

OPERATOR'S MANUAL

Intravascular Lithotripsy (IVL) Generator and Connector Cable

LBL 64052-A, 2020-08

Contents

1. Introduction	2
1.1 The IVL Generator - How Supplied	2
1.2 Required Devices and Procedure Supplies for Use with the IVL Generator	2
1.3 Device Description	2
1.4 Intended Use/Indication for Use	2
2. Safety Information	2
2.1 Terms	2
2.2 Contraindications	2
2.3 Dangers	2
2.4 Warnings	2
2.5 Cautions	3
3. Product Orientation	3
3.1 IVL Generator - Front View	3
3.2 Control and Indicator Functions	4
3.3 Front Panel Connectors	4
3.4 IVL Connector Cable	4
3.5 IVL Generator - Rear View	4
4. Product Use and Therapy Delivery	5
4.1 Additional Usage Information	6
5. Installation	7
5.1 IV Pole Mounting	7
5.2 Connecting to Line Power	9
5.3 Charging the Internal Battery	9
5.4 Environment Conditioning	9
5.5 Generator Inspection and Test	9
6. Maintenance	10
6.1 Daily Maintenance	10
6.1.1 Charging and Testing the Internal Battery	10
6.1.2 Testing the IVL Generator	11
6.1.3 Inspecting the IVL Generator	11
6.1.4 Cleaning the IVL Generator	12
6.2 Monthly Maintenance	12
6.3 Other Maintenance	12
6.4 Product Useful Life	12
7. Troubleshooting	12
8. Appendix A: Electromagnetic Compatibility Guidance	14
9. Appendix B: Symbols	16
10. Appendix C: Specifications	17
10.1 Appendix C1: General Specifications	17
10.2 Appendix C2: Performance Specifications	17

NOTE: This Operator's Manual provides information required for proper operation of the IVL Generator and IVL Connector Cable. Replacement IVL Connector Cables are available from Shockwave Medical, Inc. Refer to the applicable IVL Catheter Instructions for Use (IFU) for patient treatment information.

To Be Used Exclusively with the Shockwave Medical IVL System.

TEXT CONVENTIONS: Throughout these operating instructions, special text characters (for example, CAPITAL LETTERS such as ON, CATH, SYS) are used to indicate controls, connectors and lighted annunciators.

1. Introduction

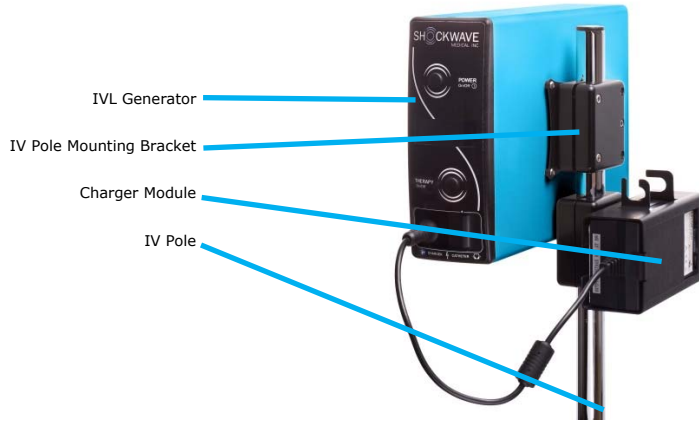
The Shockwave Medical Intravascular Lithotripsy (IVL) System is comprised of the IVL Generator, IVL Connector Cable and IVL Catheters. The IVL Generator and Connector Cable are to be used exclusively with the IVL Catheters. The IVL Catheter incorporates unique energy emitting transducers inside the distal balloon. This technology uses lithotripsy to achieve clinically significant dilation at low balloon pressures.

1.1 The IVL Generator - How Supplied

The IVL Generator is provided non-sterile and is reusable. The IVL Generator is shipped with the following items:

- IV Pole Mounts for IVL Generator and Charger
 - Charger Module
 - 1 ea* IVL Connector Cable (See Section 3.4)
 - AC Mains Cable
 - Operator's Manual
- * Additional IVL Connector Cables can be ordered separately.

The product is shipped as an assembly including the IVL Generator, IV Pole Mount and Charger Module for mounting on an IV pole, as shown below:



1.2 Required Devices and Procedure Supplies for Use with the IVL Generator

- Shockwave Medical IVL Catheter
- Sterile Sleeve, 1.52 m long for IVL Connector Cable
- One IV pole with five casters located in a circular pattern with a diameter of at least 23 inches (58 cm), and a pole diameter of 3/4 to 1 inch (19 mm to 25 mm), such as the I.V. League Ventilator Stat-Stand™ model 1059 or equivalent is required. An IV pole that is securely affixed to the procedure bed may also be used.

1.3 Device Description

The IVL Generator and Connector Cable are used with a Shockwave Medical IVL Catheter to deliver localized, lithotripsy-enhanced, balloon dilatation of calcified, stenotic arteries. The IVL Generator, IVL Connector Cable and IVL Catheters are designed to exchange data during patient treatment. This feature is designed to automatically set pulse parameters unique to each catheter type such as catheter pulse life; refer to the applicable IVL Catheter Instructions for Use for additional information.

1.4 Intended Use/Indication for Use

The Shockwave Medical IVL Generator and Connector Cable are intended for use with Shockwave Medical IVL Catheters only.

NOTE: Refer to the individual Shockwave Medical IVL Catheter Instructions for Use. It is important to carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with each IVL Catheter prior to use of the IVL Catheter with the IVL Generator and Connector Cable.

CAUTION

The IVL System is intended to be used by experienced medical personnel in a catheterization lab within the environmental ranges specified in Appendix C. This device should only be used following an arteriogram (or CT or MRI) of the vascular system and confirmation of appropriate target lumen size.

2. Safety Information

2.1 Terms

The following terms are used either in these operating instructions or on the IVL Generator:

DANGER: Immediate hazards that will result in serious personal injury or death.

WARNING: Hazards or unsafe practices that may result in serious personal injury or death.

CAUTION: Hazards or unsafe practices that may result in minor personal injury, product damage, or property damage.

2.2 Contraindications

There are no specific contraindications for use of the IVL Generator and Connector Cable. However, users should read and understand the specific indications, contraindications, warnings, and precautions included with the applicable Shockwave Medical IVL Catheter Instructions For Use (IFU).

NOTE: The contraindications listed in the IVL Catheter IFU also apply to the use of the IVL Generator and Connector Cable. Carefully review the specific indications, contraindications, warnings, precautions, and adverse events included with each IVL Catheter, prior to use of the IVL Catheter with the IVL Generator and Connector Cable.

2.3 Dangers

DANGER

EXPLOSION HAZARD

This system generates small electrical sparks during normal operation. Do not use this product in the presence of flammable gases or anesthetics.

FIRE HAZARD

The IVL Generator contains a rechargeable lithium ion battery. Do not disassemble, puncture, crush, expose to high temperatures, or incinerate the IVL Generator or battery.

2.4 Warnings

WARNINGS

GENERAL WARNINGS

Do not operate the IVL System until you have read both the Operator's Manual and the Instructions for Use provided with the IVL Catheter. An understanding of the features, functions, indicators and connectors of IVL Generator is a prerequisite for the proper use of this equipment and before clinical use. The IVL Generator is only compatible with the Shockwave Medical IVL Catheters and related accessories.

SHOCK HAZARD

This product delivers pulses of up to 3000 volts of electrical energy. Unless properly used as described in these operating instructions, this electrical energy may cause serious injury. To avoid the risk of electrical shock, this equipment must only be connected to a grounded electrical outlet (electrical supply mains with protective earth.) Use with a hospital grade receptacle. Grounding reliability can only be achieved when connected to an equivalent receptacle marked "hospital use" or "hospital grade". Only use the Charger Module provided with the IVL Generator to avoid shock.

SHOCK HAZARD

Do not attempt to service the system. It contains no operator serviceable components and dangerous high voltages may be present. No user modification or servicing of this equipment is allowed. If any part of this product appears damaged, remove from use and contact your Shockwave Medical representative for repair or replacement.

