SIS MACHINES

LOW VOLTAGE TRANSCRANIAL STIMULATOR

OPERATING MANUAL_v1.3_LVtC

This operating manual is downloadable from
https://siselectromed.com/cranial-electrical-stimulation-electrotherapy-device

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.

CONTENTS

DELIVERY AND UNPACKING

Please unpack the shipping package carefully and inspect contents immediately on receipt. Check that all ordered equipment is included in the shipping box and notify SIS Manufacturing Ltd New Zealand immediately of any missing items from your order.

Visible damage or tampering to shipping boxes must be recorded before signing the delivery receipt. Please take photographs of any received damaged items. Report the damage or tampering immediately to the shipping carrier. You must also notify SIS Manufacturing Ltd immediately of any received damaged or tampered items or of any lost shipments.

⚠ WARNING FOR BIOLOGICAL APPLICATIONS

THE LVtC STIMULATOR IS ELECTRONICALLY CALIBRATED WITH EXTREME PRECISION FOR THERAPEUTIC BIOLOGICAL ELECTRICAL STIMULATION ONLY IN COMBINATION WITH ELECTRODES APPROVED FOR BIOLOGICAL CONTACT AND MEDICAL/THERAPEUTIC APPLICATIONS. READ THE CONTRAINDICATIONS AND SAFETY INSTRUCTIONS IN THIS MANUAL BEFORE USING THE DEVICE.

DEVICE DESCRIPTION

The LVtC Stimulator is designed for low voltage waveform (AC) cranial electrical stimulation (CES) for therapeutic and research purposes.

Read section 14. MANUFACTURER'S DECLARATION of this manual for electromagnetic conformity information.

1. POWER SOURCE

The LVtC Stimulator is powered by replaceable AA type batteries. Rechargeable batteries can be used and do not compromise the correct function of the device. Refer to 7. SPECIFICATIONS for further information.

⚠ Do not use zinc-carbon batteries, which can leak and damage the device.

1.1. Inserting AA 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 4 × AA 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; maintain on at all times to protect the device.

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. Follow 3.2.3. CABLE TEST instructions.

3. CONTROLS AND OPERATION

Power on device ◯ hold down push-button-rotary-dial for 2 seconds.

Main Operating Screen	Output voltage **INTENSITY**, session **DURATION**, **CABLE TEST** status, battery charge status **LOW** displayed.							
Access menu ◯ Hold for 5 seconds.	**ENTER MENU?**	**NO**	Main Operating Screen					
		YES	Main **MENU**					
			◯ Rotate to select.					
			POWER OFF	Click to select.				
			INTENSITY		◯ Click to unlock.	◯ Rotate to adjust, click to set: **70-1000mV**. Rotate to exit adjust bar.		◯ **EXIT TO MENU** Click to select.
			CABLE TEST		1.Instructions 2.Instructions 3.**TEST** Rotate to exit test.	◯ Click to test. Rotate to exit test.	Test result: **PASSED** or **FAILED**	
			DISPLAY BRIGHTNESS		◯ Click to unlock.	◯ Rotate to adjust, click to set: **10-100%**. Rotate to exit adjust bar.		
			EXTRAS		**EXTRAS MENU** ◯ Rotate to scroll, click to select.	**VOLTAGE AMPLIFICATION**	Not for use with this model device.	◯ **EXIT TO MENU** Click to select.
						ABOUT	Device Information	
						RETURN TO MAIN MENU		
			EXIT MENU	Main Operating Screen				

3.1 POWERING ON THE DEVICE

Hold down the push-button-rotary-dial on the face panel of the device continuously for 2 seconds to power on the device (LCD display turns on).

3.2. MAIN MENU ACCESS

After powering on, press and hold the push-button-rotary-dial continuously for 5 seconds until the **ENTER MENU?** prompt appears. Rotate the push-button-rotary-dial to select **YES**, then press and release (click) the dial to select.

NOTE: If no user input is detected during 10 seconds after the **ENTER MENU?** prompt appears, then the device returns to the the Main Operating Screen.

To exit from the Main Menu back to the Main Operating Screen, rotate the push-button-rotary-dial and scroll to **EXIT MENU**, then click the dial to select.

NOTE: If no user input is detected during any 30 second period within any menu selection procedure, then the device automatically powers off.

3.2.1. POWER OFF

In the Main Menu screen, rotate the push-button-rotary-dial to scroll to **POWER OFF** the device, then click the dial to select.

