SIS MACHINES

TECHNICAL OPERATING MANUAL_M250/M250MA_v2.0

This operating manual is downloadable from https://siselectromed.com/

Due to periodic revisions, always check that you are reading the most up to date version of this manual.

PLEASE READ THIS MANUAL CAREFULLY BEFORE USING THE SIS EQUIPMENT FOR CORRECT AND SAFE OPERATION.

CONTENTS

DELIVERY AND UNPACKING

Please unpack the shipping package carefully and inspect contents immediately on receipt. Check that all ordered equipment is included in the shipping box and notify SIS Manufacturing Ltd New Zealand immediately of any missing items from your order.

Visible damage or tampering to shipping boxes must be recorded before signing the delivery receipt. Please take photographs of any received damaged items. Report the damage or tampering immediately to the shipping carrier. You must also notify SIS Manufacturing Ltd immediately of any received damaged or tampered items or of any lost shipments.

⚠ WARNING FOR BIOLOGICAL APPLICATIONS

THE SIS MACHINES MODELS M250/M250MA ARE ELECTRONICALLY CALIBRATED WITH EXTREME PRECISION FOR THERAPEUTIC BIOLOGICAL ELECTRO-STIMULATION IN COMBINATION WITH THE SIS SILVER-NYLON ELECTRODES. USE OF OTHER ELECTRODES CAN CAUSE ADVERSE AND UNPREDICTABLE BIOLOGICAL EFFECTS. FOR OTHER BIOLOGICAL ELECTRO-STIMULATION APPLICATIONS, IF SIS SILVER-NYLON ELECTRODES CANNOT OR ARE NOT USED, ONLY USE SURFACE, INSERTED OR IMPLANTED ELECTRODES APPROVED FOR BIOLOGICAL CONTACT AND MEDICAL/THERAPEUTIC APPLICATIONS. READ THE CONTRAINDICATIONS AND SAFETY INSTRUCTIONS IN THIS MANUAL BEFORE USING THIS EQUIPMENT.

DEVICE DESCRIPTION

The SIS machines M250/M250MA models are designed for electromedical, nanoampere to low milliampere direct current (DC) electrotherapy applications, and for low intensity (amperage) DC silver iontophoresis stimulation (SIS) when used with SIS electrodes. The M250MA can be used for liquid medication intophoresis, and for cell apoptosis stimulation. The M250/M250MA are also designed for use as a nanoampere to low milliampere (M250MA) constant-current generators for non-medical, non-therapeutic, non-diagnostic, research, laboratory and experimental purposes, Life Sciences, and water treatment.

1. POWER SOURCE

The M250/M250MA is powered by replaceable AAA type batteries. Rechargeable batteries can be used and do not compromise the correct function of the device. Refer to section 15. DEVICE SPECIFICATIONS for further information.

⚠ Do not use zinc-carbon batteries that can leak and damage the device.

1.1. INSERTING AAA BATTERIES

A. POWER OFF the device if it is operating.
B. Remove the shockproof silicon cover from the casing.
C. Remove the battery compartment cover.
D. Insert 3×AAA batteries. Ensure correct polarity of the batteries—follow the battery diagram and ⊕⊖ polarity symbols inside the battery compartment.
E. Replace the battery compartment cover.
F. Replace the shockproof silicon cover over the casing.

2. ELECTRODE CABLE CONNECTION

2.1. CONNECTION OF ELECTRODE CABLE (HARNESS)

Unplug the Seal Cap from the connection socket (Jack) in the top end panel of the device. Insert the cable connector plug all the way into the connection socket. Screw tighten the Locking Ring on the cable connector plug to the socket; DO NOT use excessive force.

2.2. CABLE TESTING

Perform a cable connection and integrity test from the CABLE TEST screen before each application.

