

Understanding the Safety Switch Feature

BACKGROUND INFORMATION

This article provides an understanding of the **Safety Switch** (Automatic Lead Configuration) feature as well as suggestions for evaluating lead integrity following the occurrence of a Safety Switch.

Safety Switch feature

All Boston Scientific pacemakers allow clinicians to manually program lead configuration (bipolar or unipolar) for each chamber connected to a bipolar lead. In addition, certain pacemakers also incorporate a **Safety Switch** feature, which automatically switches the pacing and sensing lead configuration from bipolar to unipolar if the automatic daily measured bipolar impedance is unacceptably low ($<100 \Omega$) or high ($>2500 \Omega$). This feature allows the device to preserve pacing and sensing through a unipolar configuration following an out-of-range bipolar impedance measurement.

Loose setscrews, lead fractures, or lead abrasions may cause lead impedance values to fall outside of the normal range. If the **Safety Switch** feature has been activated (programmed ON) for one or more leads, PULSAR[®] MAX and PULSAR MAX II devices will automatically switch to unipolar pacing and sensing when two of the last eight daily impedance measurements are out-of-range. INSIGNIA[®] and ALTRUA[™] devices automatically switch to unipolar after only one out-of-range daily impedance measurement.

If the **Safety Switch** feature is activated in the atrium and/or ventricle, out-of-range daily impedance measurements will cause the following to occur:

- Pacing and sensing lead configurations automatically change to unipolar for the affected chamber (only).
- The Minute Ventilation (MV) rate response feature is disabled (if the MV signal was being measured from the lead on which the Safety Switch occurred).

Evaluating Lead Integrity

If a Safety Switch has occurred, an "Automatic Lead Configuration Switch Notification" window appears upon device interrogation. Additionally, a "Lead Configuration Switched" message appears in the Clinical Events window on the System Summary screen. Any time these messages are received, the lead system should be thoroughly evaluated to understand the root cause of the out-of-range lead impedance measurement. Table 1 provides suggestions to review the **Safety Switch** notification and evaluate lead integrity.

CRM PRODUCTS REFERENCED*
PULSAR[®] MAX (models 1270/
1171/1170), PULSAR MAX II
(models 1280/1181/1180), and all
INSIGNIA[®] and ALTRUA[™]
pacemakers

*Products referenced herein may not be approved in all geographies. For comprehensive information on device operation, reference the appropriate product labeling.

CRM CONTACT INFORMATION

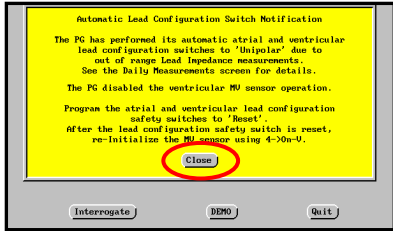
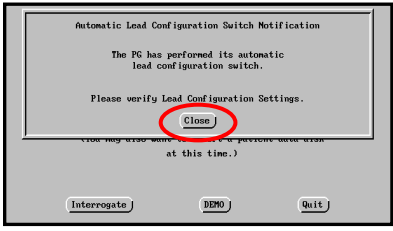
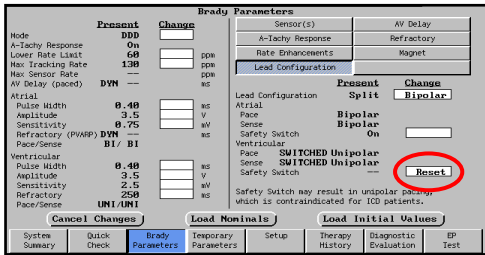
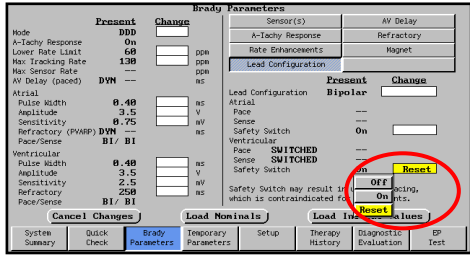
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Table 1. Reviewing the Safety Switch Notification and Evaluating Lead Integrity