3.2.2. INTENSITY

The minimum and default factory setting of the Output Voltage is 70 millivolts (mV). The Output Voltage resets to the default setting each time the device is powered off.

In the Main Menu screen, rotate the push-button-rotary-dial to scroll to **INTENSITY**, then click the dial to select. The **INTENSITY** adjustment screen will be displayed:

- ► Click the push-button-rotary-dial once to unlock the adjustment box, slowly rotate the dial to adjust the peak Output Voltage (V) intensity in steps of 10 millivolts (mV) from 70mV-1000mV, then click the dial again to set.

Rotate the push-button-rotary-dial to scroll to **EXIT TO MENU**, then click the dial to exit back to the Main Menu screen.

3.2.3. CABLE TEST

! NOTE: Perform a cable (harness) test at the start of each new session to ensure stimulation is being delivered by the device.

In the Main Menu screen, rotate the push-button-rotary-dial to scroll to **CABLE TEST**, then click to select. The **CABLE TEST** screen will be displayed:

Follow these steps ►

1. Connect the cable (harness) to the machine.
2. Hold the gold ends of the cable in continuous contact with each other.
3. Click the push-button-rotary-dial to select **TEST**, then wait approximately 5 seconds for the result of the test to be shown.

If the result of the cable test is **PASSED** then the cable is OK.
If the result of the cable test is **FAILED**, repeat the cable test:

- Re-check 2. ELECTRODE CABLE CONNECTION instructions.
- Repeat the cable test.
- If the repeat cable test result is **FAILED** then the cable has a fault and needs replacing.

Click **EXIT TO MENU** to return to the Main Menu screen.

3.2.4. DISPLAY BRIGHTNESS

The LCD display has a secondary backlight that automatically turns on when the user operates the push-button-rotary-dial to control the device. The default factory setting of the backlight brightness is 10% and re-sets each time the device is powered off.

The backlight is factory set to turn off automatically after 10 seconds for power-saving if no further user operation is detected at any time.

In the Main Menu screen, rotate the push-button-rotary-dial to scroll to **DISPLAY BRIGHTNESS**, then click the dial to select. The **DISPLAY BRIGHTNESS** screen will be displayed:

► Click the push-button-rotary-dial once to unlock the adjustment box, slowly rotate the dial to adjust the screen backlight brightness from 10% to 100% in steps of 10%, then click the dial again to set.

Rotate the push-button-rotary-dial to **EXIT TO MENU**, then click the dial to return to the Main Menu screen.

NOTE: The backlight display brightness setting will affect overall battery life during extended operation.

3.2.5. EXTRAS

In the Main Menu screen, rotate the push-button-rotary-dial to scroll to **EXTRAS**, then click the dial to select. The **EXTRAS MENU** screen will be displayed:

VOLTAGE AMPLIFICATION
ABOUT
RETURN TO MAIN MENU

Rotate the push-button-rotary-dial to scroll through the extras menu options, then click the dial to select.

Select and click on **RETURN TO MAIN MENU** to exit the extras menu and return to the Main Menu screen.

3.2.5.1. VOLTAGE AMPLIFICATION

Not for use with this model device.

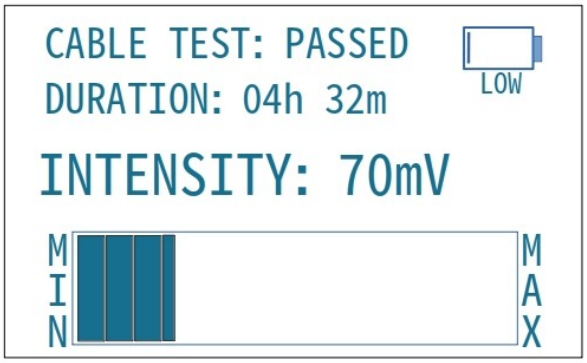
3.2.5.2. ABOUT

The Model Code, Serial Number, Software and Firmware versions, and Build Date of the device are displayed.

Click **EXIT TO MENU** to return to the extras menu screen.

4. DISPLAY

Main operating screen



4.1. The user-programmed maximum positive offset (peak) Output Voltage **INTENSITY** is shown in millivolts (**mV**), and represented by the horizontal bar from **MIN** to **MAX**.

4.2. The session **DURATION** from the time of the last power ON is displayed in hours (**h**) and minutes (**m**), and is updated every 1 minute.

