SIS MACHINES

TECHNICAL OPERATING MANUAL_v7.6_W200

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.

This operating manual covers SIS machine model W200. Read this manual carefully before using the SIS equipment.

CONTENTS

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 W200 MODEL IS ELECTRONICALLY CALIBRATED WITH EXTREME PRECISION IN THE 'WOUND' AND 'REGEN' (REGENERATION) OPERATIONAL MODES FOR THERAPEUTIC BIOLOGICAL ELECTRO-STIMULATION ONLY IN COMBINATION WITH THE SIS SILVER-NYLON CLOTH ELECTRODES. ONLY USE SIS ELECTRODES WITH SIS MACHINES IN THESE APPLICATIONS: USE OF OTHER ELECTRODES CAN CAUSE ADVERSE AND UNPREDICTABLE BIOLOGICAL EFFECTS. READ THE CONTRAINDICATIONS AND SAFETY INSTRUCTIONS INCLUDED IN THIS MANUAL. THE INSTRUCTIONS IN THIS MANUAL ARE NOT INTENDED TO REPLACE STANDARD WOUND CARE. THE SIS EQUIPMENT SHOULD BE USED FOR ACUTE AND CHRONIC WOUNDS ONLY AS PART OF OVERALL PROFESSIONAL WOUND CARE OR FOR EMERGENCY TRAUMA WOUND PROTECTION. A STANDARD WOUND CARE RESOURCE IS AVAILABLE AT: http://www.rch.org.au/rchcpg/hospital_clinical_guideline_index/wound_care/

DEVICE DESCRIPTION

The SIS machine model W200 is designed for electromedical direct current (DC) silver iontophoresis, electromedical measurement and supplementation of endogenous wound bioelectrics and fibroblast and other cellular modification.

OPERATIONAL MODES

'WOUND' operational mode is used for acute and chronic superficial and deeper surface wound treatment.

'REGEN' (REGENERATION) operational mode is used to stimulate the modification of fibroblast cells to hematopoietic-like stem cells for the healing and regeneration of surface injured tissue or of internal fibrotic tissue.

1. POWER SOURCE

All SIS machine models are powered by replaceable AAA type batteries (not included with delivery of device for air shipping regulations reasons).

Rechargeable batteries *can* be used to power the device 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×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 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 ⊕Positive Electrode.

- The SIS electrode that is connected to the **black** wire of the electrode harness is the SIS ⊖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 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 harness to the electrode wires.

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.

Press and release the **SOUND|DISPLAY** button to turn the OLED display on or off. Hold down the **SOUND|DISPLAY** button continuously for 3 seconds to turn the audio alerts on or off.

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 automatically turns off after 2 minutes for power saving.

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

WOUND operational mode is the default operational mode of the W200 model after powering on.

Press and release the **PROGRAM** button to interrupt the current operational mode and enable selection of the device model-specific operational modes;

the lower right Mode Window will become highlighted. Press and release the ⇩ ⇧ buttons repeatedly to select the required operational mode. Press and release the **PROGRAM** button again to program the selected operational mode.

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.

3.2. OUTPUT SETTINGS

The ⇩ ⇧ and **PROGRAM** buttons also adjust and program the following parameter:

Press and release the ⇩ ⇧ buttons repeatedly to select the SIS ⊕Positive Electrode size for use in 'REGEN' operational mode for internal fibrotic tissue.* Press and release the **PROGRAM** button to program the selected SIS ⊕Positive Electrode size.

***There is no user selection of SIS ⊕Positive Electrode size for surface injured tissue, since the constant low Output Voltage self-adaptively scales in real-time to the injured tissue's properties.

4. APPLICATION INSTRUCTIONS

5. Surface Wound, Surgical Wound or Skin Ulcer

Diagrams of SIS electrode applications for surface wounds are available from http://www.siselectromed.com/wound-healing

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

5.1. OPERATIONAL MODE SETTING

WOUND operational mode is the default setting of the W200 model after powering on.

5.2. Follow 2.2. ELECTRODE HARNESS POLARITY instructions.

5.2.1. SECURING SIS ELECTRODES TO BODY

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:

- When positioning an SIS electrode onto normal intact skin, extend the dressing tape beyond all edges of the electrode.

