SIS MACHINES

PROGRAMMABLE AC MICROCURRENT STIMULATOR (model PACSTIM)

OPERATING MANUAL_v1.0_PACSTIM

This operating manual is downloadable from:
https://siselectromed.com/programmable-microcurrent-stimulator-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 SIS PACSTIM 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 SIS PACSTIM device is designed for alternating current (AC) frequency-based stimulation in the low microcurrent range.

The device can also be used for inserted needle or surface electrode electro-acupuncture.

The PACSTIM also includes a factory programmed cAMP MODE for increasing or modulating the production and utilization of Cyclic AMP (3′,5′-cyclic adenosine monophosphate) cellular second messenger for therapeutic, research and experimental laboratory purposes; in cAMP MODE the device is also programmed for simultaneous neuropathic pain blocking. The PACSTIM can be used for nociceptive pain blocking (analgesia) when connected to the Amplifier Module 1CH-AMP; see section 9. AMPLIFIER MODULE.

Read section 17. MANUFACTURER'S DECLARATION of this manual for electromagnetic conformity information.

1. POWER SOURCE

The PACSTIM is powered by replaceable AA type batteries. Rechargeable batteries can be used and do not compromise the correct function of the device. Refer to the DEVICE SPECIFICATIONS section of this manual 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.

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 scroll.				
			POWER OFF	Click to select.			
			INTENSITY		◯ Click to unlock.	◯ Rotate to adjust, click to set: **70-1000mV**.	
			CABLE TEST		◯ 1.Instructions 2.Instructions 3.**TEST**	◯ Click to test.	Test result: **PASSED** or **FAILED**
			DISPLAY BRIGHTNESS		◯ Click to unlock.	◯ Rotate to adjust, click to set: **10-100%.**	
			EXTRAS		**EXTRAS MENU**		
			EXIT MENU		Main Operating Screen		

◯ **EXIT TO MENU** Click to select.

3.0. CONTROLS AND OPERATION

EXTRAS MENU

◯ Rotate to scroll.				
VOLTAGE AMPLIFICATION	◯ Click to select.	**TURN ON / OFF** ◯ Click to toggle.		
ABOUT		Device Information		
MODE:	◯ Click to toggle.	**cAMP MODE / PROGRAMMABLE MODE**		
PROGRAMMABLE MODE SETTINGS	◯ Click to select.	**STIM 1** **STIM 2** **REST TIME 1** **REST TIME 2** **STIM TIME 1** **STIM TIME 2** **MOD 1** **MOD 2**	◯ Rotate to toggle. Click to select.	◯ Rotate to adjust. Click to set.
		SAVE AND RETURN TO MAIN MENU		
RETURN TO MAIN MENU		Main **MENU**		

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.
  *steps of 100mV from 1V-15V if VOLTAGE AMPLIFICATION mode is turned ON.

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.

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
MODE:
PROGRAMMABLE MODE SETTINGS
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

NOTE: Only available when the SIS PACSTIM is connected to the external amplifier module (1CH-AMP)—see 9. AMPLIFIER MODULE instructions.

Click the push-button-rotary-dial to **TURN ON** or **OFF** the voltage amplification mode, shown on the display as **STATUS: ON** or **OFF**.

Rotate the dial to **EXIT TO MENU** and click the dial to return to the **EXTRAS MENU** screen.

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.

3.2.5.3. MODE

Click the push-button-rotary-dial to toggle between **PROGRAMMABLE** and **cAMP** operational mode.

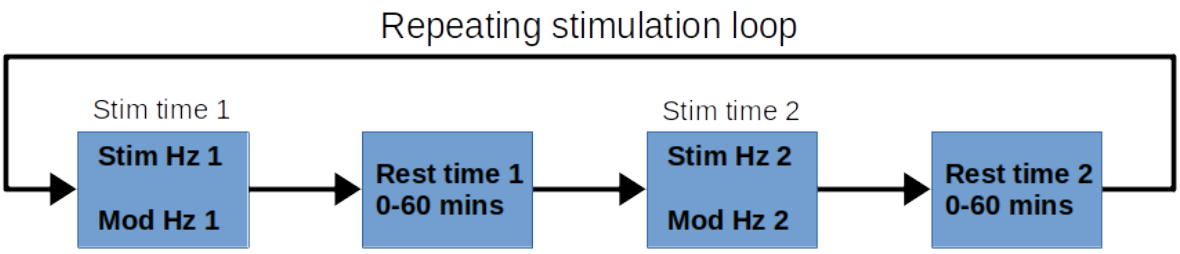
3.2.5.4. PROGRAMMABLE MODE SETTINGS

Rotate the push-button-rotary-dial to toggle between the programmable settings of the PACSTIM:

