SIS MACHINES

TECHNICAL OPERATING MANUAL_W250_v1.8

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 MACHINE MODEL W250 IS 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.

QUICK START APPLICATION FOR WOUNDS AND ULCERS

Read and follow the instructions in these sections of this manual:

1. POWER SOURCE

2. ELECTRODE CABLE (HARNESS) CONNECTION

3. KEYPAD CONTROLS AND OPERATION

4. Surface Wound, Surgical Wound, Skin Ulcer

DEVICE DESCRIPTION

The SIS machine model W250 is designed for electromedical low intensity (amperage) direct current and voltage stimulation and silver iontophoresis for a surface wound or ulcer, electromedical measurement, supplementation or replacement of endogenous wound bioelectrics, and stimulation of surface or internal tissue fibroblast and other cell modifications and transdifferentiations.

1. POWER SOURCE

The W250 is powered by replaceable AAA type batteries. Rechargeable batteries can be used and do not compromise the function of the device. Refer to 13. DEVICE SPECIFICATIONS section 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 on the rear panel of the device.

d. Insert 3×AAA batteries, ensuring correct polarity—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.

NOTE: Position and secure the SIS electrodes to the body first, then connect the electrode cable to the two electrode wires, and then operate the W250.

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">Operational MODE displayed.
STATUS displayed.</td></tr>
<tr><td>PROGRAM</td><td>Access Main Menu</td><td colspan="3" rowspan="2"></td></tr>
<tr><td></td><td>⇩ ⇧ scroll through Main Menu options</td></tr>
<tr><td rowspan="10"></td><td>EXIT</td><td rowspan="10">PROGRAM
to select</td><td colspan="2">Return to Main Operating Screen.</td></tr>
<tr><td>WOUND</td><td colspan="2">Wound and ulcer healing operational mode.</td></tr>
<tr><td>REGEN</td><td colspan="2">Tissue regeneration operational mode.</td></tr>
<tr><td>STIM DATA</td><td>Output Current
Output Voltage
Measured bioelectric data</td><td rowspan="8">PROGRAM or
⇩ ⇧
Return to Main Menu</td></tr>
<tr><td>STATISTICS</td><td>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>ABOUT</td><td colspan="2">Information about device</td></tr>
<tr><td>SOUND
———
DISPLAY</td><td colspan="4">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 operation with **STATUS: OK**

and the DISPLAY setting has not been changed from AUTO-OFF (DEFAULT), 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.

3.1. ELECTRODE STIMULATION EFFICIENCY (ESE) MONITORING

The W250 monitors the contact of the SIS or other electrode(s) with the body, both 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 is not under user control, except in REGEN mode when the device has calibrated to internal fibrotic tissue.

APPLICATIONS

4. Surface Wound, Surgical Wound, Skin Ulcer

! NOTE: Apply standard, available procedures for cleaning/irrigating wounds.

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

The W250 can more accurately monitor the electrode↔skin/wound contact the smaller the size of the electrodes. Do not use over-sized SIS electrodes: select an electrode size that best matches the wound dimensions and geometry. Use the SIS Small round 4.75cm ødiameter electrode for most small to medium size wounds. Use the 15×10cm Large rectangular SIS electrode for larger area wounds. Cut the (+)positive electrode to the size and shape of the wound if necessary. For superficial wound applications**,** the (-)return electrode can be smaller than the (+)positive electrode.

4.2. ELECTRODE POSITIONING

Diagrams of typical SIS electrode positionings for wounds and ulcers are available from:

https://siselectromed.com/wound-healing-infected-wound-chronic-wound-diabetic-ulcer/

For each electrode placement, follow 4.3. SECURING ELECTRODES instructions.

NOTE: 4.2.1. SUPERFICIAL WOUND electrode positioning has the strong advantage of not contacting the wound bed and so not mechanically interfering with granulation tissue formation.

4.2.1. SUPERFICIAL WOUND (INFECTED)

A. Position the SIS (+)positive electrode onto the surrounding normal tissue as close as possible/no more than 2cm (3/4") from the edge of the wound; place electrode carefully not to physically disturb the wound.

B. Position the SIS (-)return electrode onto intact skin as much as possible directly behind the center of the wound on the opposite anatomical surface of the injured body part.