- On 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.

5.2.2. ELECTRODE SKIN CONTACT

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.

The lower end of *dry*, intact skin electrical resistance (R), measured in units of 'Ohms' (Ω), is approximately 50kiloohms (kΩ). Relatively large variation from this lower limit depending on many factors, up to approximately 1megaohm (MΩ), *is normal*, and the SIS machine continuously self-adapts to the R value encountered. Wet skin usually has a lower R value range. Real-time updating **R =** is shown on the OLED display. Generally, the closer to the lower end value **R =** 50kΩ, the better the electrode-skin contact and the SIS machine can operate more efficiently with lower voltage:

- Shave the skin if necessary to establish or improve electrode contact.
- Wet the silver-nylon surfaces of the SIS electrodes with distilled, tap or other clean water if available to reduce the electrical resistance **R =** of the electrode-skin contact area (interface).
- Check 5.2.1. SECURING SIS ELECTRODES TO BODY instructions. Replace or apply additional dressing tape if necessary.
- Check electrode is not discolored (12-72 hours lifetime); replace if necessary.

Monitor 10. AUDIO AND VISUAL ALERTS.

! INFORMATION: RECOMMENDED ELECTRODE LIFETIME FOR INFECTED WOUND
SIS POSITIVE (RED WIRED) ELECTRODE: 12-24 HOURS
SIS RETURN (BLACK WIRED) ELECTRODE: 24-72 HOURS

5.3. SIS ELECTRODE WOUND POSITIONING

There are 3 methods of applying SIS electrodes to wounds. When appropriate, 5.3.1. SUPERFICIAL WOUND electrode positioning has the advantage of not contacting the wound bed and so not mechanically interfering with the formation of granulation tissue.

5.3.1. SUPERFICIAL WOUND (INFECTED)

a. Cut the SIS ⊕Positive Electrode to the size and shape of the wound.

b. 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. Secure electrode to body.

c. Select an SIS ⊖Return Electrode approximately the same size or larger than the SIS ⊕Positive Electrode; cut electrode to size if necessary.

d. Position the SIS ⊖Return Electrode onto intact skin as much as possible directly behind the wound on the opposite anatomical surface of the injured body part. Secure electrode to body.

- Check 5.2.2 ELECTRODE SKIN CONTACT instructions.

! NOTE: If 5.3.1. SUPERFICIAL WOUND electrode positioning is not achievable (e.g. due to a wound dressing considered not removable), or if the SIS machine display shows the **NO WOUND** and/or **NO CAL!** alerts and powers off, then position the SIS ⊕Positive and ⊖Return Electrodes across the wound as close as possible to the wound edges; follow 5.4.a.6. SUPERFICIAL WOUND CALIBRATION instructions. Revert to 5.3.1. SUPERFICIAL WOUND electrode positioning when possible.

5.3.1.a. DYNAMIC SIS ⊕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 [refer to 5.2.2. ELECTRODE SKIN CONTACT], it might be advantageous to re-position the electrode at a different o'clock location around the wound edges (e.g. in the repeating sequence: 3-6-9-12 o'clock) to distribute stimulation evenly to the entire wound over time.

5.3.2. DEEPER WOUND (INFECTED)

a. Cut the SIS ⊕Positive Electrode to the size and shape of the wound bed.

b. 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 in any direction, or as minimally as possible.

c. Cover the SIS ⊕Positive Electrode with saline/sterilizing liquid-rinsed gauze or other non-adherent moisture-holding wound dressing, if available. Secure electrode and non-adherent dressing to the body.

d. Select an SIS ⊖Return Electrode approximately the same size or larger than the SIS ⊕Positive Electrode; cut electrode to size if necessary.

e. Position the SIS ⊖Return Electrode onto intact skin as much as possible directly behind the wound on the opposite anatomical surface of the injured body part. Secure electrode to body.
- Check 5.2.2. ELECTRODE SKIN CONTACT instructions.

NOTE: If 5.3.2. DEEPER WOUND electrode positioning is not achievable (e.g. a wound dressing considered not removable), apply 5.3.1. SUPERFICIAL WOUND electrode configuration. Revert to 5.3.2. DEEPER WOUND electrode positioning when possible.

