Peripheral IVL Case Setup and Execution
Peripheral IVL System Set-up

1. Start
   - Press Power Button to turn Generator ON
   - The ON indicator will turn green
   - The Therapy Status light will turn yellow, indicating that the Generator is ready to activate when ready

2. Confirm
   - Confirm Battery capacity via battery symbol
     - If the battery symbol is empty, additional charging of the battery is recommended before use

3. Detach
   - Detach the Charger Cable from the Generator

4. Slide
   - Slide the Connector Door to the left

5. Attach
   - Insert the proximal end of the Connector Cable to the Generator

Note: If Power Button light turns yellow, please refer to the Generator Manual.
# Peripheral IVL Catheter Specs

## M5 Specifications

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Diameter (MM)</th>
<th>Length (MM)</th>
<th>Sheath Compatibility</th>
<th>Working Length</th>
<th>Pulses/Cycle</th>
<th>Cycles</th>
<th>Pulses (Max)</th>
<th>Crossing Profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>M5IVL3560</td>
<td>3.5</td>
<td>60</td>
<td>6F</td>
<td>110</td>
<td>30</td>
<td>10</td>
<td>300</td>
<td>.054</td>
</tr>
<tr>
<td>M5IVL4060</td>
<td>4.0</td>
<td>60</td>
<td>6F</td>
<td>110</td>
<td>30</td>
<td>10</td>
<td>300</td>
<td>.057</td>
</tr>
<tr>
<td>M5IVL4560</td>
<td>4.5</td>
<td>60</td>
<td>6F</td>
<td>110</td>
<td>30</td>
<td>10</td>
<td>300</td>
<td>.058</td>
</tr>
<tr>
<td>M5IVL5060</td>
<td>5.0</td>
<td>60</td>
<td>6F</td>
<td>110</td>
<td>30</td>
<td>10</td>
<td>300</td>
<td>.062</td>
</tr>
<tr>
<td>M5IVL5560</td>
<td>5.5</td>
<td>60</td>
<td>6F</td>
<td>110</td>
<td>30</td>
<td>10</td>
<td>300</td>
<td>.064</td>
</tr>
<tr>
<td>M5IVL6060</td>
<td>6.0</td>
<td>60</td>
<td>6F</td>
<td>110</td>
<td>30</td>
<td>10</td>
<td>300</td>
<td>.066</td>
</tr>
<tr>
<td>M5IVL6560</td>
<td>6.5</td>
<td>60</td>
<td>7F</td>
<td>110</td>
<td>30</td>
<td>10</td>
<td>300</td>
<td>.068</td>
</tr>
<tr>
<td>M5IVL7060</td>
<td>7.0</td>
<td>60</td>
<td>7F</td>
<td>110</td>
<td>30</td>
<td>10</td>
<td>300</td>
<td>.073</td>
</tr>
</tbody>
</table>

* Products are equivalent; either Catalog Number may be used when ordering and either product may be received.

## S4 Specifications

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Diameter (mm)</th>
<th>Length (mm)</th>
<th>Sheath Compatibility</th>
<th>Working Length</th>
<th>Pulses/Cycle</th>
<th>Cycles</th>
<th>Pulses (Max)</th>
<th>Crossing Profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>S4IVL2540</td>
<td>2.5</td>
<td>40</td>
<td>5F</td>
<td>135</td>
<td>20</td>
<td>8</td>
<td>160</td>
<td>.048</td>
</tr>
<tr>
<td>S4IVL3040</td>
<td>3.0</td>
<td>40</td>
<td>5F</td>
<td>135</td>
<td>20</td>
<td>8</td>
<td>160</td>
<td>.048</td>
</tr>
<tr>
<td>S4IVL3540</td>
<td>3.5</td>
<td>40</td>
<td>5F</td>
<td>135</td>
<td>20</td>
<td>8</td>
<td>160</td>
<td>.048</td>
</tr>
<tr>
<td>S4IVL4040</td>
<td>4.0</td>
<td>40</td>
<td>5F</td>
<td>135</td>
<td>20</td>
<td>8</td>
<td>160</td>
<td>.050</td>
</tr>
</tbody>
</table>
Peripheral IVL – Device Prep

