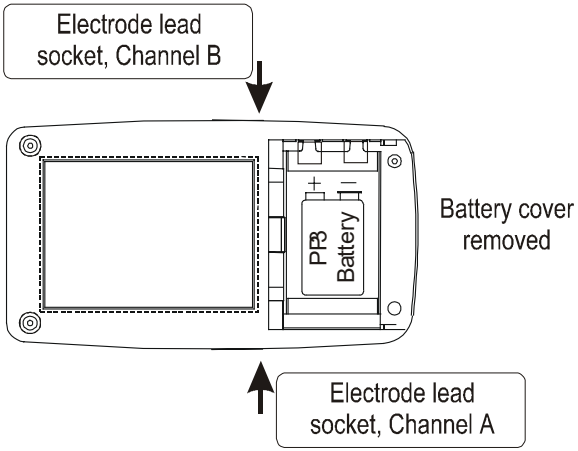
EC REP

European authorised representative.

Front Cover:



Underneath View Showing Battery Location and Electrode Sockets:

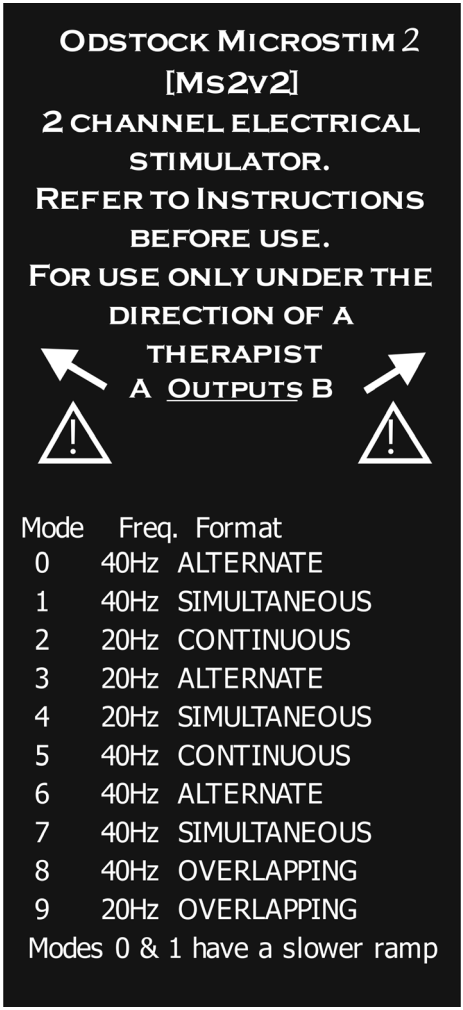


Controls & Indicators

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

Eight modes (0-7) are provided for general exercise with modes 8 & 9 provided for more specialised exercise. The stimulation formats are summarised in the following table and explained fully below.

A continuous mode is useful when finding the correct electrode sites.

Mode	Frequency	Format	Possible Use
0	40Hz	ALTERNATE Slow ramp (6s)	• Exercise modes for possible improvement in muscle fatigue resistance etc. • A slow ramp is used when there is a high level of spasticity
1	40Hz	SIMULTANEOUS Slow ramp (6s	
2	20Hz	CONTINUOUS	• Setting up electrode positions and stimulation levels
3	20Hz	ALTERNATE	• Normal quadriceps exercise mode
4	20Hz	SIMULTANEOUS	• For simultaneous contraction of 2 sets of muscles e.g. hand stimulation
5	40Hz	CONTINUOUS	• Setting up electrode positions and stimulation levels or when using a probe
6	40Hz	ALTERNATE	• Normal common-peroneal exercise mode
7	40Hz	SIMULTANEOUS	• For simultaneous contraction of 2 sets of muscles
8	40Hz	OVERLAPPING	• Shoulder subluxation
9	20Hz	OVERLAPPING	• Shoulder subluxation – reduced fatigue