5.3.3. FIRST AID: SIS ⊕POSITIVE ELECTRODE ONLY (a-b) OR WITH SIS ⊖RETURN ELECTRODE AND SIS MACHINE (a-d)

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; cut electrode to size and shape of wound if necessary.

b. Apply the SIS ⊕Positive Electrode directly over the wound. Secure electrode to body.

c. Select an SIS ⊖Return Electrode approximately the same size or larger than the SIS ⊕Positive Electrode; cut electrode to size if necessary.

d. Position the SIS ⊖Return Electrode onto intact skin as much as possible directly behind the wound on the opposite anatomical surface of the injured body part. Secure electrode to body.
- Check 5.2.2. ELECTRODE SKIN CONTACT instructions.

5.4. DEVICE TO WOUND CALIBRATION

Calibration begins when 'WOUND' or 'REGEN' operational mode is programmed and SIS ⊕Positive Electrode↔wound positioning is detected.

a. SUPERFICIAL WOUND CALIBRATION: The *maximum* SIS ⊕Positive Electrode distance from a wound edge is approximately 2cm (3/4"). This distance range usually corresponds to a periwound/adjacent-wound-edge tissue electrical resistance **R =** ≤90kΩ. If **R =** >90kΩ, the **NO WOUND** audio-visual alert is activated:

1. Check 5.2.1. SECURING SIS ELECTRODES TO BODY.
2. Moisten the periwound/adjacent-wound-edge tissue with saline, tap or other clean water if available to lower the displayed electrical resistance **R =** of the electrode-skin contact area.
3. Move the SIS ⊕Positive Electrode closer to the wound edge.
4. Cut down the SIS ⊕Positive Electrode to a smaller size.
5. Debride wound if appropriate (physician or wound nurse only).
6. Follow 3.1. OPERATIONAL MODE PROGRAMMING instructions to program **REGEN** operational mode, and 6.3.2.3.a. SELECTING SIS ⊕POSITIVE ELECTRODE SIZE instructions to program a 1.5cm² SIS ⊕Positive Electrode size; the lower left Alert Window of the display will show **INTL FIBRO**.

Monitor 10. AUDIO AND VISUAL ALERTS.

b. DEEPER WOUND CALIBRATION: Check that the **WOUND BED** audio-visual alert is activated, which indicates optimal calibration to the deeper wound. This alert will correspond to a displayed electrical resistance **R =** ≤40kΩ. If **R =** >40kΩ and **WOUND EDGE** audio-visual alert is activated:

1. Check 5.2.1. SECURING SIS ELECTRODES TO BODY.
2. Check SIS ⊕Positive Electrode does not extend beyond wound edges.
3. Moisten wound bed with saline if available to lower its **R =** value.
4. Debride wound if appropriate (physician or wound nurse only).

Monitor 10. AUDIO AND VISUAL ALERTS.

NOTE: During each stimulation cycle, there is a pre-programmed 2 minute rest period to prevent cellular polarization. The display shows: **I= 0.0nA** and **V= 0uV**.

6. Tissue Regeneration

6.1. OPERATIONAL MODE SETTING

Follow 3.1. OPERATIONAL MODE PROGRAMMING instructions to program **REGEN** operational mode.

6.2. Follow 2.2. ELECTRODE HARNESS POLARITY and 5.2.1. SECURING SIS ELECTRODES TO BODY instructions.

6.3. APPLYING SIS ELECTRODES

6.3.1. SURFACE INJURED TISSUE

a. Follow 5.3.2. DEEPER WOUND instructions for applying the SIS ⊕Positive and ⊖Return Electrodes to the surface injured tissue.

b. The Total Circuit Resistance **R=** must be ≤90kΩ [SEPTEMBER 2016 ONWARDS: ≤40KΩ] for correct operation (shown in the Main Window of the display). If **R=** >90kΩ [>40KΩ] the device automatically switches to 6.3.2. INTERNAL FIBROTIC TISSUE operation:

- Check 5.4.b. DEEPER WOUND CALIBRATION.

Monitor 10. AUDIO AND VISUAL ALERTS.

