SIS MACHINES

FG300 OPERATING MANUAL V0.3.2

This operating manual is downloadable from: https://siselectromed.com/

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. Check that all ordered equipment is included in the shipping box and notify SIS Manufacturing Ltd 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.

DEVICE DESCRIPTION

The FG300 is an open programmable device for amplitude modulated alternating current (AC) sinusoidal waveform generation.

Refer to 10. DEVICE SPECIFICATIONS. Refer to section 17. MANUFACTURER'S DECLARATION of this manual for electromagnetic conformity information.

1. POWER SOURCE

The FG300 is powered by 4 replaceable AAA type batteries. Rechargeable batteries can be used and do not compromise correct function of the device.

1.1. Inserting AAA Batteries

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

a. Power OFF the device if it is operating.
b. Remove the shockproof silicon cover from the casing.
c. Remove the battery compartment cover by sliding downwards.
d. Insert 4×AAA batteries. Ensure correct polarity of the batteries: follow the diagram and ⊕⊖ polarity symbols inside the battery compartment.
e. Replace the battery compartment cover.
f. Replace the shockproof silicon cover over the casing; maintain the silicon cover on at all times to protect the device from impacts.

2. OPERATING DEVICE

2.1. CONNECTION OF ELECTRODE CABLE

Unplug the Seal Cap from the connection socket (jack) in the top end panel of the device. Insert the cable (harness) 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. ELECTRODE CONNECTION POLARITY

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

Paired electrodes can be connected in interchangeable electrical polarity. The FG300 is an alternating current (AC) outputting waveform device.

2.3. POWERING ON AND OFF THE DEVICE

Press the POWER|ON|OFF button continuously for 2 seconds to power on the device ► OLED display on ► red BATTERY CHARGE light flashing every 5 seconds.

Press the POWER|ON|OFF button continuously for 5 seconds to power off the device ► **POWERING OFF** screen.

2.4. ELECTRODE CABLE TESTING

Perform a cable connection and continuity test from the **CABLE TEST** menu screen before each application.

2.5. MENU ACCESS

After powering on the device, press the PROGRAM button continuously for 3 seconds.

2.5.1. MENU NAVIGATION AND PROGRAMMING ADJUSTMENT

Keypad button	Action
⇩ ⇧	Navigate menu and adjust programmable variables
PROGRAM	Select menu item and set programmable variables
SOUND|DISPLAY	Exit data and variable programming menu screens

2.6. TOGGLING SOUND ON AND OFF

Press the SOUND|DISPLAY button for 2 seconds to turn the sound ON or OFF. A sound ON or OFF icon will be displayed to confirm the new setting.

4. MENU NAVIGATION

MENU:
EXIT → main display
RESTART OUT → main display
PROGRAMMING
- → **EXIT** → **MENU**
- → **LOOP 1**
  - → **EXIT** → **PROGRAMMING**
  - → **STIM 1**
    - → **STIM HZ**
    - → **MOD HZ**
    - → **STIM T**
    - → **REST T**
  - → **STIM 2**
    - → **STIM HZ**
    - → **MOD HZ**
    - → **STIM T**
    - → **REST T**
- → **LOOP 2**
  - → **EXIT** → **PROGRAMMING**
  - → **SET ALL TO 0**
  - → **STIM 3**
    - → **STIM HZ**
    - → **MOD HZ**
    - → **STIM T**
    - → **REST T**
  - → **STIM 4**
    - → **STIM HZ**
    - → **MOD HZ**
    - → **STIM T**
    - → **REST T**

VARIABLES
- → **MAXRT**
- → **CURRENT**

E DATA
- **nAMPS:**
- **VOLTSp:**
- **OHMS:**

CONTACT STATS
STATISTICS
CONTACT:
OK:
MaxR:
OPEN CIRC:
CABLE TEST
→Instructions #1
→Instructions #2
→TESTING CABLE→PASSED/FAILED
→MENU
DISPLAY
→ALWAYS ON→MENU
→AUTO-OFF→MENU
VOLT MONITOR
→ENABLE→MENU
→DISABLE→MENU
SESSION TIME
→SESSION TIME
OFF→MENU
:mins→MENU
DEV
→EXIT→MENU
→PRINT LOG→START/CANCEL→DEV
→RESET LOG→START/CANCEL→DEV
SET DEFAULT
→DEFAULT SETTINGS→OK/CANCEL→MENU
ABOUT
Model:
Serial:
Build:
Software:

The **RESTART OUT** menu option sets all programmable variable changes made in the **PROGRAMMING** and **VARIABLES** screens and restarts the stimulation cycles without needing to power off and on the device.

