Important
Medical Device Information

Cardiac Rhythm Management
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Dear Doctor,

Summary

This letter is an update to our August 2013 physician communication, which discussed a subset of COGNIS™ CRT-Ds and TELIGEN™ ICDs that had experienced an increased rate of premature battery depletion due to compromised performance of a low voltage (LV) capacitor. With one additional year of clinical experience and analysis, we have identified a second subset of devices that may exhibit compromised LV capacitor performance at a rate that is similar to the August 2013 advisory subset.

While Safety Architecture diagnostic tools have successfully detected this behavior, Boston Scientific has recently introduced updated software that will further improve Safety Architecture effectiveness. For this reason, we recommend that patients with a device in the advisory population be scheduled for an in-clinic visit at first opportunity, but within three months, to upgrade their device with this new software. After a device has been upgraded, continue normal device monitoring as directed within labeling, and promptly investigate all alerts and device beeping. We recommend that advisory patients utilize the LATITUDE™ Patient Management System (remote monitoring), which can convey Safety Architecture alerts between office visits and may accelerate the detection of diminished LV capacitor performance.

Description and Clinical Implications

The performance of an LV capacitor may be compromised in some devices after two or more years of implant time, which will increase battery use and may eventually initiate one or more Safety Architecture alerts and patient-audible beeping. The alerts and beeping were designed to inform physicians and patients before therapy is impacted. The most common alert is a yellow programmer screen that states, “Voltage is too low for projected remaining capacity. Contact Technical Services with Code 1003”. LATITUDE issues a corresponding yellow alert (nominally configured “On”). In other instances, diminished LV capacitor performance can result in an early “Explant” battery status indicator (ERI) and a replacement window that may be less than 3 months. No patient deaths have been associated with this compromised LV capacitor pattern. Advisory devices have not been available for implant for more than three years.

Devices that experience a low voltage alert require replacement. If not replaced, increased current drain could deplete the battery and impact therapy delivery and telemetry. If a Safety Architecture alert is observed, Boston Scientific Technical Services can analyze device information downloaded from a recent in-clinic or LATITUDE interrogation, which will clarify approximately how much time is available to replace the device.

COGNIS/TELIGEN Performance

A total of approximately 267,000 COGNIS and TELIGEN defibrillators have been distributed and implanted since May of 2008. Overall Cumulative Survival, including normal battery depletion, is approximately 95% at 72 months (see Appendix A).

Advisory population

Approximately 22,800 devices identified in the August 2013 communication remain in service. We have identified an additional 27,300 active devices that may exhibit diminished LV capacitor performance at a rate that is similar to the August 2013 advisory population. The projected cumulative rate of occurrence for LV capacitor malfunction within the total advisory population is approximately 2.9% at 60 months. Due to Safety Architecture alerts and timely physician response, the potential for life-threatening harm from loss of therapy is estimated to be less than 1 in 125,000 (0.0008%) at 60 months.

A list of advisory devices (model and serial number) implanted at or followed by your clinic/center is included with this letter. In addition, an on-line search tool is available at ***www.bostonscientific.com/ppr*** to determine if a specific model/serial number combination is within the advisory subset.

Patient Monitoring Recommendations

Updated Software

Boston Scientific has recently introduced updated programmer software (Model 2868, version 3.04) that enhances the effectiveness of the Safety Architecture tools later in device life. We recommend that patients with a device in the advisory population be scheduled for an in-clinic follow-up at first opportunity, but within 3 months, using a programmer with the new software. In-clinic interrogation with an updated programmer will automatically download Safety Architecture software upgrades from the programmer into individual patient devices, enhancing detection of a compromised LV capacitor before therapy delivery is impacted. See Appendix B for additional information on how to identify the current version of programmer software.

LATITUDE™ Patient Management System

Boston Scientific recommends that advisory patients utilize the LATITUDE Patient Management System (remote monitoring), which offers additional/supplemental device checks between office visits. Use of LATITUDE may accelerate detection of Safety Architecture alerts, and can notify if/when scheduled check-ups have not occurred. Verify that the yellow alert "Voltage was too low for projected remaining capacity" is configured "On".