6.3.2. INTERNAL FIBROTIC TISSUE

6.3.2.1. SELECTING SIS ELECTRODE SIZE

The SIS ⊕Positive Electrode must completely 'cover' the target internal organ or tissue, as much as possible. The electrode must be at least the same size or slightly larger than the target internal organ or tissue as it would be seen 2-dimensionally in an X-ray taken from the position and anatomical plane of the electrode on the body surface. Do not use an over-sized SIS ⊕Positive Electrode, as the SIS machine can more accurately monitor the electrode's contact with the body the smaller its size.

The SIS ⊖Return Electrode must 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 across the SIS electrode wire inside the SIS electrodes.

6.3.2.2. POSITIONING SIS ELECTRODES ON THE BODY

a. Position the SIS ⊕Positive Electrode onto the skin directly over the target organ or tissue. Secure electrode to body.

b. Position the SIS ⊖Return Electrode onto the opposite anatomical surface of the body to the SIS ⊕Positive Electrode so that the target organ or tissue is aligned as much as possible between the two SIS electrodes.* Secure electrode to body.

**This electrode positioning configuration focuses silver ion flow into the target organ or tissue between the two SIS electrodes. 'Wasted' current flow through the skin between the electrodes is thereby prevented or minimized.*

6.3.2.3 SELECTING SIS ⊕POSITIVE ELECTRODE SIZE

a. The Main Window of the display will show:

ADJ ELCTRODE SZE
MIN=1.5, MAX=50
SELECT: 1.5 CM²

Press and release the **PROGRAM** button to program the default 1.5cm² SIS ⊕Positive Electrode size.

Follow 3.2. OUTPUT SETTINGS instructions to select and program a larger applied SIS ⊕Positive Electrode.

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

If the device cannot calibrate with the programmed SIS ⊕Positive size:

- Check 5.2.2. ELECTRODE SKIN CONTACT instructions.

Monitor 10. AUDIO AND VISUAL ALERTS.

6.4. CONSTANT CURRENT SCALING

When applied to an internal fibrotic tissue target, the constant Output Current is automatically scaled to the user-programmed size of the SIS ⊕Positive Electrode [Figure 1]. The smallest electrode size that can be programmed is 1.5cm².

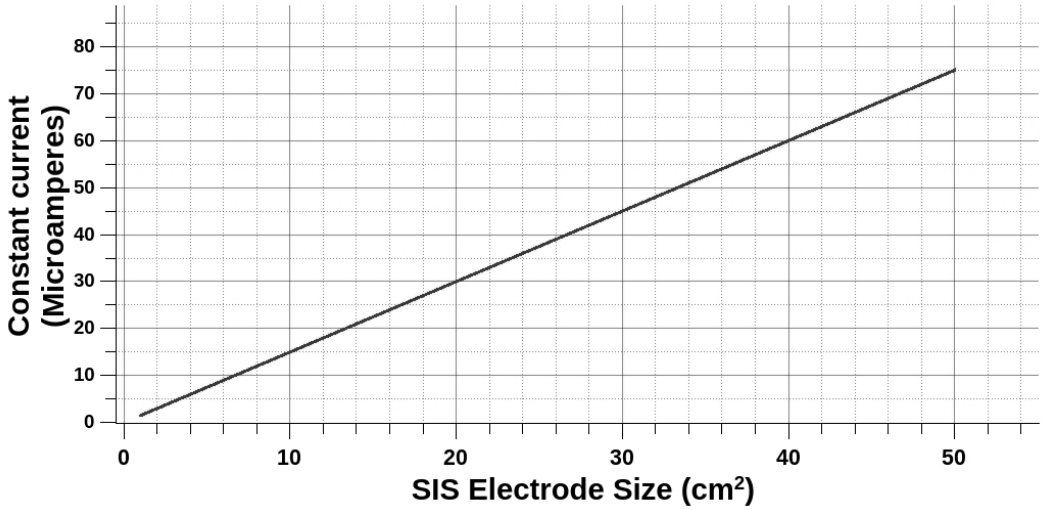


Figure 1: *Automatic scaling of constant Output Current to user-programmable SIS ⊕Positive Electrode size.*

To override the automatic constant Output Current scaling:

- Select and program either a larger or smaller SIS ⊕Positive Electrode than actually used. For example, to program an Output Current of 60microamperes for an actually used 30cm² SIS ⊕Positive Electrode, select and program a 40cm² SIS ⊕Positive Electrode.