ROTATIONAL (+)POSITIVE ELECTRODE POSITIONING
For a larger superficial wound, depending on the limitations of wound location and geometry, each time the SIS (+)positive electrode is replaced, it can be advantageous to re-position the (+)electrode at a different o'clock location around the wound edges, for example in the repeating sequence: 3-6-9-12 o'clock, for distributing stimulation evenly to the entire wound, over time. The (-)return electrode should always remain in the same location.

4.2.1.1. Across Wound Electrode Positioning

If SUPERFICIAL WOUND electrode positioning A & B are not achievable—for example due to a wound dressing considered not removable—then:

C.	Position the SIS (+)positive and (-)return electrodes onto intact skin on opposite sides across the wound as close as possible to wound edges; position the (+)positive electrode closest to the most infected side.

Revert to SUPERFICIAL WOUND electrode positioning when possible.

4.2.2. DEEPER WOUND (INFECTED) - ! WARNING: PHYSICIAN OR CERTIFIED WOUND NURSE ONLY

A. Rinse the SIS (+)positive electrode with saline/sterilizing fluid if available. Position the electrode directly onto the wound bed; the electrode should not extend beyond wound edges or as minimally as possible.

B. Cover the SIS (+)positive electrode with saline/sterilizing liquid-rinsed gauze or other non-adherent moisture-holding wound dressing if available.

C. Position the SIS (-)return electrode onto intact skin as much as possible directly behind the center of the wound on the opposite anatomical surface of the injured body part.

NOTE: If DEEPER WOUND electrode positioning is not achievable—for example due to a wound dressing considered not removable—then apply SUPERFICIAL WOUND electrode configuration. Revert to DEEPER WOUND electrode positioning when possible.

4.2.3. FIRST AID: SIS (+)POSITIVE ELECTRODE ONLY (A) OR WITH SIS (-)RETURN ELECTRODE AND SIS MACHINE (A & B)

A. Select an SIS (+)positive electrode large enough to cover the entire wound and extending at least 2cm (3/4") beyond the edges of the wound on all sides. Position the electrode directly over the wound.

B. Position the SIS (-)return electrode onto intact skin as much as possible directly behind the center of the wound on the opposite anatomical surface of the injured body part.

4.3. 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.

Use adhesive fixation tape, stretch strap, bandages or other emergency means to secure the electrode to the body:

- ➔ When positioning an SIS electrode onto normal intact skin, extend the dressing tape beyond all edges of the electrode.
- ➔ When positioning an SIS electrode onto periwound/adjacent-wound-edge tissue, if it is impossible to extend the dressing tape beyond the edge of the SIS (+)positive electrode adjacent to the wound edge without physically disturbing the wound, do not extend the dressing tape beyond this edge of the electrode.

4.4. CONNECTION OF ELECTRODE CABLE TO ELECTRODES

4.4.1 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 doing so can cause excessive mechanical force on the cable connection to the electro-stimulator.

4.5. OPERATIONAL MODE

WOUND operational mode is the default setting of the device. Follow on-screen alert messages.

! IMPORTANT INFORMATION

MAXIMUM RECOMMENDED SIS ELECTRODE LIFETIME FOR WOUND AND ULCER TREATMENT:

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

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

5. DEVICE↔WOUND CALIBRATION

The following table gives further guidance on how to improve device-to-wound calibration if the CANNOT CALIBRATE alert cannot be corrected, or if the ACROSS WOUND mode is activated with electrodes positioned for SURFACE WOUND or DEEPER WOUND stimulation,:

WOUND DEPTH	INCREASING CONDUCTIVITY	(+)ELECTRODE POSITIONING AND SIZE	OTHER ACTIONS
SUPERFICIAL	Wet the periwound/ adjacent-wound-edge tissue with saline or clean water if available.	Move closer to the wound edge. Cut down electrode to a smaller size.	Debride wound if appropriate: Physician or wound nurse only.
DEEP	Moisten wound bed with saline or clean water if available.	Check electrode does not extend beyond wound edges.	

Refer to the ELECTROTHERAPY ELECTRODE↔SKIN CONTACT section of this manual for further information.