NOTE: The device has a factory set, automatic power-down timer that powers off the device after a continuous treatment session duration of 10 hours.

4.3. A low battery charge status (approximately 20% remaining) is indicated by **LOW** flashing below the battery icon appearing in the top right of the display.

4.4. The **CABLE TEST** status for the current treatment session is shown at the top of the display. **CABLE TESTED: NO** is displayed at the start of each new session until a cable test has been performed.

After a cable test has been completed, either **PASSED** or **FAILED** is displayed for the remainder of the current session.

APPLICATION INSTRUCTIONS

5. ELECTRODES

Two electrodes must be used with the LVtC Stimulator. The electrodes are physically interchangeable depending on the specific application.

5.1. ELECTRODE TYPE

Two types of electrode can be used with the LVtC Stimulator:

ELECTRODE TYPE	TYPICAL CIRCUIT RESISTANCE	NOTES
SIS silver-nylon cloth	≤50-100 kiloohm	Follow INSTRUCTIONS FOR USE (IFU) on the IFU card inside each SIS electrode pack. Electrodes MUST BE KEPT MOIST DURING USE.
Self-adhesive hydrogel electrotherapy electrodes	≥400 kiloohm	Check that the black or blue hydrogel layer of the electrode remains sticky; re-wet or replace if needed. Only use high quality electrodes.

NOTE: SIS silver-nylon electrodes are the recommended and optimal electrodes to use with the LVtC Stimulator for maximum conductivity and signal transmission.

5.2. SELECTING ELECTRODE SIZE

If applying SIS silver-nylon electrodes, use the Small round 4.7cm (1.87 inch) ødiameter circular size.

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

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

If applying self-adhesive hydrogel electrodes, select a size appropriate to the size of the head; usually a 1-2cm square or circular electrode will be correct.

5.3. ELECTRODE POSITIONING

Figure 1 illustrates the normal electrode positioning for the LVtC Stimulator.

Position the electrodes symmetrically on the left and right side temples of the head. The area of the temple is the side of the head behind and slightly above the level of the eyes (anatomically: overlying the superior aspect of the sphenoid bone).

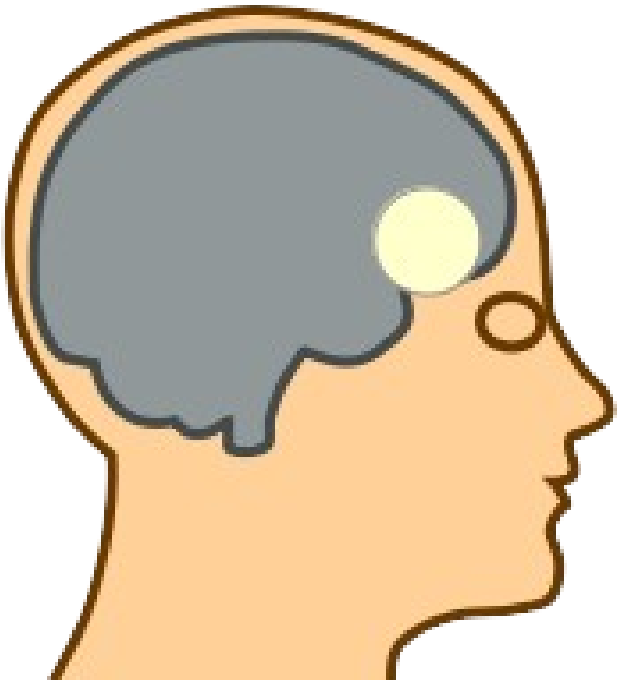


Figure 1: Positioning of the electrodes on the temples; right side shown, left side positioning is symmetrical to the right side.

5.4. SECURING ELECTRODES TO BODY

- If SIS silver-nylon cloth electrodes are used, follow the INSTRUCTIONS FOR USE (IFU) on the IFU card included in each SIS electrode pack.
- If self-adhesive hydrogel electrodes are used, apply directly to the skin. The hydrogel layer must be kept very moist to maintain sufficient conductivity for therapeutic effect; refer to section 5.1. ELECTRODE TYPE instructions.

5.5. CONNECTING ELECTRODE HARNESS TO ELECTRODES

Position and secure the electrodes to the body first, and then connect the electrode harness (cable) to the two electrode wires.

Insert the two gold metal 'banana plugs' at the ends of the electrode cable into the plastic connectors at the ends of the 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 device.

