



# SIS MACHINES

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## **TECHNICAL OPERATING MANUAL\_v8.0\_M200**

This operating manual is downloadable from <http://www.siselectromed.com>

**CAUTION:** 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.**

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## DELIVERY AND UNPACKING

Please unpack the shipping package carefully and inspect contents immediately on receipt. You must 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 notify SIS Manufacturing Ltd immediately of any received damaged or tampered items or of any lost shipments.



## **WARNING FOR BIOLOGICAL APPLICATIONS**

THE SIS MACHINE M200 IS ELECTRONICALLY CALIBRATED WITH EXTREME PRECISION IN THE 'MICRO' [MICROCURRENT ( $\mu\text{A}$ )—MICROBIAL SETTINGS] OPERATIONAL MODE FOR THERAPEUTIC BIOLOGICAL ELECTRO-STIMULATION ONLY IN COMBINATION WITH THE SIS SILVER-NYLON ELECTRODES. ONLY USE SIS ELECTRODES IN THESE APPLICATIONS: USE OF OTHER ELECTRODES CAN CAUSE ADVERSE AND UNPREDICTABLE BIOLOGICAL EFFECTS. FOR OTHER BIOLOGICAL ELECTRO-STIMULATION APPLICATIONS, USE SIS SILVER-NYLON ELECTRODES WHERE POSSIBLE. IF SIS SILVER-NYLON ELECTRODES CANNOT BE USED, ONLY USE 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 machine M200 model is designed for electromedical, nanampere (nA) to microampere ( $\mu$ A) low intensity direct current (LIDC) electrical stimulation and silver iontophoresis.


The device is also designed for stand-alone, nano- to micro-ampere LIDC generation for non-medical non-therapeutic non-diagnostic research, laboratory and experimental purposes, Life Sciences, microiontophoresis and water treatment.

## OPERATIONAL MODE


'MICRO' (MICROCURRENT) operational mode with a nanoampere adjustment and resolution constant Output Current capability, is used for any *in vivo* or *in vitro* nano- to micro-ampere (100nA-200 $\mu$ A) application.

### 1. POWER SOURCE

The M200 is powered by replaceable AAA type batteries (not included with delivery of device for air shipping regulations reasons). Rechargeable batteries can be used and do not compromise its correct function.

 Do not use zinc-carbon batteries, which 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 $\times$ 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 HARNESS (CABLE) CONNECTION

#### 2.1. CONNECTION OF ELECTRODE HARNESS TO SIS MACHINE

For a 3 pin type connector, bring the harness connector in contact with the connection socket, *but do not attempt to insert*. With minimum force, rotate the harness connector slowly to align its 3 pin receivers with the 3 pins inside the connection socket; the harness

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connector will engage and insert easily into the connection socket when correctly aligned. Screw tighten the harness connector to lock to the SIS machine connection socket.

AUGUST 2016 ONWARDS: For a 3.5mm type connector, insert the harness connector plug directly into the SIS machine connection socket.

## 2.2. ELECTRODE HARNESS POLARITY

It is usually easier to position and secure the SIS electrodes to the body or to the in vivo circuit interface first, and then connect the SIS electrode harness to the two SIS electrode wires. Two SIS electrodes are always needed for biological targets. SIS electrodes are physically interchangeable:

- The SIS electrode that is connected to the **red** wire of the electrode harness is the SIS  $\oplus$ Positive Electrode.
- The SIS electrode that is connected to the **black** wire of the electrode harness is the SIS  $\ominus$ Return Electrode.

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

## 2.3. CONNECTION OF ELECTRODE HARNESS TO SIS ELECTRODES

Insert the two gold metal 'banana plugs' at the ends of the SIS electrode harness (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. See **WARNING** below before use.

NOTE: Do not tape the connections of the harness to the electrode wires.

**⚠ WARNING:** Before powering on the SIS machine, connect the electrode harness to one of the SIS electrodes only (in any order), then power on the SIS machine, then connect the electrode harness to the second electrode.