3. KEYPAD CONTROLS AND OPERATION

<table>
<tr><td>POWER
⏻
ON OFF</td><td colspan="4">Power device ON, 2 seconds hold.
Power device OFF, 5 seconds hold.</td></tr>
<tr><td>Main Operating Screen</td><td colspan="4">Output CURRENT and STATUS displayed</td></tr>
<tr><td>PROGRAM</td><td>Access Main Menu</td><td colspan="3" rowspan="2"></td></tr>
<tr><td rowspan="11"></td><td>⇩ ⇧ scroll through Main Menu options</td></tr>
<tr><td>EXIT</td><td rowspan="10">PROGRAM
to select</td><td colspan="2">Return to Main Operating Screen</td></tr>
<tr><td>STIM DATA</td><td>Output Current and Voltage and measured bioelectric data</td><td rowspan="10">PROGRAM
or ⇩ ⇧
return to Main Menu</td></tr>
<tr><td>STATISTICS</td><td colspan="2">Electrode stimulation efficiency data</td></tr>
<tr><td>CABLE TEST</td><td>Instructions 1
PROGRAM
Instructions 2
PROGRAM</td><td>Result:
PASSED
or
FAILED</td></tr>
<tr><td>DISPLAY</td><td colspan="2">⇩ ⇧
AUTO-OFF (DEFAULT) or ALWAYS ON</td></tr>
<tr><td>TIMER</td><td colspan="2">Session duration data</td></tr>
<tr><td>MONITORING</td><td colspan="2">⇩ ⇧
AUTO (DEFAULT) or OFF</td></tr>
<tr><td>POLARITY</td><td colspan="2">⇩ ⇧
AUTO (DEFAULT) or OFF</td></tr>
<tr><td>ABOUT</td><td colspan="2">Information about device</td></tr>
<tr><td>DISPLAY</td><td colspan="4">Sound turned ON or OFF, 2 seconds hold.
OLED display turned ON or OFF, 1 second hold, when DISPLAY set to AUTO-OFF (DEFAULT).</td></tr>
</table>

The default device settings after powered on are OLED display and sound turned on.

If no keypad input is detected during normal **STATUS: OK** operation and the AUTO-OFF default DISPLAY setting has not been changed to ALWAYS ON, then the display turns off after 2 minutes for power saving.

At any time when the menu is accessed, if no user input is detected after 2 minutes, the device automatically powers off.

The red **BATTERY CHARGE** LED flashes every 5 seconds while the device is operating; the LED is not under user control.

APPLICATIONS

4. SIS electrodes

NOTE: Position and secure the SIS electrodes to the body first, and then connect the SIS electrode cable to the two SIS electrode wires.

NOTE: Read and follow the INSTRUCTIONS FOR USE (IFU) on the IFU card included in each SIS electrode pack.

4.1. Electrode size

4.1.1. INTERNAL INFECTIONS

The SIS (+)positive electrode must completely 'cover' a target internal organ or other anatomical structure or area. The electrode must be at least the same size or slightly larger than the target internal organ or other anatomical structure as it would be seen 2-dimensionally in a diagnostic X-ray/CAT scan/ MRI scan/ultrasound taken from the position and anatomical plane of the electrode on the body surface.

The SIS (-)return electrode should be (approximately) the same size or larger than the SIS (+)positive electrode.

4.1.2. SURFACE INFECTIONS

Use an SIS electrode size that most closely matches the dimensions of the opposite sides of the area of the infection, where the electrodes will be positioned. For example, for an area of infection that can be totally contained

within a 2cm×10cm rectangle, the 4.75cm ødiameter round SIS electrodes should be applied next to the 2cm length sides of the infected area, or the 10cm×15cm SIS electrodes should be applied across the 10cm length sides.

NOTE: Do not use over-sized SIS electrodes. The M250/M250MA can more accurately monitor electrode↔skin contact the smaller the electrode size.

4.2. Securing SIS electrodes

The contact of the entire surface of an electrode placed onto non-damaged skin should be as uniform as possible to surface anatomy geometry.

NOTE: The silver-nylon side of an SIS electrode is the active surface that contacts the body.

Use adhesive fixation tape, stretch strap, bandages or other emergency means to secure the electrode to the body; adhesive tape should extend beyond all edges of the electrode.

! IMPORTANT INFORMATION:

RECOMMENDED ELECTRODE LIFETIME FOR SEVERE INFECTION :

SIS (+)POSITIVE (RED WIRED) ELECTRODE: 12-24 HOURS

SIS (-)RETURN (BLACK WIRED) ELECTRODE: 12-48 HOURS

4.3. Connection of electrode cable to electrodes

- The SIS electrode that is connected to the **red** wire of the electrode harness is the SIS **(+)positive electrode**.
- The SIS electrode that is connected to the **black** wire of the electrode harness is the SIS **(-)return electrode**.