PARAMETER	NOTES
STIM 1	Base stimulation frequency #1 (Hz)
STIM 2	Base stimulation frequency #2 (Hz)
REST TIME 1	Rest period between STIM 1 and STIM 2 (minutes)
REST TIME 2	Rest period between STIM 2 and STIM 1 (minutes)
STIM TIME 1	Duration of STIM 1 (minutes)
STIM TIME 2	Duration of STIM 2 (minutes)
MOD 1	Modulation frequency of STIM 1 (Hz)
MOD 2	Modulation frequency of STIM 2 (Hz)

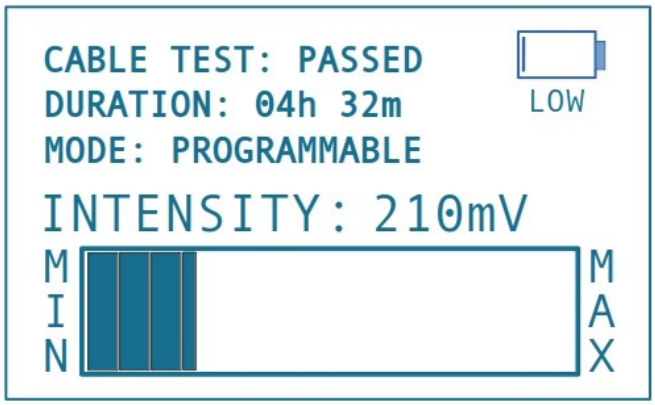
Click **SAVE AND RETURN TO MAIN MENU** to return to the **EXTRAS MENU** screen.

FLOWCHART OF OPERATION



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 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.

4.5. The operational **MODE:** is shown indicating the user setting of either **PROGRAMMABLE** or **cAMP**.

APPLICATION INSTRUCTIONS

5. ELECTRODES

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

5.1. ELECTRODE TYPE

Cutaneous electrotherapy electrodes:

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/replace if needed. Only use high quality electrodes.

SIS silver-nylon electrodes are the recommended and optimal electrodes to use with the PACSTIM for maximum conductivity and signal transmission.

Also refer to 7. SPECIAL APPLICATIONS for use of the SIS electrodes over medical dressings.

In some applications, a combination of SIS and hydrogel electrodes is appropriate, depending on ease of application and conformity to surface anatomy geometry.

5.2. ELECTRO-ACUPUNCTURE (E-AP)

Use the Alligator-Pin Converter wires to connect the gold 'banana plugs' at the ends of the electrode cable to the metal shafts or non-inserted ends of acupuncture needles, or to non-invasive acupuncture or trigger point electrodes or probes.

5.3. OTHER ELECTRODE TYPES

Use the Alligator-Pin Converter wires to connect the gold 'banana plugs' of the electrode cable to any other non-invasive contact electrode or probe.

5.4. ELECTRODE SIZE

Use electrodes that most closely match the anatomical size, geometry and planar (cross-sectional) direction of treatment of the target anatomical structure or tissue.

If SIS silver-nylon electrodes are used:

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

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

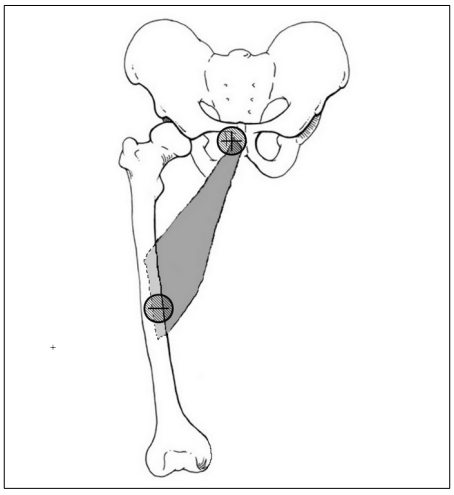
5.5. ELECTRODE POSITIONING

There are two types of pathology or treatment targets: longitudinal (e.g. a whole muscle or a section of nerve), and point (e.g. a joint or local blunt trauma).

Position the electrodes at each end of the target tissue, or across the point target anatomical structure or tissue. Wherever possible, there should be target tissue along the straight line path between the electrodes—this electrode alignment is especially important for longitudinal targets.

For deeper anatomical targets, wherever possible, also position the electrodes so that there is soft tissue along the straight line path between the electrodes.