Changing Modes

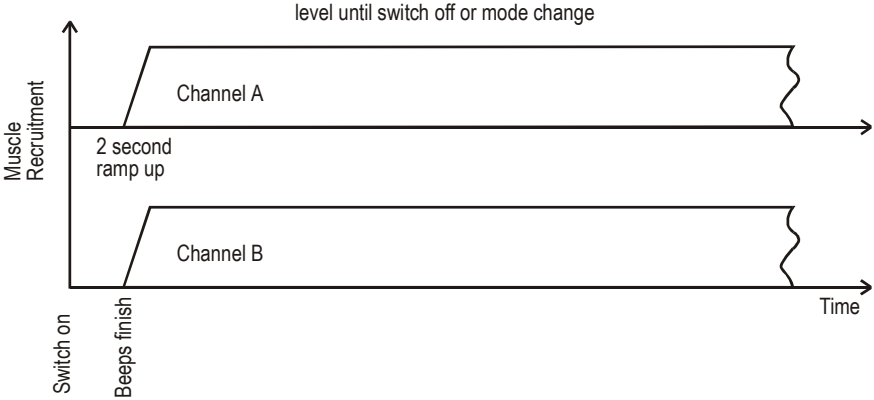
While the stimulator is operating, the mode switch can be used to change to a stimulation mode which has the same stimulation frequency. For example, while exercising on mode 3 the user may only select modes 2 or 4. After a short delay

the stimulation intensity will decrease to zero and a bleep will inform the user that the mode has changed. The intensity will then increase to the previously set level and exercise will continue in the new mode. If a mode with a different stimulation frequency is required, it is necessary to switch OFF the stimulator, select the new mode and then switch ON the stimulator. This is a safety feature to avoid unexpectedly high stimulation levels.`

Stimulation Formats

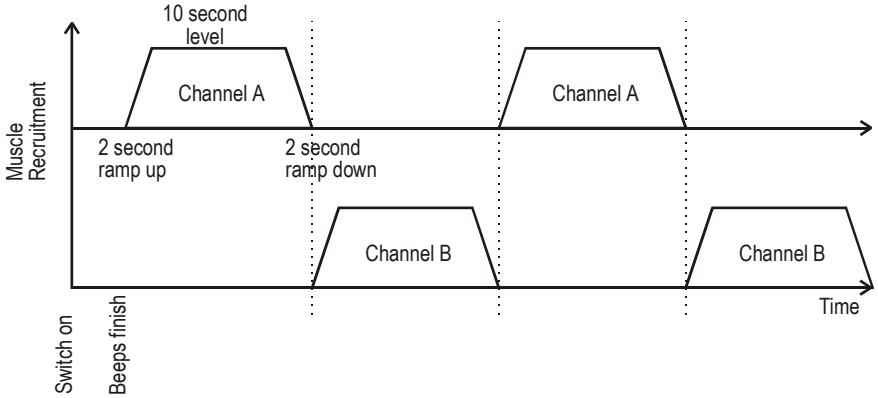
The formats continuous, alternate, simultaneous and overlapping describe the manner in which the intensity of the stimulation output of channels A & B change relative to each other.

Continuous



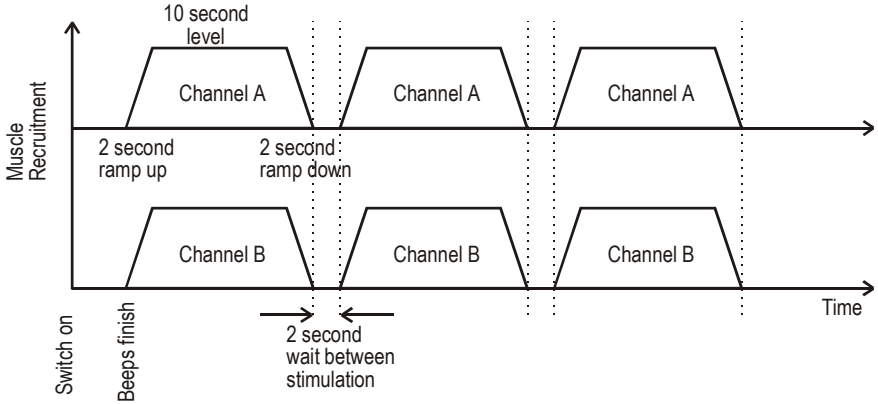
The intensity of both outputs gradually increases from zero to the maximum set by each channel level control and remains at this level until another mode is selected or the stimulator is switched off. This format is normally used before an exercise period to allow location of optimum electrodes positions and comfortable stimulation levels.