Insert the two gold metal 'banana plugs' at the ends of the black and red wires of the electrode cable into the two white plastic connectors at the ends of the SIS electrode wires; insert the 'banana plugs' all the way in until they are no longer visible.

NOTE: Do not tape the connections of the electrode cable to the electrode wires as doing so can cause excessive mechanical force on the cable connection to the electro-stimulator.

5. Infection treatments

! NOTE: The SIS machines M250/M250MA can be targeted at almost any infected anatomical structure or location. However, the devices cannot determine the type of microbe(s) present; standard diagnostics and differentiating information based on anatomical location, clinical signs, presentation and/or laboratory testing must be applied.

5.1. Electrode positioning

Diagrams of typical SIS electrode positionings for common infections are available from: **https://siselectromed.com/applications**

NOTE: Avoid positioning electrodes over bones wherever possible.

5.1.1. INTERNAL INFECTION

A. Position the SIS (+)positive electrode onto intact skin skin directly over the target infected organ or other anatomical structure.

B. Position the SIS (-)return electrode onto intact skin on the opposite anatomical surface of the body to the SIS (+)positive electrode so that the target infected organ or other anatomical structure is aligned between the two SIS electrodes.

5.1.2. SURFACE INFECTION

A. Position the SIS (+)positive and (-)return electrodes on opposite sides across and as close as possible to the target infected area; do not place electrodes on the infected area.

6. OUTPUT CURRENT

Adjust ⇩ ⇧ and PROGRAM the output **CURRENT** for either a bacterial or viral infection treatment:

- Bacterial infection treatment or *in vitro* anti-bacterial effect: use the default output **CURRENT** setting of **2.5 microAmps**.

- Viral infection treatment or an *in vitro* anti-viral effect: adjust the output **CURRENT** to **7.5 microAmps**.

7. Direct Current (DC) Electrotherapy

The M250 (M250MA) is a multirole microcurrent (and milliampere) electro-stimulator.

If necessary, use the alligator clip adapters supplied with the SIS machine to convert the M250/M250MA electrode harness for connection to many other electrodes. Insert the gold 'banana plugs' at the ends of the black and red wires of the electrode harness into the plastic connector ends of the adapters.

7.1. OUTPUT CURRENT POLARITY

(+)positive conventional current polarity is produced by the M250/M250MA.

The **black-wired ‘banana plug’** of the electrode cable is the conventional **(-)negative terminal (electrode)**. The **red-wired ‘banana plug’** is the conventional **(+)positive terminal (electrode)**. That is, there is a galvanic cell polarity current flow out of the device.

To model the current flow produced inside the body, the electrolyte cell model is most appropriate to apply between the terminals of the electrode cable.

These theories and conventions come from the basic definitions of Anode and Cathode, as the poles that an Anion (+ve charge) and Cation (-ve charge) are attracted to, respectively.

For practical electrotherapy considerations, these differences are summarized in the following table:

ELECTRIC CELL TYPE	ENERGY CONVERSION	CONVENTIONAL CURRENT FLOW	ELECTRON FLOW	ELECTRODE TERMING
Galvanic	Chemical energy into electrical energy.	Flows out of the (+)terminal and into the (-)terminal.	Reverse direction to conventional current flow.	(+)electrode is the Cathode. (-)electrode is the Anode.
Electrolytic	Electrical energy into chemical energy.	Flows out of the (-)terminal and into the (+)terminal.	Reverse direction to conventional current flow.	(+)electrode is the Anode. (-)electrode is the Cathode.

7.2. OUTPUT CURRENT POLARITY REVERSAL

The M250/M250MA reverses the direction of current flow for 10 seconds every 10 minutes. This function has been factory programmed for use of the device with SIS electrodes, for removing electro-chemical debris from the active surfaces of the electrodes resulting from the reduction and oxidation reactions from the applied electric voltages.

NOTE: For most DC applications where other non-SIS electrodes are used, this function is not required and can be turned **OFF** in the POLARITY screen.

7.3. ELECTRODE STIMULATION EFFICIENCY (ESE) MONITORING

The M250/M250MA monitors the contact of the SIS or other electrode(s) with the body, or with the stimulation target for *in vitro* applications, in real-time and statistically via complex measurement, logging and assessment algorithms with self-adaptive AI aspects. The highly summarized logged ESE data are shown in the STATISTICS screen.

