



March 23, 2009

Subject: Product Advisory – Inappropriate therapy associated with certain right ventricular (RV) lead complications may occur more frequently if the Respiratory Sensor is programmed On.

Dear Doctor,

This letter provides important patient management information regarding Boston Scientific COGNIS[®] CRT-Ds and TELIGEN[®] ICDs. Our records indicate that you have implanted or are monitoring patients with one of these devices. The patient management recommendations described below and reviewed by our independent Patient Safety Advisory Board will eliminate incremental risks described in this advisory.

Background

COGNIS CRT-Ds and TELIGEN ICDs include a Respiratory Sensor that can be activated to monitor the patient's respiratory rate. Daily minimum, maximum, and median respiratory rate data are stored in the defibrillator for up to one year, and can be reviewed for patterns or trends on the programmer's Respiratory Rate Trend screen.

Description

For any implantable defibrillator, delivery of appropriate therapy is dependent upon lead system integrity. Conversely, if any component of the defibrillator system is compromised, appropriate therapy cannot be assured. For example, certain RV lead complications (such as chronic lead fracture and acute lead connection issues) can cause inappropriate shocks or anti-tachycardia pacing, and/or inhibition of pacing. Boston Scientific has recently determined that if the Respiratory Sensor is programmed On, such RV lead complications may cause additional oversensing, thereby increasing the probability of inappropriate therapy. Five to eight successive inappropriate shocks could leave the device unable to treat an actual arrhythmia until the current episode ends. To date, the greatest extent of inappropriate therapy has been observed in a single pacemaker-dependent patient with a fractured lead. No patient deaths have been reported.

Rate of Occurrence

Boston Scientific estimates that the Respiratory Sensor is programmed On in approximately 8,000 COGNIS and TELIGEN devices worldwide. Inappropriate therapy as described above has been reported 15 times (0.2%). However, additional events can be prevented if the recommendations below are followed.

Patient Management Recommendations

Device programming records should be reviewed for each patient with a COGNIS CRT-D or TELIGEN ICD to determine if the Respiratory Sensor is programmed to On or Off.

- **When the Respiratory Sensor is Off, this advisory does not apply and routine follow-up is indicated.**
- **If the Respiratory Sensor is On, Boston Scientific recommends that the Respiratory Sensor be programmed Off** as follows:
 1. Select the **SETTINGS** tab
 2. Select the **SETTINGS SUMMARY** tab
 3. In the **BRADY** section, select the **NORMAL SETTINGS** details icon
 4. In the **SENSORS AND TRENDING** section, select the **ACCELEROMETER** details icon
 5. For **RESPIRATORY SENSOR**, select **Off**, and press **PROGRAM**

However, physicians should review concurrent risks such as pacemaker dependency, historic lead fracture performance, patient age and activity level, etc. when considering the most appropriate management options for each patient.

Boston Scientific continues to explore opportunities to further mitigate implantable systems against system malfunctions such as lead fractures. A change to non-invasively address this issue is under development and will be made available following regulatory submission and approval.

Devices Affected

Only COGNIS CRT-Ds and TELIGEN ICDs with the Respiratory Sensor programmed On are potentially susceptible to this behavior.

Further Information

Boston Scientific recognizes the impact of this communication on you and your patients and wants to reassure you that patient safety remains our primary concern. If you have any questions regarding this communication, please contact your local Boston Scientific CRM representative, United States Technical Services at 1.800.CARDIAC (227.3422) or European Technical Services at +32 2 416 7222.

Sincerely,

A handwritten signature in black ink, appearing to read "William E. Young". The signature is fluid and cursive, with a large, stylized initial "W".

William E. Young
Vice President, Reliability and Quality Assurance
Boston Scientific Cardiac Rhythm Management