<p>Step 1. Review and close the "Automatic Lead Configuration Switch Notification" window.</p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p>INSIGNIA / ALTRUA Safety Switch notification</p> </div> <div style="text-align: center;">  <p>PULSAR MAX / PULSAR MAX II Safety Switch notification</p> </div> </div>																																																																																													
<p>Step 2. Review Daily Impedance Measurements for unacceptable bipolar lead impedances (<100 Ω or >2500 Ω) to assist with troubleshooting lead system integrity (i.e. loose setscrews, lead fractures, or lead abrasions). A significant change in the daily impedance values may or may not be noted as measurements older than the previous week are displayed as a weekly average.</p>																																																																																													
<p>Step 3. Evaluate lead integrity in a <u>Unipolar</u> configuration.</p> <ol style="list-style-type: none"> Perform manual lead impedance measurements and view results via Diagnostic Evaluation. <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> <table border="1" data-bbox="244 745 707 875"> <thead> <tr> <th rowspan="2"></th> <th colspan="2">Atrial</th> <th colspan="2">Ventricular</th> <th rowspan="2"></th> </tr> <tr> <th>Previous</th> <th>Present</th> <th>Previous</th> <th>Present</th> </tr> </thead> <tbody> <tr> <td>Impedance</td> <td>500</td> <td>500</td> <td>500</td> <td>500</td> <td>Ω</td> </tr> <tr> <td>Amplitude</td> <td>3.5</td> <td>3.5</td> <td>3.5</td> <td>3.5</td> <td>V</td> </tr> <tr> <td>Pulse Width</td> <td>0.40</td> <td>0.40</td> <td>0.40</td> <td>0.40</td> <td>ms</td> </tr> <tr> <td>Current</td> <td>6</td> <td>6</td> <td>6</td> <td>6</td> <td>mA</td> </tr> <tr> <td>Lead Configuration (paced)</td> <td>Bipolar</td> <td>Bipolar</td> <td>Bipolar</td> <td>Unipolar</td> <td></td> </tr> <tr> <td>Energy</td> <td>8.9</td> <td>8.9</td> <td>8.3</td> <td>8.3</td> <td>μJ</td> </tr> </tbody> </table> <p>INSIGNIA / ALTRUA</p> <p>The Lead Impedance Test displays "Unipolar" for Present Lead Configuration as the test results are Unipolar since the polarity remains switched.</p> </div> <div style="text-align: center;"> <table border="1" data-bbox="884 745 1378 875"> <thead> <tr> <th rowspan="2"></th> <th colspan="2">Atrial</th> <th colspan="2">Ventricular</th> <th rowspan="2"></th> </tr> <tr> <th>Previous</th> <th>Present</th> <th>Previous</th> <th>Present</th> </tr> </thead> <tbody> <tr> <td>Impedance</td> <td>500</td> <td>500</td> <td>500</td> <td>500</td> <td>Ω</td> </tr> <tr> <td>Amplitude</td> <td>3.5</td> <td>3.5</td> <td>3.5</td> <td>3.5</td> <td>V</td> </tr> <tr> <td>Pulse Width</td> <td>0.40</td> <td>0.40</td> <td>0.40</td> <td>0.40</td> <td>ms</td> </tr> <tr> <td>Current</td> <td>7</td> <td>7</td> <td>7</td> <td>7</td> <td>mA</td> </tr> <tr> <td>Lead Configuration (paced)</td> <td>BIPOLAR</td> <td>BIPOLAR</td> <td>BIPOLAR</td> <td>BIPOLAR</td> <td></td> </tr> <tr> <td>Energy</td> <td>9.8</td> <td>9.8</td> <td>9.8</td> <td>9.8</td> <td>μJ</td> </tr> </tbody> </table> <p>PULSAR MAX / PULSAR MAX II</p> <p>Unlike INSIGNIA, Lead Impedance Test wording for PULSAR MAX/PULSAR MAX II does not change from "BIPOLAR" to "UNIPOLAR" for Present Lead Configuration following a Safety Switch, although the actual configuration is unipolar.</p> </div> </div>			Atrial		Ventricular			Previous	Present	Previous	Present	Impedance	500	500	500	500	Ω	Amplitude	3.5	3.5	3.5	3.5	V	Pulse Width	0.40	0.40	0.40	0.40	ms	Current	6	6	6	6	mA	Lead Configuration (paced)	Bipolar	Bipolar	Bipolar	Unipolar		Energy	8.9	8.9	8.3	8.3	μJ		Atrial		Ventricular			Previous	Present	Previous	Present	Impedance	500	500	500	500	Ω	Amplitude	3.5	3.5	3.5	3.5	V	Pulse Width	0.40	0.40	0.40	0.40	ms	Current	7	7	7	7	mA	Lead Configuration (paced)	BIPOLAR	BIPOLAR	BIPOLAR	BIPOLAR		Energy	9.8	9.8	9.8	9.8	μJ
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<p>Step 4. Evaluate lead integrity in a <u>Bipolar</u> configuration.</p> <ol style="list-style-type: none"> Reset the Safety Switch parameter of the affected chamber by selecting Reset on the Brady Parameters screen and pressing the PROGRAM key on the programmer. Note: Consider the safety of pacemaker-dependent patients as the lead configuration will now return to bipolar. <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p>INSIGNIA / ALTRUA</p> </div> <div style="text-align: center;">  <p>PULSAR MAX / PULSAR MAX II</p> </div> </div> <ol style="list-style-type: none"> Perform manual bipolar lead impedance measurements and view results via Diagnostic Evaluation. If measurements are normal, consider pocket manipulation and/or isometrics to evaluate the possibility of an intermittent issue. Evaluate pacing thresholds and perform lead troubleshooting. 																																																																																													
<p>Step 5. Program the lead configuration to the polarity that yields acceptable values.</p>																																																																																													
<p>Step 6. If the Minute Ventilation (MV) rate response sensor was active when the Safety Switch occurred, re-initialize MV:</p> <ol style="list-style-type: none"> Select Brady Parameters → Sensor(s) Select MV. For PULSAR MAX/ PULSAR MAX II devices, if the root cause of the out-of-range bipolar impedance measurement has been resolved select 4→ON to re-initialize from the ventricular channel. For INSIGNIA devices, select either 4→ON—A or 4→ON—V, choosing either the atrial or ventricular chamber, whichever channel has shown acceptable bipolar lead impedance measurements. 																																																																																													