USER MANUAL

Ver. 2.2

sgm™
medical monitoring.

SGM-STIM-1

CONSTANT CURRENT, HIGH ENERGY, SINGLE AND MULTIPLE PULSE STIMULATOR FOR TRANSCRANIAL ELECTRICAL STIMULATION

SGM-STIM-1

WARRANTY

SGM d.o.o. warrants that our products will be free from defects in material and workmanship under normal use and service for a period of twenty-four (24) months from the date of shipment from our warehouse.

This warranty is void if the Product is subject to accident, misuse, neglect, improper handling, improper installation, improper repair or is modified or altered. The sole and exclusive obligation of SGM under this warranty is the repair or replacement of such defective or missing parts which are causing the malfunction. If SGM does not replace or repair such parts, the end-user's sole remedy against SGM shall be to obtain a refund of the price paid for such Products(s) as are proven to be defective. To obtain service under this warranty, the end user must bring the malfunction to the attention of SGM within the twenty-four (24) month period following the product shipment from SGM and no later than thirty (30) days after the occurrence of such malfunction, whichever occurs first.

SGM shall not be liable under this warranty unless SGM's examination of the product shall disclose, to its satisfaction, that the defects have not been caused by misuse, neglect, improper handling, improper installation, improper repair, modification or alteration.

THERE ARE NO OTHER WARRANTIES WHICH EXTEND BEYOND THE DESCRIPTION ON THE FACE HEREOF. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY, AND FITNESS FOR A PARTICULAR PURPOSE, ARE HEREBY EXCLUDED.

SGM reserves its right to discontinue any instrument or to change its specification without notice, and without responsibility for incorporating changes in instruments already sold.

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GENERAL PRECAUTIONS

Operation with SGM-STIM-1 stimulator is allowed only to a highly qualified operator. Please make sure that all users of the SGM-STIM-1 system read these instructions and understand the conditions for safe use of the system. Failure to understand the information may lead to dangerous situations.
Carefully read this User Manual before using the SGM-STIM-1stimulator.
HV switch must always be easily accessed and should not be covered with anything.
If there is a DC component on the device output – immediately turn of the device, and send it to repair.
Protective earth terminal must always be properly connected.
Only equipment that complies with IEC 60601 should be connected to the trigger input or output of this stimulator.
To prevent unpredictable effects, only devices complying with safety standard EN60601-1:2006+A11:2011+A1:2013. are allowed in the patient environment.
Electrical equipment for medical uses requires special EMC precaution and needs to be installed and serviced according to the EMC documentation of the device.
SGM-STIM-1 is inappropriate for use in oxygen-rich environment.
Portable and mobile RF equipment can effect electrical equipment for medical use.
SGM-STIM-1 is intended for use only in moderate climates of the surgery room.
No modification of this equipment is allowed.
SGM-STIM-1 should be disposed of in accordance with European directive 202/96/EC.
Ensure that during operation SGM-SGM-1 is positioned in such a way as to allow operating of the disconnection device.
The patient connections are driven from isolated current source. The leakage values from the patient connections to the ground reference are within relevant limits for class BF equipment according to EN60601-1:2006+A11:2011+A1:2013.
Device is classified as TYPE IIa CLASS BF equipment.
SGM-STIM-1 does not display any system messages during operation.
SGM-STIM-1 output extender is defined as applied part (see section 3 - Accessories)

For all servicing requirements please contact:
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WARNINGS AND CONTRAINDICATIONS

- Do not use SGM-STIM-1 on patients with cardiac and brain pacemakers.
- Avoid using SGM-STIM-1 on body areas in close proximity with any implantable electric device.
- SGM-STIM-1 should not be used for stimulation in the vicinity of uterus during pregnancy.
- SGM-STIM-1 may cause involuntary spasms of muscles of the mouth, tongue and lower jaw.
- Do not remove device covers - high voltage is present within the unit.
- Device is not to be used for trans-thoracic surgeries.
- Do not use this device in explosive atmosphere or in the presence of flammable anesthetics.
- Avoid accidental contact between connected but unapplied APPLIED PARTS and patient or other conductive parts including those connected to protective earth.
- SGM-STIM-1 is not defibrillation-proof.
- Connecting a patient to HF surgical equipment and to evoked response equipment simultaneously may result in burns at the site of the electrical stimulator and possible damage to the electrical stimulator.
- Operation in close proximity (for example 1 m) to shortwave or microwave therapy equipment or GSM devices may produce instability in electrical stimulator output.
- The stimulator is not suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

This stimulator is intended for use by healthcare professionals only. This stimulator may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or reallocating the stimulator or shielding the location.

