

IMPORTANT DIAGNOSTIC INFORMATION



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25 October 2011

Subject: Additional shock lead impedance measurement information is available

Dear Doctor,

Boston Scientific created a Product Update titled "Shock Lead Impedance Testing" (copy attached), which provides detail regarding our shock lead impedance measurement technique and interpretation of test results. Importantly, this Product Update specifies that

- "Check Shock Lead" messages from the programmer and Red Alerts from the LATITUDE[®] remote monitoring system are not necessarily indicative of a lead system problem. Instead, they are a prompt that the lead impedance value has moved outside of the typical operating range, and further investigation is prudent.
- Standard lead troubleshooting tests can be used to assess lead system integrity.
- If assistance is needed in troubleshooting out-of-range shock lead impedance measurements, Boston Scientific Technical Services can be contacted for help.

Current Boston Scientific defibrillator systems measure shock lead impedances up to 200 ohms, and export results to the programmer and LATITUDE monitoring system via the Daily Measurements feature. A measured shock lead impedance that is greater than 125 ohms or less than 20 ohms will generate an alert message on programmer screens and a "Red Alert" within LATITUDE (if activated). However, **the measured value that prompted the alert is not displayed**. Similarly, out-of-range impedance measurements are not plotted on programmer or LATITUDE trending graphs. Boston Scientific has received reports that, in some instances, this has made it more difficult for physicians to troubleshoot the system and determine whether the out-of-range impedance value truly reflected an underlying lead/system issue.

In order to help resolve this, we want to make you aware that **health care professionals may now call Boston Scientific Technical Services to obtain the measured lead impedance value (up to 200 ohms) in the event of an alert**. We hope that having access to the specific measured value will aid the troubleshooting process.

Further Information

Please contact Boston Scientific Technical Services for instructions on how to obtain more detailed shock lead impedance information when needed. If you have any questions regarding this communication, contact your local Boston Scientific representative or Boston Scientific Technical Services.

Sincerely,

A handwritten signature in black ink, appearing to read "S de Baca", enclosed in a simple oval shape.

Steven C de Baca
Vice President, Quality Assurance
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Boston Scientific Corporation

Attachment: "Shock Lead Impedance Testing" Product Update

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