

Urgent Medical Device Correction **For All Claria MRI™ CRT-D SureScan™ and Amplia MRI™ CRT-D SureScan™**

December 2016

Dear Physician,

Medtronic is writing to inform you about a device software issue that may occur with all models of Claria MRI™ CRT-D SureScan™ and Amplia MRI™ CRT-D SureScan™ devices. The issue is a loss of LV pacing that occurs following a specific device programming sequence. If it occurs, this issue can be corrected by re-programming the device. All tachyarrhythmia detection and therapy features remain fully operational. Medtronic records indicate you have implanted and/or are following one or more patients with one of these devices.

A software update is being developed to address this issue in Claria MRI™ and Amplia MRI™ devices. This software update will also address an unrelated transient mode switch behavior in all Quadripolar models of Claria MRI™, Amplia MRI™, and Compia MRI™ CRT-D SureScan™ devices. Further information will be communicated once the software update receives applicable regulatory approvals.

Issue Description

All models of Claria MRI™ and Amplia MRI™ devices are included in the affected population (refer to Table A below). This issue can only occur in devices that have been programmed from Managed Ventricular Pacing (MVP) mode to a pacing mode with AdaptivCRT™ enabled.

When a patient with AdaptivCRT enabled (shipped setting) is subsequently programmed to MVP mode and then re-programmed back to DDD or DDDR, AdaptivCRT is not re-enabled. When this programming sequence occurs, LV pacing is not delivered, despite parameters indicating AdaptivCRT is enabled (Appendix A, Figure 1). This will result in RV only pacing, which may be undesirable for the patient. LV pacing will remain disabled until a specific programming sequence is manually completed; refer to the Patient Management section of this letter (Appendix A) for details.

Through 10 November 2016, two events have been reported to Medtronic related to this issue. A review of available data revealed an overall occurrence rate of 0.38%. **Medtronic has not received any reports of patient injury related to this issue.**

Until the software update has been approved and the device models listed in Table A receive the update, follow the programming recommendations found in Appendix A. These recommendations also apply to any new device implants.

Medtronic will notify all applicable regulatory agencies about this Urgent Medical Device Correction. Please share this notification with others in your organization as appropriate.

As part of the software update previously mentioned, Medtronic will also address an unrelated transient mode switch behavior that may occur in MRI Quadripolar CRT-D device models (Claria MRI™, Amplia MRI™ and Compia MRI™). The mode switch behavior is unrelated to ventricular tachyarrhythmia detection and therapies. This behavior only occurs when a VectorExpress™ Test is started, but then aborts due to a fast or unstable rate, or due to a manual user abort (i.e., manually selecting STOP Test). Under these scenarios, the device remains in the transient mode switch state until any of the following occur:

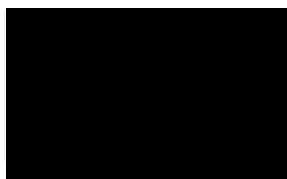
- An automatic Atrial Capture Management™ (ACM) pacing threshold search,
- An automatic delivery of any ATP or shock therapy, or
- An in-office follow-up activity, such as a pacing parameter programming or conducting one of the following in-office tests: Sensing, Threshold, Underlying Rhythm, or CardioSync™. A "Test Started" indication is sufficient to clear the transient state.

Through 10 November 2016, Medtronic has not received any field reports or complaints of this transient mode switch behavior.

We sincerely regret any difficulties this may cause you and your patients. Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients.

If you have any questions, please contact your local Medtronic Representative.

Sincerely,



Joo Ee Yap
Business Director CRHF SEA

Table A

Model Name	Product Model
Amplia MRI™ CRT-D SureScan™	DTMB1D1 DTMB2D1 DTMB1D4 DTMB2D4
Amplia MRI™ Quad CRT-D SureScan™	DTMB1Q1 DTMB2Q1 DTMB1QQ DTMB2QQ
Claria MRI™ CRT-D SureScan™	DTMA1D1 DTMA2D1 DTMA1D4 DTMA2D4
Claria MRI™ Quad CRT-D SureScan™	DTMA1Q1 DTMA2Q1 DTMA1QQ DTMA2QQ