## 3. KEYPAD CONTROLS

Hold down the **POWER ON OFF** button continuously for 2 seconds and then release the button to power on the device. Hold down the **POWER ON OFF** button continuously for 5 seconds and then release the button to power off.

The **SOUND|DISPLAY** button turns on and off the audio alerts and the organic light emitting diode (OLED) screen display. The default setting of the device when powered on is OLED display and sound turned on. If no keypad input is detected during normal operation, the OLED display turns off after 2 minutes for power saving. Press and release the **SOUND|DISPLAY** button to turn the OLED display on or off. Hold down the **SOUND|DISPLAY** button

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continuously for 3 seconds to turn the audio alerts on or off.

The **BATTERY CHARGE** LED and 'BATTERY CHARGE' audio-visual alerts are not under user control. The **BATTERY CHARGE** LED remains flashing at all times when the device is operating.

## 3.1. OPERATIONAL MODE PROGRAMMING

**MICRO** operational mode is the default setting of the M200 model.

## 3.2. OUTPUT SETTINGS

The ↓ ↑ and **PROGRAM** buttons adjust and program the Output Current. Press and release the ↓ ↑ buttons repeatedly to increase or decrease the constant Output Current. Hold down the ↓ ↑ buttons continuously to fast scroll through the constant Output Current parameter. Press and release the **PROGRAM** button to program the selected constant Output Current.

# 4. APPLICATION INSTRUCTIONS

! NOTE: The M200 model SIS machine can be targeted at almost any infected anatomical structure or location. However, the device 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.

## 4.1. OPERATIONAL MODE

Follow 5.1. OPERATIONAL MODE SETTING instructions to program a bacterial or viral infection treatment.

If no keypad input is detected during any 10 second period during this selection procedure, the last operational mode automatically resumes at the point of its interruption.

## 4.2. SELECTING SIS ELECTRODE SIZE

Do not use an over-sized SIS ⊕positive electrode: the SIS machine can more accurately monitor the electrode↔skin contact the smaller the electrode size. In all applications, the SIS ⊖Return Electrode should be approximately the same size or larger than the SIS ⊕Positive Electrode.

**DO** cut the SIS electrodes to size and shape as necessary.

**DO NOT** cut the SIS electrode wire inside the SIS electrodes.

### 4.2.1. INTERNAL INFECTION

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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.

## 4.2.2. SURFACE INFECTION

Use an SIS ⊕Positive and ⊖Return 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 across the 2cm sides of the infected area, or the 10cm×15cm SIS electrodes should be applied across the 10cm sides.

4.2.3. Follow 2.2. ELECTRODE HARNESS POLARITY instructions.

## 4.3. ELECTRODE POSITIONING

### 4.3.1. INTERNAL INFECTION

Diagrams of SIS electrode applications for common infections are available from <http://www.siselectromed.com/applications>

- a. Position the SIS ⊕Positive Electrode onto intact skin directly over the target infected organ or other anatomical structure. Secure electrode to body.
- 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 SIS electrodes. Secure electrode to body.

### 4.3.2. SURFACE INFECTION

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.

## 4.4. ELECTRODE SKIN CONTACT

Real-time updating, Total Circuit Resistance **R =** is shown on the OLED display. The SIS machine can operate more efficiently using lower Output Voltage the lower the **R =** value. Optimally, the R value should not exceed 50-100kΩ:

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1. Shave the skin if necessary to establish or improve electrode contact.
2. Wet the silver-nylon surface (electrically active side) of the SIS electrode with clean water if available to reduce the Total Circuit Resistance **R =** contribution of the electrode↔skin contact area.
3. Check that the entire surface of the electrode is contacting the body.
4. Check 4.5. SECURING SIS ELECTRODES TO BODY instructions. Replace or apply additional dressing tape if necessary.
5. Check electrode is not discolored (12-72 hours lifetime); replace if necessary.

Monitor 7. AUDIO AND VISUAL ALERTS.