SHOCK OR FIRE HAZARD

Do not immerse any portion of the IVL Generator in water or other fluids. Do not immerse IVL Connector Cables in water or other fluids. Avoid spilling any fluids on the IVL Generator. Spilled liquids may cause the IVL Generator to perform inaccurately or malfunction. Do not clean with solvents or flammable agents as this may cause damage to the IVL Generator and possibly cause harm to the user. Do not autoclave or sterilize the IVL Generator or IVL Connector Cables as this may cause the IVL Generator or IVL Connector Cable to malfunction.

POSSIBLE FIRE

Use care when operating this device close to oxygen sources (such as bag-valve-mask devices or ventilator tubing). Turn off gas source or move source away from patient during therapy.

ELECTRICAL INTERFERENCE HAZARDS

Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference (RFI) which could affect the performance of this device. If use of equipment in close proximity is necessary, observe the device to verify normal operation in the configuration in which the device will be used. Do not operate the IVL Generator near cauterizers, diathermy equipment, or other portable and mobile RF communications equipment. Refer to Appendix A for recommended distances of equipment. Contact your Shockwave Medical representative if assistance is required.

POSSIBLE ELECTRICAL INTERFERENCE

Using cables, emitters, or accessories not specified for use with this product may result in increased emissions and/or decreased immunity from electromagnetic or radio frequency interference (RFI) which could affect the performance of this product or of equipment in close proximity. Use only parts and accessories specified in these operating instructions.

POSSIBLE DEVICE SHUTDOWN

This device operates only from an internal battery source. It is recommended to charge the IVL Generator battery periodically once every 3 or 4 months, even when not in use. Available battery capacity is indicated on the IVL Generator front panel display as a battery symbol that is filled in solid proportionate to charge status. A lightning bolt symbol is displayed inside the battery symbol during charging. The IVL Generator may shut down without warning if the IVL Generator is operated while the battery symbol is empty (no portion filled in). Remove the IVL Generator from use and contact your Shockwave Medical representative in the event the displayed battery symbol is frequently empty or if the battery symbol is not full after twelve hours of charging.

SAFETY RISK AND POSSIBLE EQUIPMENT DAMAGE / POSSIBLE INJURY OR SKIN BURNS

The IVL Generator and its accessories (including IVL Catheters and IVL Connector Cables) contain ferromagnetic materials. As with all ferromagnetic equipment, these products must not be used in the presence of the high magnetic field created by a Magnetic Resonance Imaging (MRI) device. The high magnetic field created by an MRI device will attract the equipment with a force sufficient to cause death or serious personal injury to persons between the equipment and the MRI device. This magnetic attraction may also damage and affect the performance of the equipment. Burns may also occur due to heating of electrically conductive materials such as IVL Connector Cables and IVL Catheters. Consult the MRI manufacturer for more information.

USE ENVIRONMENT

The IVL Generator is intended for use in a professional healthcare environment. The IVL Generator should not be used in a MRI imaging shield room or near High Frequency surgical equipment.

The customer or the user of the IVL Generator should assure that it is used in the intended environment.

Allow the IVL Generator and its accessories (including IVL Catheters and IVL Connector Cables) to adjust to room temperature and humidity conditions for at least twenty four hours before use. See Appendix C for specified operating conditions. Operating the equipment outside of these environmental conditions may cause equipment malfunction or damage.

IMPROPER DEVICE PERFORMANCE HAZARDS

Using other manufacturers' cables, catheters, power adapters, or batteries may cause the device to perform improperly and may invalidate the safety agency certifications. Use only the accessories that are specified in these operating instructions.

2.5 Cautions

CAUTIONS

GENERAL CAUTIONS

The Shockwave Medical IVL System is intended for use by a physician, or on the order of, a physician. Prior to using the IVL Generator, the user should be familiar with the controls and functions of the system described in this manual. Do not press more than one button at a time on the IVL Generator. The IVL Generator may not respond to either user input. If the shipping container has been damaged in transit or if any part of this product appears damaged, cracked, chipped or missing, remove from use and contact your Shockwave Medical representative for repair or replacement.

IVL POLE TIP HAZARD

Observe the recommendations noted herein for mounting the IVL Generator to an IV pole. Failure to comply with recommendations could result in an injury to the user or patient.

CATHETER MOVEMENT HAZARD

Use caution to prevent unintentional movement of the IVL Connector Cable and IVL Catheter during treatment. Failure to comply with this recommendation could result in an injury to the patient.

EQUIPMENT DAMAGE

The IVL Generator delivers low-energy, short-duration, high-voltage pulses to the IVL Catheter through the IVL Connector Cable. The system is designed not to deliver pulses unless an IVL Catheter Connector is mated with the IVL Connector Cable. It is important not to allow the contacts or internal surfaces of unmated connectors to be contaminated with fluids. Do not allow any connector to become contaminated by or immersed in fluids. Failure to observe these precautions may damage the cables or catheter and then they should be replaced.

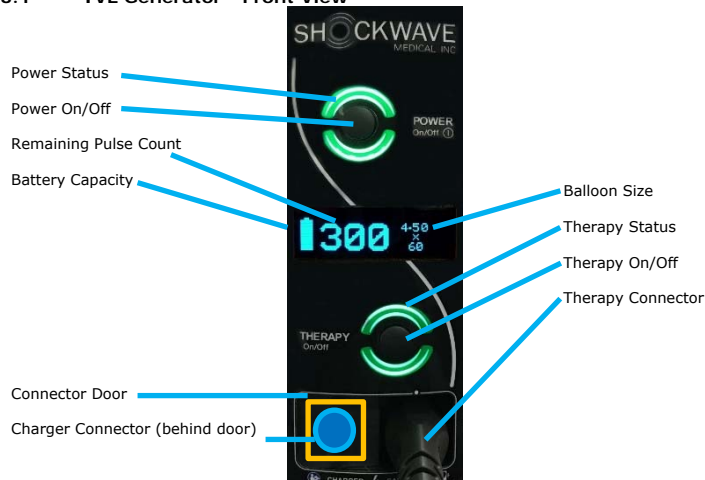
CATHETER DAMAGE

The IVL Catheters require inflation pressure using the correct mixture of 50% contrast and 50% saline to operate reliably. Deliver therapy pulses only when the balloon contains fluid. Only inflate the balloon to the specified pressure ranges indicated in the IVL Catheter Instructions For Use. Failure to observe these precautions may damage the IVL Catheter balloon and could possibly result in patient injury.


3. Product Orientation

Refer to the Installation and Maintenance sections for information on how to prepare the IVL Generator for use. The figure in 3.1 shows the front view of the IVL Generator. All indicators are shown activated in this view for illustration purposes only. The table of 3.2 (next page) lists the controls and provides a brief description.

