



SIS MACHINES

LOW VOLTAGE TRANSCRANIAL STIMULATOR OPERATING MANUAL_v1.1_LVtC

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 NZ 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 NZ immediately of any items received damaged or tampered or of any lost shipments.



WARNING FOR BIOLOGICAL APPLICATIONS


THE LVtC STIMULATOR IS ELECTRONICALLY CALIBRATED WITH EXTREME PRECISION FOR THERAPEUTIC BIOLOGICAL ELECTRO-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 cranial electrical stimulation (CES) for therapeutic and research purposes. Read 13. MANUFACTURER'S DECLARATION.

1. POWER SOURCE

The LVtC Stimulator is powered by replaceable AA type batteries (not included with delivery for air shipping safety reasons). Rechargeable batteries can be used and do not compromise the correct function of the device.

 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. CONNECTING ELECTRODE CABLE

Insert the cable (harness) connector plug all the way into the connection socket (jack) in the top end panel of the device; two faint clicks occur during insertion. Screw tighten the cable locking-ring to the socket, to secure the connection.

3. ELECTRODES

Two electrodes must be used with the LVtC Stimulator; the electrodes are physically interchangeable.

3.1. ELECTRODE TYPE

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

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ELECTRODE TYPE	TYPICAL CIRCUIT RESISTANCE	NOTES
SIS silver-nylon cloth	≤50-100kiloohm. Contributes lower circuit resistance than standard electrotherapy electrodes; superior for signal transmission.	Follow INSTRUCTIONS FOR USE (IFU) on the printed IFU card inside each SIS electrode pack.
Self-adhesive hydrogel transcutaneous electrical nerve stimulation (TENS)	≥500kiloohm.	Check that the black hydrogel layer of the electrode remains sticky; re-wet/replace if needed. Only use high quality electrodes.

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

3.3. ELECTRODE POLARITY

It does not matter which way around the electrodes are positioned across the head.

See 6.2. ELECTRODE POSITIONING instructions for electrode positioning on the head.

3.4. CONNECTING ELECTRODE HARNESS TO ELECTRODES

It is usually easier to position and secure the electrodes to the body first and then connect the electrode 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 cable to the electrode wires, as this can put excessive mechanical strain on the electrode cable if the device is dropped or pulled away from the body strongly while in use.

3.5. SECURING ELECTRODES TO BODY

- If SIS silver-nylon cloth electrodes are used, follow the APPLYING ELECTRODES instructions on the printed IFU card included in each SIS electrode pack.
- If self-adhesive hydrogel electrodes are used, apply directly to the skin.

4. CONTROLS

4.1 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).

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 (see 5.2. below).

4.1.1. OPERATIONAL MODE PROGRAMMING

The operational mode of the LVtC Stimulator is factory set for low voltage cranial electrical stimulation (CES).

4.2. MENU ACCESS AND CONTROLS

After powering ON, again 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 push-button-rotary-dial to select—the main **MENU** screen will be displayed.

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 press and release the push-button-rotary-dial to select—the device will return to the main operating screen.

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

4.2.1. POWERING OFF THE DEVICE

In the main **MENU** screen, rotate the push-button-rotary-dial to scroll to **POWER OFF**, then click to select—the device will power off (display turns off).

4.2.2. OUTPUT VOLTAGE SETTING (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 to select—the **INTENSITY** adjustment screen will be displayed.

- ▶ Click the push-button-rotary-dial once, rotate the dial to adjust the peak Output Voltage intensity in steps of 10millivolts (mV), 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.

4.2.3. CABLE (HARNESS) TEST

! NOTE: Perform a cable 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:

- ▶ **A.** Connect the cable (harness) to the machine.
- B.** Hold the gold ends of the cable in continuous contact with each other.
- C.** Click the push-button-rotary-dial to select **TEST**, then wait approximately 5 seconds until the result of the cable test is displayed.

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:

- Check 2. CONNECTING ELECTRODE CABLE instructions.
- Re-test the cable (steps **B** & **C**).
- If the cable test result is still **FAILED** then the cable has a fault and needs replacing.

Click **EXIT TO MENU** to return to the main **MENU** screen.

4.2.4. DISPLAY BRIGHTNESS ADJUSTMENT

The LCD display has a secondary backlight that automatically turns on at any time 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, 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.