3. DATA SCREENS

Screen: Main display

VOLTSp: 300mV
OHMS: 250kΩ
TIMER: 2h 3m

Screen: **E DATA** electrical stimulation parameters

nAMPS: 2.2uA
VOLTSp: 300mV
OHMS: 250kΩ

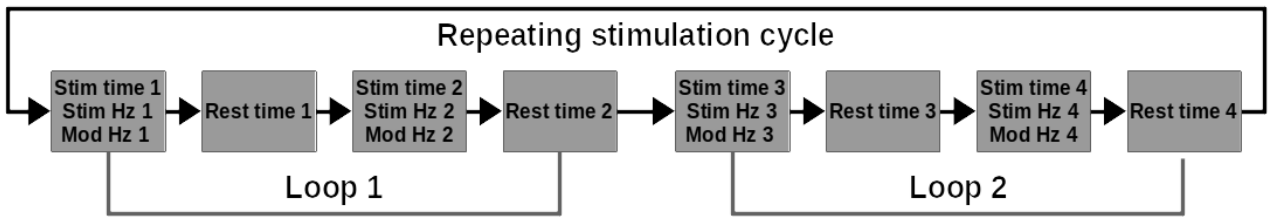
Screen: **CONTACT STATS**

STATISTIC	VALUE (UPDATING % WITHIN SESSION)
CONTACT	Algorithm determined statistically sufficient contact with stimulation target based on **MAXRT** and **CURRENT** programmable values set in **VARIABLES** menu.
OK	Part of **CONTACT** value. Contact with stimulation target within algorithm determined, allowed measured DC resistance variance range.
MaxR	DC total circuit resistance exceeding working peak voltage of device calculated from **MAXRT** parameter set in **VARIABLES** menu.
OPEN CIRC	Physically broken open circuit, no stimulation delivered.

Table 1.

4. PROGRAMMING

4.1. SEQUENCE OF PROGRAMMABLE VARIABLES



Loop 1 and Loop 2 are independently fully programmable.

Loop 2 can be programmed to duplicate Loop 1, or can be inactivated with the **SET ALL TO 0** option in the **PROGRAMMING** → **LOOP 2** menu section. If Loop 2 is inactivated then Rest time 3 and and Rest time 4 are also inactivated.

4.2. PROGRAMMABLE STIMULATION PARAMETERS AND RANGES

STIMULATION BLOCK	PARAMETER			
LOOP 1	**STIM HZ**	**MOD HZ**	**STIM T**ime	**REST T**ime
STIM 1	1-20,000 Hz	0-100 Hz	1-20 mins	0-20 mins
STIM 2	1-20,000 Hz	0-100 Hz	1-20 mins	0-20 mins
LOOP 2				
STIM 3	1-20,000 Hz	0-100 Hz	1-20 mins	0-20 mins
STIM 4	1-20,000 Hz	0-100 Hz	1-20 mins	0-20 mins
STIM HZ: base carrier frequency. **MOD HZ**: modulating signal frequency.				
Table 2.				

5. VARIABLES

5.1. USER PROGRAMMABLE VARIABLES AND DISPLAY DATA

VARIABLE	FUNCTION
MAXRT	Upper limit of direct current (DC) total circuit load (resistance) alert trigger value utilized by realtime and statistical circuit monitoring algorithm.

CURRENT	Nominal DC current target for self-adaptive peak output voltage **VOLTSp**. Shown as **nAMPS** in **E DATA** screen. See also section 6. OUTPUT VOLTAGE AND CURRENT.		
SESSION TIME	Stimulation session auto-off timer.		
	RANGE	STEP SIZE	DEFAULT VALUE
MAXRT	10-300 kiloohms	10 kiloohms	300 kiloohms
CURRENT	0.1-20 microamps	100 nanoamps	2.2 microamps
SESSION TIME	30-600 minutes	30 minutes	OFF
	DESCRIPTION		
VOLTSp	Peak AC output voltage		
nAMPS	Nominal direct current (DC) set in the **VARIABLES** menu.		
OHMS	Newest averaged DC total circuit Resistance measurement		
TIMER	Elapsed session time		

Table 3.

6. OUTPUT VOLTAGE AND CURRENT

The peak output voltage (V) of the device **VOLTSp** auto-regulates using the programmable nominal direct current **CURRENT** (I) parameter set in the **VARIABLES** menu and the newest average total circuit resistance (R) **OHMS** value that is automatically measured by the device at the start of each LOOP 1 stimulation cycle, computed with Ohm's Law for a DC circuit: $V = I \times R$.

The nominal DC **CURRENT** parameter can be utilized as a convenient means to determine and set the actual, constant alternating current (AC) delivered by the constant voltage output waveform to the stimulation target.