Standard sequence of operation is described in sections 2.2 to 2.7 of this document.

WARNINGS AND CONCLUSIONS FROM

CLINICAL EVALUATION REPORT According to MEDDEV 2.7.1.
For the Medical Device: SGM – STIM – 1 (CROSTIM)

8.0 CONCLUSION

A. Transcranial electric stimulation using muscle responses (muscle MEP) provides an effective means of monitoring and/or mapping motor pathways during surgery. Although complete op timal warning criteria have not been elucidated yet, simple criteria such as disappearance of the response are very useful guides.
B. Care must be taken to prevent injury and to assure that anesthesia does not affect the muscle MEP responses.
C. Significant changes in the muscle MEP during surgery bear a strong correlation with injury to the motor pathways.
D. Patient's risk of injury using this stimulator is very low, while the benefit in preventing and detect ing neurologic injury is very high.

1. TECHNICAL DESCRIPTION

1.1 INTRODUCTION

Nowadays, intraoperative monitoring of motor evoked potential is the ultimate way to monitor the integrity of motor pathways. Development of motor-evoked potentials methods is critical to prevent intraoperative paraplegia, hemiplegia, and other types of motor deficit. The future of this method is closely related to the availability of appropriate electrical stimulators. According to research and clinical experience, a trans-cranial electrical stimulator is an appropriate tool for intraoperative eliciting of motor-evoked potentials. This is a very specific type of medical equipment and it must meet all the criteria for this delicate purpose.

Use of constant-voltage electrical trans-cranial stimulators has an inherent problem - output current delivered to the patient is closely related to the resistance (impedance) of the stimulating electrodes. Therefore, in order to overcome this problem, constant current stimulation principle is used in the SGM-STIM-1 trans-cranial electrical stimulator. A constant-current trans-cranial electrical stimulator has better control of electrical charge delivered to the patient then constant voltage, and within reasonable limits is insensitive to changes of load impedance.

According to the Medical Device Directive MDD93/42/EEC, the device is classified as CLASS IIa equipment.

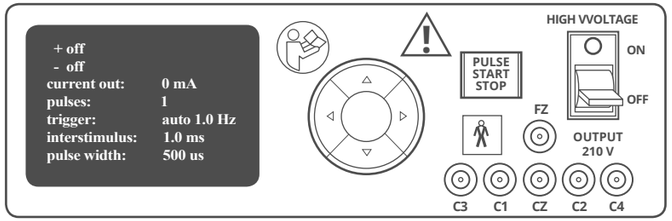
Classification according to the degree of protection against electric shock is TYPE BF equipment.

1.2 STIMULATOR CONTROLS

The stimulator user interface is organized on the front and rear device panels.
On the rear panel are all controls that are used before the patient is connected to the stimulator.
These are: mains connection elements, input connector for triggering the device from an external source, and output connector for triggering other equipment.
Controls on the front panel are used for adjustments and stimulation control during patient stimulation.

1.2.1 FRONT PANEL

LCD display and simple navigation keyboard are used for stimulation parameters setup.
Up/Down arrow key enables vertical navigation within the display to select stimulation parameter.
During this navigation, a small yellow circle indicates the selected parameter. **+ and - output selector:** First two rows on the presentation panel show the selection of positive (+) and negative (-) electrode. At the start, both electrodes are in the “off” mode. Using Left/Right key, active electrodes can be selected. During this process, if the same electrode is selected as both positive and negative, output is blocked and the electrode is in “off” mode. For fast switching of electrode polarity, press center key.



Current out: Menu entry is used for output current intensity adjustment. It can be increased or decreased from 0 to 250 mA, in 1 mA steps, using right or left key respectively.

Pluses: Menu option enables selection from 1 to 9 output pulses within one train.

Trigger: Preset to “auto” option as default, with 1.0 Hz repetition rate.
This mode is used for continuous stimulation with single pulse or group of pulses at repetition rate between 0.1 Hz and 4.0 Hz with 0.1 Hz resolution. Stimulation can be started and stopped with PULSE - START-STOP button.

Using OK navigation key, trigger mode can be adjusted to “external” or “manual” mode.

“External” triggering mode will use trigger pulses from other electronic equipment to generate output from the stimulator.

