**ANZCDACC Advisory Notice 24th December 2017**

**Device:** Boston Scientific VALITUDE™ CRT-P Model U128, VISIONIST™ CRT-P Models U225, U226, U228, ACCOLADE™ Pacemakers Models L310, L311, L331, PROPONENT™ Pacemakers Models L210, L211, L231

**TGA Reference:** *RC-2017-RN01509-1*

**Advisory grade TGA:** TBA

**ANZDACC Advisory Grade:** Semi-Urgent

**Description:** Field reports of intermittent over sensing of the Minute Ventilation (MV) sensor signal with certain Boston Scientific pacemaker and cardiac resynchronization therapy pacemaker systems (pacemakers) has occurred. MV sensor signal over sensing may cause pre-syncope or syncope due to periods of pacing inhibition. This MV behaviour may occur with any manufacturer's pacing lead system, but Boston Scientific has determined it to be more likely for affected Boston Scientific pacemakers using Medtronic or Abbott/St. Jude (Abbott) leads implanted in either the right atrium (RA) or right ventricle (RV).

The MV sensor in Boston Scientific pacemakers can be used for RightRate™ (rate adaptive pacing), Respiratory Rate Trend, or AP Scan™1. When the RA/RV pacing leads and lead terminal connections are operating as intended, the MV sensor signal is appropriately filtered and therefore is not detected by the pacemaker or displayed on electrograms (EGMs). However, intermittency related to the lead or pacemaker- lead connection has the potential to create a transient high impedance condition. A high impedance condition may subsequently alter the MV sensor signal such that it becomes visible on EGMs and potentially subject to oversensing on the RA or RV channels.

**Number of devices affected in Australia and New Zealand:** 4300 devices.

**Presentation:** If MV sensor signal over sensing is observed on the atrial channel, the most common clinical outcome is an inappropriate mode switch. If MV sensor signal over sensing occurs on the RV channel then pacing inhibition is possible, which has led to syncope with associated serious injury and death in some pacemaker- dependent patients. Otherwise patients may present with presyncope.

**Rate of occurrence:** To date 344 events have occurred resulting in five serious injuries and one event which may have led to a patient death. Boston Scientific investigation has shown that the probability of harm associated with MV sensor signal over sensing behaviour is significantly greater when affected pacemakers are connected to Medtronic or Abbott pacing leads.

**Recommendation:**

Until software is available to automatically resolve MV sensor signal over sensing, the Committee recommends managing the risk for patients implanted with affected pacemaker systems as follows:

- For pacemaker-dependent patients, turn the MV sensor "OFF". Note when programmed to passive, the MV sensor signal is enabled and may be over sensed.
- For all other patients, evaluate the risks of over sensing the MV sensor signal ( i.e. Effect of loss of pacing on the patient) against the benefits of MV sensor indicated pacing (i.e. improvement in exercise tolerance and fatigue etc). If the risk outweighs the benefit, turn the MV sensor "OFF"
- If transient, abrupt changes or any out-of-range RA/RV pacing impedance measurements are observed, contact Boston Scientific Technical Services to explore all non-invasive programming options prior to device replacement. In most cases, management of the system can be done non-invasively through programming changes.
- If MV sensor signal artefacts are observed on EGMs and leads are performing appropriately, consider programming the sensor to "OFF" to prevent over sensing.
- For patients with the MV sensor enabled, periodically re-assess for pacemaker dependence.
- Where possible the Committee advises enrolment of patients in Home Monitoring using the LATITUDE™ NXT Remote Patient Management System.

A software fix will be available in the near future March 2018 which will be required to be installed on all devices at risk. Until then vigilance and reprogramming as described above will be required.

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**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;**

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

**In New Zealand, report to Medsafe;**

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