



# SIS MACHINES

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## **TECHNICAL OPERATING MANUAL\_M250/M250MA\_v2.3**

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.**

# SIS MACHINE M250/M250MA MODEL OPERATING MANUAL

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# SIS MACHINE M250/M250MA MODEL OPERATING MANUAL

## 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.

## DEVICE DESCRIPTION


The SIS machines M250/M250MA models are designed for nanoampere to low milliamperere direct current (DC) generation. The M250/M250MA models are also designed for use as a nanoampere to low milliamperere (M250MA only) constant current generators for research, laboratory purposes, including Life Sciences, and for 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.

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## 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.

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## 3. KEYPAD CONTROLS AND OPERATION

<b>POWER</b>  <b>ON OFF</b>	Power device ON, 2 seconds hold. Power device OFF, 5 seconds hold.				
Main Operating Screen	Output <b>CURRENT</b> and <b>STATUS</b> displayed. ↓ ↑ keypad buttons adjust and PROGRAM the output <b>CURRENT</b> .				
<b>PROGRAM</b>	Access Main Menu				
	↓ ↑ scroll through Main Menu options				
	<b>EXIT</b>		Return to Main Operating Screen		
	<b>STIM DATA</b>		<b>Output Current and Voltage and measured bioelectric data</b>		
	<b>STATISTICS</b>		<b>Electrode stimulation efficiency data</b>		
	<b>CABLE TEST</b>	<b>PROGRAM</b> to select	<table border="1"> <tr> <td data-bbox="769 1093 1008 1254"> <b>Instructions 1 PROGRAM</b>  <b>Instructions 2 PROGRAM</b> </td> <td data-bbox="1015 1093 1235 1254">                     Result:  <b>PASSED</b>                      or  <b>FAILED</b> </td> </tr> </table>	<b>Instructions 1 PROGRAM</b> <b>Instructions 2 PROGRAM</b>	Result: <b>PASSED</b> or <b>FAILED</b>
<b>Instructions 1 PROGRAM</b> <b>Instructions 2 PROGRAM</b>	Result: <b>PASSED</b> or <b>FAILED</b>				
	<b>DISPLAY</b>		↓ ↑ <b>AUTO-OFF (DEFAULT) or ALWAYS ON</b>	<b>PROGRAM</b> or ↓ ↑ return to Main Menu	
	<b>TIMER</b>		<b>Session duration data</b>		
	<b>MONITORING</b>		↓ ↑ <b>AUTO (DEFAULT) or OFF</b>		
	<b>POLARITY</b>		↓ ↑ <b>AUTO (DEFAULT) or OFF</b>		
	<b>ABOUT</b>		<b>Information about device</b>		

<b>DISPLAY</b>	Sound turned ON or OFF, 2 seconds hold. OLED display turned ON or OFF, 1 second hold, when DISPLAY set to <b>AUTO-OFF (DEFAULT)</b> .
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The default device settings after powered on are OLED display and sound turned on.

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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.

## APPLICATION

### 4. 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. 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:**

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

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

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## 4.2. 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.

## 4.3. OTHER TYPES OF ELECTRODES

Many other types of electrodes can be used with the M250/M250MA. 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. OUTPUT CURRENT

### 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 **(-)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.

### 5.2. 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.

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NOTE: For most DC applications when other non-SIS electrodes are used, this function is not required and can be turned **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, or with the stimulation target for *in vitro* applications, in realtime and statistically via self-adaptive measurement, logging and assessment algorithms. The highly summarized logged ESE data are shown in the STATISTICS screen.

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

## 6. 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 12. DEVICE SPECIFICATIONS for further information.

It may be advantageous to turn **OFF** ESE monitoring for some *in vitro* and *in vivo* applications.



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## 7. 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 12. SPECIFICATIONS
POOR CONTACT	Electrode contact is insufficient for stable 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 stable 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 deactivate 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.	

## 8. ELECTRODE CONTACT

Total circuit resistance is shown in the STIM DATA screen as **RES** and updates every 30 seconds with an average value of multiple realtime 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 self-adapts to the electrical resistance dynamics of the electrode 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  $\leq 50\text{-}100\text{ k}\Omega$  **RES** value, in order to assess early possibility of skin irritation during extended device application.

### 8.1. 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 12. DEVICE SPECIFICATIONS.

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## 9. WATER TREATMENT

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

Turn **OFF** Electrode Stimulation Efficiency (ESE) monitoring. Refer to section 5.3. 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 (Ag) metal rods.

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

A very warm object can be placed under the glass container to act as a it convection stirrer.

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

The changing cationic silver particle (Ag<sup>+</sup>) 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 cationic silver solution (often termed “colloidal silver”), distilled or highly purified water must be used, preferably with a starting electric conductance measurement of  $\leq 1-4$  microsiemens ( $\mu\text{S}$ ).

## 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 the device 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.

FOR BIOLOGICAL STIMULATION, SIS ELECTRODES SHOULD ONLY BE USED ON THE SAME INDIVIDUAL.

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## 11. WARRANTY

The M250/M250MA (the “Device”) carries a 3 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. 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/FG300/W300 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/FG300/W300 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.

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## 11.1. Returns

Each SIS machine unit is assembled and factory calibrated. 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](http://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.

## 11.2. Disposal



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

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## 12. 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 only

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

## 13. 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 M250MA model is modified beyond this conformity certification with additional passive components only.

The device is RoHS compliant.



# SIS MACHINE M250/M250MA 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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