Instructions for Use

Intravascular Lithotripsy Generator

Model: SPM-3500

Version No.: 08

Date: November 17, 2025

Manufacturer: Spectrumedics Medical Technology (Shanghai) Co., Ltd

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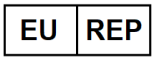
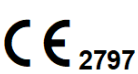
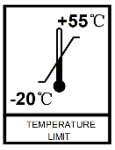
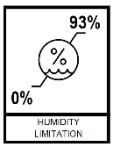
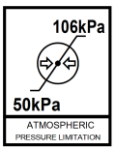
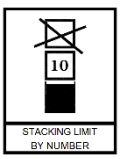
Notes:

1. **Please read the instructions for use (IFU) carefully before operation and operate this equipment according to the prescribed procedures!**
2. **It is very important for the safety of patients and operators to follow the IFU completely. Please pay special attention to all warning words!**
3. **This product is only used with the company's IVL catheter. In case of product failure caused by the use of accessories not provided by our company and the possible increase in electromagnetic emission or reduction in immunity of this product, our company does not assume responsibilities for safety and quality assurance!**
4. **This product needs to be used by trained medical professionals!**

Description of Symbols:

	Defibrillator-proof CF type equipment
	Consult accompanying documents
	Class II equipment
	Dangerous voltage
	Trigger switch
	Model number
	Product SN
	Production date
	Manufacturer
	Medical device
	Unique Device Identification
	EC-Representative
	CE marking

	Waste from Electrical and Electronic Equipment Directive. The Generator and Connector Cable should not be disposed of in the normal waste stream and should be sent to separate collection facilities for recovery and recycling.
SPECTRUMEDICS	Logo
	This way up
	Fragile, handle with care
	Keep dry
	Temperature limit
	Humidity limitation
	Atmosphere pressure limitation
	Stacking limit by number

1. Product Description

Intravascular Lithotripsy Generator (hereinafter referred to as IVL Generator) can be used in combination with Coronary Intravascular Lithotripsy (IVL) Catheter (hereinafter referred to as IVL Catheter) to perform shockwave-assisted percutaneous angioplasty of calcified stenosed arteries. Please refer to the relevant IFU of IVL Catheter for more information.

1.1. Intended purpose

The product is used in medical facilities. It is used in combination with the Coronary Intravascular Lithotripsy (IVL) Catheter (model: SWCA-2) produced by our company for lesion preparation and balloon dilation of primary coronary artery calcification lesions (coronary artery stenosis ≥ 50%) in adult patients.

1.2. Intended clinical benefits

Coronary Intravascular Lithotripsy (IVL) Catheter and Intravascular Lithotripsy Generator provide effective and safe treatment for severe coronary artery calcification, demonstrated by a high rate of clinical success and a low rate of Major Adverse Cardiovascular Events (MACE), which is non-inferior to the current state of the art.

1.3. Product composition

The product consists of the host, power adapter, trigger switches (footswitch, handle switch), and catheter connecting cable.

1.4. Operating principle

IVL Generator utilizes electrohydraulic shockwave technology. The host generates adjustable pulsed high voltage through a boost circuit and a high-voltage pulse release circuit, which is then delivered to the IVL Catheter (with electrodes axially distributed inside the catheter and a balloon filled with a 1:1 mixture of saline and contrast solution). An arc discharge is created between the electrode pairs of the IVL Catheter, forming a discharge channel. Rapid expansion and rupture of bubbles on the electrode surface generate mechanical shockwaves within the balloon. These shockwaves selectively fracture both superficial and deep calcified plaques in the blood vessel lumen, causing the calcified plaques to undergo fatigue and micro-fragmentation in situ. This process restores the elasticity of the calcified blood vessels and improves vascular compliance.

1.5. Mode of supply

The IVL Generator is supplied in a non-sterile, reusable manner.

Standard configurations inside the packaging box:

- Host *1;
- Power adapter *1;
- Footswitch *1;
- Handle switch *1;
- Catheter connecting cable *1;
- Instructions for use *1;

Instruments and surgical supplies to be used with the IVL Generator (not in the supply range)

- IVL Catheter;
- A sterile protective sleeve (185 cm in length) is used for catheter connecting cable during surgery.