Additional Recommendations

- After a device has been upgraded with new software, Boston Scientific recommends normal device monitoring as described in device labeling.
- Remind patients to contact the clinic if beeping is heard from their device, as instructed in the patient manual. Note that "Beep When Explant is Indicated" is nominally programmed "On" when shipped from the factory.
- Device replacement is not recommended for advisory devices displaying normal behavior.
- Promptly investigate alerts, device beeping, and unanticipated replacement indicator messages.
- Following a Safety Architecture alert, contact Boston Scientific Technical Services as directed on programmer screens. Technical Services can facilitate an evaluation of device information downloaded from a recent in-clinic or remote LATITUDE interrogation, which may help to clarify available replacement time. Note that "Approximate time to Explant" and "Time Remaining" estimates displayed on the programmer are not accurate following a low voltage alert.

Boston Scientific has reviewed these recommendations with an independent panel of physicians and safety advocates, and they support the above recommendations.

Additional Information

Boston Scientific closely monitors the performance of implanted devices. Please report all adverse clinical events to Boston Scientific and appropriate regulatory authorities, and return explanted products to the manufacturer. We will continue to include detailed, up-to-date product performance information within our ***Product Performance Report***, published quarterly at ***www.bostonscientific.com/ppr***.

Boston Scientific recognizes the impact of this communication for both you and your patients, and wants to reassure you that patient safety remains our primary concern. If you have additional questions regarding this communication or would like to report clinical events, please contact your Boston Scientific representative or Technical Services.

Sincerely,

[redacted]
Vice President, Quality Assurance

[redacted]
Senior Vice President and Chief Medical Officer, CRM

Appendix A

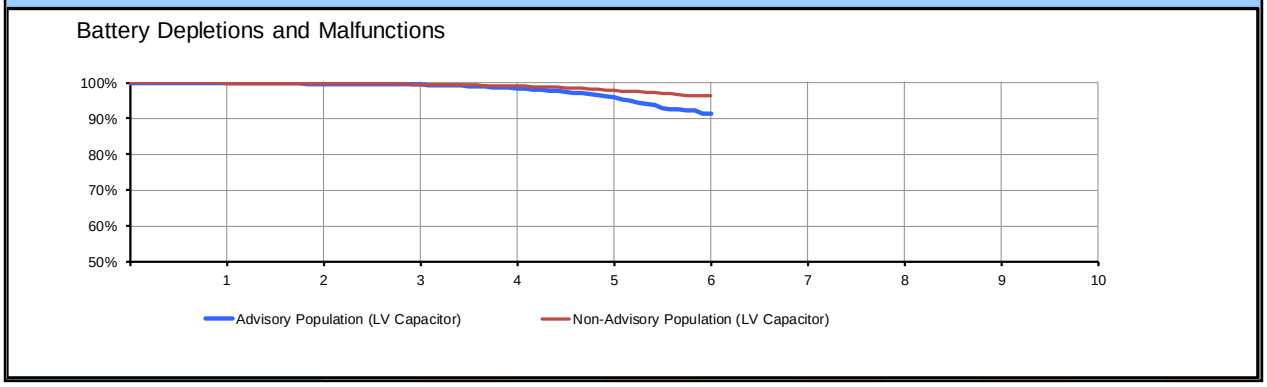
All-cause* Cumulative Survival for devices within and outside of the Low Voltage Capacitor Advisory subset population (United States data)

COGNIS CRT-D Models N106/N107/N108/N118/N119/N120/P106/P107/P108N120/P106/P107/P108

U.S. Registered Implants: 75,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 50,000

U.S. Normal Battery Depletions: 450
U.S. Unconfirmed Reports of Premature Battery Depletions: 29

U.S. Confirmed Malfunctions: 450
Without Compromised Therapy: 328
With Compromised Therapy: 116