3.1 IVL Generator - Front View



3.2 Control and Indicator Functions

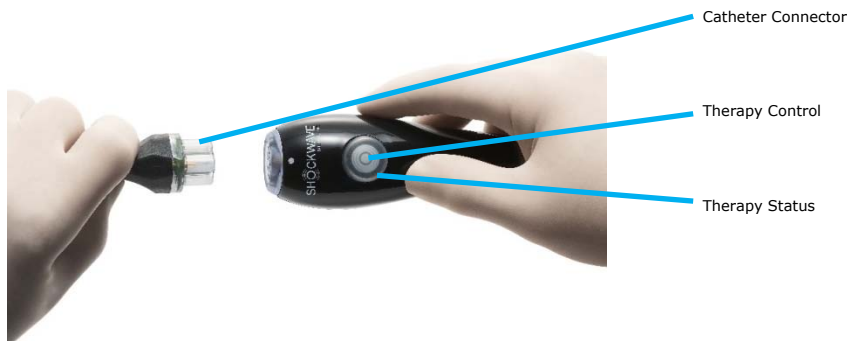
CONTROL	DESCRIPTION	MORE INFO
POWER ON/OFF	Turns IVL Generator on or off.	Refer to 3.1 IVL Generator Front View
THERAPY ON/OFF	Press to activate the IVL Generator.	IVL Connector Cable and a valid IVL Catheter must be connected to activate.
INDICATOR	DESCRIPTION	MORE INFO
POWER STATUS Indicator	On green when IVL Generator is on. On yellow when user action is required regarding the IVL Catheter (CATH). On red when internal diagnostics have detected a problem (SYS).	Refer to 3.1 IVL Generator Front View See Section 4 step 6. See Section 7.
BATTERY CAPACITY Display/ Charging Status	Indicates battery charge remaining.	See Section 4 step 2.
BATTERY CHARGING Indicator	Lightning bolt symbol appears when the Charger Module is connected and is charging the battery from mains power. 	Charge IVL Generator before use. See Sections 5.2 and 5.3.
BALLOON SIZE Display	IVL Catheter Balloon Diameter and Length	When IVL Connector Cable and valid IVL Catheter connected.
PULSE COUNT Display	Number of Pulses available.	Counts down from available Pulse Count Per Catheter during treatment as each pulse is delivered. Refer to applicable IVL Catheter IFU for the Max Pulse Count.
THERAPY STATUS Indicator	On green when the device is ready to deliver therapy. Flashes to indicate therapy is in process. On yellow when therapy is paused or deactivated.	See Section 4, Steps 5 – 9.

3.3 Front Panel Connectors

FEATURE	DESCRIPTION	MORE INFO
CONNECTOR DOOR	Slide right to connect charger. Slide left to connect IVL Connector Cable.	See Section 4, Step 4.
CHARGER CONNECTOR	Used to connect to charger module.	See Section 5.3
THERAPY CONNECTOR	Used to connect to IVL Connector Cable (the Connector Cable connects the IVL Generator to the IVL Catheter).	See Section 4 Step 4.

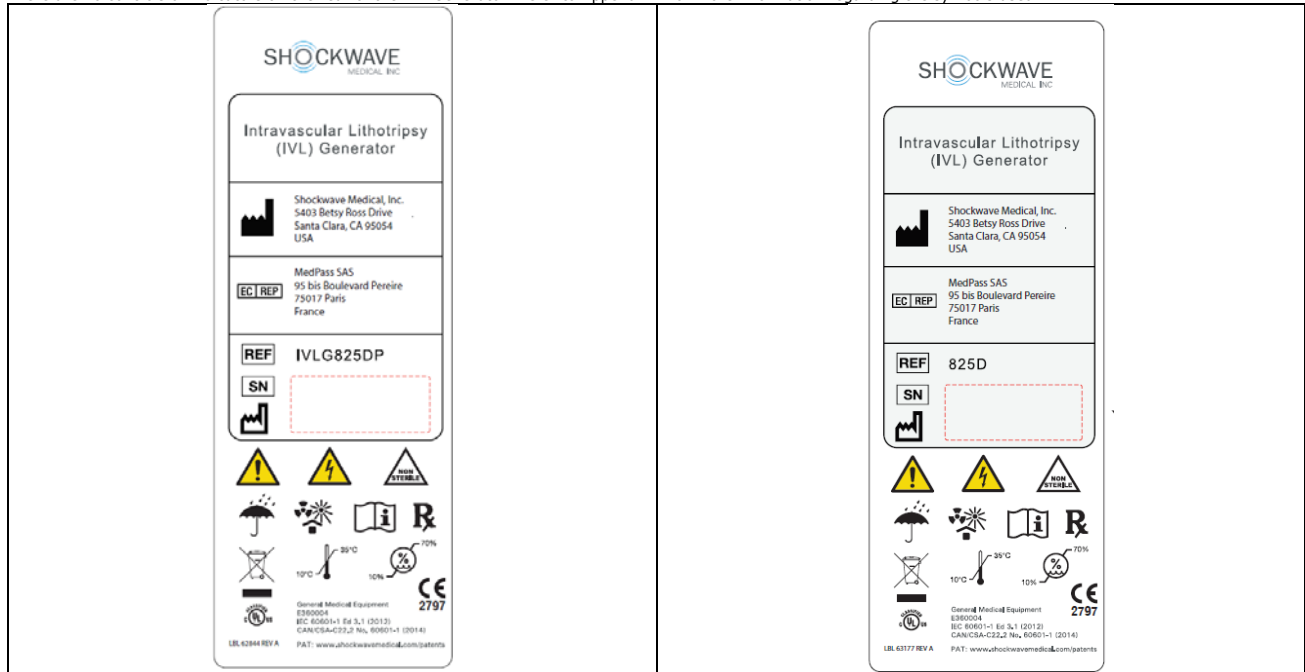
3.4 IVL Connector Cable

Pressing and holding the THERAPY CONTROL on the IVL Connector Cable initiates therapy delivery. The IVL Generator must first be activated (THERAPY STATUS indicators on IVL Generator front panel and CATHETER CONNECTOR will be green). Refer to Section 4.0, Step 8 for more information.



3.5 IVL Generator – Rear View





There are no controls or indicators on the rear of the IVL Generator. Refer to Appendix B for more information regarding the symbols used.



4. Product Use and Therapy Delivery

Before use read all sections of this operator's manual and familiarize yourself with all controls, displays and connector features. Charge the IVL Generator before use (see Sections 5.2, 5.3). Also refer to the IFU provided with the IVL Catheter for additional information before use. Not all clinical procedures will follow the sequence below. The following steps serve as a guide for use of the IVL Generator in clinical applications.

Step	Picture or additional info if applicable
<p>Step 1 – Turn the Generator On Momentarily depress the POWER ON/OFF button. All indicators on the IVL Generator will come on briefly as a test. The THERAPY STATUS indicator will come on yellow and green during this test. The POWER STATUS indicator will continue to be on green.</p>	
<p>Step 2 – Confirm Battery Capacity With the Generator powered on, the BATTERY CAPACITY will be shown in the right side of the display. The battery symbol should be at least partially filled as shown.</p> <p>If the battery symbol is empty, additional charging of the battery is recommended before use because there may not be an adequate charge to complete a patient treatment.</p>	
<p>Step 3 – Check Diagnostics Confirm that the display is as pictured with no error messages displayed. If an error message is displayed, refer to Troubleshooting, Section 7.0.</p> <p>Normal display with no errors shown to the right.</p>	
<p>If a yellow light is displayed, refer to Troubleshooting, Section 7.0.</p> <p>If any error messages come on during use, refer to Troubleshooting, Section 7.0.</p> <p>Error Condition – Catheter error shown to the right.</p>	
<p>Step 4 – Connect IVL Connector Cable Disconnect the Charger Module from the CHARGER CONNECTOR if it is connected.</p> <p>Slide the CONNECTOR DOOR fully to the left, revealing the THERAPY CONNECTOR as shown.</p> <p>Connect the GENERATOR CONNECTOR end of the Connector Cable to the THERAPY CONNECTOR. Orient the connector and gently push in. The connector is magnetic and will engage as the magnet gets close. Push gently to confirm connector is fully engaged.</p>	<p>Slide CONNECTOR DOOR to left to reveal the THERAPY CONNECTOR</p>  <p>THERAPY CONNECTOR:</p> 
<p>Step 5 – Prepare IVL Catheter for Use Prepare the catheter for use following the instructions in the IVL Catheter IFU. Use a sterile sleeve to cover the distal end of the IVL Connector Cable. Protect the connector from contamination by fluids.</p>	<p>N/A</p>
<p>Step 6 – Connect IVL Catheter Take care not to contaminate either connector end with fluids or other foreign matter during this procedure prior to mating. Connect the IVL Catheter to the CATHETER CONNECTOR end of the IVL Connector Cable using the same method outlined in step 4.</p> <p>NOTE: Ensure that the sterile sleeve also covers the CATHETER CONNECTOR. The THERAPY STATUS indicator on the IVL Generator front panel and the CATHETER CONNECTOR will be yellow, indicating that the IVL Generator is ready to activate.</p> <p>The IVL Catheter balloon dimensions will appear in the BALLOON SIZE display. The total number of available pulses for the selected IVL catheter will appear in the PULSE COUNT field.</p>	
<p>Step 7 – Position the IVL Catheter Following conventional angioplasty catheter technique, introduce and position the IVL Catheter as desired. Use caution to prevent unintentional movement of the IVL Connector Cable and IVL Catheter during treatment.</p>	<p>(Refer to the IVL Catheter IFU)</p>
<p>Step 8 – Activate the IVL Generator Inflate the IVL Catheter and verify pressure per the instructions indicated in the IVL Catheter IFU. Press the THERAPY ON/OFF button once. The THERAPY STATUS indicator on the IVL Generator front panel and on the CATHETER CONNECTOR will now be green, indicating that the IVL Generator is now ready to deliver therapy. To deactivate the IVL Generator at any time, simply press the IVL Generator THERAPY ON/OFF button again and verify that the THERAPY STATUS indicator light is yellow.</p>	