1.6. Appearance features

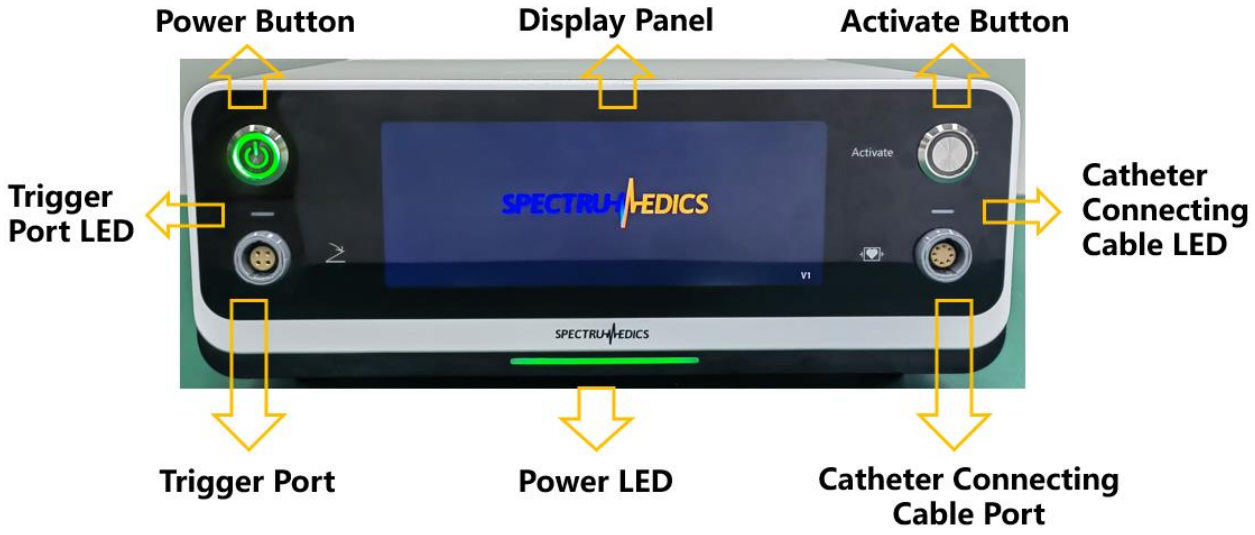


Figure 1 Host of IVL Generator

2. Technical Indicators

Host	Technical Indicators
Host size/weight	120mm×300mm×210mm；<4kg
Rated voltage	12VDC
Input power	40VA
Type of protection against electric shock	Class II
Degree of protection against electric shock	Defibrillation-proof type CF applied part
Waterproof rating	Host: IPX0; Footswitch: IPX8
Working mode	For each discharge (pulse) 10 times, force a pause of 10 seconds
Catheter identification	Automatic
Classification according to the safety degree of product used in the flammable anesthesia gas mixed with air, oxygen or nitrous oxide	Equipment that cannot be used in the presence of flammable anesthetic gas mixed with air or with oxygen or nitrous oxide
Classification according to the mode of operation	Intermittent loading with continuous operation (ON: 10s/OFF: 10s)
Recovery Time After Defibrillation Voltage Application	5s
Output	Generator positive/negative pulse output voltage: (1.5±0.2)kV Pulse width: ≤30us Pulse output interval: (1±0.1)s
Power adapter	**Technical Indicators**
Rated voltage	100-240V~
Rated frequency	50/60Hz
Rated input current	1.5A

3. Installation and Use

3.1. Environmental requirements for use

Ambient temperature range: +10℃ ~ +40℃;

Relative humidity range: 30% ~ 75%;

Atmospheric pressure range: 62 kPa ~ 106 kPa.

3.2. Combined use

The IVL Generator is intended to be used in conjunction with the company's IVL Catheter. The connection diagram for combined use is shown in Figure 2, where the IVL Catheter constitutes the applied part. The name, model, specifications, and treatment procedures of the compatible IVL Catheter are provided in the table below.

