



# 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 behavior 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 utilizing 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 behavior:

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](http://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 behavior. 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 behavior 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 behavior.

**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](http://www.bostonscientific.com/ppr-intl).

Boston Scientific recognizes 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,



Kenneth Stein, MD, FACC, FHRS  
Senior Vice President and Chief Medical Officer, CRM



Renold Russie  
Vice President, Quality Assurance, CRM

## Appendix

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

**Normal Brady V-Amplitude**  
 Select a manual pace amplitude, or Auto to use an amplitude from the PaceSafe™ RV automatic threshold feature. Select Daily Trend™ to passively collect the PaceSafe™ RV automatic threshold test results as a daily trend when a manual pace amplitude is selected.

**Do NOT select** (points to Daily Trend checkbox)

**Do NOT select** (points to Auto button)

**Select a fixed output that exceeds pacing threshold** (points to 3.5 V button)

Auto	1.0	2.0	3.0	6.0
0.1	1.1	2.1	3.1	6.5
0.2	1.2	2.2	3.2	7.0
0.3	1.3	2.3	3.3	7.5
0.4	1.4	2.4	3.4	
0.5	1.5	2.5	3.5	
0.6	1.6	2.6	4.0	
0.7	1.7	2.7	4.5	
0.8	1.8	2.8	5.0	
0.9	1.9	2.9	5.5	

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”

**Settings**

**Ventricular Tachy Settings**  
 VF 200 bpm Monitor Only  
 VT 160 bpm Monitor Only

**Brady/CRT Settings**  
 Mode DDI Pacing Output  
 Lower Rate Limit 60 ppm Atrial 4 ms  
 Paced AV Delay 60 ms Right Ventricular **Auto 2.0 V @** 4 ms  
 A-Refractory (PVARP) 280 ms Left Ventricular 4 ms  
 RV-Refractory (RVRP) 250 ms Sensitivity  
 LV-Refractory (LVRP) 250 ms Atrial AGC 0.25 mV  
 Ventricular Pacing Chamber BiV Right Ventricular AGC 0.6 mV  
 LV Offset 0 ms Left Ventricular AGC 1.0 mV

**Leads Configuration (Pace/Sense)**  
 Atrial Bipolar  
 Right Ventricular Bipolar

**“Auto” or “Trend” indicates that the RVAT test feature is enabled.** (points to Auto 2.0 V @)

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

**STARTING TEST VALUES**

Test Type Amplitude **Test Type**  
 Mode DDD Select Auto Amplitude to use the PaceSafe™ RV automatic threshold feature to measure the pace threshold amplitude.  
 Lower Rate Limit 90 Auto Amplitude  
 Paced AV Delay 120 Amplitude  
 Pacing Lead Config Bipolar Pulse Width

**Do NOT select** (points to Auto Amplitude button)

**Select Amplitude** (points to Amplitude button)

Start Threshold Test