Product Update

Boston Scientific

Shock Lead Impedance Testing

Product Update articles provide clinical and technical information focused on the function and performance of Boston Scientific Cardiac Rhythm Management products.

Summary
Lead impedance measurements are a useful tool for evaluating the integrity of an implantable defibrillator's shock lead system. Recent trends in lead model selection (more single coil leads), introduction of lead vector programmability (single coil shocking vectors can be programmed for dual coil leads), and circuit technology advancements within newer defibrillator generations have introduced differences in both test methodology and interpretation of lead impedance test results. The discussion below explains changes in lead configuration preferences and new test methodology in COGNIS®, TELIGEN®, INCEPTA™, PUNCTUA™, and ENERGEN™ defibrillator families, and clarifies how to interpret test result differences from prior defibrillator-lead combinations.

Products Referenced*

COGNIS®, TELIGEN®, INCEPTA™, PUNCTUA™, and ENERGEN ™ CRT-Ds and ICDs, and LATITUDE® remote patient monitoring system

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

Shock Lead Impedance Measurement Tools

Evaluating shock lead impedance, in combination with other non-invasive diagnostic techniques, can help assess and troubleshoot potential lead integrity and lead/pulse generator connection issues. All Boston Scientific defibrillators provide two shock lead impedance measurement tools:

<u>High-energy shocks:</u> Shock lead impedance is measured and displayed for every therapeutic or commanded shock. This high-energy diagnostic tool is designed to provide immediate feedback regarding lead system integrity by detecting out-of-range shock lead impedance values and initiating appropriate programmer screens and device tones. Note that this article will focus on low-energy rather than high-energy impedance tests.

<u>Low-energy test:</u> Shock lead impedance is also measured every 21 hours using a painless, sub-threshold measurement, also referred to as a Shock Lead Integrity Test. During this test, the pulse generator delivers a low-energy pulse through the shocking electrodes, and measures the resulting impedance. Due to the significantly lower energy test signal, this measurement technique may yield test results that are different than measurements conducted during shock delivery.

"Check Shock Lead" Messages and LATITUDE Red Alerts

Boston Scientific defibrillators and the LATITUDE remote patient monitoring system can provide a notification for shock lead impedance measurements that exceed a specified minimum or maximum:

- When measured shock lead impedance is less than 20 ohms or greater than 125 ohms[§], the implanted defibrillator generates a "Check Shock Lead" message (via the programmer). Out-of-range values are displayed as either ">125 ohms" or "<20 ohms"; the actual measured value is not displayed when limits are exceeded. Similarly, out-of-range impedance measurements are not plotted in trending graphs available on the programmer, but rather appear as data gaps that can be identified using the slider.
- The LATITUDE remote patient monitoring system will generate a Red Alert if/when it detects a Check Shock Lead message within an implanted defibrillator. Following review, Red Alerts can be dismissed from the LATITUDE website display. However, notification for a new occurrence of an out-of-range shock lead impedance will not be sent until the implanted defibrillator is interrogated with a programmer at an in-clinic follow-up and the previous message has been reviewed.

<u>It is important to note that Check Shock Lead messages and LATITUDE Red Alerts are not necessarily indicative of a lead system problem, but rather are a prompt that the lead impedance value has moved outside of the typical operating range.</u> Standard lead troubleshooting tests can be used to assess lead system integrity. This may include

[§]Programmable in some older devices, with nominal value of 80 ohms additional low-energy impedance tests with and without isometrics, programming and reviewing other shock lead configurations, reviewing historical impedance measurements and other diagnostic data stored within device memory, X-ray or fluoroscopic review of lead and lead connections, maximum energy shocks, and (if necessary) invasive visual inspection. ***Contact Boston Scientific Technical Services for further help (if needed) in troubleshooting out-of-range shock lead impedance measurements.***

Factors that Influence Shock Lead Impedance Measurements

While many technical and physiologic variables can impact shock lead impedance measurements, there are three factors that have had a larger influence on shock lead impedance measurements in recent years – use of single coil leads, lead configuration programmability (which allows single-coil configurations), and lead impedance measurement test methodology.

Single Coil Leads

Boston Scientific device tracking records (United States) indicate that a greater number of single-coil leads are being implanted today than previously – perhaps as high as 15% or more in 2010/2011 (up from 2-3% in 2002). Higher use of single-coil leads may cause more instances of out-of-range impedance measurements (Check Shock Lead messages and LATITUDE Red Alerts), specifically for patients with higher baseline shock lead impedance measurements, as explained below.

The smaller total electrode surface area of a single-coil lead system causes average lead impedance to be higher than dual-coil lead configurations. LATITUDE data[†] indicates that the average lead impedance is 10-25 ohms higher for a single coil system than a TRIAD configuration (RV coil to RA coil and can). The typical patient with a single coil lead will see an average of 55 to 75 ohms, with day-to-day variations as high as 70 to 90 ohms. However, the 5% of patients with the highest average single-coil impedance (75-100 ohms) will see day-to-day variations as high as 90 to 130 ohms, which may be above the device's reporting limit of 125 ohms (see Figure A1 in Appendix). A summary of LATITUDE single-coil shock lead impedance data[†] is provided in Tables 1 and 2.