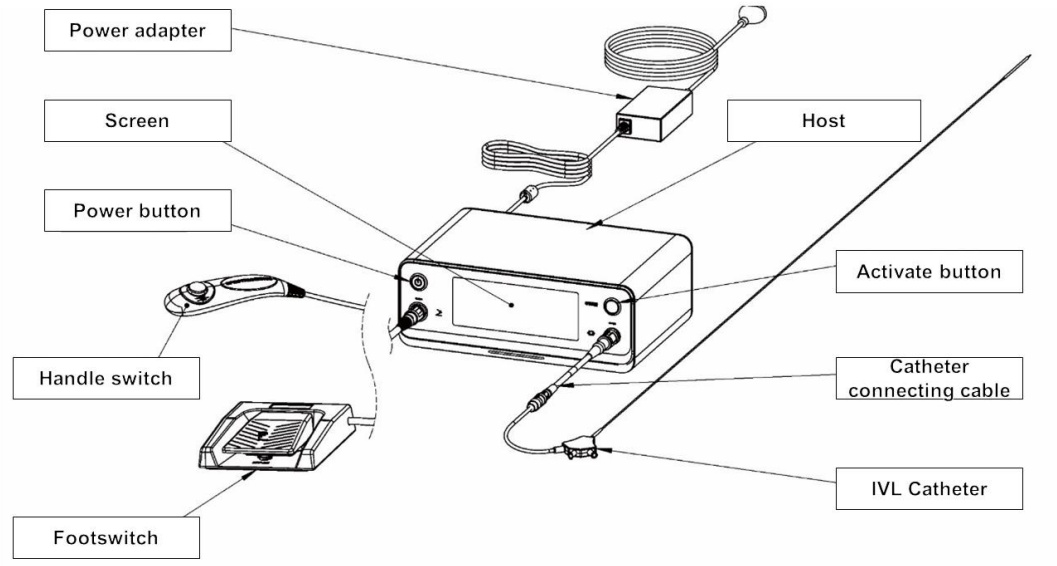
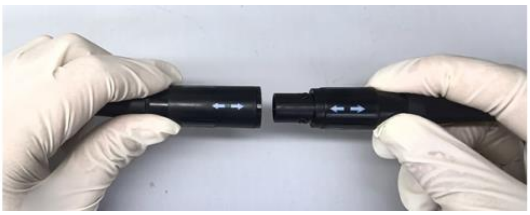


Figure 2 Schematic diagram of the connection between the Intravascular Lithotripsy Generator and the IVL Catheter

Product Name	Model	Specification	Treatment Procedures
Coronary Intravascular Lithotripsy (IVL) Catheter	SWCA-2	25012	Maximum number of pulses: 120; Number of pulses in one treatment cycle: 10; Total treatment cycles: 12.
		27512	
		30012	
		32512	
		35012	
		37512	
		40012	

3.3. Installation and operation process

Steps Description	Attached Figures

1. Install Place the host of the IVL Generator on a dry and level workbench.	
2. Connect the Power Insert one end of the power adapter into the power port on the rear panel of the host, and connect the other end to the mains power supply. Once connected, the indicator light strip below the host's display illuminates.	
3. Connect the Trigger Switch Insert the trigger switch cable into the trigger switch port on the front panel of the host. *Note: The figure shows the connection of the foot switch, and the connection method of the handle switch is the same. When using the handle switch during surgery, a sterile protective cover is required.*	
4. Connect the Catheter Connecting cable Insert one end of the catheter connecting cable into the catheter connecting port on the front panel of the host.	
5. Power on the Equipment Press the power button. The display shows the logo, followed by the message "Connect Catheter."	
6. Prepare the IVL Catheter Prepare the IVL Catheter according to the Instructions for use of IVL Catheter.	None
7. Connect the IVL Catheter First, place the catheter connecting cable in a sterile protective sleeve. Then, connect the catheter connecting cable interface to the prepared IVL catheter interface. The host screen displays “Activate catheter” and shows the catheter information.	

