Boston Scientific Model 3200 S-ICD Programmer

ANZCDACC Advisory Notice 20th January 2017

Advisory Grade TGA: TBA (Hazard Alert (Recall for product correction))

ANZDACC Advisory Grade: Routine

Description: Potential RF interference during programmer interrogation of S-ICD with potential to cause temporary and/or permanent unintended programming changes. Latitude remote monitoring not affected.

Ten observations of unintended programming have been reported.
One inappropriate shock and therapy programmed off in another device. One device returned to nominal factory settings.

Risk: Overall risk of adverse event is calculated at 1/25,000 in 5 years for EMBLEM devices and 1/200,000 in 5 years for SQ-RX devices.

In Australia there are 385 devices affected and New Zealand 93 devices.

Presentation: Patients with inappropriate shocks, failure to deliver therapy due to unintended programming (therapies off), unexpected programming changes on home monitoring or at routine review.

Advice: A software update will be released at a future date to rectify this issue. Home monitoring is recommended and if a programmer needs to be used that the device should be reinterrogated immediately after ending session to ensure that there hasn't been any unintended programming.

Use remote monitoring for routine follow up whereever possible. Reduce frequency of in clinic checks while following medical society guidelines.

Do not leave patient unattended in clinic while an active telemetry session is in progress. Ensure external defibrillation equipment and appropriately trained staff are readily available during in office follow up.

Minimize duration of programmer communication and end telemetry session promptly.

Contact Boston Scientific technical services for assistance should unintended programming occur.