Important
Medical Device Information

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Dear Doctor,

This letter provides important product performance information regarding Boston Scientific AUTOGEN™ DR ICDs and CRT-Ds. These devices include the option of enabling a Right Ventricular Automatic Threshold (RVAT) test to determine the RV pacing threshold and adjust amplitude in an ambulatory setting. 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). 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.

Boston Scientific is developing a software solution that will prevent this device behaviour from occurring when the RVAT test feature is enabled. Following geography-specific regulatory approval, this software solution will be implemented via a non-invasive download from the programmer.

Patient Management Recommendations

The RVAT test can be used in-clinic to run an automatic threshold test (nominally enabled) or it can be enabled for ambulatory use (nominally not enabled). Until a software solution can be implemented, Boston Scientific recommends the following:

1. For ambulatory RVAT tests, we recommend that the RVAT test feature is not enabled in AUTOGEN DR ICDs and CRT-Ds, due to the potential risk of asystole occurring during the RVAT test. If the ambulatory RVAT test feature has been enabled, Boston Scientific recommends disabling the RVAT feature at the first opportunity, but within three months. To ensure the RVAT test feature is not enabled for ambulatory use:
    - Select the **SETTINGS** tab
    - Select the **SETTINGS SUMMARY** tab
    - In the **BRADY** section, select the **NORMAL SETTINGS** details icon
    - In the **PACING and SENSING** section, select the desired pacing **RV Amplitude** (do not select **Auto**)
    - Ensure that **DAILY TREND** is not selected
    - Press **PROGRAM** to implement the selected fixed amplitude pacing output.

    Refer to the Appendix for a corresponding programmer screen image and an excerpt from a printed report that can help identify if the RVAT test feature is enabled.

2. For in-clinic/commanded RVAT tests, we recommend that physicians test thresholds manually, rather than utilising the automatic RVAT test. Under the Test Type field, select Amplitude (do not select Auto Amplitude). Refer to the Appendix for a corresponding programmer screen image.

Models Potentially Affected
All AUTOGEN defibrillators include the RVAT test feature. If the RVAT test feature is enabled in any AUTOGEN DR ICD or CRT-D device model and noise signals are continuously sensed in an RV noise window following an Atrial pace, the device may be impacted by this device behaviour:

Device Family	Model Numbers
AUTOGEN CRT-D	G172 / G173 / G175 / G177 / G179
AUTOGEN DR ICD	D046 / D047 / D176 / D177

An online search tool is available at ***www.bostonscientific.com/ppr-intl*** to determine if a specific device is affected by a product advisory.

Single-chamber AUTOGEN ICDs (VR models) have not demonstrated this behaviour. The Left Ventricular Auto Threshold (LVAT) test (for AUTOGEN CRT-Ds) and the Right Atrial Auto Threshold (RAAT) test (for AUTOGEN CRT-Ds and dual-chamber ICDs) are not subject to this device behaviour and are performing as intended. In addition, Boston Scientific pacemaker and CRT-P models with similar automatic pacing threshold test features are performing as intended and thus are not subject to this device behaviour.

Additional Information
Boston Scientific will continue to include detailed, up-to-date product performance information within our ***Product Performance Report***, published quarterly at ***www.bostonscientific.com/ppr-intl***.