Alternate



The intensity of each output gradually increases from zero to the maximum set by the channel level control, remains at this level for a set time and gradually decreases 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 the quadriceps or agonist / antagonist muscle pairs.

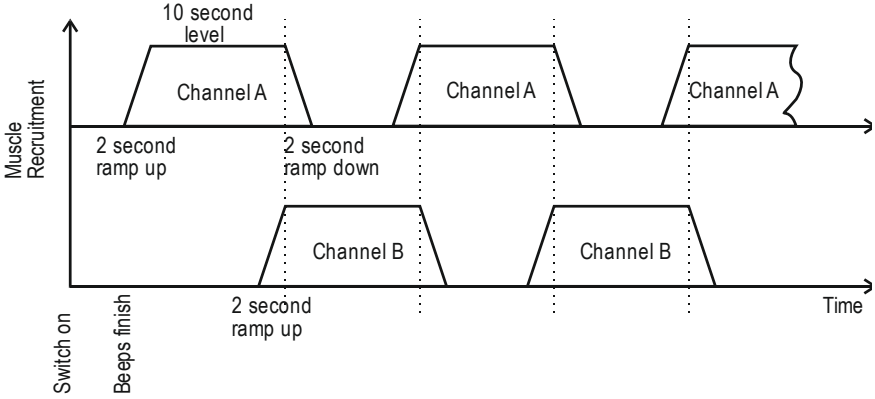
Simultaneous



The intensity of both outputs gradually increases from zero to the maximum set by each channel level control, remain at this level for a set time and gradually

decrease 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. Elbow and finger extensors.

Overlapping



Channel A is the first to ramp up to the maximum pulse width. While A is still on, channel B ramps up as well, after 8 seconds. When B reaches maximum pulse width channel A starts to ramp down to zero. Channel B continues and channel A ramps up again. When A is at maximum channel B ramps down. Channel A then continues and B will ramp up again and the sequence repeats. Overlapping mode is used for shoulder subluxation exercise. One electrode pair is placed over the anterior and posterior deltoid muscles and the other over the supraspinatus and middle deltoid muscles. The first pair of muscles lifts the humerus into the glenoid-humerus socket while the second pair maintains it in that position while the first pair is resting.

To avoid unexpected changes in muscle contraction, only adjust the stimulation intensity while the yellow LED next to the intensity control is lit.

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.

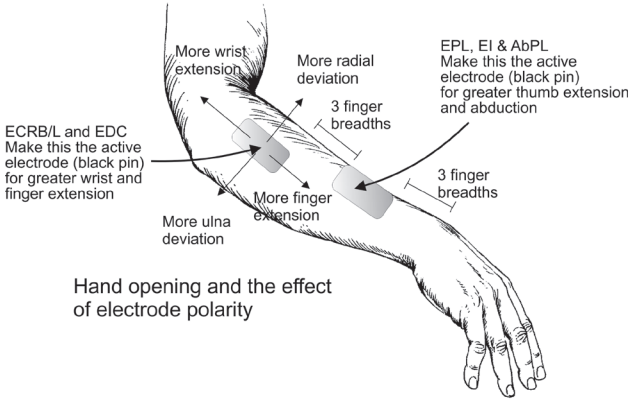
3. Place the electrodes on the skin in the desired positions. The electrode with the black plug is the active electrode. The electrode with the red plug is the indifferent electrode Adhesive tape will be required to hold the electrodes in place. Care should be taken when putting on clothing over the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



Hand opening and the effect of electrode polarity

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.

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.

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 (20 or 40Hz).

Stimulation wave form: Nominally square with passive charge balancing.

Stimulation pulse width: 330µs maximum .

The Microstim2 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
Microstim 2V2	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

Notes

Notes

Notes

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Registered Company No. 5532620
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Revision: 13.00
Manual Product Code: 11-003-0008
QF/018

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CE 2797

NHS Salisbury NHS Foundation Trust