*Best Practice in Intravascular Lithotripsy*

# Supplemental DATA

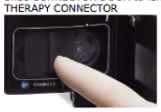
| Step | Picture or additional info if applicable |
|---|---|
| **Step 1 – Turn the Generator On**<br>Momentarily depress the POWER ON/OFF button. All indicators on the IVL Generator will come on briefly as a test. The THERAPY STATUS indicator will come on yellow and green during this test. The POWER STATUS indictor will continue to be on green. |  |
| **Step 2 – Confirm Battery Capacity**<br>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.<br><br>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. |  |
| **Step 3 – Check Diagnostics**<br>Confirm that the display is as pictured with no error messages displayed. If an error message is displayed, refer to Troubleshooting, Section 7.0.<br><br>Normal display with no errors shown to the right. |  |
| **If a yellow light is displayed, refer to Troubleshooting, Section 7.0.**<br><br>**If any error messages come on during use, refer to Troubleshooting, Section 7.0.**<br><br>Error Condition – Catheter error shown to the right. |  |
| **Step 4 – Connect IVL Connector Cable**<br>Disconnect the Charger Module from the CHARGER CONNECTOR if it is connected.<br><br>Slide the CONNECTOR DOOR fully to the left, revealing the THERAPY CONNECTOR as shown.<br><br>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. | Slide CONNECTOR DOOR to left to reveal the THERAPY CONNECTOR<br>  <br>THERAPY CONNECTOR:<br>  |
| **Step 5 – Prepare IVL Catheter for Use**<br>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. | N/A |
| **Step 6 – Connect IVL Catheter**<br>Take care not to contaminate either connector end with fluids or other foreign matter during this procedure prior to mating.<br>Connect the IVL Catheter to the CATHETER CONNECTOR end of the IVL Connector Cable using the same method outlined in step 4.<br><br>**NOTE:** Ensure that the sterile sleeve also covers the CATHETER CONNECTOR.<br>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.<br><br>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. |  |
| **Step 7 – Position the IVL Catheter**<br>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. | (Refer to the IVL Catheter IFU) |
| **Step 8 – Activate the IVL Generator**<br>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. |  |
| **Step 9 – Deliver Therapy**<br>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.<br><br>**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. |  |
| **Step 10 – Pause Period / Resume Therapy**<br>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. |  |
| **Step 11 – IVL Catheter End of Life**<br>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. |  |
| **Step 12 – IVL Catheter Replacement**<br>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.<br><br>**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. |  |

Figure 1: Steps by steps IVL Use and therapy delivering

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