5.6. ELECTRODE CONNECTION POLARITY

- The electrode that is connected to the red wire of the electrode harness is denoted the (+)positive electrode.
- The electrode that is connected to the black wire of the electrode harness is denoted the (-)negative or ‘return’ electrode.

Polarity of connection of the electrode harness to the (+)positive and (-) negative electrodes on the body can be either way around.

6. INTENSITY SETTING

In general, due to the advanced LVtC Stimulator technology, strong therapeutic effects can be readily achieved with very low intensity stimulation even in the low millivolt (mV) range.

The default, minimum **INTENSITY** setting after powering on the device is **70mV**. For many applications, this minimum setting is sufficient for achieving very significant therapeutic effects. For most applications, the maximum **INTENSITY** setting necessary is **250 mV**, even for strong and rapid therapeutic effect.

7. SPECIFICATIONS

Parameter	Unit	Minimum	Typical	Maximum	Accuracy	Additional Notes
Input Battery Voltage	V	4.6	-	6	N/A	-
Output Voltage	V	0.07	-	±3.3	±10mV	P-P
Input Current	mA	50	-	100	N/A	-
Output Current	mA	0	-	10	N/A	-
Internal Frequency	MHz			48		-
Operating Temperature Range	°C	-	-	-	N/A	-

8. CONTRAINDICATIONS AND SAFETY

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 LVtC 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. Keep the protective shockproof silicon cover on at all times during operation and storage. Avoid leaving the device exposed to direct, strong sunlight. Do not leave on or next to heaters or other heat-emitting elements.

10.2. STORAGE

Remove the batteries from the device during long-term storage to prevent damage from battery leaks, and to avoid gradual draining of charge of the batteries. Store the device in a dry place away from heat-generating sources.

10.3. SIS ELECTRODES

The silver-nylon stimulation surface of an SIS electrode that has been applied only to normal intact skin can be cleaned by gently wiping with a clean damp cloth or cotton wool (use tap/other clean water) to remove dead skin cells, sweat and electrochemical debris.

11. WARRANTY

The LVtC Stimulator (the “Device”) carries a 5 year limited Warranty for defects in materials, components, assembly and operation of its electronic hardware. This Warranty is subject to all of the following exclusions and conditions. The Device enclosure is not opened except the battery compartment nor tampered with in any manner. No modifications or repairs are made to the Device other than by one of our engineers. No voltage or current source is applied to the harness connection socket or to anywhere else on the Device. No power supply other than specified in the operating manual is applied to the Device. For biological applications, the Device has not been used with non-SIS electrodes that are not approved for skin contact, therapeutic and medical applications. The Device is not used beyond its intended applications. You can experiment with the Device if you wish, but subject to all other Warranty conditions and exclusions and not in such a way that could reasonably be expected to damage the Device in any way as determined by our engineers. SIS machine models M250/M250MA/W250/LVtC/LVtC must not be used in any manner that requires an IP rating above IP40 to protect them from ingress of dust or other sub-1mm particulate matter, or that requires protection from water or other liquids that can damage or interfere with the internal electronics of the Device. The SIS electrode harness (connecting cable) plug and jack of the M250/M250MA/ W250/LVtC/LVtC/PACSTIM 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 for a period of three months only on the condition that it is not used in any way that contradicts the recommendations for use given in this operating manual and Warranty. If a non-SIS electrode harness is used with the Device this warranty shall be void. This Warranty is expressly limited solely to the original purchaser of the SIS equipment and does not extend to any transferee or temporary user of the Device. This Warranty does not cover damage caused by improper connection of the components of the SIS equipment (harness, connectors, sockets, electrodes), damage caused by accident, abuse, misuse, neglect or improper maintenance, damage caused by unusual physical or electrical stress, routine cleaning or normal cosmetic and mechanical wear. Non-compliance to any degree with any one of these Warranty conditions shall automatically void this warranty completely. SIS Manufacturing Ltd New Zealand expressly disclaims all warranties not stated in this limited Warranty.

If a Device is found to be faulty, we promise to honor this Warranty as quickly and efficiently as we can and either repair or replace the defective Device at our discretion. We will return to the original purchaser a fully and correctly functional Device that meets all of its design and functional specifications perfectly, as speedily as possible.

12. RETURNS

Each SIS machine is factory calibrated. In case of suspected malfunction of an SIS machine, please contact SIS Manufacturing Ltd, New Zealand. 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. 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 device is RoHS compliant.

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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