	
8. IVL Catheter Delivery Using standard percutaneous angioplasty, deliver the IVL Catheter to the target lesion site.	None
9. Start the IVL Generator After clicking the catheter activation button, the interface displays the catheter type, the number of pulses per treatment cycle, the current treatment cycle count, and the remaining number of pulses. Additionally, the interface indicates the treatment pressure of the catheter.	
10. Start Treatment Observe the balloon position and lesion characteristics under the angiographic machine, then press the trigger switch to activate the host for discharge treatment. The trigger switch allows for either single or continuous discharge. Single Discharge: Press and immediately release the trigger switch to discharge once. Continuous Discharge: Hold the trigger switch to discharge 10 times continuously, then release the switch once. The host enters a mandatory 10-second pause, displayed as a countdown on the interface. After the countdown ends, hold the trigger switch again until the discharge is complete. With each discharge, the remaining pulse count decreases by 1. Use the angiographic machine to confirm the treatment effectiveness (for additional information, refer to the Instructions for use of IVL Catheter). To stop treatment, simply release the trigger switch.	 
11. Service Life of IVL Catheter When the IVL Catheter completes 120 discharges, the pulse count displays as 0. If further treatment is required, replace the catheter with a new one.	
12. Power Off Click the power button to turn off the host. If the host is not used for an extended period, disconnect the power adapter from the mains power supply.	None

4. Safety Information

4.1. Definition

"Warning": Used to indicate that it would result in serious personal injury, death, or actual property damage if ignored.

"Caution": Used to indicate that it will produce minor personal injury or property damage if ignored.

4.2. Contraindications

1) The 0.014-inch guidewire cannot pass through the lesion;
2) It is contraindicated in patients whose lesion is diagnosed to be unsuitable for vasodilatation;
3) Pregnant or lactating women are contraindicated;
4) Thrombotic lesions;
5) A single coronary artery for blood supply;
6) Vascular dissection;
7) Graft disease.

4.3. Warnings

Explosion hazard: It is strictly forbidden to use this product in the presence of flammable anesthetic gas mixed with air or with oxygen or nitrous oxide!

Electric Shock Hazard: Operators are strictly prohibited from replacing components on their own!

Modification of this equipment is not permitted!

4.4. Be careful

1) **This product is not waterproof:** Liquid should be prevented from entering the equipment. In particular, the power connection on the back and the catheter connecting cable on the front must be protected from moisture. Do not use the equipment if any liquid enters the equipment or outlet.
2) **Electric shock hazard:** The grounded AC power supply connected to this product must comply with IEC electrical safety standards. The specifications of the power supply circuit must be the same as those shown on the nameplate on the back of the equipment.
3) **Electromagnetic interference:** This product should be ensured to operate in an environment without strong electromagnetic field interference.

4.5. Precautions for use

1) **Unexpected power failure during use:** After connecting the IVL catheter, please do not touch the power switch or pull the power cord during normal use to prevent the host from abnormal shutdown; Otherwise, the IVL Catheter that has been connected and discharged will not continue to be used.
2) **IVL Catheter unexpected disconnection:** This product is connected to the IVL Catheter, in the normal use process, do not arbitrarily disconnect the connection of the IVL Catheter and the host (except replacing the IVL Catheter); Otherwise, it will cause the connected and discharged IVL Catheter to be unable to continue to use.
3) **Excitation times of the IVL Catheter:** The service life of the IVL Catheter is 120 times. After the first connection, please check whether the display times are consistent before discharge. If abnormal, please stop using it immediately.
4) **Replace the catheter:** If the catheter needs to be replaced during the use, it needs to be re-operated according to the steps of 3.3 Installation and Operation Process after the catheter is replaced.

5) **Selection of IVL Catheter:** Refer to the diameter of the vessel and choose 1:1 size of IVL Catheter. If a 1:1 size is not available, use an adjacent larger diameter balloon (for example, a 4.0mm IVL Catheter in a vessel with a reference diameter of 4.5 mm);

6) Additional treatment may be performed if deemed necessary. If multiple inflations are required because the lesion length is greater than the balloon length, it is recommended that the balloon overlap by at least 2 mm in case the treatment segment is missing. However, care should be taken not to exceed 60 pulses in the same treatment segment, so the overlapping treatment segment should not exceed 120 pulses;

7) If more than one catheter is used, the changes in monitoring indicators should be closely observed to identify the differences in balloon tolerance in different patients.

8) During the use of the product, ensure that all components are securely connected.

9) The power plug serves as the disconnecting device for the mains supply. During product use, ensure its placement does not interfere with the disconnection operation of the mains power.