**! INFORMATION: RECOMMENDED ELECTRODE LIFETIME FOR SEVERE INFECTION:  
SIS POSITIVE (RED WIRED) ELECTRODE: 12-24 HOURS  
SIS RETURN (BLACK WIRED) ELECTRODE: 24-48 HOURS**

## THEORY

Electrical resistance is measured in units of Ohms ( $\Omega$ ):

*1megaOhm (M $\Omega$ ) = 1000 kiloOhm (k $\Omega$ ) = 1,000,000 Ohms ( $\Omega$ ).*

The SIS machine continuously self-adapts to the electrical resistances of the SIS electrode ↔ skin contact areas. The wetter these areas, the lower their contributing electrical resistance. Relatively large variations in electrode ↔ skin contact area electrical resistances can occur depending on many factors, up to approximately 1M $\Omega$ ; there is no SIS machine operational lower limit. The Total Circuit Resistance (R) is the sum of the electrical resistances at both the electrode ↔ skin [or wound for W200 SIS machine] contact areas plus the internal body electrical resistance in the pathway between the two SIS electrodes.



## 4.5 SECURING SIS ELECTRODES TO BODY

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 surgical or wound dressing tape (e.g. Fixomull®) and/or Velcro® or other stretch strap, bandages or other emergency means to affix or hold the SIS electrodes to the body; adhesive tape should extend beyond all edges of an electrode.

## 5. CONSTANT ULTRA-LOW OUTPUT CURRENT

### 5.1. OPERATIONAL MODE SETTING

For an *in vitro* anti-bacterial effect or *in vivo* bacterial infection treatment, use the default Output Current setting **I = 2.5uA**. For an *in vitro* anti-viral effect or *in vivo* viral infection treatment follow 3.2. OUTPUT SETTINGS instructions to program **I = 7.5uA**.

1 Microampere ( $\mu\text{A}$ ) = 0.001 Milliampere (mA) = 0.000,001 Amperes (A).

### 5.2. DISABLING ELECTRODE MONITORING

MoNiToring (MNT) of 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 can be user enabled or disabled.

To access ELectRODE MoNiToring press and release the **PROGRAM** button twice. The display Main Window of the display will show:

**ELCTRODE MNT**  
**SELECT: ON**

Press and release the  $\downarrow$   $\uparrow$  buttons to select electrode contact MNT **ON** or **OFF**. Press and release the **PROGRAM** button to program the MNT selection; the device will then return to the programmed operational mode.

NOTE: If MNT is disabled, measurement of Total Circuit Resistance (R) is inactivated; the display will not show an **R =** value.

**5.3.** Follow 2.2. ELECTRODE HARNESS POLARITY instructions. For *in vivo* applications, follow 4.2. SELECTING SIS ELECTRODE SIZE and 4.5. SECURING SIS ELECTRODES TO BODY instructions.

**5.4.** Use the alligator clip adapters supplied with the SIS machine to convert the SIS 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.

**5.5.** Follow 3.2. OUTPUT SETTINGS instructions to program the constant Output Current. Positive conventional current polarity is always applied.

Monitor 7. AUDIO AND VISUAL ALERTS if MNT is enabled.

## 6. WATER TREATMENT

### 6.1. OUTPUT CURRENT SETTING

Follow 3.2. OUTPUT SETTINGS instructions to program **I = 20uA**; then follow 5.2. DISABLING ELECTRODE MONITORING to inactivate ELECTRODE MONITORING.

1 Microampere ( $\mu\text{A}$ ) = 0.001 Milliampere (mA) = 0.000,001 Amperes (A).

### 6.2. ELECTRODES

Connect two SIS electrodes, other pure silver or other pure metal electrodes to the SIS electrode harness.

Follow 5.4. instructions to convert the SIS electrode harness for connection to many other electrodes and applications, as required.

Immerse the electrodes into the water container near its opposite edges. The two electrodes must not contact each other.

The interior surface of the water container should preferably not be metallic. If a container with a metallic interior surface is used, then the electrodes must be immersed without making contact with the interior surface.

The maximum recommended volume of water that can be treated using this method is approximately 1-2 liters.

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 (“colloidal silver”), distilled or highly purified water must be used, preferably with a starting electric conductance measurement of  $\leq 1$  microsiemens ( $\mu\text{S}$ ).

