

## ANZCDACC Advisory Notice 14th July 2017

**Device:** EMBLEM™ S-ICDs (Models A209 and A219) and SQ-RXTM S-ICDs (Model 1010)

**TGA Ref:** RC-2017-RN-00830-1

**Advisory Grade TGA:** TBA

**ANZDACC Advisory Grade:** Routine

**Description:** Environmental radiation corrupting S-ICD device memory causing delivery of atypical energy (similar to arrhythmia induction) and disabling of tachycardia therapies in a patient with a S-ICD. This resulted in induction of VF and contributed to the patient's death. Laboratory testing by Boston Scientific engineers identified that this event could be reproduced by corrupting two specific adjacent bits of device memory in the S-ICD. It was determined by the Boston scientific engineers that the corruption was a result of an event known as a single event upset (SEU). A SEU is a change in the state of device memory induced by environmental radiation effecting a specific memory location. The patient in question did not have any additional exposure to radiation (eg ionizing radiation therapy).

**Risk:** This is an isolated event it had occurred in 1 of 37 000 S-ICD's distributed worldwide. Due to being an isolated event it is difficult to confidently predict the overall risk, however based on available data the risk of occurrence is estimated at 1 in 300 000 over 5 years.

### **Number of devices affected in Australia and New Zealand:**

**Presentation:** Currently only one device has been affected worldwide which resulted in sudden death due to arrhythmia induction and deactivation of tachycardia therapies.

**Advice:** In considering the following advice the recommendations related to the Advisory notice titled: **Boston Scientific Model 3200 S-ICD Programmer** posted on the ANZDACC website on the 27<sup>th</sup> of January needs to be taken into consideration.

The memory corruption is undetectable with integration with the Subcutaneous ICD therefore the following is recommended.

- Standard inpatient follow as per physician routine practice (increased follow up is not recommended)
- Continue latitude (remote monitoring) as normal
- Follow precautions with radiation therapy as described in S-ICD manual.
- Prophylactic S-ICD replacement is not recommended.

Boston scientific is developing a software upgrade to correct the issue and is expected to be submitted to the TGA in July 2017. Until this is available this alert should be considered when assessing the risk vs benefits of the S-ICD for each patient.