4.6. Adverse reactions

Potential adverse reactions are consistent with standard catheter-based cardiac interventions and include but are not limited to:

- Acute vascular occlusion
- Overreaction to contrast agent, anticoagulant, and/or antithrombotic therapy
- Aneurysm
- Arrhythmia
- Arteriovenous fistula
- Bleeding complications
- Cardiac tamponade or pericardial effusion
- Cardiopulmonary arrest
- Cerebrovascular accident (CVA)
- Coronary artery/vessel occlusion, perforation, rupture, or dissection
- Coronary artery spasm
- Death
- Emboli (air, tissue, thrombus, or atheromatous emboli)
- Emergency or non-emergency coronary artery bypass grafting
- Emergency or non-emergency percutaneous coronary intervention
- Complications at the puncture site
- Breakage of the guidewire or fail/failure of any assembly of the device may result in device embolization,

dissection, serious injury, or surgical intervention

- Hematoma at the site of vessel puncture
- Bleeding
- Hypertension/hypotension
- Infection/sepsis/fever
- Myocardial infarction
- Myocardial ischemia or unstable angina
- Pain
- Peripheral ischemia
- Pseudoaneurysm
- Renal failure/insufficiency
- Treated coronary artery restenosis leads to revascularization
- Shock/pulmonary edema
- Slow blood flow, no reflow, or sudden coronary occlusion
- Stroke
- Blood clots
- Acute occlusion of a blood vessel
- Vascular Injury that requires surgical repair
- Vascular dissection, perforation, rupture, or spasm

Side-effect identified in the identification from literature search include:

- Major adverse cardiovascular events (MACE): Mainly including cardiac death, target vessel revascularization, and MI.
- Angiographic complications, such as dissections, slow/no flow, and abrupt vessel closure.

In addition, patients may be exposed to other risks associated with coronary intervention procedures, including conscious sedation and local anesthesia, the use of X-ray contrast agents during angiography, medications used to manage subjects during the surgery, and the risk of radiation exposure from fluoroscopy.

Identify risks associated with the device and its use:

- Allergic/immune reactions to the catheter material or coating
- Device failure, failure, or loss of balloon pressure leading to device embolism, dissection, serious injury, or surgical intervention
- Premature atrial or ventricular contractions

- Atrial or ventricular capture

5. Troubleshooting

SN	Failure Phenomenon	Cause of Failure	Troubleshooting
1	After connecting the product to the mains power supply, the light strip below the display screen does not illuminate.	The power adapter has become disconnected from the host.	Reconnect the power adapter to the host or contact support.
2	Click the power button of the product, but the green light on the power button does not illuminate.	The power button is malfunctioning.	Contact support.
3	After the product is ready for use, click the power button, and the display screen shows "Invalid Catheter."	The catheter is abnormal.	Replace the catheter.
4	After the display screen shows "Activate Catheter," click the catheter activation button, but the green light on the activation button does not illuminate.	The activation button is malfunctioning.	Contact support.
5	During the product's discharge process, the display screen shows "Connect Catheter."	The catheter has become disconnected.	Replace the catheter.
6	During the product's discharge process, the display screen shows "Connect Switch."	The trigger switch has become disconnected.	Reconnect the trigger switch cable by unplugging and plugging it back in.
7	During the product's discharge process, when hold on the trigger switch, the discharge count displayed on the screen does not decrease.	The charging voltage is abnormal.	Restart the product and replace the catheter, or contact support.
8	During the product's operation, the display screen shows "001-Contact support".	The circuit board communication is abnormal.	Contact support.
9	During the product's operation, the display screen shows "002- Contact support".	The DC high-voltage module is faulty.	Contact support.

6. Cleaning and Maintenance

Cleaning: The use environment of the product should meet the "use environment requirements". When the equipment (including footswitch, catheter connecting cable and other accessories) needs to be cleaned, the cleaning steps should be carried out as follows:

1) In off-working state, shutdown and disconnect the connection between the power cord and the host.

2) Use a soft cloth, dip 75% ethanol to wipe the surface of the product, pay attention to avoid the interface parts.

3) After cleaning, place it in a ventilated and cool environment to air dry.

Notes: Do not submerge the product in the liquid. Do not pour liquid on the product or accessories. Do not allow liquid to enter the case.

Maintenance: Check the product's power cord, footswitch and catheter connecting cable before use. If they are found to be damaged or broken, they are prohibited to use and you need to contact our staff. If the operator finds a failure or abnormality, he/she must contact our staff. When the product is in use by a patient, maintenance is not permitted.

