SIS MACHINES

TECHNICAL OPERATING MANUAL_M250/M250MA_v1.2

This operating manual is downloadable from https://www.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 the DEVICE SPECIFICATIONS section of this manual 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 (HARNESS) CONNECTION

2.1. CONNECTION OF ELECTRODE CABLE TO SIS MACHINE

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

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OLED display turned ON or OFF (1 second hold) when DISPLAY set to AUTO-OFF (DEFAULT).</td></tr>
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The default device settings after powered on are OLED display and sound turned on. NOTE: If no keypad input is detected during operation with **STATUS: OK** and the DISPLAY setting has not been changed from the default AUTO-OFF, then the display turns off for power saving after 2 minutes.

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

APPLICATIONS

4. 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.

It is usually easier to position and secure the SIS electrodes to the body first, and then connect the SIS electrode cable to the two SIS electrode wires.

Read and follow the INSTRUCTIONS FOR USE (IFU) on the IFU card included in each SIS electrode pack. **NOTE:** The silver-nylon side of an SIS electrode is the active surface that contacts the body.

4.1. ELECTRODE SIZE AND POSITIONING

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

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

4.1.1. INTERNAL INFECTION

The SIS (+)Positive Electrode must completely 'cover' the target internal organ or other anatomical structure. 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.

NOTE: For each electrode placement, follow SECURING ELECTRODES instructions.

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.

4.1.2. SURFACE INFECTION

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:

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.

4.2. SECURING ELECTRODES

The contact of the entire surface of an SIS electrode positioned onto normal, intact (i.e. 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.

4.3. CONNECTION OF ELECTRODE CABLE TO ELECTRODES

4.3.1 ELECTRODE CABLE POLARITY

- 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 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 this can cause excessive mechanical force on the cable connection to the electro-stimulator.

4.4. 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**.

! IMPORTANT INFORMATION:

RECOMMENDED SIS ELECTRODE LIFETIME FOR SEVERE INFECTION:

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

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

5. 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.

5.1. 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 **-ve terminal (electrode)**, and the **red-wired ‘banana plug’** is the conventional **+ve 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 to 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 (+ charge) and Cation (- 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.

5.2. OUTPUT CURRENT POLARITY REVERSING

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

For most DC applications where other electrodes are used, this function is not required and can be disabled (**OFF**) in the POLARITY screen.

5.3. ELECTRODE STIMULATION EFFICIENCY (ESE) MONITORING

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

ESE monitoring can be enabled (**AUTO (DEFAULT)**) or disabled (**OFF**) for various DC electrotherapy applications as necessary, in the MONITORING screen. ESE monitoring can only be disabled when the programmed output **CURRENT** is less than **10 microAmps**. When ESE is disabled, no data are shown in the STIM DATA and STATISTICS screens.

5.4. 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.

Use the alligator clip adapters to connect from the electrode cable directly to either inserted metal AP needle shafts, 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.

It will usually be advantageous to disable Electrode Stimulation Efficiency

(ESE) monitoring for most applications, especially when inserted AP needles are used. Refer to section 7 of this manual for further information.

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.

5.5. DC Battlefield Acupuncture

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

Disable Electrode Stimulation Efficiency (ESE) monitoring. Refer to section 7 of this manual for further information.

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.

5.6. 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 disable Electrode Stimulation Efficiency (ESE) monitoring for some applications. Refer to section 7 of this manual 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.

5.7. Low Intensity DC Microcurrent Electrical Neuromuscular Stimulation (MENS)

Injured muscle regeneration enhancement treatment.

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.

5.8. Scar Pain Treatment

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

Disable Electrode Stimulation Efficiency (ESE) monitoring. Refer to section 7 of this manual for further information.

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.

5.9. Liquid Medication Iontophoresis

M250MA drug iontophoresis also termed transcutaneous drug delivery, via standard silver-silver chloride and other pH Buffered iontophoresis electrodes.

Maximum stimulation current is 2.0 mA. Refer to the DEVICE SPECIFICATIONS section of this manual for more information.

It may sometimes be advantageous to disable Electrode Stimulation Efficiency (ESE) monitoring. Refer to section 7 of this manual for further information.

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.

5.10. Cell Apoptosis Stimulation

Use SIS 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 decreases the contributing electrical resistances of the electrode↔skin contact areas below the values achieved with wet SIS electrodes. Refer to the section 7 of this manual for further explanation.