6. TISSUE REGENERATION

6.1. INTERNAL FIBROTIC TISSUE

6.1.2. ELECTRODE POSITIONING

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.

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.

Follow 4.4. CONNECTION OF ELECTRODE CABLE TO ELECTRODES instructions.

6.1.3. OPERATIONAL MODE

Select REGEN operational mode.

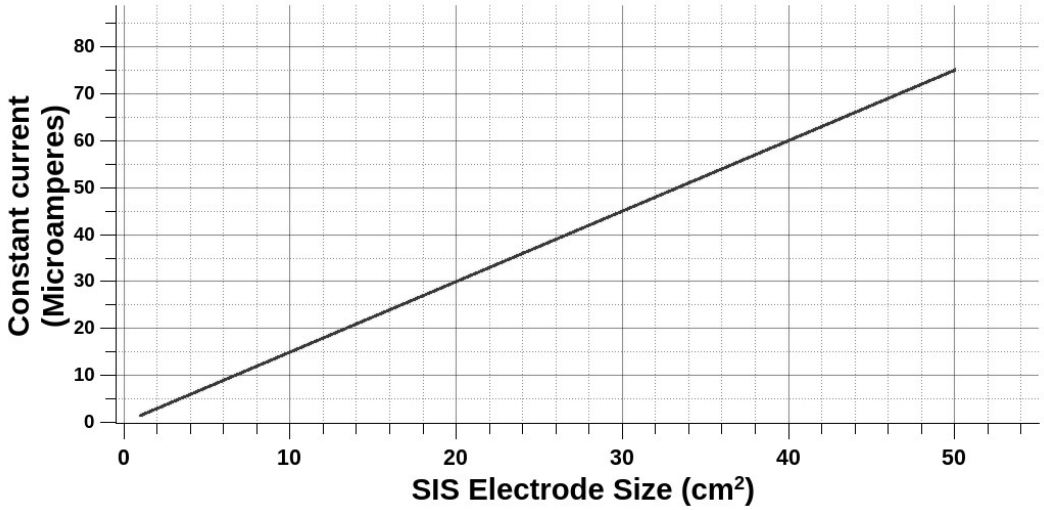
The starting, total circuit resistance must be >40 kΩ for operation to begin; if <40 kΩ, operation automatically switches to the SURFACE INJURED TISSUE mode. The total circuit resistance value is shown in real-time in the STIM DATA screen as **RES:**. Refer to **8.1. NOTE** for explanation how to vary the starting total circuit resistance.

6.1.4. SELECT (+)POSITIVE ELECTRODE SIZE

Select and program the SIS (+)positive electrode size.

6.1.5. CONSTANT CURRENT SCALING

The output **CURRENT** is automatically scaled to the user-programmed surface area size of the SIS (+)positive electrode, as shown below and in real-time in the STIM DATA screen. The smallest electrode that can be programmed is 1.5 cm^2; the maximum size of any electrode shape is 50 cm^2:



If a standard 4.75cm (1.87") ⌀diameter Small circular SIS electrode is used, which has an actual surface area of 17.7cm² [πr^2], select and program its approximate surface area of 20cm². Similarly, for an irregular shaped SIS electrode cut to the size of an injured tissue area, calculate and program its approximate overall surface area.

6.1.5.1. To override the automatic constant output current scaling for any reason, select and program either a larger or smaller SIS (+)positive electrode than actually used. For example, to program an output current of 60 microAmps for an actually used 30cm² SIS (+)positive electrode, select and program a 40cm² (+)positive electrode size.

6.1.6. TOTAL CIRCUIT RESISTANCE OPERATING LIMITS

The total circuit resistance operating limit of the W250 for all possible user-programmed SIS (+)positive electrode sizes is shown in the table below; the actual measured total circuit resistance is shown in real-time in the STIM DATA screen as **RES**.

(+)positive Electrode surface area (cm²)	1.5	2.5	5	10	15	20	25	30	35	40	45	50
Total circuit resistance operating limit in kΩ(MΩ)	(3.4)	(2)	(1)	500	333	250	200	166	142	125	111	100

If the total circuit resistance shown in the STIM DATA screen cannot be maintained continuously below the corresponding operating limit, treat a smaller target internal fibrotic tissue area at one time with a smaller (+)positive electrode size.

