Medtronic

Urgent Field Safety Notice
Claria MRI™ CRT-D SureScan™ and Amplia MRI™ CRT-D SureScan™
Patient Management Recommendations

12 December 2016

Medtronic reference: FA747

Dear Physician, Healthcare Professional,

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 that your facility has received one or more 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 is available for distribution.

Issue Description
All models of Claria MRI™ and Amplia MRI™ devices are included in the affected population (refer to Appendix 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 B, 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 B) 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 is available and the device models listed in Appendix A receive the update, follow the programming recommendations found in Appendix B. These recommendations also apply to any new device implants.

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.

Medtronic

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

Please share this notification with others in your organization as appropriate.

Medtronic has notified the Competent Authority of your country of this action.

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 Medtronic Representative.

Sincerely,

Medtronic Saudi Arabia

Medtronic

Appendix A: List of impacted model numbers:

Model Name	Product Model
Amplia MRI™ CRT-D SureScan™	DTMB2D1 DTMB1D4 DTMB2D4
Amplia MRI™ Quad CRT-D SureScan™	DTMB2Q1 DTMB1QQ DTMB2QQ
Claria MRI™ CRT-D SureScan™	DTMA2D1 DTMA2D4
Claria MRI™ Quad CRT-D SureScan™	DTMA2Q1 DTMA2QQ

## Appendix B: 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
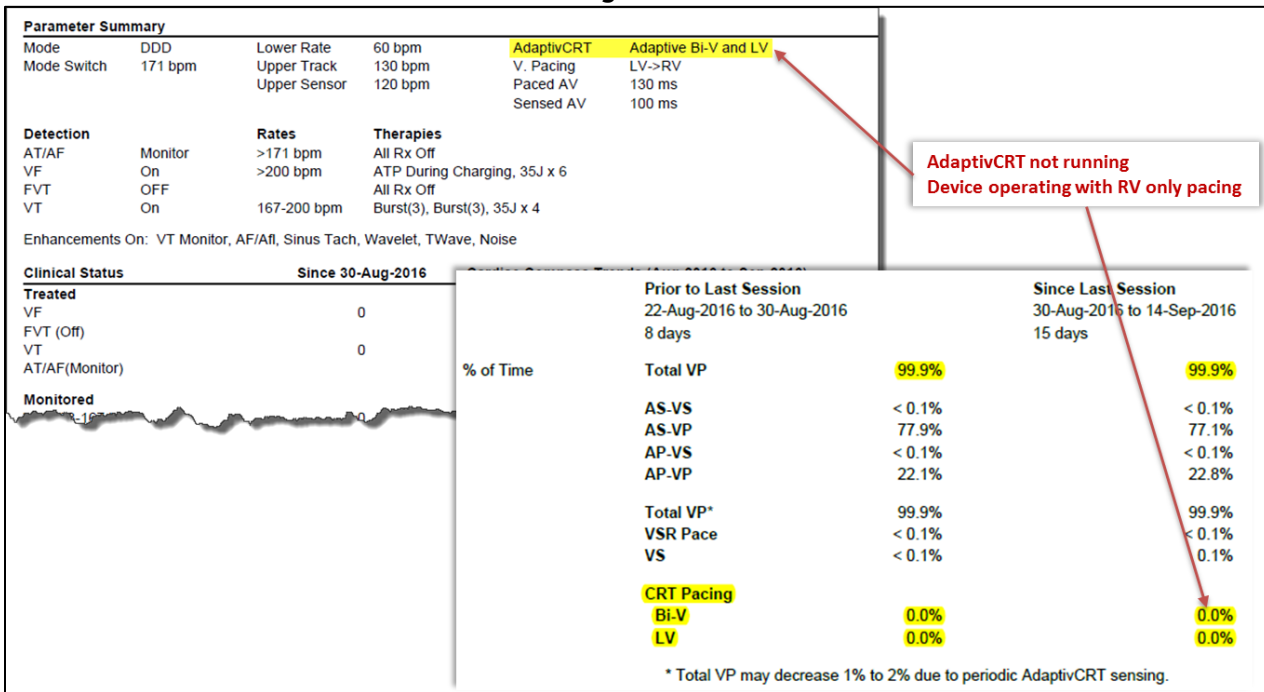
2. **For patients identified with loss of LV pacing:**
   Perform the following programming steps to restore the device to its expected operating state with AdaptivCRT enabled:
   - Select the CRT parameter window, select *Nonadaptive CRT,* and select *PROGRAM*.
   - Select the CRT parameter window, 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.