Before using the product, it is recommended to inspect the product's exterior to ensure that no components have

visible damage (such as cracks or fragments) and that the electrical contacts are free of foreign objects. Then, power on the device to check if it can operate normally without any abnormal prompts. The product does not require recommended periodic testing. However, if medical institutions have specific requirements, they may perform visual and power-on inspections according to their defined intervals.

Due to confidentiality agreements regarding technology and patents, design materials such as circuit diagrams and component lists are not included in the packaging. Our company can provide circuit diagrams, component lists, annotations, or other necessary materials required for the repair of device components to authorized professional technicians.

7. Packaging, Transportation and Storage

7.1. Packaging requirements

Double corrugated carton +plastic bag + foam.

7.2. Transportation requirements

Rain and snow should be avoided, inverted and collision;

Transportation environment temperature requirements: -20℃ ~ +55℃;

Relative humidity requirements: ≤ 93%;

Atmospheric pressure requirements: 50 kPa ~ 106 kPa.

7.3. Storage requirements

This product can not be stacked in the open air, and can not be stacked on the soil ground, such as short-term stacking should be strictly protected from rain and snow intrusion; When the product is not in use for a long time, it should be put into the packaging box according to the direction indicated in the packaging box and stored properly. The storage environment should conform to:

Storage environment temperature requirements: -20℃ ~ +55℃;

Relative humidity requirements: ≤ 93%;

Atmospheric pressure requirements: 50 kPa ~ 106 kPa.

8. Environmental Requirements

When the IVL Generator reaches the service life, the product should be stopped and scrapped. The specific treatment method should meet the relevant local laws and regulations. The company does not assume any responsibility for the user's disposal or disposal of this product and the related costs.

9. Production Date

See host nameplate.

10. Service Life

The service life of the host of this product is 8 years, and the service life of the trigger switches and catheter connecting cable is 3 years respectively.

11. Electromagnetic Compatibility

The product complies with IEC 60601-1-2 " Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests".
The product does not have essential performance.


Warning:

- IVL Generator should not be used in close proximity or stacked on top of other equipment. If it must be used in close proximity or stacked on top of other equipment, it should be observed to verify that it can operate normally in the configuration it is used in;
- Except for the cables sold by the manufacturer of the IVL Generator as spare parts of the components, the use of accessories and cables other than the provisions may lead to an increase in the electromagnetic emission of the IVL Generator or a decrease in the immunity of the IVL Generator, and the company does not assume the responsibility for safety and quality assurance;
- The IVL Catheter (model: SWCA-2) provided by the manufacturer of the IVL Generator should be used;
- Portable and mobile radio frequency (RF) communication equipment may affect IVL Generator.

Cable Information

SN	Name	Cable Length (m)	Shielded or Not
1	Power adapter cord	1.6	No
2	Footswitch cable	2.0	No
3	Handle switch cable	2.0	No
4	Catheter connecting cable	1.8	Yes
5	AC power cord	1.6	No

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The **<Intravascular Lithotripsy Generator (Model: SPM-3500)>** is intended for use in the electromagnetic environment specified below. It is recommended that the customer or user of the **<Intravascular Lithotripsy Generator (Model: SPM-3500)>**ensure that it is used in such an environment.		
Emission testing	**Compliance**	**Electromagnetic environment - guidance**
RF Emissions CISPR 11	Group 1	The **<Intravascular Lithotripsy Generator (Model: SPM-3500)>** uses RF energy only for its internal function. However, its RF emissions are very low and is not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The **<Intravascular Lithotripsy Generator (Model: SPM-3500)>** is suitable for use in all establishments other than

