

## Update to Field Safety Notice Claria MRI™ CRT-D SureScan™ and Amplia MRI™ CRT-D SureScan™ Software Update

May 2017

Medtronic reference: FA747

Dear Physician or Healthcare Professional,

In December 2016, Medtronic issued an Urgent Field Safety Notice 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 approvals and is ready to begin applying a programmer software update 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 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 at.

Sincerely,



Mohamad El Khatib  
Business Manager - CRHF

### Appendices:

- A: Directions on how to apply the software update
- B: December 2016 Field Safety Notice

## 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 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?

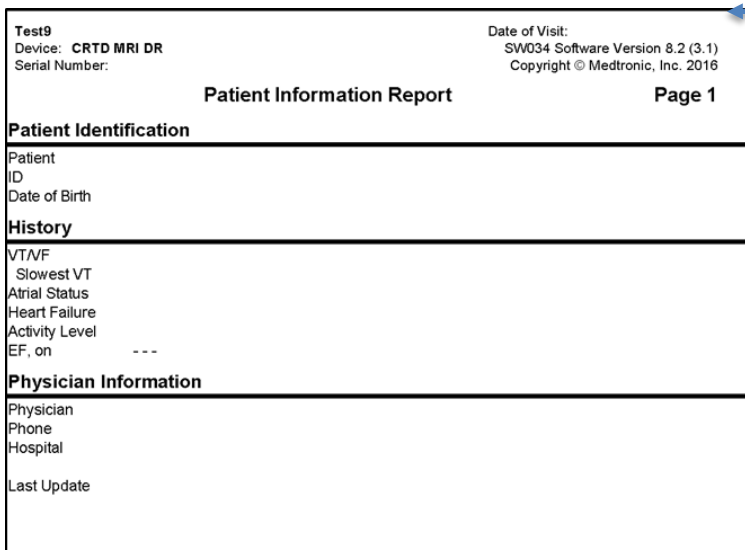
To verify that all Claria MRI™ and Amplia MRI™ devices or Quadripolar models of Compia MRI™ devices have successfully received the update:

#### 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



Test# Device: CRTD MRI DR Serial Number:	Date of Visit: SW034 Software Version 8.2 (3.1) Copyright © Medtronic, Inc. 2016	
<b>Patient Information Report</b>		<b>Page 1</b>
<b>Patient Identification</b>		
Patient ID Date of Birth		
<b>History</b>		
VT/VF Slowest VT Atrial Status Heart Failure Activity Level EF, on ---		
<b>Physician Information</b>		
Physician Phone Hospital Last Update		

**Figure 1b:** Full Page Printout showing updated Software Version in the lower left corner.

Parameters			
Device: CRTD MRI DR	Serial Number: I	Date of Visit:	
Patient:	ID:	Physician:	
<b>Pacing Summary</b>			
<b>Mode</b>	<b>Rates</b>	<b>CRT</b>	
Mode VVI	Lower 65 bpm	AdaptivCRT	Nonadaptive CRT
		V. Pacing	RV
<b>Pacing Details</b>			
	<b>Atrial</b>	<b>RV</b>	<b>LV</b>
Amplitude		6.00 V	
Pulse Width		1.50 ms	
Capture Management		Adaptive	
Amplitude Margin		2.0 X	
Min. Adapted Amplitude		2.00 V	
Acute Phase Remaining		120 days	
Sensitivity	0.30 mV	0.30 mV	
Pace Polarity		Bipolar	
Sense Polarity	Bipolar	Bipolar	
<b>Refractory/Blanking</b>		<b>Arrhythmia Interventions</b>	
PVAB Interval	150 ms	V. Sense Response	Off
PVAB Method	Partial	V. Rate Stabilization	Off
A. Blank Post AS	100 ms	<b>Post Shock Pacing</b>	
V. Blank Post VP	240 ms	Post Shock Pacing*	
V. Blank Post VS	120 ms	V. Amplitude	6 V
		V. Pulse Width	1.50 ms
		* Settings for first 25 beats post shock	
		Post VT/VF Shock Pacing	Off
<b>Additional Features</b>			
		Rate Drop Response	Off
		Sleep	Off
		MRI SureScan	Off
<b>Device Information</b>			
Device	Medtronic	CRTD MRI DR	
Device Configuration ID:	1-0-0		
SW034 Software Version 8.2 (3.1) Copyright © Medtronic, Inc. 2016			
Page 1		Printed: Parameters	

**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.