1. Remove
   - Remove Catheter from sterile packaging
   - Remove Catheter from tray and loop
   - Remove protective sheath from tip

2. Prepare
   - Prepare Balloon using standard technique
   - Ensure vacuum is pulled at least twice
   - Utilize 1:1 saline/contrast mixture during preparation and use

3. Connect
   - Feed Connector Cable through sterile sleeve
   - Connect proximal end of Catheter to distal end of Connector Cable
   (Note: image not shown)

Refer to the Catheter IFU for full details and Warnings and Precautions.
Peripheral IVL – Device Positioning

Advance and Position:
Advance the Catheter over .014” Guidewire to the treatment site and position the Catheter using standard technique

1Refer to the Catheter IFU for full details and Warnings and Precautions.
Peripheral IVL – Device Use

1. Inflate
   • Inflate to 4 atm

2. Activate
   • Press “Activate” button to arm the Generator – Light will turn from orange to green to indicate “active state” to deliver treatment
   • To deactivate the Generator at any time, simply press this button again
     Note: If the Therapy Button light turns yellow, please refer to the Generator Manual

3. Deliver
   • Press and hold Button on Connector Cable for 10 seconds to deliver energy
   • Audible clicks and flashing LED will confirm therapy is being delivered
   • Do not exceed 80 pulses in a single segment
     Note: Monitor catheter pressure and modulate to maintain at 4 atm as needed
Peripheral IVL – Device Use

4. Expand
   - Expand to reference vessel diameter and maintain per standard practice

5. Deflate
   - Following treatment, deflate Balloon to re-establish blood flow
   - Repeat steps 1 - 4 to complete a single treatment (2 cycles)
   - Repeat treatment until desired luminal gain is achieved

Note: When repositioning the Catheter to treat another segment of the same lesion overlap by at least 1 cm
Peripheral IVL Energy Optimization

**Oversize Device 10% vs. RVD to Facilitate Energy Transfer**

- Optimal
- Undersized

Wall apposition facilitates efficient energy transfer. Optimized balloon sizing leads to improved patency.

**Overlap Segments 1cm to Avoid Therapeutic Miss**

- Full Therapeutic Coverage
- Therapeutic Miss

The sonic pressure waves create a spherical field effect that drops as the longitudinal distance from the emitters increases.

**Purge Air After Each Cycle to Facilitate Effective Energy Delivery**

1. Purge balloon 2-3 times with a 10 or 20mL syringe prior to use
2. Deflate balloon between each cycle

Vapor bubbles are a barrier to efficient energy delivery. Sonic pressure waves produce air within the catheter and deflating the balloon will clear out the bubbles.

**Do Not Pulse Over 4atm to Avoid Balloon Damage**

Energy Delivery is Not Improved by Over-Inflation

Energy delivery is not improved by increased inflation pressure. To avoid damage to the balloon, do not deliver energy at pressures greater than 4atm.

*Refer to the Generator Manual for full details and Warnings and Precautions.

*Refer to the Catheter IFU for full details and Warnings and Precautions.
# Catheter and System Errors