The diagram below illustrates electrode positioning for the adductor longus muscle as an example of a longitudinal target. The (+)electrode and ‘return’ (-)electrode are positioned along the line of the muscle:



5.5.1. EXTRA NOTES FOR OPERATION IN cAMP MODE:

Stimulation can affect (block the function of) all the smaller nerve fibers with thin or no myelin in and around the target tissue, depending on electrode positioning:

- ➔ Ascending sensory C-fibers and A-delta fibers (mostly for pain and other irritating sensations)
- ➔ Descending efferent C-fibers to arterioles.

5.6. 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.

5.7. CONNECTING ELECTRODE CABLE TO ELECTRODES

Position and secure the electrodes to the body first, and then connect the electrode cable (harness) 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 electro-stimulator.

5.8. ELECTRODE CONNECTION POLARITY

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

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

6. INTENSITY SETTING

In general, due to the advanced PACSTIM technology, strong therapeutic effects can be readily achieved with very low intensity stimulation.

The default, minimum **INTENSITY** setting after powering on 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, e.g., neuropathic pain 'blocking' in **cAMP MODE**.
In general, the main considerations for setting the Output Voltage **INTENSITY** are:

- Distance between electrodes—depending on anatomical target and electrode configuration, refer to 5.5. ELECTRODE POSITIONING instructions.
- Density of target tissue (bone, adipose, muscle, etc).
- Density of surrounding tissues (bone, adipose, muscle, etc).
- Type of electrode used—lower or higher conducting (SIS vs hydrogel).
- Size of electrodes used—affecting voltage and current densities.

Greater distance between electrodes, and higher target and/or surrounding tissue densities, might both or separately require higher intensity stimulation. Larger electrode size might also require higher intensity stimulation.

A higher intensity stimulation might also be needed when using TENS type hydrogel electrodes compared to SIS silver-nylon electrodes. Refer to section 5.1. ELECTRODE TYPE instructions.

7. SPECIAL APPLICATIONS

In some special applications of the PACSTIM in **cAMP MODE** the (+)electrode and/or (-)electrode can be applied onto a wet gauze or other similar medical dressing, which is then applied directly onto or near the injured or pathological tissue or treatment area, e.g., onto intact peri-wound skin, directly onto an exposed wound, or onto a pathological tissue growth consisting of neoplastic tissue.

In such instances, because the gauze can contribute extra electrical

resistance to the stimulation circuit, and also in order to allow for the gradual drying out of the gauze with normal evaporation across the duration of treatment that will affect its conductivity, a higher **INTENSITY** setting towards or in the **500-1000mV** range may be necessary or optimal.

8. DUAL CHANNEL SPLITTER MODULE 2CH-SPL

8.1. INSTRUCTIONS FOR USE (STEPS 1-18)

1) Insert 2 × AA batteries into the dual channel splitter module (2CH-SPL).
2) Connect one end of the 2CH-SPL two-ended cable to the connection socket (jack) on the top end panel of the PACSTIM. 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.
3) Connect the second end of the 2CH-SPL two-ended cable to the connection socket labeled **IN** on the top end panel of the 2CH-SPL. Screw tighten the Locking Ring on the cable connector plug to the socket; DO NOT use excessive force.
4) Power on the PACSTIM (see section 3. CONTROLS AND OPERATION instructions).
5) Power on the 2CH-SPL by switching the top switch upwards to the **ON** position.
6) Access the main **MENU** of the PACSTIM.
7) Navigate in the main **MENU** of the PACSTIM to **CABLE TEST**.
8) Switch the CABLE TEST switch on the 2CH-SPL to the **right**.
9) Follow the PACSTIM cable test menu instructions to perform a cable test. If the result of the cable test is **PASSED** then proceed to the next step; if the result of the cable test is **FAILED** then re-check the 2CH-SPL two-ended cable connections carefully at both ends—refer to step 2.
10) Switch the CABLE TEST switch on the 2CH-SPL back to the **left** (default position during device operation).
11) Navigate in the main **MENU** to **INTENSITY**.
12) Set the required **INTENSITY** setting (see 3.2.2. **INTENSITY** instructions).
13) Exit the main **MENU** back to the Main Operating Screen.
14) Power off the 2CH-SPL by switching the top switch downwards to the **OFF** position.
15) Connect the two electrode cables of the 2CH-SPL module to the two output sockets on its top end panel labeled **OUT1** and **OUT2**. Screw

tighten the Locking Rings on the cable connector plugs to the sockets; DO NOT use excessive force.

16) Power on the 2CH-SPL by switching the top switch upwards to the **ON** position.
17) Follow 5.6. SECURING ELECTRODES TO BODY instructions.
18) Follow 5.7. CONNECTING ELECTRODE CABLE TO ELECTRODES instructions.