Step	Picture or additional info if applicable
<p>Step 9 – Deliver Therapy</p> <p>While observing balloon positioning and lesion characteristics under fluoroscopy, press and hold the THERAPY button on the IVL Connector Cable. The IVL Generator will deliver lithotripsy pulses via the IVL Catheter balloon while the THERAPY button is depressed unless the IVL Generator determines that therapy is to be interrupted. As each therapy pulse is delivered, the THERAPY STATUS indicator will blink once, the PULSE COUNT display will decrement by one, and the Generator will sound one click. Confirm therapy delivery by continuously monitoring under fluoroscopy (see IVL Catheter IFU for additional information). To stop therapy, simply release the THERAPY button.</p> <p>NOTE: There is no need to make any adjustments for dosage levels or pulse rates. All such settings are pre-programmed for given catheter types.</p>	
<p>Step 10 – Pause Period / Resume Therapy</p> <p>The IVL Generator is designed to force a brief pause in therapy at designated intervals. If the user attempts to deliver a quantity of pulses without pausing, the IVL Generator will automatically interrupt therapy for a pause period. The THERAPY STATUS indicator will be yellow during this period. To resume therapy, wait for the THERAPY STATUS indicator to become green again (two beeps will sound). Simply release and press the THERAPY CONTROL again to resume therapy. Refer to the applicable IVL Catheter IFU for specifics on the maximum number of continuous pulses allowed and the duration of the pre-programmed pause period. Care must be taken not to exceed the recommended maximum number of pulses in the same treatment segment.</p>	
<p>Step 11 – IVL Catheter End of Life</p> <p>The IVL Generator is designed to sense the end of the useful life of the IVL Catheter. Should this occur the PULSE COUNT will indicate "0" pulses remaining and the IVL Generator will interrupt therapy. The display will indicate a catheter error and a yellow light will appear around the POWER ON/OFF button. Replacing the IVL Catheter with a new one is required before the IVL Generator may be used again. Refer to the applicable IVL Catheter IFU for maximum pulse count per catheter (useful life) specifications.</p>	
<p>Step 12 – IVL Catheter Replacement</p> <p>Detach the IVL Catheter by first sliding the sterile sleeve out of the way moving it proximally along the IVL Connector Cable. Next, gently pull the CATHETER CONNECTOR and IVL Connector Cable apart to separate the IVL Catheter from the IVL Connector Cable connector (see illustration). Take care not to contaminate the connectors with fluids or other foreign matter during this procedure. Position IVL Connector Cable to help ensure the connector remains free of contamination until the IVL Catheter can be replaced.</p> <p>CAUTION: Discard the used IVL Catheter per standard hospital procedures. Used IVL Catheters cannot be re-sterilized and are designed for single use only. Re-use of IVL Catheters can lead to patient injury. Connect a new IVL Catheter and resume patient treatment following the steps outlined above, beginning at step #5. Refer to the IVL Catheter IFU for information about recommended balloon overlap to prevent geographic miss. However, care must be taken not to exceed the recommended maximum number of pulses in the same treatment segment as indicated in the IVL Catheter IFU.</p>	

CAUTION
EQUIPMENT DAMAGE
The IVL Generator delivers low-energy, short-duration, high-voltage pulses to the IVL Catheter through the IVL Connector Cable. The system is designed not to deliver pulses unless an IVL Catheter connector is mated with the IVL Connector Cable and IVL Generator. It is important not to allow the contacts or internal surfaces of unmated connectors to be contaminated with fluids. Do not allow any connector to become contaminated by or immersed in fluids. Failure to observe these precautions may damage the cables or catheters.

4.1 Additional Usage Information

The following topics and additional information may be useful in the use of the IVL Generator in treatment scenarios that may differ from the basic sequence of events defined in Section 4.0 above.

TOPIC	ADDITIONAL INFORMATION
Tones	<p>The IVL Generator is designed to supplement its visual indicators with tones. The IVL Generator will sound tones as follows:</p> <ul style="list-style-type: none"> • Click – Sounds once per therapy pulse to confirm therapy delivery in process. • Two beeps – Positive confirmation of a user action. Occurs when connecting a valid catheter or when arming or disarming the IVL Generator. Also occurs at the end of the pre-programmed therapy pause period. • Three beeps – Negative prompt. Occurs when attempting to activate the IVL Generator but when one or more conditions are preventing activation. Examples include attempting to activate the IVL Generator without a valid IVL Catheter attached or while holding down the THERAPY button. Also occurs when the IVL Generator is deactivated and in the event built in diagnostics detect a malfunction.
Use of Multiple IVL Catheters	<ul style="list-style-type: none"> • Multiple IVL Catheters may be used during the treatment of a single patient. The IVL Generator is designed to track the useful remaining life of each IVL Catheter; however, no more than one of any given size IVL Catheter may be in use simultaneously. • Connect and use IVL Catheters of varying sizes by following steps 5 – 9 above. • Discard used IVL Catheters after patient treatment. Used IVL Catheters cannot be re-sterilized and are for single use only. Re-use of IVL Catheters can lead to patient injury.
Automatic Off Feature	<p>The IVL Generator is designed to turn itself off and conserve battery power after periods of inactivity as follows:</p> <ul style="list-style-type: none"> • No IVL Catheter is connected – Will turn off after five hours. • IVL Catheter connected – Will turn off after one hour. • If the IVL Generator has turned itself off, simply press the POWER ON/OFF button to turn the IVL Generator back on. Patient treatment may resume by following steps outlined in Section 4.0.
Following Usage	<p>Follow these steps to prepare the IVL Generator for future use:</p> <ul style="list-style-type: none"> • Press POWER ON/OFF button once to turn the IVL Generator off. • Remove and discard the IVL Catheter and sterile sleeve. • Coil and secure the IVL Connector Cable • Slide the CONNECTOR DOOR to the right to protect the THERAPY CONNECTOR • If the last case of the day has been completed, or if the BATTERY CHARGING symbol is indicating empty, then place the battery on charge. The Charger Module must be connected to AC Mains and to the IVL Generator CHARGER CONNECTOR per Sections 5.2 - 5.3. • Confirm the IVL Generator is charging; a lightning bolt symbol should appear inside the battery symbol. <p>NOTE: The battery is self-discharging and requires periodic recharges, recommended once every 3 or 4 months, even when not in use during storage so that the battery will not discharge to an unacceptably low voltage level, which could ultimately result in battery damage.</p>

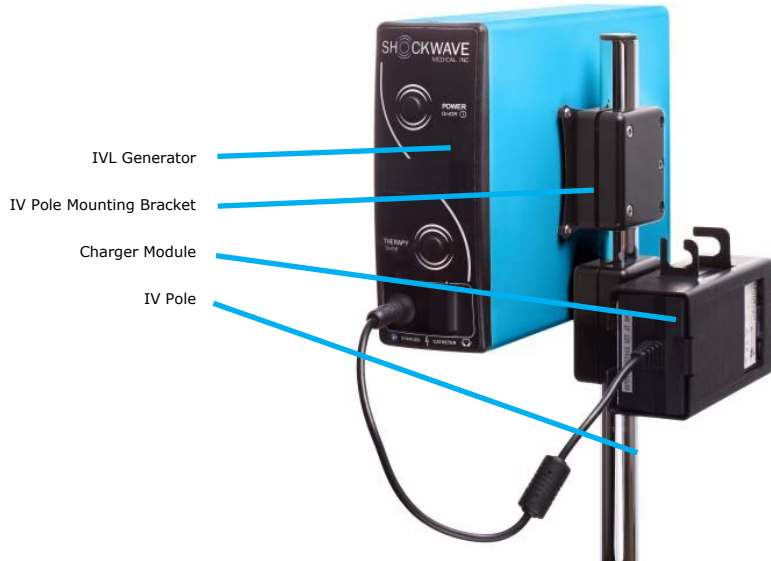
5. Installation

Important - Follow all steps in Sections 5.0 – 5.5 prior to use of this product.

WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The IVL Generator is shipped as an assembled product, ready to install on an IV pole as outlined in Section 1.1. It is designed to be mounted to an IV pole prior to use. Once mounted, it will appear as shown below.



Care should be taken in selecting a stable IV pole which should have a wide base and locking-style casters. An IV pole with five casters, located in a circular pattern with a diameter of at least 23 inches (58 cm), such as the I.V. League Ventilator Stat-Stand™ model 1059 (or equivalent) is recommended.

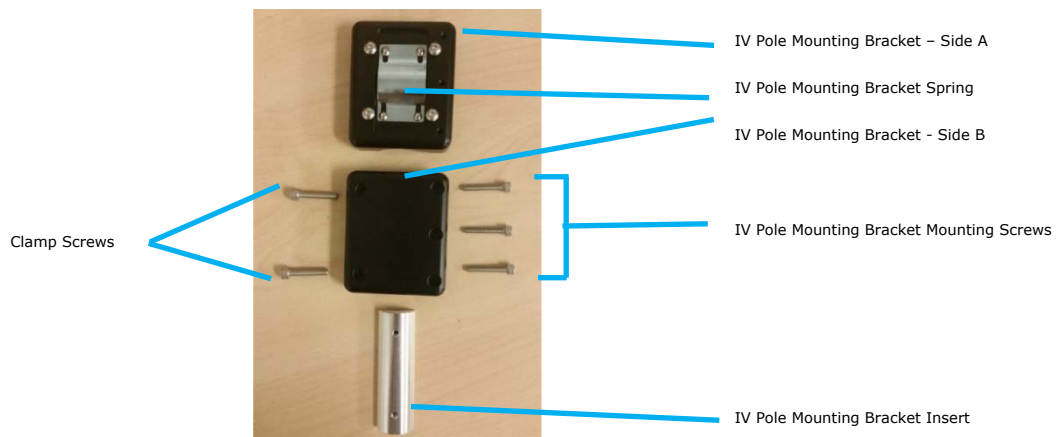
The IVL Generator should be mounted such that its top surface is no more than 50 inches (127 cm) from the floor. Consult your biomedical department in the event there are any questions regarding the stability of the intended IV pole and mounting location. Mounting the IVL Generator to an unstable IV pole could present a tip over hazard to staff or patients.

5.1 IV Pole Mounting

STEP 1 – Locate and identify mounting hardware (see image below).

Two identical sets of IV pole mounting hardware are provided. One set is used to mount the IVL Generator and one set is used to mount the battery Charger Module.

IV Pole Mounting Hardware

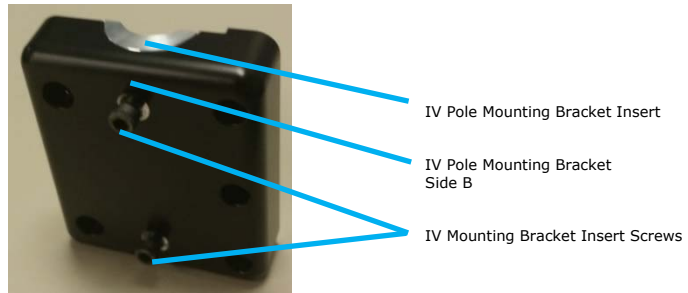


STEP 2 – Determine the IV pole diameter at the desired mounting location.

The mounting bracket will accommodate IV pole diameters from 3/4 to 1 inch (19 mm to 25 mm).

NOTE: If the pole diameter is 1 inch (25 mm) proceed to step 3.

If the IV pole is 3/4 inch (19 mm) in diameter, attach the IV Pole Mounting Bracket Insert to the side B mounting bracket as shown below and proceed to step 3.



STEP 3 – Mount the brackets to the IV Pole as follows:



IV Pole Mounting Bracket Side A IV Pole Mounting Bracket Side B



Mounting Screw



Allen Key (5/32")

Slide the bracket to the desired position on the pole for the battery charger. Install and tighten the clamp screw.



Clamp Screw



Tighten with Allen Key (5/32")

Install and tighten the remaining mounting (2ea) and clamp screws (1ea).

Install the second mounting bracket in the same fashion. Position the second bracket so that it rests on top of the first bracket. Orient the brackets so that they are facing opposite directions.

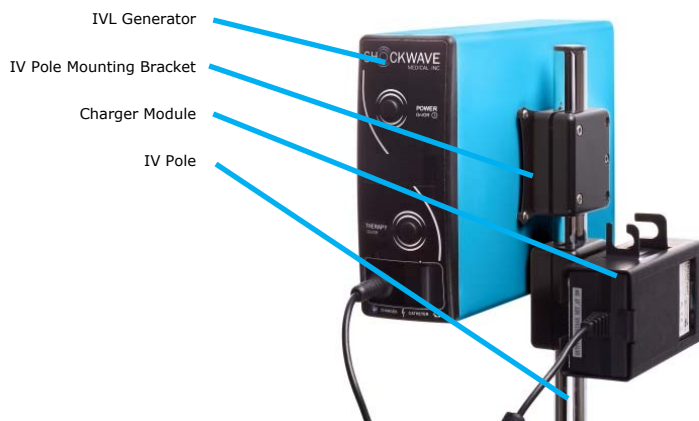


STEP 4 – Mount the IVL Generator to the top bracket:

Align the holes in the mounting plate on the right side of the IVL Generator with the bracket mounting studs. Push the IVL Generator towards the bracket to engage the mounting studs then push the IVL Generator down to lock in place.



STEP 5 – Mount the battery Charger Module in the same fashion as the IVL Generator.



CAUTION – IV POLE TIP HAZARD

Observe the recommendations noted herein for mounting the IVL Generator to an IV pole. Failure to comply with recommendations could result in an injury to the user or patient.

5.2 Connecting to Line Power

The IVL Generator normally operates from an internal, rechargeable battery system. However, in order to charge the battery system, the Charger Module must first be connected to line power. Locate the AC Mains Cable shipped with the IVL Generator and connect it to the AC Mains input. Choose a safe location where connection of this power cable to AC Mains will not create a trip hazard and connect it to the AC Mains outlet.

The Charger Module is designed to operate from power supplies world-wide. See Appendix C for more information.

WARNING – SHOCK HAZARD

To avoid the risk of electrical shock, this equipment must only be connected to a grounded electrical outlet (electrical supply mains with protective earth.) Use with a hospital grade receptacle. Grounding reliability can only be achieved when connected to an equivalent receptacle marked "hospital use" or "hospital grade". Only use the Charger Module provided with the IVL Generator to avoid shock.

5.3 Charging the Internal Battery

Charging the battery requires the Charger Module be connected to AC Mains, and the Charger Module must also be connected to the CHARGER CONNECTOR located on the front panel of the IVL Generator (see Section 3.1).

It will be necessary to disconnect the IVL Connector Cable from IVL Generator, if one is attached. To do so, gently pull the IVL Connector Cable connector straight from the IVL Generator. Move the CONNECTOR DOOR fully to the right to cover the THERAPY CONNECTOR and expose the CHARGER CONNECTOR.