"Manual" triggering mode - allows the operator to send single output stimulus (pulse or group) as determined by pressing the PULSE-START-STOP button on the front panel.

With similar manipulation, interstimulus and pulse width menu entries can be used for adjustment of interstimulus interval between 1 and 10 ms, and pulse width from 100 to 1000 µs.

OUTPUT CONTROL:
This section is used to control the delivery of output pulses to the patient. It consists of HIGH VOLTAGE ON/OFF switch, PULSE START/STOP push button and a set of plug-in connectors for stimulating electrodes. Black toggle switch in the HIGH VOLTAGE ON position enables the unit to deliver output pulses. This is not the primary power supply switch, and it blocks functioning of the high voltage module. HIGH VOLTAGE OFF position disables output pulses while the trigger output will still deliver output pulses.

OUTPUT INDICATION:
Green indicator in this section shows that the internal high-voltage supply is activated, and output stimulus will be delivered. If output current cannot be delivered (due to wrong output selection, disconnection of electrode wiring or disconnection of electrode from the patient) this indicator will start to flash with high frequency.

Yellow PULSE START/STOP push button is the manual trigger switch. Its function depends on the selected trigger mode:
In manual trigger mode, upon depressing this switch, a single output pulse or group of pulses would be produced, characterized by the pulse settings.
In auto trigger mode, depressing this switch will activate or stop automatic generation of output pulses.

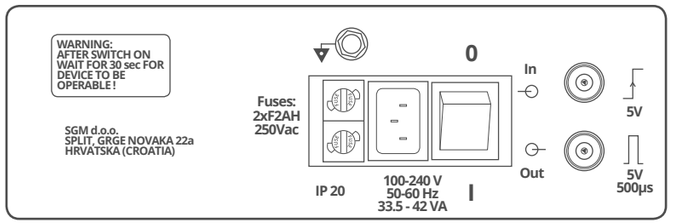
After every activation of this control, light indicator (on PULSE START/STOP switch) shows that stimulus is sent to the patient.

In external trigger mode, PULSE START/STOP push button is disabled and delivering of pulses is controlled by external triggering device.

Connectors for stimulating electrodes are arranged as standard points in accordance with international 10/20 electrode positions schematics: C1, C2, C3, C4, CZ and FZ (in front of CZ), and they are DIN42802 terminated sockets.

1.2.2 BACK PANEL

The back panel features mains connection and triggering sockets.
Main inlet, power switch and main fusing are integrated in one block.
Potential equalizing stud Din 42801 is used as potential reference for unit and bonding point.



TRIGGER OUT socket delivers positive TTL pulse in synchronism with the start of each stimulation pulse in a single pulse mode of operation. When pulse groups are being generated, one output trigger pulse is produced in synchronism with the first pulse in the train.


5V, 500µs

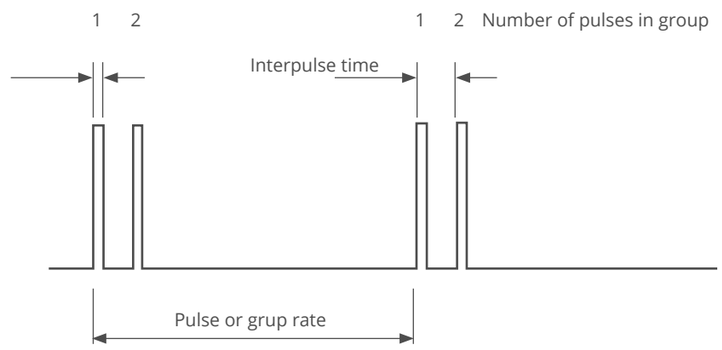
TRIGGER IN socket allows the stimulator to be triggered from a positive going edge of an applied external signal, which should be TTL compatible.


