Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2014-RN-01011-1
Product Name/Description[iii]	COGNIS Implantable Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and TELIGEN DR & VR Implantable Cardioverter -Defibrillators (ICDs) Affected model numbers: COGNIS CRT-D : N106/N107/N108/N118/N119/N120/P106/P107/P108 TELIGEN DR ICD:E110/E111/F110/F111 TELIGEN VR ICD: E102/E103/F102/F103 Devices manufactured prior to March of 2010. ARTG Numbers: 154039, 154037, 154034, 154033, 154035, 154038, 154036
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Action Commencement Date[vi]	22/09/2014
Responsible Entity[vii]	Boston Scientific Pty Ltd
Reason / Issue[viii]	This is an update to the August 2013 physician communication (TGA Ref.: RC-2013-RN-00906-1). The performance of an LV capacitor may be compromised in some devices after two or more years of implant time, which will increase battery use and may eventually initiate one or more Safety Architecture alerts and patient-audible beeping. The most common alert is a yellow programmer screen that states, "Voltage is too low for projected remaining capacity. Contact Technical Services with Code 1003". LATITUDE issues a corresponding yellow alert (nominally configured "On"). In other instances, diminished LV capacitor performance can result in an early "Explant" battery status indicator (ERI) and a replacement window that may be less than 3 months. Boston Scientific has identified a second subset of devices that may exhibit a similar issue. No patient deaths have been associated with this issue. Affected devices have not been available for implant for more than three years.
Recall Action[ix]	Hazard Alert

Recall Action Instructions[x]	Boston Scientific has recently introduced updated software that will further improve Safety Architecture effectiveness. Boston scientific recommend that patients with a device in the affected population be scheduled for an in-clinic visit to upgrade their device with this new software. After a device has been upgraded, continue normal device monitoring as directed within labelling, and promptly investigate all alerts and device beeping. Devices that experience a low voltage alert require replacement. If not replaced, increased current drain could deplete the battery and impact therapy delivery and telemetry. If a Safety Architecture alert is observed, Boston Scientific Technical Services can analyse device information downloaded from a recent in-clinic or LATITUDE interrogation, which will clarify approximately how much time is available to replace the device. Fro more details, please see http://www.tga.gov.au/safety/alerts-device-cognis-crt-d-and-teligen-icd-130924.htm .
Contact Information[xi]	02 8063 8239 - Boston Scientific Technical Services

Footnotes

[i] Type of Product: Medicine, Medical Device, or Biological

[ii] TGA Recall Reference: Unique number given by the TGA

[iii] Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

[iv] Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- Wholesale - includes wholesalers and state purchasing authorities.
- Hospital - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- Retail - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.
- Consumer - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

[v] Recall Action Classification: Recall actions of therapeutic goods are classified based on the potential risk the deficiency poses to patients / consumers. They are classified as Class I, Class II or Class III.

- Class I recall action occurs when the product deficiency is potentially life-threatening or could cause a serious risk to health.
- Class II recall action occurs when the product deficiency could cause illness, injury or result in mistreatment, but are not Class I.
- Class III recall action occurs when the product deficiency may not pose a significant hazard to health, but action may be initiated for other reasons eg. quality related issues.

[vi] Recall Action Commencement Date: The date the recall strategy and communication was agreed by the TGA.

[vii] Responsible Entity: Sponsor / Supplier / Importer responsible for the recall actions.

[viii] Reason / Issue: Reason for the recall action.

[ix] Recall Action: Recall action is an action taken to resolve a problem with a therapeutic good already supplied in the