NOTE: Total circuit resistance values above 100 kΩ will trigger cautionary HIGH RESISTANCE device alerts; refer to section 7. AUDIO AND VISUAL ALERTS for further guidance.

Also refer to the ELECTROTHERAPY ELECTRODE↔SKIN CONTACT section of this manual for further information.

6.2. SURFACE INJURED TISSUE

6.2.1. ELECTRODE POSITIONING

A. Follow 4.2.2. DEEPER WOUND instructions for positioning the SIS (+)positive and (-)return electrodes to the surface injured tissue.

B. The starting, total circuit resistance must be <40 kΩ for operation to begin; if >40 kΩ, operation automatically switches to the INTERNAL FIBROTIC TISSUE mode. The total circuit resistance value is shown in real-time in the STIM DATA screen as **RES:**. Refer to **8.1. NOTE** for explanation how to vary the starting total circuit resistance.

6.2.2. OPERATIONAL MODE

Select REGEN operational mode.

6.2.3. (+)POSITIVE ELECTRODE SIZE

There is no user selection of SIS (+)positive electrode size. The output voltage self-adaptively scales to the injured tissue's bioelectric properties.

7. AUDIO AND VISUAL ALERTS

Alert Message	Meaning	Action Required
STANDBY CALIBRATING	Device is calibrating to wound or internal tissue target pathway.	Wait.
STATUS: OK	Device is operating within normal limits. Electrode contact is established.	None.
MODE: WOUND	The device has calibrated to the wound.	None.
MODE: ACROSS WOUND	The device has calibrated to an Across Wound electrode positioning.	None. The device will automatically switch to a SURFACE WOUND or DEEPER WOUND stimulation when achievable. Refer to 5. DEVICE↔WOUND CALIBRATION instructions.
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. If in WOUND mode, refer to 5. DEVICE↔WOUND CALIBRATION instructions.
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 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 appropriate application instructions. If in WOUND mode, refer to 5. DEVICE↔WOUND CALIBRATION instructions. Power on device again if necessary.
POWERING OFF	The device is powering off due to uncorrected alert status, lack of user activity within the menu selection screens, low battery charge, or user powering down the device.	

8. 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

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

8.1. NOTE: A major factor that affects electrode ↔ skin/wound contact area electrical resistances, is moisture. The wetter these areas the *lower* their contributing electrical resistances to the total circuit resistance; the drier these areas the *higher* their contributing electrical resistances to the total circuit resistance.

BIOELECTRIC WOUND ASSESSMENT

Bioelectrically, as a wound or ulcer heals, the through-wound electrical resistance linearly *increases*. If the electrode ↔ skin/wound contact electrical conductivity factors are held relatively constant over time, or if their known dynamics are calibrated out of the total circuit resistance measurements, then the target through-wound electrical resistance measurements can be reliably obtained, at regular measurement intervals, enabling bioelectric data-based assessment of the (rate of) wound healing.

W250 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 W250 continuously and rapidly self-adapts to the electrical resistance dynamics of the electrode ↔ skin/wound contact areas.

The device-generated Output Voltage is shown in the STIM DATA screen as **VOLTS**. An Output Voltage 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 intact (non-wound) skin irritation during extended device application.

9. 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.

8. 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. MAINTENANCE

10.1. 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.

10.2. 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.

10.3. 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 M250/M250MA/W250/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 M250/M250MA/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 or Panasonic recommended
Output Voltage in Current Stimulation Mode	V	0	-	11.8	-	Measured across 30kΩ 0.1% Sense Resistor†
Output Voltage in Voltage Stimulation Mode	V	0	5	5.5	-	-
Output Current	uA	0	-	200	0-1.5uA ±10% 1.5-200uA ±1%	30kΩ load
Design Operating Range	°C	-20	+25	+80	-	-
Resistance Measuring	kΩ	0.1	-	10000	±5%	-

†Resistance value selected to simulate physiological bioelectric skin parameters.

14. MANUFACTURER'S DECLARATION

ELECTROMAGNETIC DEVICE 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.

SIS MACHINE W250 MODEL OPERATING MANUAL

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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