5V

1.3 TECHNICAL SPECIFICATIONS

1.3.1 STIMULUS OUTPUT	
Current range	0-250 mA in 1 mA steps
Pulse width	100 - 1000 microseconds square wave
Maximum output voltage	210 V
Number of electrodes	6

1.3.2 STIMULUS PULSE RATES	
Pulse or group rate	0.1 – 4.0 Hz in 0.1 steps
Burst selections	Number of pulses – 1 to 9
Interstimulus time	1 - 10 ms in 0.1 ms steps



1.3.3 TRIGGER FACILITIES	
Manual	Push button mounted on front panel
Auto	
External	TTL compatible positive edge logic signal
Trigger output	Positive TTL compatible signal 500 µs wide

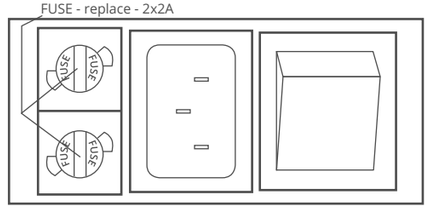
1.3.4 OTHER	
Mechanical dimensions	250x263x85 mm
Weight	2 kg
Power	100 – 240 V @ 50-60 Hz
Rating	< 50VA
Startup time	30 sec

1.4 MAINS CONNECTION

This device is shipped complete with mains lead; if the mains plug has to be removed because of incompatibility with the local situation, when connecting other type of mains plug, the connections are:

Line	-	black
Neutral	-	yellow
Ground	-	green/yellow

A mains plug must be constructed so that if the lead is pulled out, the ground wire cannot come in contact with the line or neutral pins.
Fuse that is to be replaced must be of correct dimensions and be rated at 2 Amps.



Fuses that should be used when replacing are: 2 x High breaking capacity fuse 2 A (250)
Stimulator power supply module is of medical type, and can be used for mains voltages between 110 and 220 V (50 to 60 Hz) without additional adjustments (automatic voltage control).

1.5 ENVIRONMENTAL CONDITIONS

Transport and storage temperature: -19°C to 60°C
Transport and storage relative humidity: 10% to 80% (non-condensing)

Please Note: Following transportation and if storage temperature is outside the operating temperature range, allow the unit to acclimate for 3 hours prior to use.

Operating temperature: 5°C to 30°C
Operating relative humidity: 30% to 70% (non-condensing)
Atmospheric pressure: 50kPa to 106kPa

Maximum altitude: 3000 m (height above sea level)

The device does not deliver any heat to the environment.

1.6 OUTPUT IMPENDANCES AND CURRENT

IMPENDANCE (OHM)	CURRENT (mA): 500µs PULSE WIDTH	CURRENT (mA): 1000µs PULSE WIDTH
220	224	224
400	224	200
1000	130	120
2200	70	66
5600	30	29

1.7 ELECTRODES INTENDED FOR USE

There are several disposable neurological electrodes intended for use with this stimulator for a specific purpose. Only electrodes terminating with Safety DIN42802 connectors should be used with the stimulator. Electrodes are not included in SGM-STIM-1 package. Electrodes must CE mark certified or FDA approved, sterile and intended as single use for IOM. Any electrodes used, different from the ones stated above, are excluded as they may cause risk such as: wound infection, cytotoxicity, irritation and sensitization.

2. INSTRUCTIONS FOR USE

2.1 PRECAUTIONS WHEN USING THE SGM-STIM-1 STIMULATOR

The following remarks apply to the use of stimulators designed for percutaneous use: To avoid any risk of establishing an unintentional path to earth, connections from the stimulator to the patient have to be isolated from the ground. This means that a ground connection must not be made to either terminal on the stimulator or to either stimulating electrode. It is also undesirable to place a ground electrode on the patient close to one of the stimulating electrodes. A patient with an implanted electrode device should not be subjected to electrical stimulation unless specialist medical opinion has first been obtained.

Explanations of symbols used on SGM-STIM-1

Front Panel

	ATTENTION, CONSULT ACCOMPANYING DOCUMENTS
	CAUTION
	TYPE BF APPLIED PART

Back Panel

	TRIGGER INPUT
	TRIGGER OUTPUT
	POSITIVE GOING PULSE
	SQUARE WAVE PULSE
	OFF (POWER)
	ON (POWER)
	EQUIPOTENTIALITY
	DATE OF MANUFACTURE

2.2 POWERING THE STIMULATOR

Before powering the stimulator, toggle switch on the front panel has to be set in HIGH VOLTAGE OFF position.
Connect the stimulator to the mains supply with an appropriate cable.
Turn the stimulator on with the main power switch on the rear panel.
Wait approximately 30 seconds to allow internal microprocessor and high-voltage generator to be operable.
After start-up, the following factory-preset values will appear on the display:

Output current ..... 0 mA
Number of pulses..... 1
Trigger mode..... auto 1.0 Hz
Inter-stimulus interval..... 4 ms
Pulse width..... 500 µsec

2.3 DEFINITION OF STIMULUS PROPERTIES

Stimulator output waveform is rectangular pulse train with adjustable parameters as defined in section "1.3 TECHNICAL SPECIFICATIONS". Using display and navigation keyboard, select output current amplitude, number of output pulses in a group, stimulus ratio and inter-stimulus interval.