ESE monitoring can be turned **OFF** for various DC electrotherapy applications in the MONITORING screen. When ESE is disabled, no data are shown in the STIM DATA and STATISTICS screens.

7.4. TYPES OF ELECTRODES

Many types of cutaneous or inserted electrodes can be used with the M250/M250MA, specific to the DC electrotherapy application. Refer to section 9. ELECTROTHERAPY ELECTRODE↔SKIN CONTACT for further information.

7.5. DC electro-acupuncture

DC electro-acupuncture (E-AP) clinical applications utilizing the DC electrical properties of the acupuncture meridians and their basic relationship with neuroanatomy and neurophysiology.

It will usually be advantageous to turn **OFF** ESE monitoring for most E-AP applications, especially when inserted AP needles are used. Refer to sections 7.3. and 9 for further information.

7.5.1. ELECTRODES

Use the alligator clip adapters to modify the gold metal 'banana plugs' at the ends of the electrode cable for connection to the metal parts of the shafts of inserted AP needles, or to non-invasive AP point electrodes and probes. Usually, nanoampere (**nanoAmps**) stimulation is the appropriate output **CURRENT** range, and is highly therapeutically effective for DC E-AP. Higher currents do not usually have any or have much less therapeutic effects.

Supporting and clinical guidance literature is available from:
https://siselectromed.com/research/#microcurrent

SIS Manufacturing does not supply nor recommend individual E-AP protocols nor treatments. DC E-AP is an advanced clinical AP application to be performed by a specialist E-AP practitioner.

7.6. DC battlefield acupuncture (BFA)

Battlefield Acupuncture (BFA) for clinic, home or emergency field use. Simple, fast, needle or non-invasive ear BFA point treatment for pain relief.

Turn **OFF** ESE monitoring (see section 7.3). Refer to section 9. for further information.

7.6.1. ELECTRODES

Use inserted needle or non-invasive contact probe electrodes.

Supporting and clinical guidance literature is available from
https://siselectromed.com/research/#microcurrent

SIS Manufacturing does not supply nor recommend individual BFA protocols nor treatments. Refer to the published literature or consult your healthcare professional.

7.7. Transcranial DC stimulation (tDCS)

Polarity-dependent cortical (brain) modulation of neural networks and spontaneous neuronal activity. tDCS is a type of trans- cranial electrical stimulation (CES).

It may be advantageous to turn **OFF** ESE monitoring for some applications (see section 7.3). Refer to section 9 for further information.

7.7.1. ELECTRODES
Use SIS silver-nylon cloth or standard self-adhesive hydrogel electrodes. Refer to section 7 for further information.

SIS Manufacturing does not supply nor recommend individual tDCS protocols nor treatments. Refer to the published literature or consult your healthcare professional.

7.8. Low intensity DC microcurrent electrical neuromuscular stimulation (MENS)
Injured muscle regeneration enhancement treatment.

7.8.1. ELECTRODES
Use SIS silver-nylon cloth or standard self-adhesive hydrogel electrodes. Refer to section 7 for further information.

Supporting and clinical guidance literature is available from:
https://siselectromed.com/research/#microcurrent

SIS Manufacturing does not supply nor recommend individual MENS protocols nor treatments.

7.9. Scar pain treatment
Drug free, non-invasive deactivation and treatment of persistent pain in scars.

Turn **OFF** ESE monitoring if using a contact probe type electrode (refer to section 7.3.).

7.9.1. ELECTRODES
Use non-invasive contact probe, SIS silver-nylon cloth, or standard self-adhesive hydrogel electrodes.

Supporting and clinical guidance literature is available from:
https://siselectromed.com/research/#microcurrent

SIS Manufacturing does not supply nor recommend individual scar pain treatment protocols nor treatments.

7.10. Ionic solution medication iontophoresis

M250MA drug iontophoresis, also termed transcutaneous drug delivery.

Maximum stimulation current is 2.0 mA. Refer to section 15. DEVICE SPECIFICATIONS for more information.

Adjust ⇩ ⇧ and PROGRAM the required milliampere (**milliAmps**) output **CURRENT**.

The maximum Output Current achievable at any time during medication solution iontophoresis is dependent on the actual total circuit resistance. Refer to 9.1. MAXIMUM OUTPUT CURRENT and monitor on-screen alerts.

