Important
Medical Device Information

Cardiac Rhythm Management
4100 Hamline Avenue North
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www.bostonscientific.com

August, 2013

Dear Doctor,

This letter provides important product performance information regarding a subset of COGNIS® CRT-Ds and TELIGEN® ICDs manufactured prior to December 2009, and describes how "Safety Architecture" can assist you in monitoring these devices. Boston Scientific has determined that the performance of a low voltage capacitor in this subset of devices may be compromised over time, causing increased current drain that can lead to premature battery depletion. All cases reported to date have been detected by diagnostic tools within Boston Scientific's Safety Architecture *before* device function was compromised.

"Safety Architecture" refers to a set of diagnostic monitoring tools in COGNIS and TELIGEN designed to mitigate potential device performance and clinical risks. These tools periodically assess device performance, including battery voltage, power consumption, and charge time, and have proven effective in identifying instances of unexpected battery use (via programmer alert screens or replacement indicators) *before* therapy becomes unavailable. Early identification can also be facilitated by patient-audible beeping tones that lead the patient to seek medical assistance, and use of the LATITUDE® Patient Management System (remote monitoring) that can provide notification for Safety Architecture performance alerts between office visits.

For this subset of devices, Boston Scientific recommends normal device monitoring as directed within labeling. In addition, we recommend that you call Technical Services when investigating a Safety Architecture alert. Following a Safety Architecture alert or Explant indicator due to diminished low voltage capacitor performance, the normal 3-month replacement window may be shortened and increased current drain could deplete the battery and compromise therapy/telemetry. Technical Services can help estimate how much time is available to replace the device, should a low voltage alert or Explant indicator occur.

Description and Clinical Implications
Boston Scientific has identified a low voltage (LV) capacitor component that, in some devices, may experience diminished performance after two or more years of implant time. This can increase battery use and eventually trigger one or more Safety Architecture alerts, accompanied by patient-audible beeping. The most common alert is a yellow screen displayed on the programmer upon initial interrogation which states: "Voltage is too low for projected remaining capacity. Contact Technical Services with Code 1003". In other instances, diminished LV capacitor performance can result in an unanticipated "Explant" ("ERI") battery status alert and a replacement window that may be less than 3 months.

All devices that experience diminished LV capacitor performance require replacement. If not replaced, increased current drain could deplete the battery and compromise therapy or telemetry. If a Safety Architecture alert is observed, call Technical Services for an analysis of "save-to-disk" information, which will clarify how much time is available to replace the device.

Rate of Occurrence
Appendix A provides an "all-cause" cumulative survival comparison between COGNIS/TELIGEN devices within the identified subset and devices outside of the subset. A total of approximately 264,000 COGNIS and TELIGEN defibrillators have been distributed and implanted since May of 2008. However, a subset of ~38,500 devices (15% of the total) that were manufactured prior to December 2009 has experienced a higher number of LV capacitor malfunctions (approximately 0.67% or 1 in 150). Devices from this subset have not been available for implant since November of 2010. In contrast to the subset population, the rate of diminished LV capacitor performance for other COGNIS/TELIGEN devices (225,500) is approximately 0.0093% or 1 in 10,700.

Recommendations
There are no additional clinical recommendations beyond the current standard of patient care and normal device monitoring, which are 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.
- Physicians should promptly investigate alerts and unanticipated replacement indicator messages.
- Following a Safety Architecture alert, contact Boston Scientific Technical Services as directed on programmer screens [24 hours per day / 7 days per week]. Technical Services can facilitate an evaluation of "save-to-disk" information (while the device is still implanted) to help clarify available replacement time. Note that "Approximate time to Explant" and "Time Remaining" estimates displayed on the programmer are not accurate following a Safety Architecture low voltage alert.
- Boston Scientific's LATITUDE Patient Management System (remote monitoring) can improve detection time for battery performance messages by conveying Safety Architecture alerts and/or notifying when scheduled check-ups have not occurred. Note that weekly battery voltage alerts are nominally configured "On" in LATITUDE.