If a standard 4.7cm (1.87") diameter Small circular SIS electrode is used, select and program its approximate surface area of 20cm². Similarly, for any irregular shape SIS electrode, calculate and program its approximate surface area.

6.4.1. TOTAL CIRCUIT RESISTANCE OPERATING LIMITS

The maximum SIS ⊕Positive Electrode size of any shape is 50cm². This is the SIS electrode size limit that the device can supply with the correctly scaled constant Output Current for possible fibroblast cell modification.

During operation, the Total Circuit Resistance to the Output Current that the device encounters mostly consists of the electrical resistances of the intact skin in contact with the SIS ⊕Positive and ⊖Return Electrodes. The Total

Circuit Resistance **R =** is continuously displayed in the Main Window of the display. The higher the Total Circuit Resistance **R =** *the smaller* the maximum SIS ⊕Positive Electrode size that can be applied [Table 1]:

- Follow 5.2.2. ELECTRODE SKIN CONTACT instructions to maintain the Total Circuit Resistance **R =** within the operating limit for the user-programmed SIS ⊕Positive Electrode size and automatically scaled constant Output Current.
- If the maximum Total Circuit Resistance operating limit for the size of the SIS ⊕Positive Electrode applied cannot be (continuously) achieved, use a smaller SIS ⊕Positive Electrode and/or treat a smaller target internal fibrotic area at one time.

Electrode Size (cm^2)	1.5	2.5	5	10	15	20	25	30	35	40	45	50
Maximum Total Circuit Resistance (**MΩ**, kΩ)	**3**	**1.8**	921	460	307	230	184	152	131	115	102	92

Table 1: *Maximum Total Circuit Resistance operating limits for user-programmable electrode sizes and automatically scaled constant Output Currents [Figure 1].*

For example, for a $20cm^2$ user-programmed SIS ⊕Positive Electrode, the SIS machine will produce a constant Output Current of 30microamperes [Figure 1], with a Total Circuit Resistance operating limit of **R =** 230kΩ [Table 1].

10. AUDIO AND VISUAL ALERTS

The user-programmed operational mode is displayed in the lower right Mode Window of the OLED display. Alerts [Table 2] are displayed in the lower left Alert Window. The following real-time values are shown in the Main Window of the display [Figure 2]:

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 activation or deactivation is indicated by the 🔊🔇 symbols in the upper right of the Main Window.

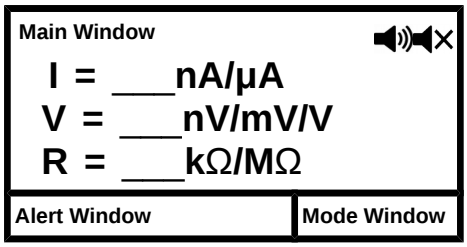


Figure 2: *OLED display layout.*

STDBY CALI	**ST**AN**DBY CALI**BRATING to skin or wound.
CONTACT OK	Electrode **CONTACT OK.**
CONTCT LOW	Electrode **CONT**A**CT LOW** statistically.
CNTCT FLUC	Electrode **C**O**NT**A**CT FLUC**TUATING**.**
CIRC BREAK	Effective or physical **CIRC**UIT **BREAK**.
WOUND BED	Calibrated to **WOUND BED**.
WOUND EDGE	Calibrated to **WOUND EDGE**.
NO WOUND	**NO WOUND** detected.
NO CALI	**NO CALI**BRATION possible.
SURF INJRY	Calibrated to **SURF**ACE **INJ**U**RY**.
INTL FIBRO	Calibrated to **INT**ERNA**L FIBRO**TIC tissue.
BATT LOW	**BATT**ERY **LOW** charge.
MNT OFF	Circuit **M**O**NIT**ORING **OFF**.
VOLT ALERT	High Output **VOLT**AGE **ALERT**.

Table 2: Displayed audio-visual alert abbreviations of all SIS machine models.