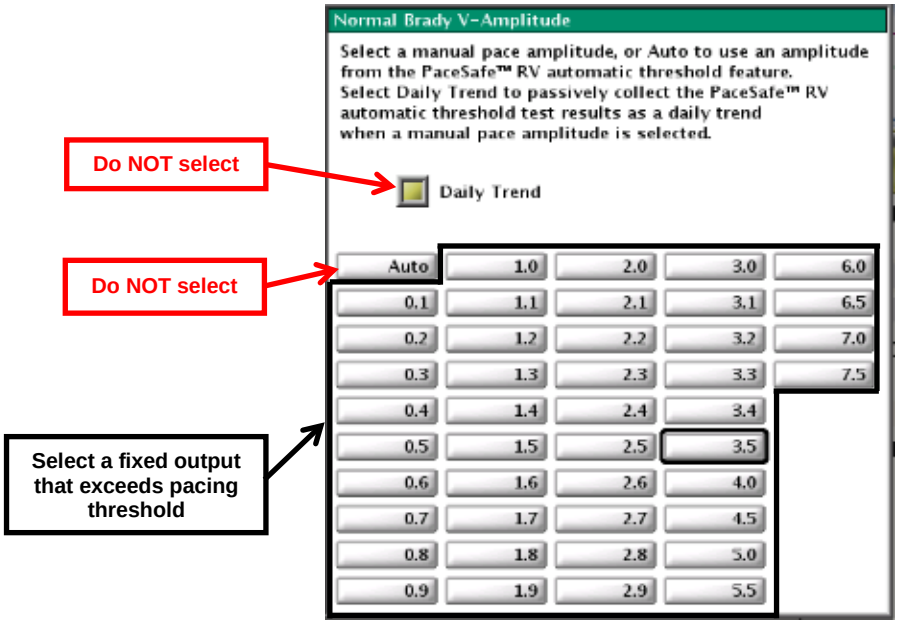
Boston Scientific recognises the impact of this communication on both you and your patients, and wants to reassure you that patient safety remains our primary concern. If you have additional questions regarding this communication or would like to report clinical events, please contact your Boston Scientific representative or Technical Services.

Sincerely,

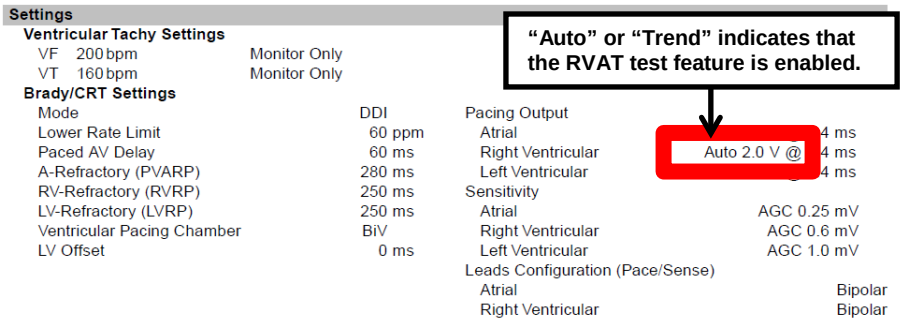
Jyl Langhorne
Marketing Manager, UK & Ireland
Rhythm Management

Appendix

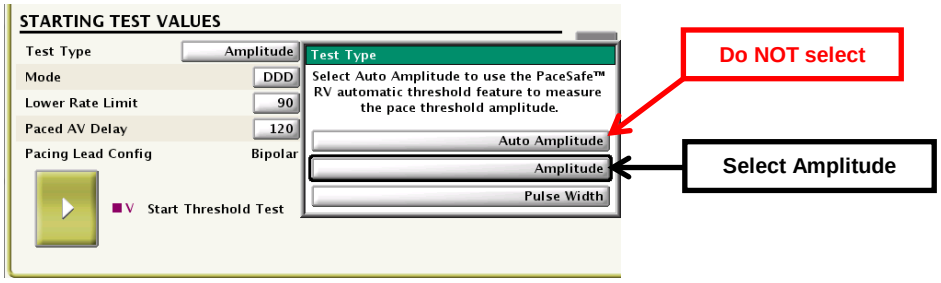
To ensure the RVAT test feature is not active for ambulatory use:



On a printed report (within the Settings Section), determine if the RVAT test feature is enabled by reviewing the RV pacing output for: “Auto” or “Trend”



To ensure the RVAT test feature is not active for in-clinic use:



Boston Scientific

Cardiac Rhythm Management

AUTOGEN RVAT NOVEMBER 2014
100000023523-FA

Acknowledgement Form

(The information hereunder is required for regulatory effectiveness checks and can be subject to audits.)

Hospital _____

Address _____

Telephone No: _____

I confirm that I have received the notification concerning the
AUTOGEN™ DR ICDs and CRT-Ds.

_____ _____
Physician Name (print) Title

_____ _____
Signature Date dd-mmm-yyyy

When completed - return the Form to your local Boston Scientific Office for the attention of: QA - Fax: 01442 411816 or email UK-Quality@bsci.com