Connect the cable coming from the front of the Charger Module to the CHARGER CONNECTOR on the front of the IVL Generator (see Section 3.1). Ensure that the CHARGER MODULE cable is fully seated into the CHARGER CONNECTOR. The BATTERY CHARGING indicator will be displayed with a lightning bolt inside the battery symbol to indicate the battery is now charging (see Step 2 of Section 5.5 for illustration).

Charge the battery for at least twelve hours prior to use. After twelve hours, BATTERY CAPACITY should show a completely filled in battery symbol (see Step 4 of Section 5.5 for illustration).

NOTE: The battery is self-discharging and requires periodic recharges, recommended once every 3 or 4 months, even when not in use during storage so that the battery will not discharge to an unacceptably low voltage level, which could ultimately result in battery damage.

5.4 Environment Conditioning

The IVL Generator is designed to be used indoors in a controlled environment. Refer to Appendix C for specified operating conditions.

Allow the IVL Generator to be stored in the ambient conditions of the usage environment for at least 24 hours before turning it on. This must be done with the IVL Generator unpacked and removed from its shipment materials. This is important because shipping, storage and use environments may vary widely and could cause condensation within the IVL Generator or its accessories. Such condensation could result in a possible malfunction or equipment damage if operated.

WARNING – USE ENVIRONMENT




The IVL Generator is intended for use in a professional healthcare environment. The IVL Generator should not be used in a MRI imaging shield room or near High Frequency surgical equipment.




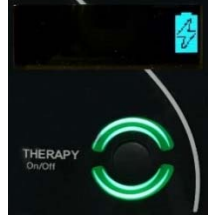

The customer or the user of the IVL Generator should assure that it is used in the intended environment.

Allow the IVL Generator and its accessories (including IVL Catheters and IVL Connector Cables) to adjust to room temperature and humidity conditions for at least twenty four hours before use. See Appendix C for specified operating conditions. Operating the equipment outside of these environmental conditions may cause equipment malfunction or damage.

5.5 Generator Inspection and Test

Inspection and test of the IVL Generator following installation per the steps below is recommended prior to placing the IVL Generator into clinical service. Also confirm that the inspection and test requirements of your Biomedical Department have been satisfied prior to placing this equipment into clinical service.

Step	Picture or additional info if applicable
<p>Step 1 – Physical Condition Inspection Inspect all surfaces of the IVL Generator exterior including the Charger Module. Confirm there is no visible damage such as cracks or chips in any component. Disconnect the Charger Module from the IVL Generator and slide the CONNECTOR DOOR left and right. Verify it is not damaged, also verify it is retained in its track and it slides easily left to right. Reconnect the Charger Module to the IVL Generator. Inspect the IVL Connector Cable and AC Mains Cable. Confirm there are not any damaged, split or cracked materials and electrical contacts are free of extraneous matter.</p>	
<p>Step 2 – Confirm Battery Charging The Charger Module must be connected to AC Mains and to the IVL Generator CHARGER CONNECTOR per Sections 5.2 - 5.3. Confirm the BATTERY CHARGING indicator is displayed.</p>	
<p>Step 3 – Turn the IVL Generator On Momentarily depress the POWER ON/OFF button. The POWER STATUS and THERAPY STATUS indicators will turn on briefly as a test. The indicators will come on green and then yellow during this test. The POWER STATUS indicator will remain green if no internal fault is detected. The THERAPY STATUS indicator will turn off.</p>	

Step	Picture or additional info if applicable
<p>Step 4 – Confirm Battery Capacity If the battery has been charging for at least twelve hours, as indicated in Section 5.3, the battery capacity shown in the BATTERY CAPACITY display should be full as shown.</p>	
<p>Step 5 – Check Diagnostics When powered on, the IVL Generator will perform an array of built in tests designed to detect certain malfunctions. If an error is detected, an error message will be displayed. If there are no error messages, these tests passed successfully. If an error message is displayed, refer to Troubleshooting, Section 7.0.</p>	 Normal  Error Condition
<p>Step 6 – Initiate the Output Test This test is initiated manually by depressing and holding the THERAPY ON/OFF button and releasing this button when the THERAPY STATUS indicator comes on green. Pressing this button for three seconds is required.</p>	
<p>Step 7 – Confirm Output Test Result The output test requires approximately 15 seconds to complete. During this time the THERAPY STATUS indicator will remain on green. Upon successful completion of this test, the IVL Generator will sound four beeps. If an error is detected, an error message will be displayed. If the display remains blank with only the battery symbol, this test has passed successfully. This is the final step of the recommended inspection and test procedure.</p>	

WARNING – SHOCK HAZARD

Do not immerse IVL Connector Cables in water or other fluids. Avoid spilling any fluids on the IVL Generator. Spilled liquids may cause the IVL Generator to perform inaccurately or malfunction.

6. Maintenance



This section describes the maintenance that clinical and / or biomedical staff should be familiar with performing on a regular basis. Recommendations for regular maintenance and maintenance intervals are noted below.

NOTE: The battery is self-discharging and requires periodic recharges, recommended once every 3 or 4 months, even when not in use during storage so that the battery will not discharge to an unacceptably low voltage level, which could ultimately result in battery damage. There are no user serviceable parts within the IVL Generator. Do not open the IVL Generator enclosure. Refer all such servicing needs to your Shockwave Medical representative.

6.1 Daily Maintenance

6.1.1 Charging and Testing the Internal Battery

The IVL Generator operates from an internal battery. Charging the IVL Generator at the end of each day is recommended so that the battery will be fully charged for cases occurring the following day. Twelve (12) hours of charge time will restore the battery to full charge.

<p>Confirm Battery Charging The Charger Module must be connected to AC Mains and to the Generator CHARGER CONNECTOR per Sections 5.2 - 5.3.</p> <p>Confirm the BATTERY CHARGING indicator is displayed.</p>	
<p>Confirm Battery Capacity If the battery has been charging for at least twelve hours the battery capacity shown in the BATTERY CAPACITY display should indicate full as shown.</p> <p>See the table on the next page for battery capacity information.</p>	

BATTERY SYMBOL	CAPACITY
Completely Filled	Fully charged
½ Full	Four or more treatment cases
¼ Full	Two or more treatment cases
Empty	Less than two treatment cases; recharge as soon as practical

A treatment case, for the purposes of interpreting the BATTERY CAPACITY display, is conservatively defined as 900 therapy pulses delivered over one hour. Actual battery performance will vary based on actual therapy delivered.

If the battery does not indicate full charge following twelve (12) hours of charging, remove the IVL Generator from service and contact your Shockwave Medical representative.

NOTE: The battery is self-discharging and requires periodic recharges, recommended once every 3 or 4 months, even when not in use during storage so that the battery will not discharge to an unacceptably low voltage level, which could ultimately result in battery damage.

WARNING – POSSIBLE DEVICE SHUTDOWN
This device operates only from an internal battery source. It is recommended to charge the IVL Generator battery once every 3 or 4 months, even when not in use. Always operate the IVL Generator when the battery symbol is at least ¼ Full. IVL Generator may shut down without warning when the battery symbol is Empty. Remove the IVL Generator from use and contact your Shockwave Medical representative in the event the battery symbol frequently appears Empty or if the battery symbol does not appear full after twelve hours of charging.