Subset Population
A subset of COGNIS and TELIGEN defibrillators manufactured prior to December 2009 may be impacted by a higher rate of diminished LV capacitor performance:

Device Family	Subset Population Model Numbers	Subset Population
COGNIS CRT-D	N106/N107/N118/N119/P106/P107	A subset of devices manufactured prior to December 2009
TELIGEN DR ICD	E110/F110	
TELIGEN VR ICD	E102/F102	

A list of the identified subset of devices (model and serial number) implanted and/or followed by your clinic is attached to this communication. 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 identified subset.

Additional Information
An independent panel of physicians and safety advocates regularly reviews Boston Scientific's field performance data, including this malfunction pattern. Boston Scientific 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 on 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,

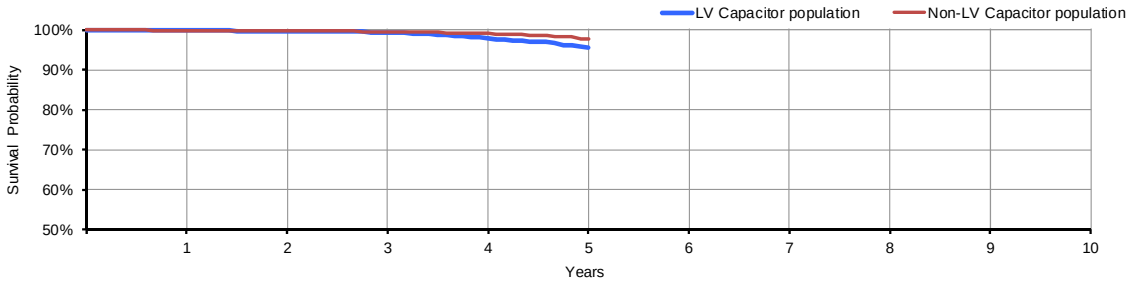
Renold Russie
Vice President, Quality Assurance

Kenneth Stein, MD, FACC, FHRS
Senior Vice President and Chief Medical Officer, CRM

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

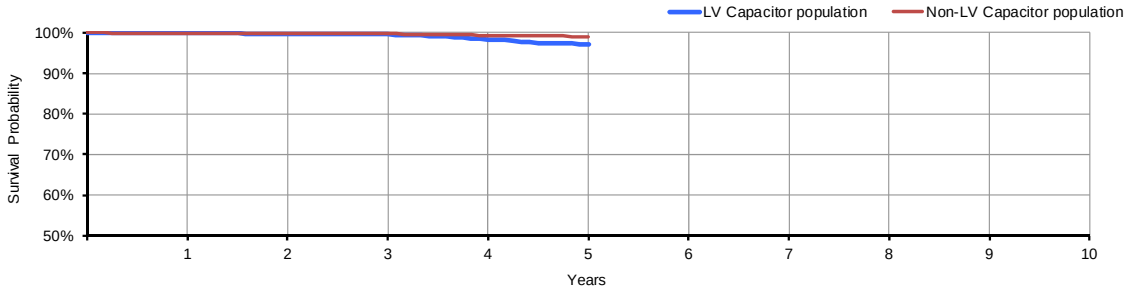
COGNIS CRT-D Models N106/N107/N108/N118/N119/N120/P106/P107/P108

U.S. Registered Implants: 75,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 55,000



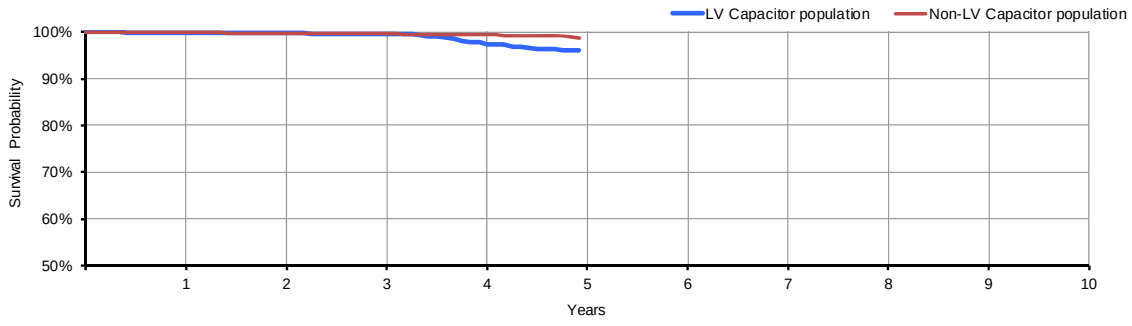
TELIGEN DR ICD Models E110/E111/F110/F111

U.S. Registered Implants: 66,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 52,000



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: 30,000



*Includes normal battery depletions and confirmed malfunctions.