Harmonic emissions IEC 61000-3-2	Not applicable	domestic and may be used in residential establishments and those directly connected to the public low-voltage power distribution network supplying buildings for domestic use, provided that the following warning is understood: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or disrupt operations of nearby equipment. It may be necessary to adopt mitigation procedures such as re-orienting or relocating the **<Intravascular Lithotripsy Generator (Model: SPM-3500)>** or shielding the location
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The **<Intravascular Lithotripsy Generator (Model: SPM-3500)>** is intended for use in the electromagnetic environment specified below. It is recommended that the customer or user of the **<Intravascular Lithotripsy Generator (Model: SPM-3500)>** ensure that it is used in such an environment.			
Immunity Assay	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidelines**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV by contact ±15kV through the air	±8kV by contact ±15kV through the air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients / Burst IEC 61000-4-4	±2kV of power supply lines ±1kV for input/output lines	±2kV of power supply lines ±1kV for input/output lines	It is recommended that the quality of the power supply be that of a typical hospital or commercial environment. It has no output lines.
Surge IEC 61000-4-5	±1kV line(s) to line(s) ±2kV line(s) to earth	±1kV line(s) to line(s) Not applicable	It is recommended that the quality of the power supply be that of a typical hospital or commercial environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% Ut 100% of voltage drop on Ut) per 0,5 cycles. 0% Ut (100% of voltage drop on Ut) per 1 cycles. 70% Ut (30% of voltage drop on Ut) per 25/30 cycles. 0% Ut (100% of voltage drop on Ut) per 250/300 cycles.	0% Ut 100% of voltage drop on Ut) per 0,5 cycles. 0% Ut (100% of voltage drop on Ut) per 1 cycles. 70% Ut (30% of voltage drop on Ut) per 25/30 cycles. 0% Ut (100% of voltage drop on Ut) per 250/300 cycles.	It is recommended that the quality of the power supply be that of a typical hospital or commercial environment. If the user of the **<Intravascular Lithotripsy Generator (Model: SPM-3500)>** requires continued operation during power interruption, it is recommended that the **<Intravascular Lithotripsy Generator (Model: SPM-3500)>** be powered from an uninterruptible power supply.

Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Magnetic fields at the frequency of the supply should be at levels that are characteristic in a typical location in a typical hospital or commercial environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz outside the ISM bands 6 Vrms 150 kHz to 80 MHz in ISM bands 10 V/m 80MHz to 2,5GHz	3 Vrms 150 kHz to 80 MHz outside the ISM bands 6 Vrms 150 kHz to 80 MHz in ISM bands Not applicable	It is recommended that portable or mobile RF communications equipment not be used in close proximity to any part of the **<Intravascular Lithotripsy Generator (Model: SPM-3500)>** including cables, with separation distance less than recommended, calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum rated output power of the transmitter in Watts (W), according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). It is recommended that the established field strength of the RF transmitter, as determined by an electromagnetic site survey, be less than the compliance level in each frequency band. Interference may occur around equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800MHz, the higher frequency range applies. NOTE 2 These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
A The ISM (industrial, medical and scientific) bands between 150KHz and 80MHz are 6.765MHz to 6.795MHz; 13.553MHz to 13.567MHz; 26.957Mhz to 27.283MHz; and 40.66Mhz to 40.70MHz. B Compliance levels in the ISM frequency bands between 150KHZ and 80MHz and in the frequency band between 80MHz to 2.5GHz are intended to reduce the likelihood of mobile and portable communications equipment causing interference if it is inappropriately translated to the patient environment. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges. C The field strengths established by fixed transmitters such as base stations, telephone (cellular/cordless) land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the			

electromagnetic environment due to fixed RF transmitters, it is recommended to consider an electromagnetic site survey. If the field strength measurement at the location where the **<Intravascular Lithotripsy Generator (Model: SPM-3500)>** is used exceeds the applicable RF compliance level above, the **<Intravascular Lithotripsy Generator (Model: SPM-3500)>** should be observed to verify that operation is Normal. If abnormal performance is observed, additional procedures may be required, such as re-orienting or relocating the **<Intravascular Lithotripsy Generator (Model: SPM-3500)>**.

D Above the frequency range of 150kHz to 80 MHz, the field strength should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the **<Intravascular Lithotripsy Generator (Model: SPM-3500)>**

The **<Intravascular Lithotripsy Generator (Model: SPM-3500)>** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the **<Intravascular Lithotripsy Generator (Model: SPM-3500)>** should help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **<Intravascular Lithotripsy Generator (Model: SPM-3500)>** as recommended below, according to the maximum output power of the communication equipment.

Maximum power power output of the output (W)	Separation distance according to transmitter frequency (m)		
	150kHz to 80MHz d=1,2√P	80MHz to 800MHz d=1,2 √P	800MHz to 2,5GHz d=2,3√P
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters with a maximum output power rating not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transformer in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.