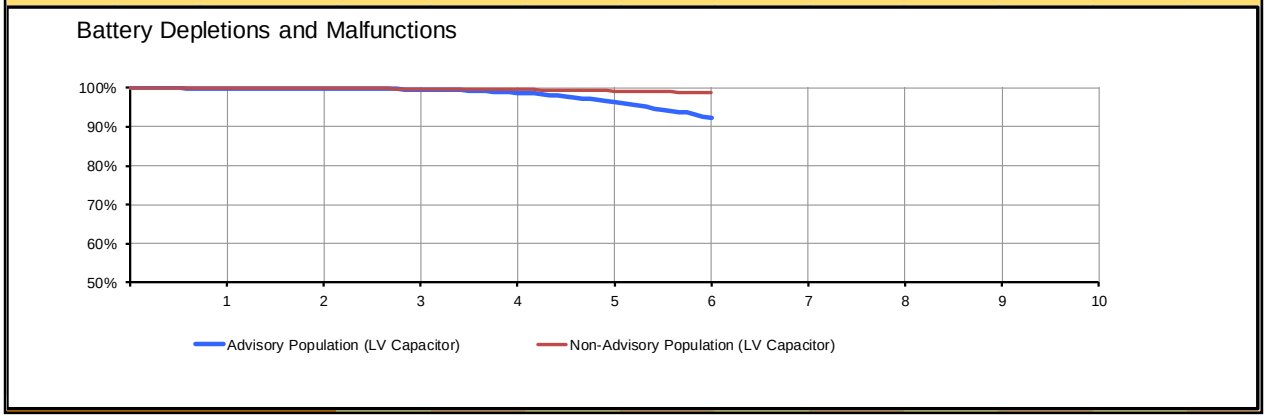


TELIGEN DR ICD Models E110/E111/F110/F111

U.S. Registered Implants: 66,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 48,000

U.S. Normal Battery Depletions: 100
U.S. Unconfirmed Reports of Premature Battery Depletions: 30

U.S. Confirmed Malfunctions: 468
Without Compromised Therapy: 392
With Compromised Therapy: 76

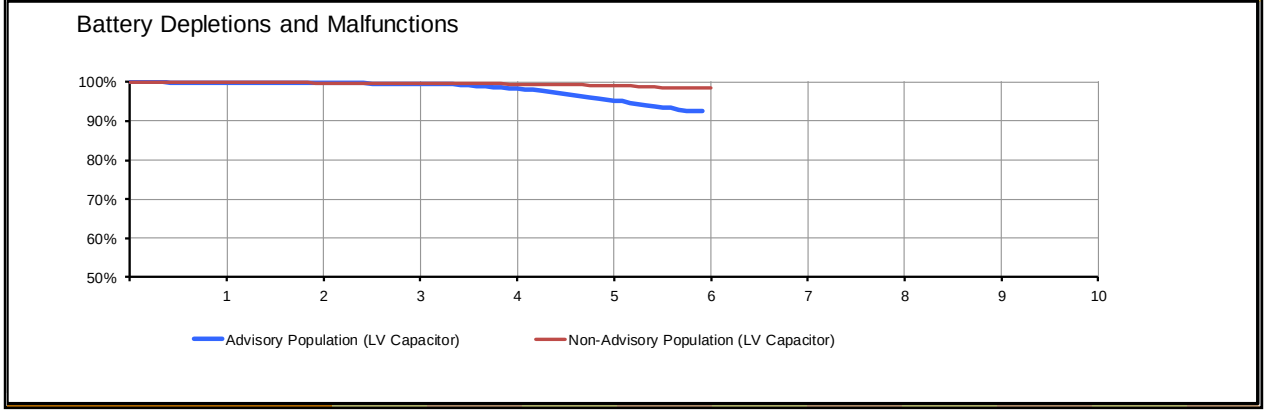


TELIGEN VR ICD Models E102/E103/F102/F103

U.S. Registered Implants: 38,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 28,000

U.S. Normal Battery Depletions: 52
U.S. Unconfirmed Reports of Premature Battery Depletions: 11