6.1.2 Testing the IVL Generator

The IVL Generator will automatically perform an array of built in tests designed to detect certain malfunctions each time it is turned on. In addition, the IVL Generator features an automated test of the lithotripsy output system which may be initiated by the user. Confirmation of satisfactory test results is recommended daily, before cases are initiated, or as directed by your Biomedical Department. These tests may be done as follows:

Step	Picture or additional info if applicable
<p>Step 1 – Turn the IVL Generator On Momentarily depress the POWER ON/OFF button. All indicators on the IVL Generator will come on briefly as a test. The THERAPY STATUS indicator will come on green and yellow during this test. The POWER STATUS indicator will continue to be on green.</p>	
<p>Step 2 – Check Diagnostics When powered on, the IVL Generator will perform an array of built in tests designed to detect certain malfunctions. If an error is detected, an error message will be displayed. If no error is displayed, these tests passed successfully.</p> <p>If an error message is displayed, refer to Troubleshooting, Section 7.0.</p>	
<p>Step 3 – Initiate the Output Test The Charger Module must be connected to AC Mains and to the IVL Generator CHARGER CONNECTOR to run this test.</p> <p>This test is initiated manually by depressing and holding the THERAPY ON/OFF button and releasing this button when the THERAPY STATUS indicator comes on green. Pressing this button for three seconds is required.</p>	
<p>Step 4 – Confirm Output Test Result The output test requires approximately 15 seconds to complete. During this time the THERAPY STATUS indicator will remain on green. Upon successful completion of this test, the IVL Generator will sound four beeps. If no error message appears on the display then this test has passed successfully.</p>	

6.1.3 Inspecting the IVL Generator

Physical inspection of the IVL Generator on a daily basis is also recommended to help ensure that all components required for reliable operation are in good condition.

Physical Condition Inspection

Inspect all surfaces of the IVL Generator exterior including the Charger Module. Confirm there is no visible damage such as cracks or chips in any component.

Disconnect the Charger Module from the IVL Generator and slide the CONNECTOR DOOR left and right. Verify it is not damaged, also verify it is retained in its track and it slides easily left to right. Reconnect the Charger Module to the Generator.

Inspect the IVL Connector Cable and AC Mains Cable. Confirm there are not any damaged, split or cracked materials and electrical contacts are free of extraneous matter.

**6.1.4 Cleaning the IVL Generator**

Dirt and extraneous matter may be removed from the IVL Generator and IVL Connector Cable using a soft cotton cloth or a lint free wipe. If needed, use only isopropyl alcohol sparingly as a cleaning agent.

Do not allow any fluids to penetrate the exterior surfaces of the device. Allow equipment to dry thoroughly before testing or use.

Clean connector areas carefully. Do not attempt to clean interior surfaces of connectors or connector contacts. In the event that an IVL Connector Cable has become contaminated or malfunctions, remove this cable from use and contact your Shockwave Medical representative.

WARNING – SHOCK OR FIRE HAZARD

Do not immerse any portion of the IVL Generator in water or other fluids. Do not immerse IVL Connector Cables in water or other fluids. Avoid spilling any fluids on the IVL Generator. Spilled liquids may cause the IVL Generator to perform inaccurately or malfunction.

Do not clean with solvents or flammable agents as this may cause damage to the IVL Generator and possibly cause harm to the user

Do not autoclave or sterilize the IVL Generator or IVL Connector Cables as this may cause the IVL Generator to malfunction.

6.2 Monthly Maintenance

There is no specific test or inspection which is recommended to be conducted on a monthly basis in addition to the tests and inspections included in Section 6.1. However, it is recommended that the shift supervisor or Biomedical Department review staff practices on a monthly basis to help ensure this recommended maintenance is being completed on a daily basis or as directed by the Biomedical Department.

6.3 Other Maintenance

Shockwave Medical recommends that you contact your Shockwave Medical representative if you have any questions or concerns about maintenance.

Shockwave Medical recommends replacement of IVL Connector Cables every three years to reduce the possibility of failure during patient use. In the event IVL Connector Cable connectors have become contaminated or the IVL Connector Cable malfunctions, remove this cable from use and contact your Shockwave Medical representative for replacement. Additional IVL Connector Cables can be ordered separately.

NOTE: The IVL Connector Cable should not be disposed of in the normal waste stream; it should be sent to a separate collection facility for recovery and recycling.

6.4 Product Useful Life

The IVL Generator has been designed to provide a useful life of three years or more. Life expectancy is based on actual usage. Periodic inspection per the maintenance schedule above is recommended by Shockwave Medical to assess continued use.

7. Troubleshooting

If a problem is detected with the IVL System during use or testing, refer to the troubleshooting tips below. If the problem cannot be corrected, remove the equipment from service and contact your Shockwave Medical representative and or email complaints@shockwavemedical.com.

Technical Support: For Shockwave Medical Technical Support, contact your local Shockwave Medical representative or www.shockwavemedical.com.

WARNING – SHOCK HAZARD

Do not attempt to service the system. It contains no operator serviceable components and dangerous high voltages may be present. No user modification or servicing of this equipment is allowed. If any part of this product appears damaged, remove from use and contact your Shockwave Medical representative for repair or replacement.

Observation	Possible Cause	Corrective Action
Unit will not turn on	Battery requires charge	Connect Charger Module to the IVL Generator and to AC Mains. Allow the IVL Generator to charge at least twelve (12) hours prior to use
Battery will not charge (BATTERY CHARGING indicator is off)	Disconnected cable	Connect Charger Module to the IVL Generator and also to AC Mains. NOTE: two cable connections are required.
Low BATTERY CAPACITY indicated when the battery symbol is Empty	Battery requires charge	Connect Charger Module to the IVL Generator and to AC Mains. Allow the IVL Generator to charge at least twelve hours prior to use
System Error displayed and red light around POWER ON/OFF button.	Built in tests have detected a malfunction within the IVL Generator	Turn IVL Generator off, wait one second and turn the IVL Generator on again. NOTE: If SYS fault cannot be resolved, remove IVL Generator from service and contact your Shockwave Medical representative.
Catheter Error 80 Displayed Catheter beginning of life unsuccessful.	The generator was unable to mark the IVL Catheter for beginning of life. Possible causes are: <ul style="list-style-type: none"> Loose connection between the IVL Generator and IVL Catheter IVL Connector Cable defective or has reached end of life. IVL Catheter defective or has reached end of life. 	Turn the IVL Generator power OFF Check IVL Catheter and IVL Connector Cable connection <ul style="list-style-type: none"> Make sure that the sterile sleeve is not interfering with the IVL Catheter and IVL Connector Cable connection. Make sure that the connection to the IVL Generator is secure and that the IVL Generator sliding door is not interfering with the connection.
Catheter Error 81 Displayed Catheter identification unsuccessful.	IVL Generator was unable to identify the IVL Catheter type. Possible causes are: <ul style="list-style-type: none"> Loose connection between IVL Generator and IVL Catheter IVL Connector Cable defective or has reached end of life. IVL Catheter defective or has reached end of life. 	Purge and re-prepare the IVL Catheter balloon <ul style="list-style-type: none"> Make sure air bubbles are removed from balloon before and during IVL therapy. Deflate balloon by pulling vacuum at least 3 times, releasing vacuum to allow the fluid to replace the air in the balloon.

Observation	Possible Cause	Corrective Action
Catheter Error 88 Displayed Pulse delivery timeout.	The IVL Generator was unable to measure pulse energy delivery to the IVL Catheter within allowed time limit. Possible causes are: <ul style="list-style-type: none"> • Gas bubbles in the balloon • Loose connection between the IVL Generator and IVL Catheter • IVL Connector Cable defective or has reached end of life. • IVL Catheter defective or has reached end of life. 	Turn the IVL Generator power ON Press the IVL Generator front panel therapy button when ready Resume pulse delivery. If the error condition persists, replace the IVL Catheter.
THERAPY STATUS indicator on IVL Generator front panel or on the IVL Connector Cable does not turn on	Valid IVL Catheter is not connected	Make sure IVL Connector Cable is connected to IVL Generator Make sure IVL Catheter is connected to IVL Connector Cable Replace IVL Catheter
IVL Generator will not activate (THERAPY STATUS is off)	Valid IVL Catheter is not connected	See THERAPY STATUS indicator troubleshooting step above
IVL Generator will not activate (THERAPY STATUS is yellow)	THERAPY ON/OFF button is pressed	Release THERAPY ON/OFF button, try again
THERAPY STATUS changed from green to yellow	IVL System has automatically paused therapy (see Section 4.0 Step 10)	THERAPY STATUS should indicate green again, within the pause period specified in the IVL Catheter IFU
THERAPY ON/OFF button on the IVL Connector Cable is pressed, but IVL Generator does not deliver pulses	IVL Generator cannot be activated (THERAPY STATUS indicator is off)	If error message(s) appear, see troubleshooting guide above
	IVL Generator has not yet been activated (THERAPY STATUS indicator is yellow)	Press THERAPY ON/OFF button once (THERAPY STATUS should turn green)
	IVL System has automatically paused therapy (THERAPY STATUS indicator is yellow, see Section 4.0 Step 9)	THERAPY STATUS should indicate green again, within the pause period specified in the IVL Catheter IFU
	IVL Catheter or IVL Connector Cable is faulty (THERAPY STATUS indicator is green)	Replace IVL Catheter Replace IVL Connector Cable