## 7. AUDIO AND VISUAL ALERTS

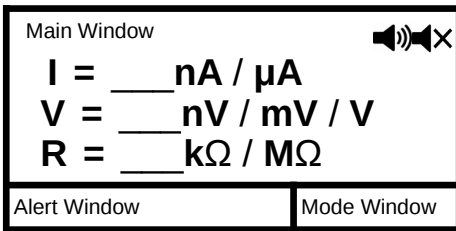


Figure 1: OLED display layout.

The user-programmed operational mode is displayed in the lower right Mode Window of the OLED display [Figure 1].

The following real-time values are shown in the Main Window of the display [Figure 1]:

1. Output Current **I =**
2. Output Voltage **V =**
3. Total Circuit Resistance **R =** averaged over the last 1-2seconds; circuit Open Load (break) detection is shown as **R = OL**.

Audio alert activation or deactivation is indicated by the symbols in the upper right of the Main Window.

Alerts [Table 1] are displayed in the lower left Alert Window.

Alert	Meaning
<b>STDBY CALI</b>	<b>STANDBY CALIBRATING</b> to skin.
<b>CONTACT OK</b>	Electrode <b>CONTACT OK</b> .
<b>CONTCT LOW</b>	Electrode <b>CONTACT LOW</b> statistically.
<b>CNTCT FLUC</b>	Electrode <b>CONTACT FLUCTUATING</b> .
<b>CIRC BREAK</b>	Effective or physical <b>CIRCUIT BREAK</b> .
<b>NO CALI</b>	<b>NO CALIBRATION</b> possible.
<b>BATT LOW</b>	<b>BATTERY LOW</b> charge.
<b>MNT OFF</b>	<b>ELECTRODE MONITORING OFF</b> .
<b>VOLT ALERT</b>	High Output <b>VOLTAGE ALERT</b> .

Table 1: Displayed M200 audio-visual alert abbreviations.

Table 2 lists the alert types, all possible audio-visual alerts, and the corrective actions for each alert:



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**TABLE 2: AUDIO-VISUAL ALERTS & CORRECTIVE ACTIONS**

		M200				CORRECTIVE ACTIONS
ALERT TYPE	AUDIO	VISUAL OLED DISPLAY				
<b>OPERATIONAL MODE INITIALIZATION</b>						
– Operational mode is programmed.	1 BEEP	<b>[MODE NAME]</b> Unhighlighted				–
– Calibrating to body.	1 BEEP 5 SEC INT	<b>STDBY CALI</b> <b>FLASHING</b> 5 SEC INT				• Standby, wait for alert to stop.
– Operation normal.	–	<b>[MODE NAME]</b>				–
<b>ELECTRODE CONTACT MONITORING</b>						
– Electrode contact OK: Within all user-programmed and factory limits.	–	<b>CONTACT OK</b>				–
– Fluctuating SIS electrode contact in short time-frame (1-2seconds) exceeds operating limits.	2 BEEPS 5 SEC INT	<b>CNTCT FLUC</b> <b>FLASHING</b> 5 SEC INT				<b>All applications</b> <ul style="list-style-type: none"> <li>• For SIS electrode(s) positioned onto intact skin, check: <ul style="list-style-type: none"> <li>◦ 4.4. ELECTRODE SKIN CONTACT.</li> </ul> </li> <li>• If alert continues, follow instructions: <ul style="list-style-type: none"> <li>◦ 7.2. ELECTRODE contact MoNiToring Setting</li> <li>◦ 7.3. ELECTRODE HARNESS CHECK</li> </ul> </li> </ul>
– SIS electrode contact statistically lower than electrode contact MoNiToring (MNT) limits for user-programmed Output Current.	3 BEEPS 5 SEC INT	<b>CONTACT LOW</b> <b>FLASHING</b> 5 SEC INT				
– Output Voltage statistically higher than 1.5volts during previous 10 minute logged monitoring period.	LONG BEEP 5 SEC INT 30 SEC DURATION	<b>VOLT ALERT</b> <b>FLASHING</b> 5 SEC INT 30 SEC DURATION				
<b>ELECTRODE CONTACT MONITORING</b>						