U.S. Confirmed Malfunctions: 328
Without Compromised Therapy: 270
With Compromised Therapy: 58



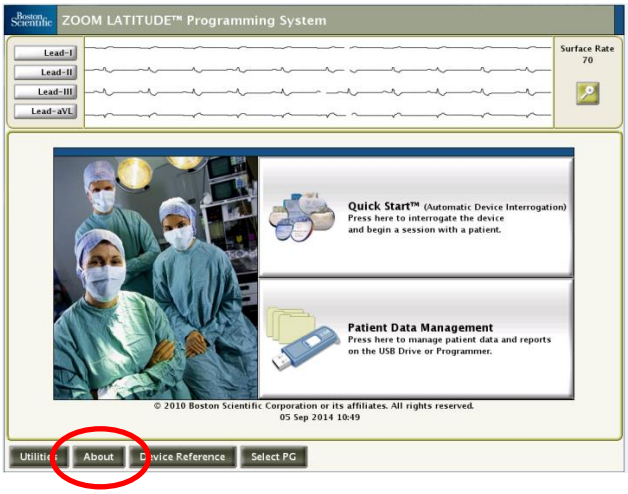
*Includes normal battery depletions and confirmed malfunctions.

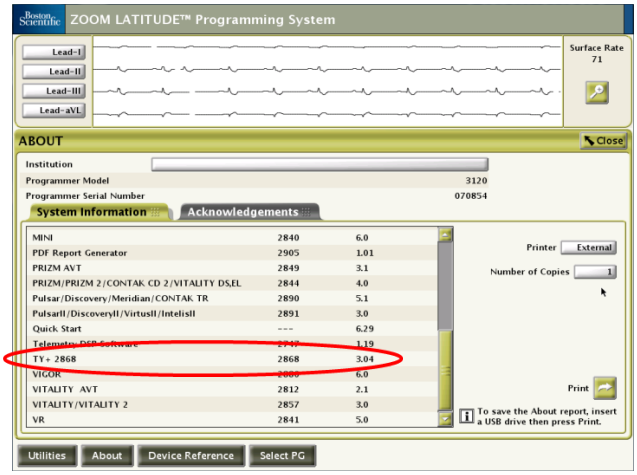
Appendix B

How to identify the current version of software for ZOOM™ LATITUDE™ programmers and implanted COGNIS™ CRT-Ds and TELIGEN™ ICD-s

How can I tell if a Model 3120 Programmer has been updated with the new version of software?

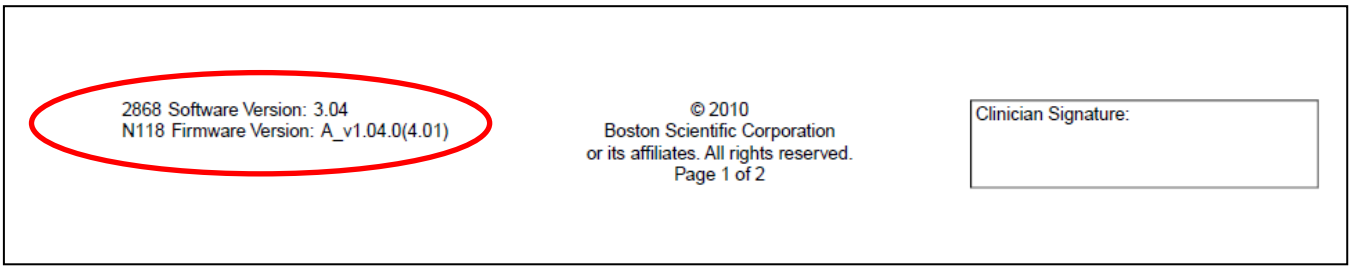
- Look for Model 2868, version 3.04 under System Information on the About screen





How can I tell if a patient's device has been interrogated with the new version of software?

- For PDF reports printed on an external printer, the programmer software version is located at the bottom of every page.
- For reports printed on the programmer printer, the programmer software version is located at the bottom of the last page



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