The application of the SIS electrodes to reach the target tissue is identical to the infection treatment methods. Read the following sections of this manual for instructions:

- 4.1. ELECTRODE SIZE AND POSITIONING
- 4.1.1. INTERNAL INFECTION or 4.1.2. SURFACE INFECTION depending on the location of the target tissue
- 4.2. SECURING ELECTRODES
- 4.3. CONNECTION OF ELECTRODE CABLE TO ELECTRODES

Program the required milliampere (**milliAmps**) output **CURRENT**.

NOTE: The maximum total circuit resistance **RES** operating limit of the M250MA for any programmed milliampere output **CURRENT** can be computed using the Ohm's Law equation. The measured, average **RES** value is shown in the STIM DATA screen.

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.

5.11. Laboratory and Research Use

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

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

Refer to the DEVICE SPECIFICATIONS section of this manual for further information.

It may be advantageous to disable Electrode Stimulation Efficiency (ESE) monitoring for some applications. Refer to section 5.3. of this manual. Also read the 7. ELECTROTHERAPY ELECTRODE↔SKIN CONTACT: BASIC THEORY section of this manual for further information.

6. AUDIO AND VISUAL ALERTS

Alert Message	Meaning / Notes	Action Required
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.
POOR CONTACT	Electrode contact is immediately or statistically 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. Shave skin if necessary to establish or improve electrode contact.
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 below minimum operating level.	Replace batteries. Refer to DEVICE SPECIFICATIONS.
CANNOT CALIBRATE	Device cannot calibrate due to alerted, uncorrected electrode contact problem.	Wait for device to power off. Re-check electrodes and cable connections. Power on device again if necessary.
POWERING OFF	The device is about to automatically power off due to uncorrected alert status, lack of user activity, low battery charge, or user powering down the device.	

7. ELECTROTHERAPY ELECTRODE ↔ SKIN CONTACT: BASIC THEORY

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 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 in to 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.

Different electrotherapy electrodes also contribute varying electrical resistances, mainly from their material composition, and also due to their size, shape, and conformity to the body surface during cutaneous application:

ELECTRODE TYPE	TYPICAL TOTAL CIRCUIT RESISTANCE PER PAIR ON INTACT SKIN
SIS silver-nylon cloth when wet	≤50 kΩ
Self-adhesive hydrogel	≥500 kΩ

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 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.

8. 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.

9. 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.

10. WATER TREATMENT

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

Disable Electrode Stimulation Efficiency (ESE) monitoring. Refer to section 5.3. of this manual for instructions.

If using SIS electrodes, connect the electrodes to the electrode cable.

Use the alligator clip adapters supplied with the SIS machine to convert the SIS electrode cable for connection to other pure silver metal electrodes.

Immerse the electrodes into the water at opposite edges of the water container. The two electrodes must not contact each other. The interior surface of the water container should not be metallic.

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

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

If SIS electrodes are used, the rate of silver ion introduction into the water will depend on the SIS electrode size; larger electrode size will give a faster rate of silver ion production, and vice versa.

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 microsiemens (µS).

11. MAINTENANCE

11.1. 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.

11.2. 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.

11.3. 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.

12. WARRANTY

SIS machine (“the Device”) models M200/M200MA/M250/M250MA/W200/W250 carry a 3 year, and SIS machine (“the Device”) models WMcAMP/LVtC 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 M200/ M200MA/M250/M250MA/W200/W250/WMcAMP/LVtC 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 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.

12.1. 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.

12.2. Disposal

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

13. DEVICE SPECIFICATIONS

Parameter	Unit	Minimum	Typical	Maximum	Tolerance	Additional Notes
Batteries	-	-	-	-	-	3 x 1.5V AAA Alkaline
Battery Life	Hours	-	20	-	-	Duracell Ultra Alkaline recommended
Output Voltage in Current Stimulation Mode	V	0	-	7.5V (11.8V)*	-	Measured across 30kΩ 0.1% Sense Resistor†
Output Voltage in Voltage Stimulation Mode	V	0	5	5.5	-	-
Output Current	uA	0	-	200 (2000)*	0-1.5uA ±10% 1.5-200uA ±1%	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.

14. MANUFACTURER'S DECLARATION

The device is pending testing for EMC conformity to EN 60601-1-2 edition 4.0, AS/NZS CISPR 11, FCC 15B, ICES-001.

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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