It may sometimes be advantageous or necessary to turn **OFF** ESE monitoring (see section 7.3.) depending on the specific conductivity properties of the active (medication soaked) electrode. Refer to section 7. for further information.

7.10.1. ELECTRODES

Use a standard silver-silver chloride or other pH buffered iontophoresis electrode as the medication delivery (+)electrode.

Use a 4.7cm (1.87 inch) ødiameter circular SIS electrode for the (-)return electrode, in order to achieve a maximal Output Current upper limit.

Refer to 7.1. OUTPUT CURRENT POLARITY for correct electrode cable connections.

Clinical practice information is available from:
http://www.electrotherapy.org/modality/iontophoresis

SIS Manufacturing does not supply nor recommend individual drug iontophoresis treatment protocols nor treatments.

7.11. Cellular apoptosis stimulation

7.11.1. ELECTRODES AND TREATMENT

Use SIS silver-nylon cloth electrodes for this application due to their lower contributing electrical resistances.

Silver iontophoresis is not required for this application; this is a DC electrotherapy stimulation application only. High quality conductive electrotherapy gel can be applied to the silver-nylon surfaces (electrically active side) of the SIS electrodes before placing them on the skin, instead of the usual method of wetting these surfaces. In some instances, the conductive gel advantageously decreases the contributing electrical resistances of the electrode↔skin contact areas below the values achieved with wet SIS electrodes. Refer to the section 7 for further explanation.
The positioning and application of the SIS electrodes in relation to the target tissue is the same as for infection treatment. Read the following sections for instructions:

- 4.1. Electrode size
- 4.2. Securing SIS electrodes
- 4.3. Connection of electrode cable to electrodes
- 5.1.1. Internal infection or 5.1.2. Surface infection

Adjust ⇩ ⇧ and PROGRAM the required milliampere (**milliAmps**) output **CURRENT**.

Supporting and clinical guidance literature is available from:
https://siselectromed.com/research/#lidc

SIS Manufacturing does not supply nor recommend individual cell apoptosis treatment protocols nor treatments.

7.12. Laboratory and research use

The M250/M250MA can be used as a low intensity (amperage) direct constant-current generator.

Applications include any nanoampere to microampere (low milliampere for M250MA model) constant-current generation.

Refer to section 15. DEVICE SPECIFICATIONS for further information.

It may be advantageous to turn **OFF** ESE monitoring for some *in vitro* applications. Refer to sections 7.3. and 9 for further information.

8. AUDIO AND VISUAL ALERTS

Alert Message	Meaning / Notes	Action
STANDBY CALIBRATING	Device is calibrating to programmed Output Current.	Wait.
STATUS: OK	Device is operating within normal limits. Electrode contact is established.	None.
STATUS: ALERT	Problem detected with electrode contact.	Follow alert message instructions.
Output Current value flashing	Total circuit resistance exceeds operating limits for programmed Output Current.	Refer to section 9.1. MAXIMUM OUTPUT CURRENT
POOR CONTACT	Electrode contact is insufficient for therapeutic effect, due to mechanical (physical) and/or electro-chemical factors.	Follow alert message instructions. Replace or apply additional dressing tape to electrodes (pads) if necessary.
UNSTABLE CONTACT	Electrode contact is varying too rapidly for therapeutic effect.	
CIRCUIT BREAK	No electrical stimulation circuit.	Follow alert message instructions.
HIGH RESISTANCE	Cautionary alert only. Device is operating within normal limits. Alert will automatically de-activate after 30 seconds.	Follow alert message instructions. Check skin for redness or other signs of irritation.
BATTERY CHARGE LOW	Remaining charge in the replaceable batteries is below the minimum operating level.	Replace batteries.
CANNOT CALIBRATE	Device cannot calibrate due to alerted, uncorrected electrode contact problem.	Wait for device to power off. Re-check appropriate application instructions. Power on device again if necessary.
POWERING OFF	Device is powering off due to uncorrected alert status, discontinued user input in menu screen, low battery charge, or user powering off device.	