The proportionality between nominal programmed DC currents and calculated AC currents in the range of 2-3 microamperes, for the typical lower and upper limits of the DC circuit resistance working range of the device (30 kiloohms to 175 kiloohms), is shown in Figure 1:

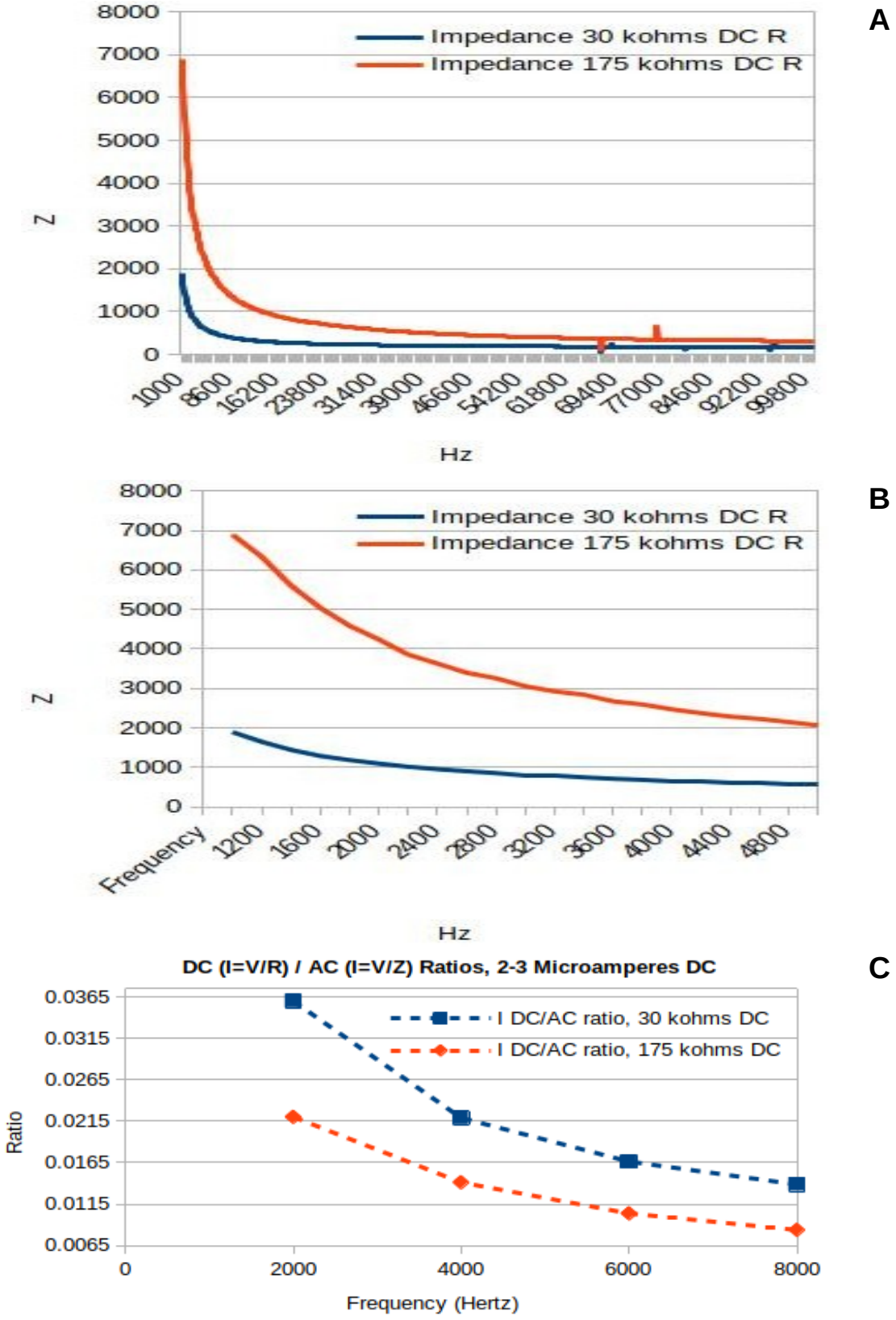


Figure 1. A: Complex impedance (Z) sweeps (0 to ~100,000 Hz range) through biological

tissue at measured DC circuit resistance values of 30 kiloohms and 175 kiloohms. **B:** Expanded view of Figure 1A for the frequency range 0 to ~5000 Hz. **C:** Proportionality between nominal programmed DC current parameter **CURRENT** and actual AC current from 0 to 8000 Hz (V / R ÷ V / Z). A known, target constant AC current can be achieved in realtime utilizing Figure 1A data or data relating to other materials and/or DC resistance ranges obtained from the same methodology.