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**TABLE 2: AUDIO-VISUAL ALERTS & CORRECTIVE ACTIONS**

M200					
<p>– Circuit break (consecutive Open Loads). Effective or physical circuit break.</p> <p>Programmed Open Load trigger is <math>R &gt; 3.8 \text{ megaohms}</math>.</p>	<p><b>10 BEEPS</b> 5 SEC INT</p>	<p><b>CIRC BREAK</b> <b>FLASHING</b> 5 SEC INT <b>OL</b> Main Window</p>			<p><b>All applications</b></p> <ul style="list-style-type: none"> <li>• Check for loose connections or breaks (including alligator clip connectors if non-SIS electrodes are used).</li> <li>• Check: <ul style="list-style-type: none"> <li>◦ 2.1. CONNECTION OF ELECTRODE HARNESS TO SIS MACHINE.</li> <li>◦ 2.3. CONNECTION OF ELECTRODE HARNESS TO SIS ELECTRODES.</li> <li>◦ 4.5. SECURING SIS ELECTRODES TO BODY.</li> </ul> </li> <li>• For SIS electrode(s) positioned onto intact skin, check: <ul style="list-style-type: none"> <li>◦ 4.4. ELECTRODE SKIN CONTACT.</li> </ul> </li> <li>• If alert continues, follow instructions: <ul style="list-style-type: none"> <li>◦ 7.3. ELECTRODE HARNESS CHECK.</li> </ul> </li> </ul>
<p>– Device powering off. Continuously insufficient electrode contact over last 4-8 minutes.</p>	<p><b>5 BEEPS</b> 5 SEC INT</p>	<p><b>NO CALI</b> <b>FLASHING</b> 5 SEC INT</p>			–
<p>– ELeCTRODE MoNiToring (MNT) turned OFF by user</p>	–	<p><b>MNT OFF</b></p>			–
<p>– Maximum circuit resistance (load) exceeded for target user-programmed Output Current.</p> <p>Device cannot deliver target Output Current.</p>	–	<p><math>I = [\text{value}] \mu\text{A}</math> <b>FLASHING</b> CONTINUOUS</p>			<p><b>All in vivo applications</b></p> <ul style="list-style-type: none"> <li>• Check for <b>CONTACT LOW</b> or <b>CIRC BREAK</b> alerts.</li> </ul> <p>Check 14. DEVICE SPECIFICATIONS: Output Voltage in Current Stimulation (modes).</p>
<p>– Stabilizing to target Output Current.</p>	–	<p><math>I = [\text{value}] \mu\text{A}</math> <b>FLASHING</b> INTERMITTENT</p>			<ul style="list-style-type: none"> <li>• No action required. Information only.</li> </ul>
<b>SOUND CONTROL</b>					
– Sound turned OFF.	–				–
– Sound turned ON.	<b>2 BEEPS</b>				–
<b>BATTERY CHARGE</b>					
– Charge OK.	–	<p><b>BATTERY CHARGE LED</b> <b>FLASHING</b> 5 SEC INT</p>			–