Appendix A

Patient Management Recommendations

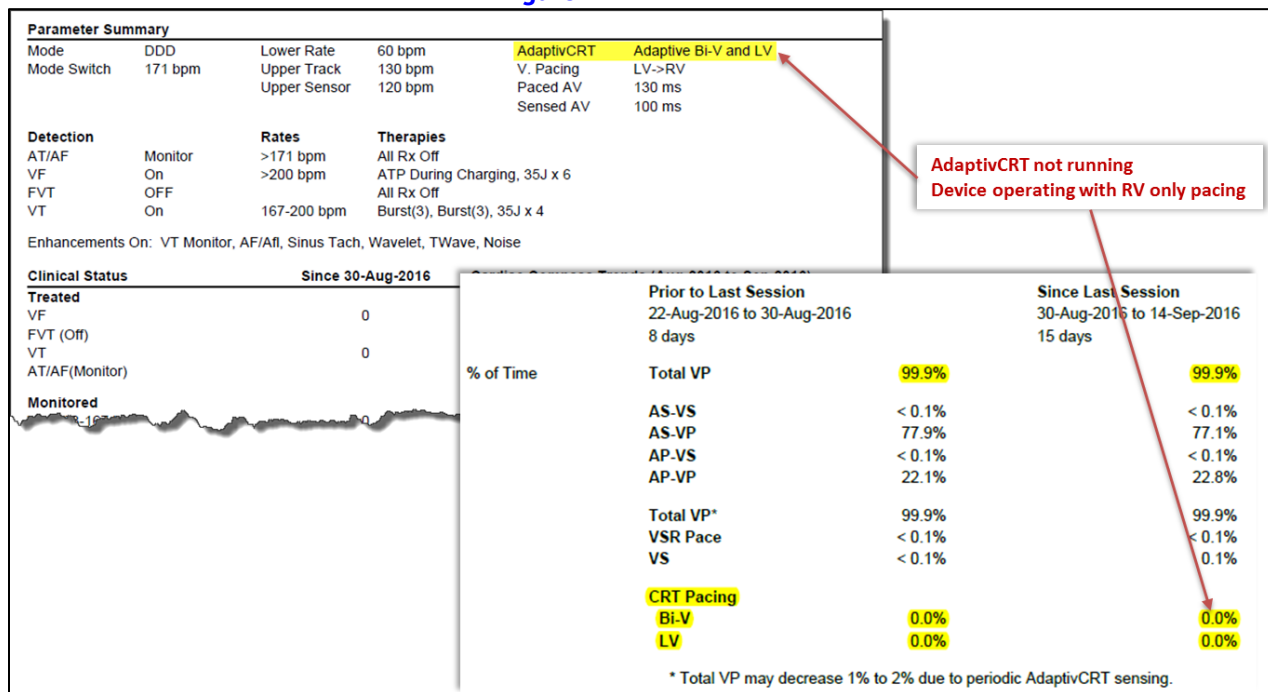
After consultation with Medtronic's Independent Physician Quality Panel, Medtronic offers the following options for managing patients with a device that may be susceptible to the AdaptivCRT/MVP interaction:

1. **At the patient's next scheduled CareLink transmission or in-office follow-up, identify if the patient's device is operating with AdaptivCRT enabled and loss of LV-pacing. Continue this practice for all subsequent device evaluations until the software update has been implemented.**

Using CareLink or Programmer interrogation session reports:

- If the CRT setting is currently programmed to *Adaptive Bi-V and LV* or *Adaptive Bi-V* (Figure 1), review rate histogram CRT Pacing percentages (CRT Pacing: Bi-V and LV).
- If Bi-V and LV pacing percentages *Since Last Session* are both near 0%, then the device has encountered the programming sequence and has lost LV pacing; proceed to step 2.

<Figure 1>



2. **For patients identified with loss of LV pacing:**

Perform the following programming steps to restore the device to its expected operating state with AdaptivCRT enabled:

- Select the CRT parameter window, select *Nonadaptive CRT*, and select *PROGRAM*.
- Select the CRT parameter window, select the desired AdaptivCRT setting (*Adaptive Bi-V and LV* or *Adaptive Bi-V*), and select *PROGRAM*.

Until the software update is available, follow the programming steps above to avoid the loss of LV pacing.