Lead Configuration Programmability

Boston Scientific COGNIS, TELIGEN, INCEPTA, PUNCTUA, ENERGEN defibrillator families have a ***programmable*** shock lead vector, providing flexibility for troubleshooting suspected lead problems and options to manage defibrillation threshold challenges. If the shock lead vector configuration for a dual-coil lead is programmed to a single-coil configuration (RV Coil to Can), the measurement will also yield results that are 10-25 ohms higher than a TRIAD configuration.

For newer devices with a dual-coil lead programmed to a TRIAD configuration (RV coil to RA coil and can), the low-energy shock lead impedance test measures each of the vectors in a TRIAD configuration <u>separately</u>. Impedance measurements from individual vectors are then mathematically combined into a single TRIAD value that is reported on the programmer screen. Inclusion of a higher impedance coil-to-can vector within a TRIAD configuration may increase the total impedance of TRIAD configurations.

Low-energy Shock Lead Impedance Test Methodology

To conduct a low-energy shock lead impedance test in older generation devices, a test pulse (15 mA for 60 μsec) is delivered to the attached lead system. The response is measured and impedance is calculated and reported.

To avoid the possibility of an impedance measurement test pulse capturing the heart, the low-energy shock lead impedance test in Boston Scientific's newest defibrillators (COGNIS, TELIGEN, INCEPTA, PUNCTUA, ENERGEN) uses a significantly smaller test pulse (80 μA for 156 μsec). The smaller test pulse yields impedance values that are typically 10 ohms higher for dual-coil leads, and 20 ohms higher for single-coil leads[†] (see Tables 1 and 2, and Figure A3 in Appendix).

Low-energy impedance measurements are taken automatically every 21 hours and thus at different times of the day. Posture, sleep/wake cycle, hydration and medication status can add variability to impedance measurements. In addition, the smaller test signal reduces the signal-to-noise ratio, which can introduce greater fluctuations in daily or commanded lead impedance test results if the device/patient encounters electro-magnetic interference (EMI) during an impedance measurement. LATITUDE data[†] indicates that impedance test results show slightly more variation in newer generation devices than older generation defibrillators for ***both*** single-coil and dual-coil leads.

Interpreting Factors that Influence Shock Lead Impedance Measurements

As stated above, single coil lead systems, whether configured via programming or via lead model selection, may exhibit shock lead impedances 10-25 ohms higher than TRIAD systems. In addition, the smaller test signal used in current Boston Scientific defibrillators can yield shock lead impedance test results that are 10-20 ohms greater than older device families. The combination of a single coil lead connected to the newest generation device can result in an impedance that is 20 to 45 ohms higher than a dual-coil system connected to an older defibrillator, and therefore may be closer to the 125 ohm limit that would generate a Check Shock Lead message in the device and LATITUDE Red Alert.

Tables 1 and 2 provide a summary of LATITUDE shock lead impedance data for single-coil and TRIAD lead configurations as measured by older and newer generation implanted defibrillators. Figures A1, A2, and A3 in the Appendix provide clinical examples of shock lead impedance measured daily and displayed in LATITUDE.

Table 1. Shock Lead Impedance† for a majority of lead systems

Defibrillator generation	Single coil lead impedance (ohms) average / highest	TRIAD lead impedance (ohms) average / highest
Prior to COGNIS/TELIGEN	55 / 70	43 / 50
COGNIS, TELIGEN, INCEPTA, PUNCTUA, and ENERGEN	74 / 90	51 / 60

Table 2. Shock Lead Impedance† for the 5% of lead systems with the highest average impedance

Defibrillator generation	Single coil lead impedance (ohms) average / highest	TRIAD lead impedance (ohms) average / highest
Prior to COGNIS/TELIGEN	70-80 / 85-95	50-55 / 60-70
COGNIS, TELIGEN, INCEPTA, PUNCTUA, and ENERGEN	90-100 / 110-130	60-65 / 70-80

Conclusion

Since an out-of-range test result may indicate lead malfunction or a non-secure connection between the lead and pulse generator, further investigation is prudent for all Check Shock Lead messages and LATITUDE Red Alerts, which indicate that shock lead impedance measurement results are outside of established limits. However, understand that some Check Shock Lead messages and Red Alerts may not be indicative of an actual lead problem but rather related to the lead type or programmed configuration (single coil) and/or a new/different impedance measurement technique. ***Contact Boston Scientific Technical Services for further help (if needed) in troubleshooting out-of-range shock lead impedance measurements.***