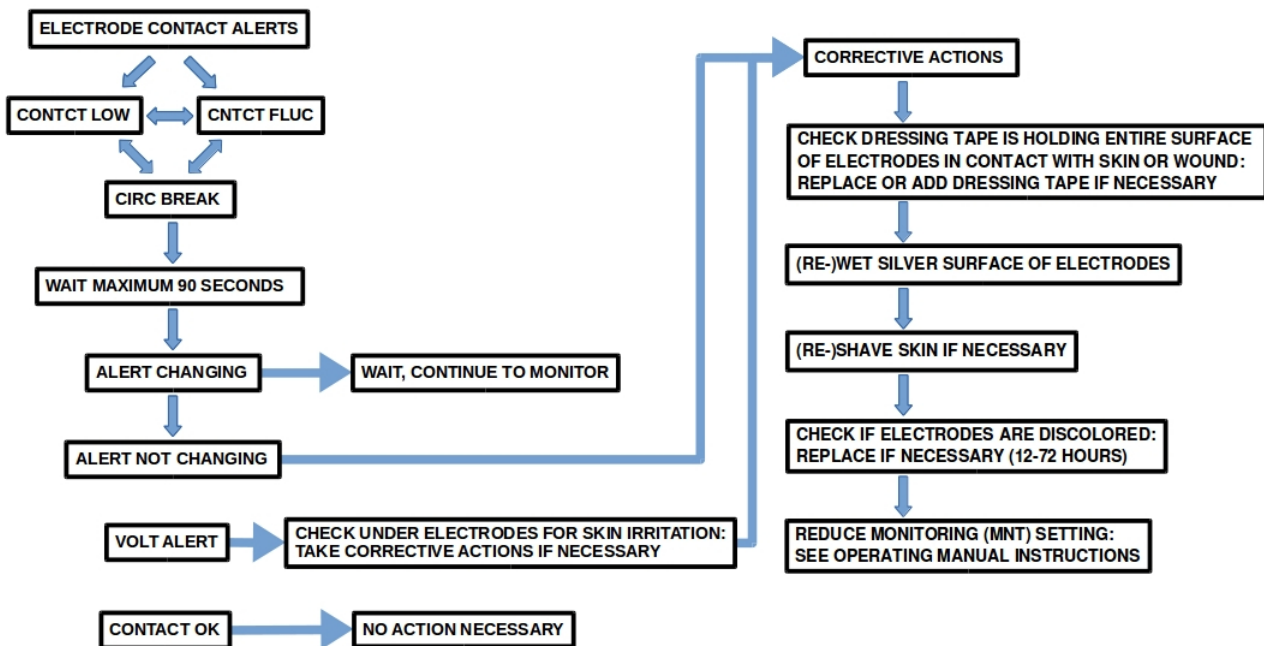
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TABLE 2: AUDIO-VISUAL ALERTS & CORRECTIVE ACTIONS

		M200			
– Charge low for correct operation.	1 BEEP 5 SEC INT	BATT LOW FLASHING 5 SEC INT. BATTERY CHARGE LED ON CONTINUOUS		CORRECTIVE ACTIONS:	
				• Replace AAA Batteries. ◦ 1.1. Inserting AAA Batteries.	

Abbreviations: SEC (seconds), INT (interval between sets of beeps).

## 7.1. AUDIO-VISUAL ALERTS RESPONSE FLOWCHART



## 7.2. Electrode Contact MoNiToring (MNT) Setting

The ELECTRODE CONTACT MONITORING audio-visual alerts are based on real-time updating statistical and algorithmic analysis of Total Circuit Resistance (R) measurements due to any changes of the contact of the SIS electrodes with the body or with their *in vitro* interfaces. This complex monitoring system ensures reliable delivery of the pre- and user-programmed target Output Currents and Output Voltages with extended, continuous use.

If the contact of the SIS or other electrode(s) continues to trigger electrode monitoring alerts even after following the corresponding CORRECTIVE ACTIONS listed in Table 2, then the user can vary a master parameter of the ELeCTRODE contact MoNiToring (MNT) algorithms.

Press and release the **PROGRAM** button to interrupt the current operational mode. Then press and release the ↓ button repeatedly until **MNT** is shown in the Mode Window of the display. Press and release the **PROGRAM** button again to select the MNT adjustment mode. The Main Window of the display will then show:

```
ADJ ELCTRODE MNT
4=MAX(FAC),1=MIN
SELECT: 4
```

The default factory (FAC) MNT setting is the maximum sensitivity, **4**; the minimum sensitivity is **1**. Each time the device is powered off and on, the device defaults to the factory MNT setting.

Press and release the ↓ ↑ buttons repeatedly to increase or decrease the sensitivity of the monitoring (1-4). Press and release the **PROGRAM** button again to program the selected MNT setting; the last programmed operational mode then automatically resumes at its point of interruption.

If no keypad input is detected during any 30 second period during this selection procedure then the device powers off.