6.1. CURRENT INTENSITY SETTING

Generally, the major considerations for setting the nominal DC **CURRENT** parameter are:

- ➔ Density of target (and before and after aligned material) along the pathway between the electrodes. Different materials have different electrical impedance values and profiles.
- ➔ Selection of the base carrier frequency to match the (combined) complex impedance profile(s) of the materials in the stimulation pathway. For most materials, the higher the stimulation base frequency, the lower the impedance values (refer to Figures 1 A-C).
- ➔ Type of electrode used with lower or higher impedance and conductivity characteristics contributing to the total circuit's complex impedance profile.
- ➔ Size of electrodes used affects current density.

7. DISPLAY

The organic light emitting diode (OLED) display can be set to remain **ALWAYS ON** or to **AUTO-OFF** after 2 minutes of no user keypad input, for power saving. When set to **AUTO-OFF**, the display can be temporarily turned on or off by pressing and releasing the SOUND|DISPLAY button.

8. VOLT MONITOR

A high voltage monitor audio-visual alert can be enabled or disabled. The alert is factory set to trigger when the total circuit load (resistance) reaches or exceeds 100000 ohms. The alert activates for 30 seconds only. See also 11. AUDIO-VISUAL ALERTS.

9. SESSION TIME

The device has a stimulation session auto-off timer option. See 5.1. USER PROGRAMMABLE VARIABLES AND DISPLAY DATA Table 3.

10. DEV

The device has a ferroelectric RAM (FRAM) based logging capacity for data logging and development purposes. Approximately 4000 rows of data can be stored in the FRAM memory that has a ~10 year storage lifetime even when the device stays powered off.

The data log can be exported to a spreadsheet via the micro USB port on the top end panel of the device using the **PRINT LOG** command. A USB serial port connection is required using the SIS development app installed on a computer running Windows version 8 or later.

Each log row stores the following data:

TIMER	R_mean	VOLTSp	CONTACT%

For meaning of data items, refer to sections 3. DISPLAY Table 1, and 5. VARIABLES Table 3. The R_mean data cell contains the **OHMS** value shown in Table 3.

The FRAM log can be erased using the **RESET LOG** command.

11. AUDIO-VISUAL ALERTS

Alert Message Device beeps	Meaning	Action
CALCULATING WAVEFORM	Device is calculating waveform shape based on programmed variables and/or default output parameters.	Wait.
WARNING !	Problem detected with electrode pad contact; check instructions displayed on screen.	Follow corrective instructions displayed on screen.
POOR CONTACT	Electrode pad contact is insufficient due to mechanical and/or electrochemical factors.	
UNSTABLE CONTACT	Electrode contact is varying too rapidly for continuity of output parameters.	
CIRCUIT BREAK	No electrical stimulation circuit.	
BATTERY CHARGE LOW	Remaining charge in the replaceable AAA batteries is below the minimum operating level.	Replace batteries.
HIGH VOLTAGE	Non critical informational alert only. The total circuit load (resistance) has reached or exceeded 100000 ohms and the output voltage has increased correspondingly to maintain the user programmed **CURRENT** variable.	Check electrode contact with and stimulation target properties. Replace or modify target and/or electrodes if necessary.
CANNOT CALIBRATE	Device cannot calibrate due to uncorrected electrode contact problem.	Wait for device to power off. Re-check operation and application instructions. Power on device again if necessary.
POWERING OFF	Device is powering down due to one of the following events: • uncorrected alert status • low battery charge • user manually powering down device	

12. SPECIFICATIONS

Parameter	Unit	Minimum	Typical	Maximum	Accuracy	Additional Notes
Input Battery Voltage	V	5.2	6.0	6.2	N/A	4 x AAA
DC Output Voltage	V	0		3.3	+/- 10mV	
AC Output Voltage	mV	0		600	+/- 5mV	peak
Input Current	mA	13	30	70	N/A	
Output Current	µA	0		20	+/- 100nA	
Internal Frequency	MHz		48			
Operating Temperature Range	°C					
Resistance Measuring	Ω	100		1000000	+/- 2%	(+/- 20, 10000-100000)

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

! Always remove the batteries from the device during long-term storage to prevent damage from battery leaks.

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

14. WARRANTY

The FG300 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. 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/FG300/W300 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/FG300/W300 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.

14.1. 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.

14.2. DISPOSAL

The device should be disposed of according to regulatory requirements for disposal of electronic goods.

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

17. MANUFACTURER'S DECLARATION

ELECTROMAGNETIC COMPATIBILITY CONFORMITY

Based on test results of previous SIS FG device model WMcAMP:
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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