September 2018

Dear Doctor,

Boston Scientific has identified a subset of approximately 2,900 active ACCOLADE™, PROPOSENT™, and ESSENTIO™ pacemakers and VISIONIST™ and VALITUDE™ cardiac resynchronization therapy pacemakers (CRT-Ps) with an elevated potential for early pacemaker replacement due to hydrogen-induced accelerated battery depletion. There have been no reports of injury related to this behavior. You are receiving this letter because you or your center has implanted or follow one or more patients with a pacemaker in this subset.

This device behavior can be identified via the regular pacemaker follow-up process, either in-clinic or through the LATITUDE™ NXT Remote Patient Management System (LATITUDE). Therefore, a follow-up interval of no more than six (6) months is recommended and is consistent with existing international societal guidelines1. If accelerated depletion is suspected, Boston Scientific recommends consultation with Technical Services to review the pacemaker diagnostic data available from either a recent data upload in LATITUDE or a Save to Disk to confirm accelerated depletion and determine an appropriate timeframe for pacemaker replacement.

Description
The pacemaker manual describes how increases in pacing requirements or changes in programmed parameters may result in an expected longevity reduction and are considered normal battery depletion. However, hydrogen exposure within the pacemaker’s circuitry may compromise the electrical performance of low voltage capacitors causing current leakage and a moderate acceleration in the rate of battery depletion. Because this accelerated depletion does not occur rapidly, a follow-up interval of no more than six months is recommended. Boston Scientific has determined a liner component to be the source of hydrogen and identified a subset of previously distributed pacemakers that have an elevated potential for exhibiting this behavior. Boston Scientific pacemakers include automated diagnostic tools, including battery status assessment and estimated longevity predictions, that dynamically adjust based on power consumption. It is important to emphasize that the accuracy of battery status and longevity estimates are not affected by this behavior.

Recommendations
- Boston Scientific recommends following patients implanted with any affected pacemaker from the advisory subset at intervals no greater than every six (6) months either in-clinic or via LATITUDE in accordance with the best practices outlined in international societal guidelines1. Appendix A provides guidance for healthcare professionals in determining accelerated battery depletion.
- Promptly investigate any suspected indication of accelerated depletion. Before surgical intervention, contact Boston Scientific Technical Services for verification of accelerated depletion and to determine an appropriate timeframe for pacemaker replacement. Please note, if accelerated depletion is identified, the Save to Disk feature2 or LATITUDE is necessary to perform an engineering assessment.
- Prophylactic replacement is NOT recommended for pacemakers with normal battery consumption as the risk of surgical replacement outweighs the risk of accelerated depletion.

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2 To save data from a programmer, insert a pen drive into a USB port, within the programmer select Utilities>Data Storage>Save All

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Clinical Impact
Approximately 500,000 ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 pacemakers and VISIONIST and VALITUDE CRT-Ps have been distributed and implanted. As a family, these pacemakers are meeting performance expectations with an overall cumulative survival of over 99% at 3 years\(^3\). However, Boston Scientific has identified a subset of pacemakers manufactured which have experienced an elevated rate of hydrogen induced depletion. The most common clinical outcome associated with this device behavior is early replacement. In all but two cases, the affected pacemakers were replaced with sufficient battery capacity for continued pacing therapy. None of the cases resulted in any patient injury.

Advisory Subset
Approximately 2,900 pacemakers within the advisory subset are active. The observed malfunction rate for hydrogen induced accelerated depletion within this advisory subset is 1.4% at 2.5 years which is 233 times higher than the non-advisory population. Because this behavior is highly detectable through regular pacemaker follow-up care, the projected potential for life-threatening harm is 0.0003% (1 in 333,333) at 5 years. There are no devices within this advisory subset that are still available for implant.

Advisory Pacemaker Subset
A model and serial number list of the affected advisory subset of ACCOLADE™, PROPONENT™, and ESSENTIO™ pacemakers; and VISIONIST™ and VALITUDE™ CRT-Ps implanted and/or followed by your clinic/center is available. An on-line search tool is also available at www.BostonScientific.com/ppr to determine if a specific model/serial number combination is included within the advisory subset.

Additional Information
An independent panel of physicians and safety advocates regularly reviews Boston Scientific’s field performance data, including this device behavior and associated 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.

Patient safety remains Boston Scientific’s highest priority. Although Boston Scientific recognizes the impact of communications on both you and your patients, we are committed to transparent communication with our physician customers to ensure you have timely, relevant information for managing your patients. If you have additional questions regarding this information or would like to report a clinical event, please contact your Boston Scientific representative or Technical Services.

Sincerely,

[Signature]

Renold Russie
Vice President, Quality Assurance

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**Approximate Time to Explant.**

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<th>Instructions</th>
<th>Example</th>
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| Review the patient's medical record and determine the date of the previous follow-up | Previous LATITUDE Follow-Up: 3 January 2018  
Current Follow-Up: 3 July 2018                                               |
| Calculate how many months since the last follow-up                           | 6 months                                                                |
| Note the longevity remaining in the battery status report during the previous follow-up | Battery Status from 3 January 2018  
Approximate time to explant 5.5 years                                         |
| Note the current longevity remaining and calculate the reduction in longevity | Battery Status from 3 July 2018  
Approximate time to explant 3.5 years                                         |
| Compare the difference in follow-up time to the longevity reduction          | Follow-up interval = 6 months  
Longevity reduction between follow-ups = 2 years  
In this example there is a significant reduction in longevity since the last follow-up, contact Technical Services for further evaluation. |
| A. If these times are similar, battery consumption is normal  
complete the remaining follow-up steps and schedule the next follow-up       |                                                                         |
| B. If the longevity reduction exceeds the follow-up time significantly, contact Technical Services for further evaluation |                                                                         |

**Table 1** Determination of Premature Battery Depletion by comparing Approximate Time to Explant between two follow-up intervals