9. ELECTROTHERAPY ELECTRODE ↔ SKIN CONTACT

Electrical resistance, which is part of total electrical impedance to the flow of electric current, is measured in units of Ohms (Ω):

1 megaOhm (MΩ) = 1000 kiloOhm (kΩ) = 1,000,000Ω

The total circuit resistance during non-invasive electrotherapy stimulation via any pair of any type of electrode is the sum of the electrical resistances at both the electrode ↔ skin/body contact areas, and the internal body electrical resistance(s) in the pathway(s) of electric current between the two electrodes. Large variations in total circuit resistance up into the MΩ range can occur depending on many device-related and bioelectric factors.

A major factor that affects electrode ↔ skin contact area electrical resistances is moisture; the wetter these areas the lower their contributing electrical resistances to total circuit resistance.

The top layer of skin, called the stratum corneum, consists mainly of dead skin cells, and usually contributes most to the total circuit resistance. Gently washing intact skin with a clean, wet sponge or cloth can reduce the contributing electrical resistance of this outermost skin layer.

Different electrotherapy electrodes contribute varying electrical resistances, due to their material composition, size, shape, and conformity to the body surface during cutaneous application. Especially common are self-adhesive ‘hydrogel’ types.

The following table compares standard hydrogel electrodes and SIS silver-plated nylon cloth electrodes, for practical electrotherapy:

ELECTRODE TYPE	TYPICAL TOTAL CIRCUIT RESISTANCE PER PAIR	NOTES
Self-adhesive hydrogel	≥400 kiloOhm.	Check that the hydrogel layer remains sticky at all times; re-wet/replace as frequently as needed.
SIS silver-nylon cloth	≤50 kiloOhm. Contributes lower circuit resistance than standard electrotherapy electrodes.	Follow INSTRUCTIONS FOR USE (IFU) on the IFU card inside each SIS electrode pack. Electrodes must be kept moist during use.

M250/M250MA FUNCTIONS

Total circuit resistance is shown in the STIM DATA screen as **RES** and updates every 30 seconds with an average value of multiple real-time measurements. The Output Voltage that produces the programmed output **CURRENT** with the given **RES** is shown as **VOLTS**.

The M250/M250MA operates more power efficiently with lower **VOLTS** the lower the **RES** value, and vice versa; there is no operational **RES** lower limit. The M250/250MA continuously and rapidly self-adapts to the electrical resistance dynamics of the electrode ↔ skin contact areas.

A **VOLTS** level and spike monitoring algorithm assesses 10 minute stimulation periods at a time, and is calibrated in relation to a relatively low ≤ 50-100 kΩ **RES** value, in order to assess early possibility of skin irritation during extended device application.

9.1. MAXIMUM OUTPUT CURRENT

The maximum total circuit resistance **RES** operating limit of the M250/M250MA for any programmed output **CURRENT** can be computed via the Ohm's Law equation, using the maximum Output Voltage in Current Stimulation Mode value for the M250/M250MA given in section 15. DEVICE SPECIFICATIONS.

10. CONTRAINDICATIONS AND SAFETY

DO NOT POSITION ELECTRODES OVER THE BRAIN. CONSULT WITH A SPECIALIST HEALTHCARE PROFESSIONAL BEFORE APPLICATION.

DO NOT POSITION ELECTRODES OVER THE HEART (CENTRAL AND LEFT SIDE OF CHEST). CONSULT WITH A SPECIALIST HEALTHCARE PROFESSIONAL BEFORE APPLICATION.

DO NOT POSITION ELECTRODES ON THE ABDOMEN IF THE SUBJECT IS PREGNANT OR MIGHT BE PREGNANT.

DO NOT POSITION ELECTRODES NEAR A PACEMAKER OR OTHER IMPLANTED ELECTRO-STIMULATOR. CONSULT WITH A SPECIALIST HEALTHCARE PROFESSIONAL BEFORE APPLICATION.

DO NOT POSITION ELECTRODES ACROSS THE EYES. CONSULT WITH A SPECIALIST HEALTHCARE PROFESSIONAL BEFORE APPLICATION.

DO NOT POSITION ELECTRODES ACROSS THE ANTERIOR NECK (CAROTID SINUS). CONSULT WITH A SPECIALIST HEALTHCARE PROFESSIONAL BEFORE APPLICATION.

DO NOT USE THE ELECTRO-STIMULATOR IF THERE IS A HISTORY OF SEIZURES. CONSULT WITH A SPECIALIST HEALTHCARE PROFESSIONAL BEFORE APPLICATION.