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IMPORTANT MEDICAL DEVICE INFORMATION FOR PHYSICIANS
Heart Rhythm Society Format

August 2013

Manufacturer	Boston Scientific Corporation	
Product(s)	*Trade Name*	*Model Number*
	COGNIS® CRT-D	N106/N107/N118/N119 P106/P107
	TELIGEN® DR ICD	E110/F110
	TELIGEN® VR ICD	E102/F102
Manufactured	A subset of COGNIS and TELIGEN devices manufactured prior to December 2009	
Performance Failure	Boston Scientific has determined that the performance of an electrical component (a low voltage capacitor) in this subset of devices may be compromised over time, causing increased current drain that can lead to premature battery depletion. All cases to date have been detected by diagnostic tools within Boston Scientific's Safety Architecture *before* device function was compromised. "Safety Architecture" refers to a set of diagnostic monitoring tools in COGNIS and TELIGEN designed to mitigate potential device performance and clinical risks. These tools periodically assess device performance, including battery voltage, power consumption, and charge time, and have proven effective in identifying instances of unexpected battery use (via programmer alert screens, replacement indicators, or audible beeping) *before* therapy becomes unavailable. Use of the LATITUDE® Patient Management System (remote monitoring) can provide notification for Safety Architecture performance alerts between office visits.	
Root Cause	A low voltage (LV) capacitor component may experience diminished performance after two or more years of implant time.	
Has all affected product been retrieved?	No devices in the identified subset remain available for implant.	
FDA classification status	pending	

CLINICAL ACUITY	**USA**	**Worldwide**
a) Total number of units currently implanted	19,670	25,831
b) Estimated number of potentially affected devices of this mode distributed	28,106	38,510
c) Observed performance failures to date	189	257
Observed rate of performance failure to date	0.67%	0.67%
d) Mean age of product in active implanted population	47 months	47 months
e) Patient deaths reported	0	0
f) Patient deaths with probable relationship to device failure	0	0

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PATIENT MANAGEMENT RECOMMENDATIONS

Verify normal device function (at normal follow-up interval)?	☒ Yes	☐ No	Follow as recommended in device labeling.
Verify normal device function (as soon as possible)?	☐ Yes	☒ No	

There are no additional clinical recommendations beyond the current standard of patient care and normal device monitoring, which are 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.
- Physicians should promptly investigate alerts and unanticipated replacement indicator messages.
- Following a Safety Architecture alert, contact Boston Scientific Technical Services as directed on programmer screens [24 hours per day / 7 days per week]. Technical Services can facilitate an evaluation of "save-to-disk" information (while the device is still implanted) to help clarify available replacement time. Note that "Approximate time to explant" and "Time Remaining" estimates displayed on the programmer are not accurate following a Safety Architecture low voltage alert.
- Boston Scientific's LATITUDE Patient Management System (remote monitoring) can improve detection time for battery performance messages by conveying Safety Architecture alerts and/or notifying when scheduled check-ups have not occurred. Note that weekly battery voltage alerts are nominally configured "On" in LATITUDE.

Programming changes:	☐ Required	☐ Recommended	☒ Not required	
Accelerated device follow-up?	☐ Yes	☒ No	Timeline: Follow as recommended in device labeling.	

DEVICE COMPONENTS AT RISK OF PERFORMANCE FAILURE

☐ Battery Failure	☐ CRT (left ventricular pacing)
☐ Diagnostic Data Failure	☐ Lead Failure
☐ Brady Therapies (lower rate pacing)	☒ Internal component: Diminished performance of low voltage capacitor accelerates battery depletion
☐ Brady Therapies (runaway pacing)	☐ EMI Susceptibility
☐ Tachy Therapies (ATP)	☐ Telemetry Failure
☐ Tachy Therapies (shock)	☐ Other (specify):

CONTACTS

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