†Data from Boston Scientific LATITUDE remote monitoring system, 2010

Appendix A: Sample LATITUDE Daily Measurement graphs

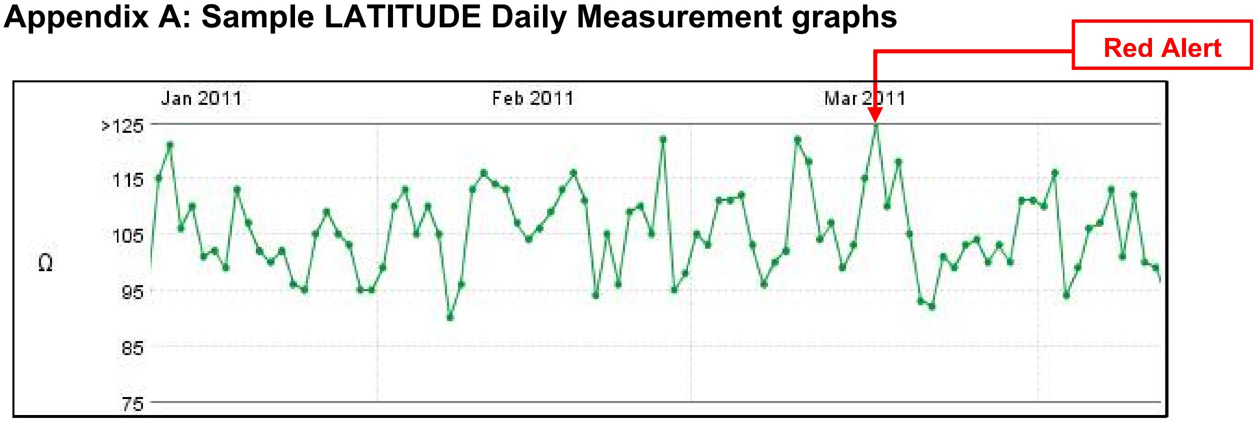

Figure A1. Normal single coil lead with high average impedance, occasionally exceeding 125 ohms.

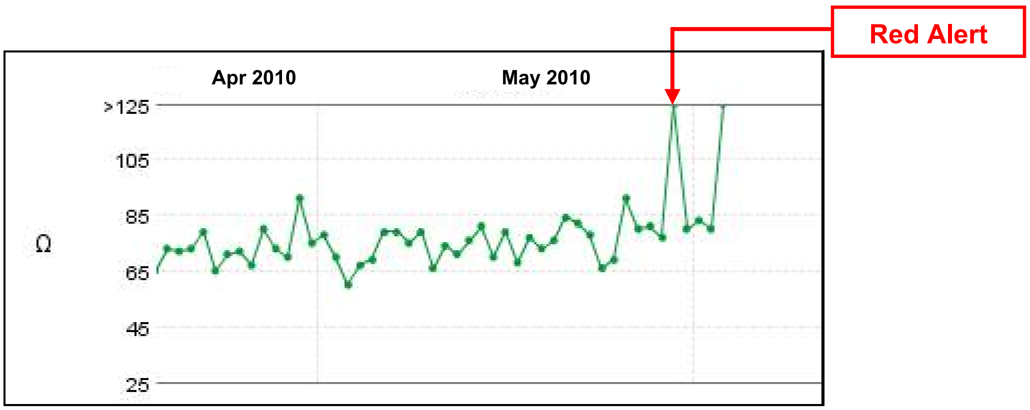

Figure A2. Single coil lead displaying 65 to 85 ohms, then exceeding 125 ohms due to a lead fracture or lead connection issue.

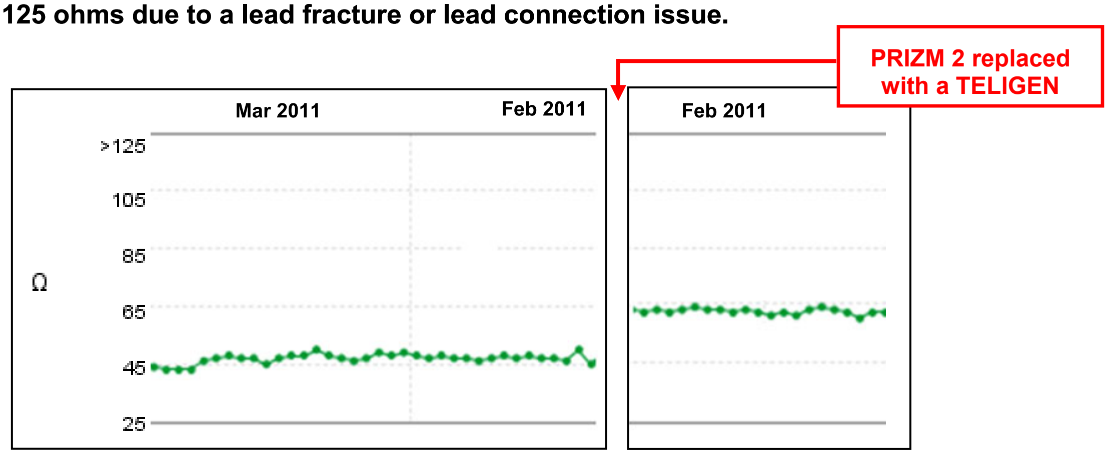

Figure A3. Average lead impedance increased by ~20 ohms when older defibrillator was replaced with a TELIGEN ICD.

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