## 7.3. Electrode Harness Check



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This procedure tests the integrity of the SIS electrode harness (cable) for non-visible internal core breaks:

1. Power off the device.
2. Follow 2.1. CONNECTION OF ELECTRODE HARNESS TO SIS MACHINE instructions. *Do not* connect electrodes to the harness.
3. Power on the device.
4. Hold the two gold 'banana plugs' at the ends of the black and red wires of the electrode harness in contact with one another for a maximum of 55 seconds; make sure the contact between the 'banana plugs' is *continuous* and *do not* touch the banana plugs with your fingers or any other object.

If **R = SC** is shown in the Main Window of the display then the harness is **OK**.

If **R = OL** is shown in the Main Window of the display then the harness is **BROKEN**. Replace the electrode harness.

## 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 IF THERE IS A HISTORY OF SEIZURES. CONSULT WITH A SPECIALIST HEALTHCARE PROFESSIONAL BEFORE APPLICATION.

**DO NOT** USE IF THERE IS A SUSPECTED OF KNOWN SERIOUS INFECTIOUS DISEASE THAT REQUIRES HEAT OR FEVER TO BE SUPPRESSED. 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.

**FOR EXTERNAL USE ONLY.**

**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. 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. Maintain the protective shockproof silicon cover on at all times during operation and storage. Avoid leaving the device exposed to direct strong sunlight without ventilation or air-conditioning. Do not leave on or next to heaters or other heat-emitting devices.

### 10.2. SIS ELECTRODES

To prolong the lifetime of an SIS electrode, when removing from the body between non-wound applications, if adhesive surgical or wound dressing tape (e.g. Fixomull®) has been used, do not tear off the tape from the electrode. Cut the tape back to the SIS electrode size and shape, leaving the tape as a layer permanently stuck to the non-stimulation white foam surface of the electrode. On the next application of the same SIS electrode to the body, apply new dressing tape on top of the previous layer. The layers of tape remaining on the SIS electrode do not interfere with its electrical characteristics for correct operation.

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 and sweat.

### 10.3. STORAGE

Remove the batteries from the device during long-term storage to prevent damage from battery leaks and to avoid very gradual draining of charge of the batteries.

Store the device in a dry place away from heat-generating sources.

## 11. WARRANTY

Each new SIS machine (“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. 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/W200/WMcAMP/LVtCS 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 WMcAMP model 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 will 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 SIS machine that meets all of its design and functional specifications perfectly, as speedily as possible.

## 12. Returns

# SIS MACHINE M200 MODEL OPERATING MANUAL

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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](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.

## 13. Disposal



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

## 14. DEVICE SPECIFICATIONS

Parameter	Unit	Minimum	Typical	Maximum	Accuracy	Additional Notes
Input Battery Voltage	V	2.5	4.5	5.1	N/A	
Output Voltage in Current Stimulation Mode(s)	V	0	-	6.91	±10mV	Measured across 30kΩ 0.1% Sense Resistor†
Output Current	uA	0	-	220	±100nA (1uA-20uA) ±420nA (20uA-200uA)	Measured across 30kΩ 0.1% Sense Resistor†
Operating Temperature Range*	°C	-10		+60	N/A	
Resistance Measuring	Ω	100	-	3.80E+06	±10%	

\*Using an environmentally controlled chamber, the device has been tested and verified for accuracy throughout the temperature range of -10 to +60°C.

†Resistor value selected to simulate physiological bioelectric skin parameters.

NOTE: If the **I = [value]uA** (flashing) ELECTRODE CONTACT MONITORING alert is activated continuously then the device is incapable of delivering the user-programmed target Output Current. Use the Ohm's Law formula **V=IR**, where **V=6.91volts** and **I** is the user-programmed and displayed target Output Current **I=**, to calculate the maximum Total Circuit Resistance **R=** operating limit for the programmed Output Current.

## 15. MANUFACTURER'S DECLARATION



RADIATED EMISSIONS CONFORMITY	
RCM	AS/NZS CISPR 11: 2011 (CISPR 11: 2010 Ed 5.1) Industrial, scientific and medical (ISM) radio-frequency equipment
CE	EN 60601-1-2
FCC	FCC15B

### FCC STATEMENT

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.



# SIS MACHINE M200 MODEL OPERATING MANUAL

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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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