<table>
<thead>
<tr>
<th>Error Code</th>
<th>Description</th>
<th>What it means</th>
<th>Recommended Actions</th>
</tr>
</thead>
</table>
| **ERROR 80** | Catheter beginning of life unsuccessful | The generator was unable to mark the catheter for beginning of life. *Possible causes are:*  
• Loose connection between the generator and catheter.  
• Defective Connector cable  
• Defective Catheter | 1. Turn the generator power OFF  
• Disconnect catheter and connector cable  
• Ensure that the sterile sleeve is not interfering with the connection  
2. Reconnect and ensure that both connections are secure  
3. Turn the generator power ON  
4. Purge and re-prep the balloon  
5. If error condition persists, run generator self-check  
6. If error condition persists, replace the catheter  
7. If error condition persists, replace the connector cable  
**NOTE:** The same catheter will not work with a replacement generator |
| **ERROR 81** | Catheter identification unsuccessful | Generator was unable to identify the catheter type. *Possible causes are:*  
• Loose connection between the generator and catheter.  
• Defective Connector cable  
• Defective Catheter | |
| **ERROR 88** | Pulse delivery timeout | The generator was unable to measure pulse energy delivery to the catheter within allowed time limit. *Possible causes are:*  
• Gas bubbles in the balloon  
• Loose connection between the generator and catheter.  
• Defective generator or connector cable  
• Defective Catheter | |
| **ERROR 90 AND 93** | Internal Generator Error | The generator has detected an error. *Possible causes are:*  
• Voltage out of range | 1. Recommended actions 1-4 above  
2. If the error condition persists, contact Shockwave Medical representative or Customer Service |
| **ERROR 71** | Failed Self Test | Error that presents as:  
• Immediately after generator starts (after startup self-test)  
• After unrecoverable Error 88 and a manual self-test | 1. Contact Shockwave Medical representative or Customer Service |
### Generator Self-Test

**What is the IVL Generator Self-Test?**

- The generator automatically performs a series of self-tests every time it is powered on.
- Additionally, the self-test performs a high-voltage check to ensure that the generator output is within the expected range.
- You may choose to run a self-test at any time if the generator seems to be behaving unexpectedly.
- There is no specific recommendation as to when to perform the self-test.

<table>
<thead>
<tr>
<th>SELF TEST</th>
<th>OUTPUT</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Plug the charger into the generator and an AC outlet&lt;br&gt;• Ensure that the battery symbol indicates charging (lightning bolt)&lt;br&gt;• Turn the generator power ON&lt;br&gt;• Once the generator finishes the power on sequence, press and hold the THERAPY button until the THERAPY button lights green&lt;br&gt;• The self-test will complete in approximately 20 seconds</td>
<td>• PASS is indicated by four audible beeps and GREEN POWER button&lt;br&gt;• FAIL is indicated by three audible beeps and RED POWER button</td>
</tr>
</tbody>
</table>
Generator Examples

- Normal Power On
- Normal Ready/Standby
- Normal Ready
- Catheter Error
- System Error
- Passed Self Test
Safety Information

- Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
- Indication for Use – The Shockwave Medical Intravascular Lithotripsy System is intended for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. Not for use in the coronary or cerebral vasculature.
- Contraindications – Do not use if unable to pass 0.014 guidewire across the lesion • Not intended for treatment of in-stent restenosis or in coronary, carotid, or cerebrovascular arteries.
- Warnings – Only to be used by physicians who are familiar with interventional vascular procedures • Physicians must be trained prior to use of the device • Use the Generator in accordance with recommended settings as stated in the Operator’s Manual
- Precautions – Use only the recommended balloon inflation medium • Appropriate anticoagulant therapy should be administered by the physician • Decision regarding use of distal protection should be made based on physician assessment of treatment lesion morphology
- Adverse Effects – Possible adverse effects consistent with standard angioplasty include: • Access site complications • Allergy to contrast or blood thinners • Arterial bypass surgery • Bleeding complications • Death • Fracture of guidewire or device • Hypertension/Hypotension • Infection/sepsis • Placement of a stent • Renal failure • Shock/pulmonary edema • Target vessel stenosis or occlusion • Vascular complications. Risks unique to the device and its use: • Allergy to catheter material(s) • Device malfunction or failure • Excess heat at target site
- Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions, and adverse events. [www.shockwavemedical.com](http://www.shockwavemedical.com)