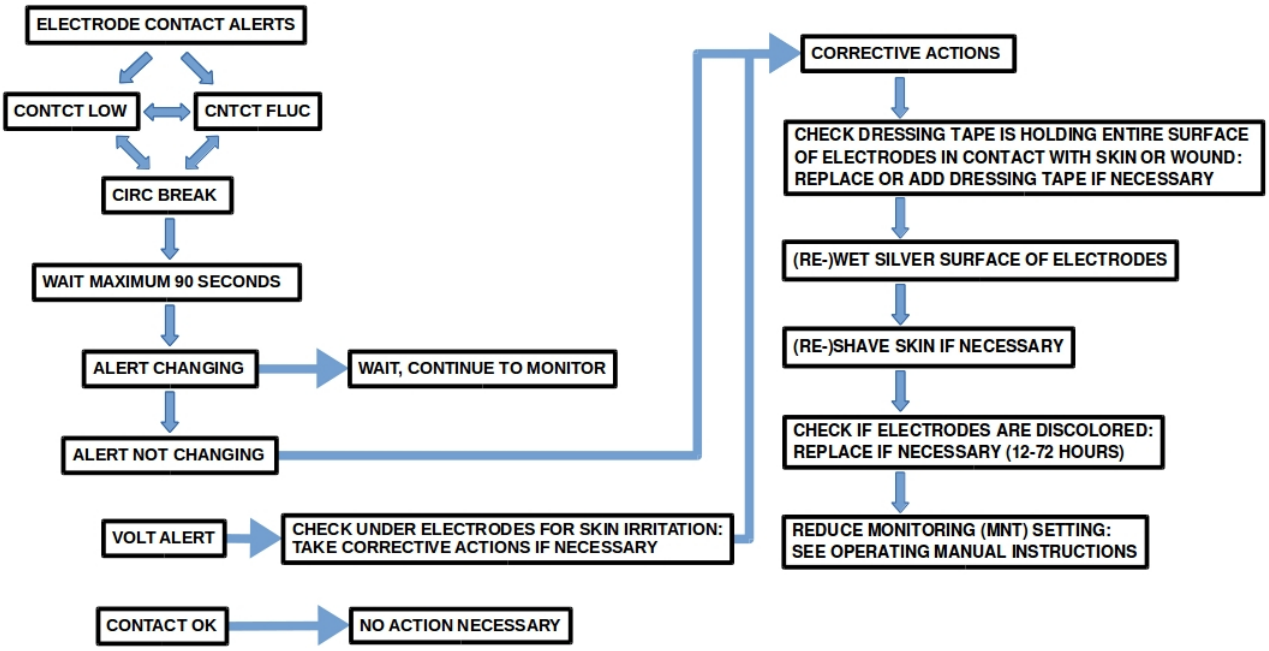
	M100/M200/W200 models				
ALERT TYPE	**AUDIO**	**VISUAL** *OLED DISPLAY*			**CORRECTIVE ACTION**
OPERATIONAL MODE INITIALIZATION					
– **Operational mode is programmed.**	***1 BEEP***	**[MODE NAME]** *Unhighlighted*			–
– **Calibrating to body.**	***1 BEEP*** *5 SEC INT*	**STDBY CAL** ***FLASHING*** *5 SEC INT*			• Standby, wait for alert to stop.
– **Operation normal.**	–	**[MODE NAME]**			–
CIRCUIT MONITORING					
– **Electrode contact OK: Within all user-programmed and factory limits.**	–	**CONTACT OK**			–
– **Fluctuating SIS electrode contact in short time-frame (1-2seconds) exceeds operating limits.**	***2 BEEPS*** *5 SEC INT*	**CNTCT FLUC** ***FLASHING*** *5 SEC INT*			**All applications** • For SIS electrode(s) positioned onto intact skin, check: ◦ 5.2.2. ELECTRODE SKIN CONTACT. • If alert continues, follow instructions: ◦ 10.2. ELECTRODE CONTACT MONITORING SETTING ◦ 10.3. ELECTRODE HARNESS CHECK **'WOUND'/'REGEN' mode applications** • For SIS ⊕Positive Electrode positioned near edge of superficial wound, check: ◦ 5.4.a. SUPERFICIAL WOUND CALIBRATION. • For SIS ⊕Positive Electrode positioned onto deeper wound bed, check: ◦ 5.4.b. DEEPER WOUND CALIBRATION.
– **SIS electrode contact statistically lower than electrode contact monitoring (MNT) limits for user-programmed Output Current.**	***3 BEEPS*** *5 SEC INT*	**CONTCT LOW** ***FLASHING*** *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*	**VOLT ALERT** ***FLASHING*** *5 SEC INT 30 SEC DURATION*			**All in vivo applications** • Check for skin irritation under contact area of SIS ⊕Positive Electrode. • To prevent or if skin irritation is present, follow instructions: ◦ 5.2.2. ELECTRODE SKIN CONTACT.