DO NOT EXPOSE THE ELECTRO-STIMULATOR TO WATER. DISCONNECT ELECTRODES FROM HARNESS (CABLE) OR REMOVE FROM BODY WHEN ENTERING WATER.

DISCONTINUE USE IF SKIN IRRITATION OCCURS.

KEEP AWAY FROM CHILDREN.

11. MEDICAL DISCLAIMER

NO ADVICE

Information provided for education and research information only. This manual contains general information about medical conditions and treatments. The information is not advice, and should not be treated as such. The information in this manual is made available on the basis that no professional advice on a particular medical matter is being provided. No liability is accepted for any injury, loss or damage incurred by use of or reliance on the information provided in this manual.

PROFESSIONAL ASSISTANCE

You must not rely on the information in this manual as an alternative to, or substitute for, medical advice from your professional healthcare provider. If you have any specific questions about any medical matter you should consult your professional healthcare provider. If you think you may be suffering from any medical condition you should seek immediate medical attention. You should never delay seeking medical advice, disregard medical advice, or discontinue medical treatment because of information in this manual.

LIMITATION OF WARRANTIES

The medical information in this manual is provided “as is” without any representations or warranties, express or implied. SIS Manufacturing Ltd NZ makes no representations or warranties in relation to the medical information in this manual. Without prejudice to the generality of the foregoing paragraph, SIS Manufacturing Ltd NZ does not warrant that: the medical information in this manual will be constantly available, or available at all; or the medical information in this manual is complete, true, accurate, up-to-date, or non-misleading. Nothing in this medical disclaimer will limit any of the liabilities of SIS Manufacturing Ltd NZ in any way that is not permitted under applicable law, or exclude any of its liabilities that may not be excluded under applicable law.

12. WATER TREATMENT

Adjust the output **CURRENT** to **20 microAmps**.

Disable Electrode Stimulation Efficiency (ESE) monitoring. Refer to section 7.3. for instructions.

Use the alligator clip adapters supplied with the SIS machine to convert the terminals of the SIS electrode cable for connection to pure silver metal rods.

Immerse the two rods into the water at opposite edges of the water container. The two rods must not contact each other. The interior surface of the water container should not be metallic, and a glass container is best.

The maximum recommended volume of water that can be treated using this method is 1 liter.

The changing ionic silver particle concentration over time in the water can be assessed using a water electrical conductivity or total dissolved solids meter (not supplied with the SIS machine).

NOTE: To produce pure ionic silver solution (often termed “colloidal silver”), distilled or highly purified water must be used, preferably with a starting electric conductance measurement of ≤1-4 microsiemens (µS).

13. MAINTENANCE

13.1. DEVICE

The device is maintenance free. Only wipe the external surfaces with a clean damp cloth. Do not use any kind of detergent or solvent. Avoid strong impacts on the device. Keep the protective shockproof silicon cover on at all times during operation and storage. Avoid leaving the device exposed to direct, strong sunlight. Do not leave on or next to heaters or other heat-emitting elements.

13.2. STORAGE

Remove the batteries from the device during long-term storage to prevent damage from battery leaks, and to avoid gradual draining of charge of the batteries. Store the device in a dry place away from heat-generating sources.

13.3. SIS ELECTRODES

The silver-nylon stimulation surface of an SIS electrode that has been applied only to normal intact skin can be cleaned by gently wiping with a clean damp cloth or cotton wool (use tap/other clean water) to remove dead skin cells, sweat and electro-chemical debris.

