UPDATE TO MEDICAL DEVICE CORRECTION
Software Update Now Available
For All Models of
Claria MRI™ CRT-D SureScan™ and Amplia MRI™ CRT-D SureScan™

April 2017

Dear Physician or Healthcare Professional,

In December 2016, Medtronic issued an Urgent Medical Device Correction letter regarding a device software issue that involved a specific programming sequence that may result in loss of LV pacing in all models of Claria MRI™ CRT-D SureScan™ and Amplia MRI™ CRT-D SureScan™ devices.

Medtronic has now obtained the necessary regulatory approvals and is ready to begin applying a programmer software update (SW034 Software Version 8.2) to correct the issue in the devices. In addition, as previously described in the December 2016 letter (attached), the software update also addresses a transient mode switch behavior that may occur in MRI Quadripolar CRT-D device models (Claria MRI™, Amplia MRI™ and Compia MRI™).

Once installed by a Medtronic Representative on the programmer, an in-clinic device interrogation will update the patient’s device automatically. To prevent possible recurrence of the issues, the patient must continue to be programmed only with programmers that have this update. The loss of LV pacing issue will still occur if the specific programming sequence described in the original advisory letter is performed using a programmer not updated with SW034 Software Version 8.2.

Directions on how to apply this update to patient devices and to verify that devices are operating correctly can be found in Appendix A. If you have any questions, or if we can be of further assistance, please contact your local Medtronic Representative or Medtronic Technical Services at 800-723-4636.

Sincerely,

Tim Samsel
Vice President, Quality and Regulatory Affairs
Medtronic Cardiac Rhythm Heart Failure (CRHF)
Appendix A

Q1. How do clinics apply this software update to each patient’s device?
For Claria MRI™ and Amplia MRI™ devices or Quadripolar models of Compia MRI™ CRT-D SureScan™ devices, once SW034 Software Version 8.2 has been installed on the programmer, each patient’s device will automatically be updated during device interrogation by an updated programmer.

As long as a programmer with SW034 Software Version 8.2 is used at each subsequent in-clinic session, the device will not be susceptible to the issues. If a non-updated programmer is used for programming, the loss of LV pacing issue described in the December 2016 advisory may be re-introduced by the programming sequence described in the letter.

If an electrical reset occurs in a device (which will clear the update), the device update will automatically be re-installed during interrogation of the device with an updated programmer.

Note: The device update can only be installed via interrogation by an updated Medtronic programmer containing SW034 Software Version 8.2.

Q2. How can I verify whether a patient’s device has been updated?
To verify that all Claria MRI™ and Amplia MRI™ devices or Quadripolar models of Compia MRI™ devices have successfully received the update:

ON A PROGRAMMER:
- Generate a Strip Chart, Full Size or PDF printout of the Parameters screen
- Verify the Software Version indicates “SW034 Software Version 8.2” (see arrows - Figure 1a and 1b)
  If the software model does not indicate SW034 Software Version 8.2, the patient’s device will need to be interrogated with a programmer that has been installed with the updated software.

Figure 1a: Strip Chart Printout showing updated Software Version in the upper right corner.
Q3. If a patient's device has previously shown evidence of loss of LV pacing due to the issue described in the December 2016 advisory, how can I verify a Claria MRI™ or Amplia MRI™ device is operating correctly post-software update?

Interrogation with a programmer that has been updated to SW034 Software Version 8.2 will restore LV pacing. To confirm that LV pacing has been restored, view the ECG and EGM morphology waveforms.

The histogram LV and BiV pacing percentages will begin to update as soon as LV pacing is restored, but it will take some time for enough events to accumulate to materially impact the values in the Histogram Report. The Report will show appropriate LV and BiV pacing percentages at the next remote or in-office follow-up.

Note: To prevent possible recurrence of the issues, the patient must continue to be programmed only with programmers that have this update. The loss of LV pacing issue will still occur if the specific programming sequence described in the original advisory letter is performed using a programmer not updated with SW034 Software Version 8.2.
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. Medtronic Patient Services is available to assist patients at 800-551-5544.

If you have any questions, please contact your local Medtronic Representative or Medtronic Technical Services at 800-723-4636.

Sincerely,

Tim Samsel
Vice President, Quality and Regulatory Affairs
Medtronic Cardiac Rhythm Heart Failure (CRHF)

<table>
<thead>
<tr>
<th>Model Name</th>
<th>Product Model</th>
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<td>Amplia MRI™ CRT-D SureScan™</td>
<td>DTMB1D1, DTMB2D1, DTMB1D4, DTMB2D4</td>
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<tr>
<td>Amplia MRI™ Quad CRT-D SureScan™</td>
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<td>Claria MRI™ Quad CRT-D SureScan™</td>
<td>DTMA1Q1, DTMA2Q1, DTMA1QQ, DTMA2QQ</td>
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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](image)

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.