	M100/M200/W200 models				
ALERT TYPE	**AUDIO**	**VISUAL** *OLED DISPLAY*			**CORRECTIVE ACTION**
CIRCUIT MONITORING					
– **Circuit break (consecutive Open Loads). Effective or physical circuit break.** **Programmed Open Load trigger is R>3.8megaohms.**	***10 BEEPS*** *5 SEC INT*	**CIRC BREAK** ***FLASHING*** *5 SEC INT* **OL** *Main Window*			**All applications** • Check for loose connections or breaks (including alligator clip connectors if non-SIS electrodes are used). • Check: ◦ 2.1. CONNECTION OF ELECTRODE HARNESS TO SIS MACHINE. ◦ 2.3. CONNECTION OF ELECTRODE HARNESS TO SIS ELECTRODES. ◦ 5.2.1. SECURING SIS ELECTRODES TO BODY. • For SIS electrode(s) positioned onto intact skin, check: ◦ 5.2.2. ELECTRODE SKIN CONTACT. • If alert continues, follow instructions: ◦ 10.3. ELECTRODE HARNESS CHECK. **'WOUND'/'REGEN' mode applications** • For SIS ⊕Positive Electrode positioned near edge of superficial wound, check: ◦ 5.4.a. SUPERFICIAL WOUND CALIBRATION. • For SIS ⊕Positive Electrode positioned onto deeper wound bed, check: ◦ 5.4.b. DEEPER WOUND CALIBRATION.
– **Device powering off. Continuously insufficient electrode contact over last 4-8 minutes.**	***5 BEEPS*** *5 SEC INT*	**NO CALI** ***FLASHING*** *5 SEC INT*			–
– **Circuit MoNiToring (MNT) turned OFF by user in 'MICRO' or 'VOLT', or auto OFF in 'WATER' operational modes.**	–	**MNT OFF**			–
– **Maximum circuit resistance (load) exceeded for target user-programmed Output Current.** **Device cannot deliver target Output Current.**	–	**I = [value]uA** ***FLASHING*** *CONTINUOUS*			**All in vivo applications** • Check for **CONTCT LOW** or **CIRC BREAK** alerts. **'REGEN' mode applications** • Check 6.4.1. TOTAL CIRCUIT RESISTANCE OPERATING LIMITS. Check 17. DEVICE SPECIFICATIONS: Output Voltage in Current Stimulation (modes).
– **Stabilizing to target Output Current.**	–	**I = [value]uA** ***FLASHING*** *INTERMITTENT*			• No action required. Information only.