8. Appendix A: Electromagnetic Compatibility Guidance


Electromagnetic Compatibility Guidance - Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
<p>The IVL Generator is intended for use in a professional healthcare environment. The IVL Generator should not be used in a MRI imaging shield room or near High Frequency surgical equipment. The customer or the user of the IVL Generator should assure that it is used in the intended environment.</p>		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The IVL Generator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Compatibility Guidance – Power Supply Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
<p>The IVL Generator is intended for use in a professional healthcare environment. The IVL Generator should not be used in a MRI imaging shield room or near High Frequency surgical equipment. The customer or the user of the IVL Generator should assure that it is used in the intended environment.</p>			
<p>WARNING Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.</p>			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment –guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 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 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the IVL Generator requires continued operation during power mains interruptions, it is recommended that the IVL Generator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
<p>NOTE: UT is the A.C. mains voltage prior to application of the test level.</p>			

Electromagnetic Compatibility Guidance – RF Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The IVL Generator is intended for use in the electromagnetic environment specified below. The IVL Generator should not be used in a MRI imaging shield room or near HF surgical equipment. The customer or the user of the IVL Generator should assure that it is used in the intended environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	[V1=3] V	Portable and mobile RF communications equipment should be used no closer to any part of the IVL Generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ where P is the 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3 CISPR11 Class A	9V/m 704-787MHz 5100MHz-5800MHz	[E1=9] V/m	
	27 V/m 385 MHz to 390 Mhz	[E1=27] V/m	
Radiated RF IEC 61000-4-3	28 V/m 430 MHz to 470 Mhz 800 MHz to 960 Mhz 1700 MHz to 1990 Mhz 2400 MHz to 2570 Mhz	[E1=28] V/m	
	3 V/m 80 MHz to 2.7 GHz	[E1=3] V/m	
NOTE 1 At 80 MHz and 800 MHz, 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.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and 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, an electromagnetic site survey should be considered. If the measured field strength in the location in which the IVL Generator is used exceeds the applicable RF compliance level above, the IVL Generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the IVL Generator. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in professional healthcare environments. If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Shockwave Generator or connector cable. Otherwise, degradation of the performance of this equipment could result.

Electromagnetic Compatibility Guidance – Separation Distances

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the IVL Generator or Connector Cable. Otherwise, degradation of the performance of this equipment could result.













No deviations from the standard were noted and no allowances were made during testing.


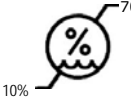




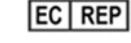




Essential Performance

IVL Generator maintains safe and effective performance in the delivery of IVL therapy when operated in the electromagnetic environment specified in the table above.

9. Appendix B: Symbols

The IVL Generator bears the following symbols:

Symbol	Description
	Refer to instruction manual Read and understand the Operator's Manual before use.
	Consult instructions for use
	Caution
	Non-sterile
	Type CF The IVL Generator is classified for use without equipment damage in the presence of cardiac defibrillators. The applied part meets electrical safety requirements for cardiac use.
	Catalogue number
	Serial number
	Protect from heat and radioactive sources
	Warning dangerous voltage
	Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.
	Patents. Refer to www.shockwavemedical.com/patents
	Intravascular Lithotripsy (IVL) Generator

Symbol	Description
	Temperature limit
	Humidity limitation
	Date of manufacture
	Manufacturer
	Keep dry
	Do not use if package is damaged
	Authorized Representative in the European Community
	Do not stack
	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.
	Conformité Européenne
	The process or combination of processes applied during the expected service life to restore used equipment to a condition of safety and performance comparable to when new.

10. Appendix C: Specifications

This appendix contains the specifications and performance characteristics for the Shockwave Medical IVL Generator. All specifications are typical at 20°C unless otherwise stated.

10.1 Appendix C1: General Specifications

Specifications	Performance Characteristics
Alarms	Built in tests and monitors are designed to detect and annunciate designated malfunctions of subsystems within the Generator. The Generator is designed to interrupt therapy delivery in the event a malfunction is detected. In addition, visual annunciators (CATH or SYS) will activate and three beeps will sound. See Sections 4.1 (Tones), 7.0 (Troubleshooting)
Classification, Product	Class II Medical Electrical (ME) Equipment
Classification, Applied Parts	Type CF
Connectors (Connector Cable)	OnAnOn 150PT series with proprietary keyway
Data Log	No data associated with patient cases is logged
Enclosure	Non-ventilated, polymeric enclosure, molded from flame retardant UL 94V-0 rated material
Environmental	Altitude: 0 - 2000 meters Humidity, operating: 10 - 70% non-condensing Temperature, operating: 10° to 35°C Temperature, storage / shipping: -20° to 65°C
Electrical Safety	ISO 60601-1 (2012) edition 3.1 standards
EMC Compatibility	See Appendix A
Mobility	Product is designed to be mounted to a stable mobile or stationary IV pole. An IV pole with five casters located in a circular pattern with a diameter of at least 23 inches (58 cm), such as the I.V. League Ventilator Stat-Stand™ model 1059 (or equivalent) is recommended.
Power	90-240VAC; 50-60Hz; Single Phase, 15A service Protectively earthed
Size	11" (28.0 cm) high x 6" (15.2 cm) wide x 11.5" (29.2 cm) deep
Shock	Shipping Shock per EXD-007C ASTM D 4169-09
Splash Resistance	10 mL saline from above (Generator) 100 mL saline from any angle (Connector Cable distal end)
Weight	6 pounds (2.7 kg)

10.2 Appendix C2: Performance Specifications

This appendix contains the specifications and performance characteristics for the Shockwave Medical IVL Generator.

Specifications	Performance Characteristics
Battery	Rechargeable Smart Lithium Ion Battery Pack (14.4V, 6.6Ah) Charge time less than twelve hours to full charge Fully charged battery capacity 12 patient cases (patient case: 900 therapy pulses delivered over one hour) 80% capacity after 300 full charge/discharge cycles Meets requirements for transport via commercial aircraft (UN Manual of Tests and Criteria part III subsection 38.3)
Diagnostics	Built in tests and monitors are designed to detect and annunciate designated malfunctions of subsystems within the IVL Generator. The IVL Generator is designed to interrupt therapy delivery in the event a malfunction is detected.
Emitter Drive Channels	Four channels, one to four channels may be used depending on catheter model connected.
Output	Proprietary pulse delivery system. Output voltage 1000 – 3000 volts peak to peak, pulse duration ~ 1µs, pulse frequency 1, 2 or 4 Hz depending on catheter model connected.
Output Voltage Accuracy	The open circuit voltage at the IVL Generator THERAPY CONNECTOR: 5% of pre-programmed set point.
Output Limits	IVL System is designed to override user input and limit the number of continuous pulses delivered based on the IVL Catheter model connected. Refer to IVL Catheter IFU.
Therapy Settings	Proprietary pulse delivery system. No user adjustable settings. Pulse delivery settings are pre-programmed, based on IVL Catheter model connected. Settings and IVL Catheter model detection employ redundant features.



Shockwave Medical, Inc.
5403 Betsy Ross Drive
Santa Clara, CA 95054, USA
www.shockwavemedical.com



MedPass SAS
95 bis Boulevard Pereire
75017 Paris
France



PN 64335 Rev A