2.4 OPERATING MODE SETUP

"Trigger": display entry is used to select trigger mode: manual, external or auto. In "auto" mode, pulse train repetition rate can be adjusted between 0.1 and 4.0 Hz.

2.5 CONNECTING THE PATIENT

Connect stimulator output sockets (C3, C1, FZ, CZ, C2, C4) to the corresponding stimulation point on the patient. Use approved electrodes with appropriate cabling. Select an active pair of electrodes using first two entries on the display. In the first row, selection of the positive electrode can be done. The second row is used for selection of the negative electrode. After powering the stimulator, both electrodes are in "off" mode. HV switch is disconnecting the device between MEDICAL DEVICE OUTPUT and PATIENT.
If the distance between the patient and stimulator is exceeding the length of the electrodes, please use Output extender. See - Appendix 1.
Stimulating electrodes must be selected in accordance with specification in the item 2.8.

2.6 STIMULATION

Set the toggle switch to HIGH VOLTAGE ON position. In manual operating mode push PULSE-START-STOP button to send single stimulus to the patient. In automatic operating mode push PULSE-START-STOP button to start or stop generation of output stimuli.

2.7 END OF STIMULATION

1. Stop the generation of output pulses if in AUTO mode of operation, using PULSE-START-STOP button.
2. Set toggle switch HIGH VOLTAGE to OFF position.
3. Deselect active output electrodes by putting them in "off" mode.
4. Disconnect the electrodes from the patient.
5. Turn off the stimulator on the main switch.
6. Disconnect the mains cable connector from the power outlet.

2.8 STIMULATING ELECTRODES

Stimulating electrodes are all standard electrodes for intraoperative monitoring with impedance < 1 kOhm and connector DIN 42802.

2.9 OUTPUT LIMITS

The SGM-STIM-1 stimulator is constant current type stimulating device, which makes it relatively insensitive to the variation of the load impedance, as long as this impedance is within reasonable limits. These limits are defined with the maximum allowed output voltage that can be applied to the patient. Maximum allowed output voltage of the stimulator determines maximum current which can be delivered into load impedance, according to the following relation:

I_out_max = 210V / Z out

OUTPUT IMPEDANCE	MAXIMAL OUTPUT CURRENT
0,461 kOhm	250 mA limited by setup
0,680 kOhm	250 mA limited by setup
1 kOhm	204 mA limited by maximum output voltage
2.2 kOhm	77 mA limited by maximum output voltage
3.3 kOhm	55 mA limited by maximum output voltage
5.6 kOhm	32 mA limited by maximum output voltage

Maximum output voltage that stimulator can deliver can be factory preset according to customer requirements and FDA or IEC regulations.

2.10 DEVICE INSPECTION AND MAINTENANCE

Routine check of the stimulator is performed after any powering of the device. Factory preset values as defined in section 2.2 must appear on the display. Accuracy of operating data can be checked by qualified personnel using 1 kOhm load resistance and appropriate equipment for measuring intensity and duration of output current pulses. The values of pulse durations, pulse repetition frequencies and amplitudes, as indicated on the equipment, shall not deviate by more than 30%, when measured with an error not exceeding +/-10%.

Device has no wearable parts that are to be replaced regularly. In case of the appearance of the DC component on the output of the stimulator, immediately switch off the preset pair of electrodes on the output selector.Preventive service is obligatory at least once every 3 years. SGM d.o.o. is the only one authorized for service and calibration of the device. No modifications of this equipment are allowed.

2.11 CLEANING

Before cleaning, disconnect the device from the mains outlet. Cleaning of the system should be kept to the minimum. If cleaning is needed, it should be done very carefully due to the sensitivity of the system. Do not use: alcohol, thinners or any other solvent to clean the system. Do not use abrasive, corrosive cleaning agents or solvents. Do not sterilize any components.

3. ACCESSORIES

Output Extender SGM S1-801 is designed for easier operation with the patient, to keep the medical stimulating equipment in appropriate distance from the patient. It is designed to easily identify and connect the proper output contact from the stimulator and to transfer it on the mobile, hand-held panel. The cable terminates with DIN 42802 touch-proof connector. Each connector is marked according to the labeling on the front panel of the stimulator and output extender panel. On the back panel of the output extender is the clip for easier stabilization of the panel in the place nearest to the patients.