	M100/M200/W200 models				
ALERT TYPE	**AUDIO**	**VISUAL** *OLED DISPLAY*			**CORRECTIVE ACTION**
'WOUND' OPERATIONAL MODE					
– **Calibrating to wound (also in 'REGEN' operational mode).**	***1 BEEP*** *5 SEC INT*	**STDBY CALI** ***FLASHING*** *5 SEC INT*			• Standby, wait for alert to stop.
– **SIS ⊕Positive Electrode positioned onto deeper wound bed: Calibration OK.**	–	**WOUND BED**			• No action required. If SIS ⊕Positive Electrode positioned near edge of superficial wound, operation is correct.
– **SIS ⊕Positive Electrode positioned onto periwound or adjacent-wound-edge tissue of superficial wound: Calibration OK.**	–	**WOUND EDGE**			• If SIS ⊕Positive Electrode positioned onto deeper wound bed, check: ◦ 5.4.b. DEEPER WOUND CALIBRATION.
– **SIS ⊕Positive Electrode not positioned on deeper wound bed.** AND – **SIS ⊕Positive Electrode not positioned near superficial wound edge.** OR – **SIS ⊕Positive Electrode too far from superficial wound edge.**	***4 BEEPS*** *VARIABLE INT*	**NO WOUND** ***FLASHING***			• For SIS ⊕Positive Electrode positioned near edge of superficial wound, check: ◦ 5.4.a. SUPERFICIAL WOUND CALIBRATION. • For SIS ⊕Positive Electrode positioned onto deeper wound bed, check: ◦ 5.4.b. DEEPER WOUND CALIBRATION. • For SIS ⊖Return Electrode positioned onto intact skin, check: ◦ 5.2.2. ELECTRODE SKIN CONTACT. • Check for wound closure.
– **Device cannot calibrate to wound (also in 'REGEN' operational mode): Fluctuating SIS electrode contact with either periwound/ adjacent-wound-edge tissue or wound bed exceeds operating limits. Powering off in 10 seconds.**	***5 BEEPS*** *5 SEC INT*	**NO CALI** ***FLASHING*** *5 SEC INT*			• Check 5.2.1. SECURING SIS ELECTRODES TO BODY. • For SIS ⊕Positive Electrode positioned near edge of superficial wound, check: ◦ 5.4.a. SUPERFICIAL WOUND CALIBRATION. • For SIS ⊕Positive Electrode positioned onto deeper wound bed, check: ◦ 5.4.b. DEEPER WOUND CALIBRATION. • In 'REGEN' operational mode for internal fibrotic tissue, check: ◦ 5.2.2. ELECTRODE SKIN CONTACT.

	M100/M200/W200 models				
ALERT TYPE	**AUDIO**	**VISUAL** *OLED DISPLAY*			**CORRECTIVE ACTION**
'REGEN' OPERATIONAL MODE					
– **SIS ⊕Positive Electrode positioned for surface injured (wound) tissue: Calibration OK.**	–	**SURF INJRY**			–
– **SIS ⊕Positive Electrode positioned for internal fibrotic tissue: Calibration OK.**	–	**INTL FIBRO**			–
SOUND CONTROL					
– **Sound turned OFF.**	–	🔇			–
– **Sound turned ON.**	***2 BEEPS***	🔊			–
BATTERY CHARGE					
– **Charge OK.**	–	**BATTERY CHARGE LED** ***FLASHING*** *5 SEC INT*			–
– **Charge low for correct operation.**	***1 BEEP*** *5 SEC INT*	**BATT LOW** ***FLASHING*** *5 SEC INT.* **BATTERY CHARGE LED** ***ON*** *CONTINUOUS*			• Replace batteries, follow instructions: ◦ 1.1. Inserting AAA Batteries.
Abbreviations: *SEC* (seconds), *INT* (interval between sets of beeps).					

10.1. HOW TO MONITOR AND RESPOND TO AUDIO-VISUAL ALERTS



10.2. Electrode Contact Monitoring Setting

The CIRCUIT MONITORING audio-visual alerts are based on real-time updating statistical and algorithmic analysis of Total Circuit Resistance 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 CIRCUIT MONITORING alerts even after following the CORRECTIVE ACTION points in the AUDIO AND VISUAL ALERTS table above, the user can vary a master parameter of the electrode contact monitoring (MNT) algorithms.

NOTE: For 'WOUND' and 'REGEN' operational modes, maintaining the maximum factory calibrated MNT setting is recommended, if possible.

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.

10.3. Electrode Harness Check

This procedure tests the integrity of the SIS electrode harness 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.

11. 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 WMcAMP 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.

12. 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.

13. MAINTENANCE

13.1. DEVICE

The device is maintenance free. Only wipe the external surfaces with a clean damp cloth. Do not use any kind of detergent or solvent. Avoid strong impacts on the device. 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.

13.2. 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.

13.3. 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.

14. 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/W200/WMcAMP 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.

15. 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.

16. Disposal

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

17. 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 'Wound' & 'Regen' Modes	V	0	-	4.82	±10mV	Measured across 30kΩ 0.1% Sense Resistor†
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.

17. 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.

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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