ANZCDACC Advisory Notice 12th October 2018

Device: Subset of Boston Scientific:
ACCOLADE MRI SR Pacemaker L310
ACCOLADE MRI DR Pacemaker L331
ACCOLADE MRI DR Pacemaker L311
PROPONENT Pacemakers
ESSENTIO Pacemakers
VISIONIST cardiac resynchronization therapy pacemakers (CRT-Ps)
VALITUDE CRT-Ps

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.

TGA Reference: Nil
Medsafe Reference Number: 23575Nil

Advisory grade TGA: TBA

ANZDACC Advisory Grade: Routine

Description:
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. This accelerated depletion does not occur rapidly and can be determined during normal follow-up.
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 behaviour.
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 behaviour.

Number of devices affected in Australia and New Zealand:
20 devices in New Zealand
0 in Australia
2900 globally affected

Presentation:
This accelerated battery depletion can be calculated using the data from 2 consecutive follow-ups, either in-clinic or via remote monitoring on LATITUDE NXT in the following way;

Approximate Time to Explant. Instructions	**Example**
1. 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

2. Calculate how many months since the last follow-up	6 months
3. 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
4. Note the current longevity remaining and calculate the reduction in longevity	Battery Status from 3 July 2018 Approximate time to explant 3.5 years
5. Compare the difference in follow-up time to the longevity reduction 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 *****	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.

***** To save data from a programmer, select (Utilities>Data Storage>Save All) during the patient session. After ending the session use the 'Patient Data Management' tab to export the data to USB.

Rate of occurrence:
Approximately 2900 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 behaviour 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.

Recommendation:

- Follow-up affected patients every six (6) months either in-clinic or via remote monitoring.
- If followed up in-clinic, ensure the 'projected longevity remaining' is documented and is available at the subsequent follow-up.
- 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 feature***** or Latitude is necessary to perform and engineering assessment.
- Prophylactic replacement in NOT recommended for pacemakers with normal battery consumption as the risk of surgical replacement outweighs the risk of accelerated depletion.

The ANZCDACC encourage you to report any adverse event or near (potential) adverse event associated with the use of a medical device including any abnormal CIED or lead function. We encourage reporting to ANZCDACC directly via the Committee chair Dr Paul Gould drpgould@gmail.com and to the following regulators.

In Australia, report to the TGA;

Online https://www.tga.gov.au/reporting-problems

In New Zealand, report to Medsafe;

Post Compliance Management Branch, Medsafe, PO Box 5013, Wellington 6145.
Email devices@moh.govt.nz
Fax 04 819 6806