14. WARRANTY

SIS machine (“the Device”) models M250/M250MA/W250/WMcAMP/LVtC/PACSTIM carry a 5 year, limited Warranty for defects in materials, components, assembly and operation of its electronic hardware. This Warranty is subject to all of the following exclusions and conditions. The Device enclosure is not opened except the battery compartment nor tampered with in any manner. No modifications or repairs are made to the Device other than by one of our engineers. No voltage or current source is applied to the harness connection socket or to anywhere else on the Device. No power supply other than specified in the operating manual is applied to the Device. For biological applications, the Device has not been used with non-SIS electrodes that are not approved for skin contact, therapeutic and medical applications. The Device is not used beyond its intended applications. You can experiment with the Device if you wish, but subject to all other Warranty conditions and exclusions and not in such a way that could reasonably be expected to damage the Device in any way as determined by our engineers. SIS machine models M250/M250MA/W250/WMcAMP/LVtC/PACSTIM must not be used in any manner that requires an IP rating above IP40 to protect them from ingress of dust or other sub-1mm particulate matter, or that requires protection from water or other liquids that can damage or interfere with the internal electronics of the Device. The SIS electrode harness (connecting cable) plug and jack of the M250/M250MA/W250/WMcAMP/LVtC/PACSTIM models are IP68 rated when mated, and the jack is IP68 rated it is mated with the Seal Cap. The electrode harness is included in this Warranty only for a period of three months, on the condition that it is not used in any way that contradicts the recommendations for use given in this operating manual and Warranty. If a non-SIS electrode harness is used with the Device this warranty shall be void. This Warranty is expressly limited solely to the original purchaser of the SIS equipment and does not extend to any transferee or temporary user of the Device. This Warranty does not cover damage caused by improper connection of the components of the SIS equipment (harness, connectors, sockets, electrodes), damage caused by accident, abuse, misuse, neglect or improper maintenance, damage caused by unusual physical or electrical stress, routine cleaning or normal cosmetic and mechanical wear. Non-compliance to any degree with any one of these Warranty conditions shall automatically void this warranty completely. SIS Manufacturing Ltd New Zealand expressly disclaims all warranties not stated in this limited Warranty.

If a Device is found to be faulty, we promise to honor this Warranty as quickly and efficiently as we can and either repair or replace the defective Device at our discretion. We will return to the original purchaser a fully and correctly functional Device that meets all of its design and functional specifications perfectly, as speedily as possible.

4.7cm (1.87 inch) odiameto

14.1. Returns

Each SIS machine unit is assembled and factory calibrated in Australia. In case of suspected malfunction of an SIS machine unit, please contact SIS Manufacturing Ltd, New Zealand. Contact details are available on the siselectromed.com website. Do not return any goods without obtaining prior approval and return instructions from SIS Manufacturing Ltd. Please include your name, contact details and a full description of the faults you suspect or have experienced with the equipment. Please keep your proof of purchase.

14.2. Disposal

In case of replacement of any SIS machine part due to repair, exchange or future upgrade, we will optimally recycle the SIS equipment.

15. DEVICE SPECIFICATIONS

Parameter	Unit	Minimum	Typical	Maximum	Tolerance	Notes
Batteries	-	-	-	-	-	3 x 1.5V AAA Alkaline
Battery Life	Hours	-	20	-	-	Duracell Ultra Alkaline recommended
Output Voltage in Current Stimulation Mode	V	0	-	7.5 (11.8)*	-	Across 30kΩ 0.1% Sense Resistor†
Output Voltage in Voltage Stimulation Mode	V	0	5	5.5	-	-
Output Current	uA	0 (1.5)*	-	200 (2000)*	0-1.5 ±1~2% (1.5-20 ±~2%)* 1.5-200 ±1% (20-2000 ±1~2%)*	30kΩ load (3.5kΩ)*
Design Operating Range	°C	-20	+25	+80	-	-
Resistance Measuring	kΩ	0.1	-	10000	±5%	-

*M250MA variant

†Resistance value selected to simulate physiological bioelectric skin parameters with wet contact surface SIS electrode.

16. MANUFACTURER'S DECLARATION

ELECTROMAGNETIC COMPATIBILITY CONFORMITY

Conformity to EN 60601-1-2: 2015 Edition 4.0: Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests; partial testing in accordance with CISPR 11: 2010—Industrial, scientific and medical equipment—Radio-frequency disturbance characteristics—Limits and methods of measurement (Australia/New Zealand/(CE Europe)) & EN 61000-4-2: 2009—Electrostatic Discharge immunity CE (Europe), FCC 47 CFR Part 15 – Radio Frequency Devices, Subpart B – Unintentional Radiators, ANSI C63.4: 2014 American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz (North America), ICES-001—Industrial, Scientific and Medical (ISM) Radio Frequency Generators Issue 4 June 2006 (Updated November 2014) (CANADA).

The device is RoHS compliant.

The specifications, descriptions and data within this document are subject to change without notice. This publication supersedes all previous publications on this subject.

The SIS machines, SIS electrodes and SIS technology are patent pending devices. The SIS machine logo and “SIS” letters are Registered Trade Marks.

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