NOTE: To check the integrity of the two electrode cables of the 2CH-SPL module, connect each cable in turn to the connection socket on the top end panel of the PACSTIM, and perform a cable test by following the **CABLE TEST** instructions in the main menu screen of the PACSTIM.

8.2. BATTERY CHARGE INDICATOR

The **BATT LOW** warning light of the 2CH-SPL module will turn red when the remaining charge of the batteries is low and there is only power left for approximately 1 hour of operation.

9. AMPLIFIER MODULE 1CH-AMP

9.1. INSTRUCTIONS FOR USE (STEPS 1-20)

1. Insert 3 × AAA batteries into the single channel amplifier module (1CH-AMP).
2. Connect one end of the 1CH-AMP two-ended cable to the connection socket (jack) on the top end panel of the PACSTIM. 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.
3. Connect the second end of the 1CH-AMP two-ended cable to the connection socket labeled **IN** on the top end panel of the 1CH-AMP. Screw tighten the Locking Ring on the cable connector plug to the socket; DO NOT use excessive force.
4. Power on the PACSTIM (see section 3. CONTROLS AND OPERATION).
5. Power on the 1CH-AMP by switching the top switch upwards to the **ON** position.
6. Access the main **MENU** of the PACSTIM.
7. Navigate in the main **MENU** to **CABLE TEST**.
8. Switch the CABLE TEST switch on the 1CH-AMP to the **right**.
9. Follow the cable test menu instructions to perform a cable test. If the result of the cable test is **PASSED** then proceed to the next step; if the result of the cable test is **FAILED** then re-check the 2 1CH-AMP two-ended cable connections carefully at both ends—refer to step 2.
10. Switch the CABLE TEST switch on the 1CH-AMP back to the **left** (default position during device operation).
11. Navigate in the main **MENU** of the PACSTIM to **EXTRAS**.
12. Navigate in the **EXTRAS MENU** and select **VOLTAGE AMPLIFICATION** mode (see 3.2.5.1. VOLTAGE AMPLIFICATION instructions).
13. Turn the **VOLTAGE AMPLIFICATION** mode **STATUS** to **ON**. Rotate the dial to **EXIT TO MENU** and click the dial to return to the **EXTRAS MENU** screen. Rotate the dial to **RETURN TO MAIN MENU** and click the dial to return to the main **MENU** screen.

14. Navigate to the **INTENSITY** screen and select the required Output Voltage setting (see 3.2.2. **INTENSITY** instructions).
15. Exit the main **MENU** back to the Main Operating Screen.
16. Power off the 1CH-AMP by switching the top switch downwards to the **OFF** position.
17. Connect the PACSTIM electrode cable to the output socket on its top end panel labeled **OUT**. Screw tighten the Locking Ring on the cable connector plug to the socket; DO NOT use excessive force.
18. Power on the 1CH-AMP by switching the top switch upwards to the **ON** position.
19. Follow 5.6. SECURING ELECTRODES TO BODY instructions.
20. Follow 5.7. CONNECTING ELECTRODE CABLE TO ELECTRODES instructions.

9.2. BATTERY CHARGE INDICATOR

The **BATT LOW** warning light of the 1CH-AMP module will turn red when the remaining charge of the batteries is low and there is only power left for approximately 1 hour of operation.

10. 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 (±15)*	±10mV (±100mV)*	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	-
*When VOLTAGE AMPLIFICATION is turned ON.						

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 PACSTIM 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. 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.

13.2. 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.

13.3. SIS ELECTRODES

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

14. WARRANTY

The PACSTIM (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 (cable) 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/WMcAMP/LVtC/PACSTIM 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 (cable) plug and jack of the M250/M250MA/W250/WMcAMP/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 only for a period of three months, on the condition that it is not used in any way that contradicts the recommendations for use given in this operating manual and Warranty. If a non-SIS electrode harness is used with the Device this warranty shall be void. This Warranty is expressly limited solely to the original purchaser of the SIS equipment and does not extend to any transferee or temporary user of the Device. This Warranty does not cover damage caused by improper connection of the components of the SIS equipment (harness, connectors, sockets, electrodes), damage caused by accident, abuse, misuse, neglect or improper maintenance, damage caused by unusual physical or electrical stress, routine cleaning or normal cosmetic and mechanical wear. Non-compliance to any degree with any one of these Warranty conditions shall automatically void this warranty completely. SIS Manufacturing Ltd New Zealand expressly disclaims all warranties not stated in this limited Warranty.

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

15. 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.

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. MANUFACTURER'S DECLARATION

ELECTROMAGNETIC COMPATIBILITY CONFORMITY

The device conforms 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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