4.2.5. DISPLAY INFORMATION ABOUT THE DEVICE

In the main **MENU** screen, rotate the push-button-rotary-dial to scroll to **ABOUT**, then click to select—the **ABOUT DEVICE** screen will be displayed.

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

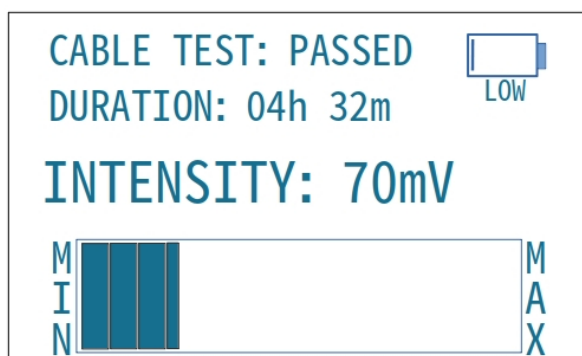
Click **EXIT TO MENU** to return to the main **MENU** screen.

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MENU CONTROLS						
ENTER MENU?	NO	Main operating screen				
	YES		Main menu options	Level 2 menu options	Level 3 menu options	
			POWER OFF			
			INTENSITY	<i>Set: 70-1000mV</i>		EXIT TO MENU
			CABLE TEST	TEST	<i>Result: PASSED or FAILED</i>	
			DISPLAY BRIGHTNESS	<i>Adjust: 10-100%</i>		
			ABOUT	<i>Information about device</i>		
			EXIT MENU			

5. DISPLAY

Main operating screen



5.1. The user-programmed peak Output Voltage **INTENSITY** is shown in millivolts (**mV**), and graphically displayed by the horizontal bar.

5.2. 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.

5.3. 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.

5.4. 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.

6. APPLICATION INSTRUCTIONS

6.1. SELECTING ELECTRODE SIZE

If applying SIS silver-nylon electrodes, use the Small round 4.7cm (1.87 inch) \varnothing diameter 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 is correct.

6.2. ELECTRODE POSITIONING

Figure 1 illustrates the electrode positioning for the LVtC Stimulator.

Position the electrodes on the left and right side 'temples' of the head (symmetrically).

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: Placement of the electrodes on the temples (right side shown).

7. SPECIFICATIONS

Parameter	Unit	Minimum	Typical	Maximum	Accuracy	Additional Notes
Input Battery Voltage	V	4.5	-	5	N/A	-
Output Voltage	V	0.05-0.25	-	±1	±10mV	Peak-to-peak
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 NEAR A PACEMAKER OR OTHER IMPLANTED ELECTRO-STIMULATOR. 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

The LVtC Stimulator 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.

10.1. 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.

Keep the Seal Cap mated to the device connector socket (jack) when not in use to prevent ingress of dust and moisture.

Store the device in a place out of direct sunlight and with ventilation or air-conditioning. Do not leave on or next to heat-generating sources.

10.2. 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).

10. 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 M200/M200MA/W200/WMcAMP/LVtC must not be used in any manner that requires an IP rating above IP40 to protect them from ingress of dust or other sub-1mm particulate matter, or that requires protection from water or other liquids that can damage or interfere with the internal electronics of the Device. The SIS electrode harness (connecting cable) plug and jack of the LVtC Stimulator are IP68 rated when mated, and the jack is IP68 rated when it is mated with the Seal Cap. The electrode harness is included in this Warranty only for a period of three months. 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, plugs, jacks, sockets, electrodes), damage caused by accident, abuse, misuse, neglect or improper maintenance, damage caused by unusual physical or electrical stress, nor cosmetic or mechanical damage from routine cleaning or normal use. 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 the 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 Device that meets all of its design and functional specifications at our cost as speedily as possible.

11. RETURNS

Each SIS machine is assembled and factory calibrated in our factory in Australia. 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.

12. DISPOSAL



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

13. MANUFACTURER'S DECLARATION

The Device is pending testing for AS/NZ/CE/FCC radiated emissions conformity.

⚠ DO NOT USE THE LVtC STIMULATOR WHILE ON AN AIRPLANE OR NEAR AVIATION GUIDANCE EQUIPMENT.

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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.



SIS Manufacturing Limited, New Zealand.

Address for all commercial and sales correspondence:

4/20 Clarendon Street, Frankston, VIC 3199, Australia.

Phone +**64** 3 669 0509. Within Australia **03** 9018 7056. Fax +**61** 3 8582 9706.

<http://www.siselectromed.com>

contact@siselectromed.com