4. EMC TABLE

THE DEVICE IS INTENDED FOR USE IN THE ELECTROMAGNETIC ENVIRONMENT SPECIFIED BELOW. THE CUSTOMER OR THE USER OF THE DEVICE SHOULD ASSURE THAT IT IS USED IN SUCH AN ENVIRONMENT.			
Emissions test	**Compliance**	**Electromagnetic environment - guidance**	
Mains Terminal Spurious Voltage EN 55011-1 Clause 8.2	Class B	The lower limit is valid for the frequency boundaries	
Radiated Field EN 55011-1 Clause 8.2	Class A	The device is suitable for use in all establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	
Harmonic Current Emissions 61000-3-2	Class A		
Voltage Variation Reduction and Flickering Reduction in the Mains IEC 61000-3-3	Compiles		
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Electrostatic discharge (ESD) IEC 61000-4-2	±4 kV contact ±4 kV air	PERFORMANCE CRITERION B ±4 kV contact ±4 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Contact discharge ±4 kV could cause display reset.
Field EN 61000-4-3	80 MHz – 2.5 GHz	PERFORMANCE CRITERION A	Mains power quality should be that of a typical commercial or hospital environment.
Electrical fast transient/ burst IEC 61000-4-4	±0,5 kV for power supply lines ±0,25 kV for input/ output Extender cable	PERFORMANCE CRITERION A ±0,5 kV for power supply lines ±0,25 kV for input/ output Extender cable	Mains power quality should be that of a typical commercial or hospital environment. Temporary loss of charging function may occur, which is self-recoverable.
Surge IEC 61000-4-5	±0,5 kV L conductor – PE conductor ±0,5 kV N conductor – PE conductor	PERFORMANCE CRITERION A ±0,5 kV L conductor – PE conductor ±0,5 kV N conductor – PE conductor	Mains power quality should be that of a typical commercial or hospital environment.

Conducted Disturbances Induced by RF Fields IEC 61000-4-6	Conductors L, N and PE 150 kHz-80 MHz Output Extender cable 150 kHz-80 MHz	PERFORMANCE CRITERION A Conductors L, N and PE 150 kHz-80 MHz Output Extender cable 150 kHz-80 MHz	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency Magnetic Field IEC 61000-4-8	Frequency 50 Hz Field intensity 3	PERFORMANCE CRITERION A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<0 % U_T for 0,5 cycle 40% U_T for 5 cycle 70% U_T for 25 cycle 0% U_T for 250 cycle	<0 % U_T for 0,5 cycle PERFORMANCE CRITERION A 40% U_T for 5 cycle PERFORMANCE CRITERION A 70% U_T for 25 cycle PERFORMANCE CRITERION A 0% U_T for 250 cycle PERFORMANCE CRITERION A	Mains power quality should be that of a typical commercial or hospital environment.
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	1 Vrms 150 kHz to 80 MHz 3V/m 80 MHz to 2,5 GHz	[V1] 1 V [E1] 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.Recommended separation distance: $d=[\frac{3,5}{V_1}]\sqrt{P}$ $d=[\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d=[\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Neurostimulator SGM-STIM-1 in operation does not use any type of EMF based device for remote control of its functionalities. Metal grounded housing of the stimulator behaves as a Faraday cage, blocking any transmission of EM fields, so functionality of SGM-STIM-1 stimulator cannot be affected with external EMF.

TROUBLESHOOTING

To protect patients from any uncontrolled stimulating activity in case of a stimulator control computer dysfunctionality, SGM-STIM-1 has a protecting system which blocks the device high voltage output if control computer does not run its software.

ISSUE	POSSIBLE CAUSE	POSSIBLE SOLUTION
Neurostimulator does not start	Problem with control computer or power supply module	Return device to the producer for testing and servicing
Device does not deliver stimulus to the patient	Stimulator output is not correctly selected, HV switch is in OFF position	Use correct output setup procedure for SGM-STIM-1
Device does not deliver stimulus to the patient	Electrode is disconnected from the patient	Check electric connection path from stimulator output to the patient. Check implantation of stimulating electrode to the patient
Stimulator triggering with external IOM device does not work	External trigger impulse amplitude or duration are not within SGM-STIM-1 specification	Correct external trigger impulse parameters, if possible

Manufactured by:

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