Boston Scientific: AUTOGEN DR ICDs and CRT-Ds (14 Dec 2014)

Number in Australia: Currently 162 devices at risk (67 DR and 95 CRT-D)

Risk: All devices have potential issue – clinical consequence dependent on pacing status

Description: Boston Scientific has identified a potential issue with the Right Ventricular Automatic Threshold (RVAT) testing component of AUTOGEN DR ICDs and CRT-Ds. In these devices, there is an option to enable RVAT testing to determine the RV pacing threshold and to automatically adjust amplitude. Boston Scientific have advised that if the RVAT test feature is enabled and noise signals are continuously sensed within a brief RV noise window following an Atrial pace, a patient may not receive effective pacing support until the RVAT test ends (i.e., up to 20 cardiac cycles). This has not been reported in AUTOGEN VR devices.

Presentation: Although no patients have been harmed in the cases reported to date, brief periods of dizziness were reported in one case. Note that there is no additional risk for patients in whom the RVAT feature is disabled.

Advice: Boston Scientific is developing a software solution that will prevent this device behaviour from occurring when the RVAT test feature is enabled. Until this time, RVAT feature should be DISABLED at time of routine follow up or within 3 months (whichever is earlier). Earlier review is required for pacemaker dependent patients where this feature is programmed on.