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URGENT MEDICAL DEVICE CORRECTION
Percepta™ CRT-P MRI SureScan™ and Percepta™ Quad CRT-P MRI SureScan™ Pacemakers

Model	Geography
W1TR01	US
W4TR01	US
W1TR04	OUS
W4TR04	OUS

June 2018

Dear Physician or Healthcare Professional:

This letter is to inform you of the potential for a device reset to occur in Percepta™ CRT-P MRI SureScan™ and Percepta™ Quad CRT-P MRI SureScan™ due to a timing interaction between the EffectivCRT™ Diagnostic and the Ventricular Safety Pacing feature (VSP). When an AP-VS interval measures 100-109ms during a short, nightly device check, a single reset is generated. This reset produces a non-programmable, wireless CareAlert™, but does not alter device therapy. If the device experiences more than five resets due to this timing sequence between in-clinic device interrogations, a full reset (sometimes referred to as a power on reset) will occur. By design, a full reset automatically reverts device operation to RV-only pacing at VVI/65 until the next programmer session is conducted – at which time the full reset condition can be cleared, and the device can be reprogrammed to its prior settings.

A Software update, Application SW040 Version 8.1, is available for installation onto all CareLink™ Model 2090 and Encore™ programmers to eliminate this issue. Once installed on a programmer, an in-clinic device interrogation will update the patient's device automatically to prevent this timing interaction from generating a reset. No changes to programmed device functionality will occur as a result of this device update.

Medtronic records indicate you are following one or more patients implanted with an affected Percepta CRT-P as noted in the enclosed Physician / Patient Detail Report. Approximately 12,364 Percepta devices manufactured prior to this software update have been distributed worldwide (7,803 in the U.S.). No other Medtronic pacemaker, ICD, CRT-D or CRT-P device models are susceptible to this issue.

Through June 14, 2018, Medtronic has confirmed 105 single reset events and 14 full reset events, with no (0) patient deaths or complications. If the Patient Management guidance provided below is followed, no additional resets due to this timing interaction will occur.

Patient Management Recommendations
In consultation with the Independent Physician Quality Panel, Medtronic recommends the following actions:

- Contact your local Medtronic Representative and schedule installation of the updated Percepta CRT-P Application Software (SW040 Version 8.1) onto Medtronic 2090 and Encore programmers.
- For a patient whose Percepta CRT-P device has experienced a Reset Alert or Observation:
  Consider scheduling an in-clinic device interrogation as soon as possible for the patient's device to receive the automatic update.
- For a patient whose Percepta CRT-P device has not experienced a Reset Alert or Observation:
  At their next scheduled in-clinic device interrogation, the patient's device will receive the automatic update.

How to verify a patient's device has received the software update:

• Ensure the programmer has been updated to Percepta Application Software "Version 8.1" by viewing the software installation history under the Programmer Icon; Refer to Image 1a and 1b in Appendix A.
• Interrogate the patient's device; Print the Parameters Report – Verify the Device ID listed at the bottom of the printout displays "Device Configuration ID: 1-0-0" or "Device Configuration ID: 1-1-0"; Refer to Images 2a and 2b in Appendix A.
• If the Parameters Report does not display the new Device ID number, verify that the correct software application has already been installed (SW040 Version 8.1).
  ○ If the programmer has not been updated, install Software Application SW040 Version 8.1 and re-interrogate the patient's device.
  ○ If the programmer has been updated and the Device Configuration ID is not 1-0-0 or 1-1-0, the patient's device was unable to successfully receive the update. Contact Medtronic Technical Services for additional instructions.

This notice must be passed to all those who need to be aware within your organization or to any organization where potentially affected devices have been transferred.

Medtronic will notify all applicable regulatory agencies about this matter.

Please complete the enclosed Clinician Confirmation Certificate and return via email to RS.CFQFCA@medtronic.com

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Complete and submit the report** Online**:** www.fda.gov/medwatch/report.htm
- Regular Mail or Fax**:** Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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 (Monday-Friday, 8 a.m.-5 p.m. Central Time). If you have any questions, please contact your local Medtronic Representative or Medtronic Technical Services at 800-505-4636.

Sincerely,

Chris Harrold
Vice President, Quality and Regulatory
Medtronic Cardiac Rhythm and Heart Failure

APPENDIX A

PROGRAMMER USER SCREENS

Software Installation History Screen
Image 1a

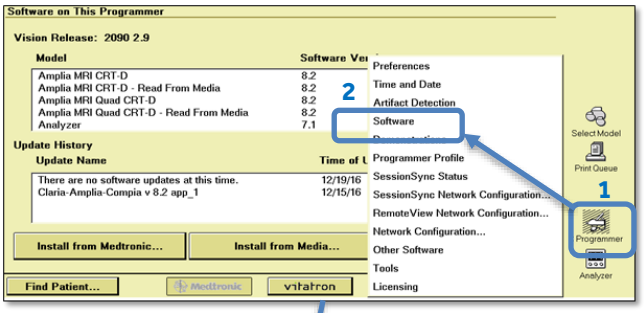
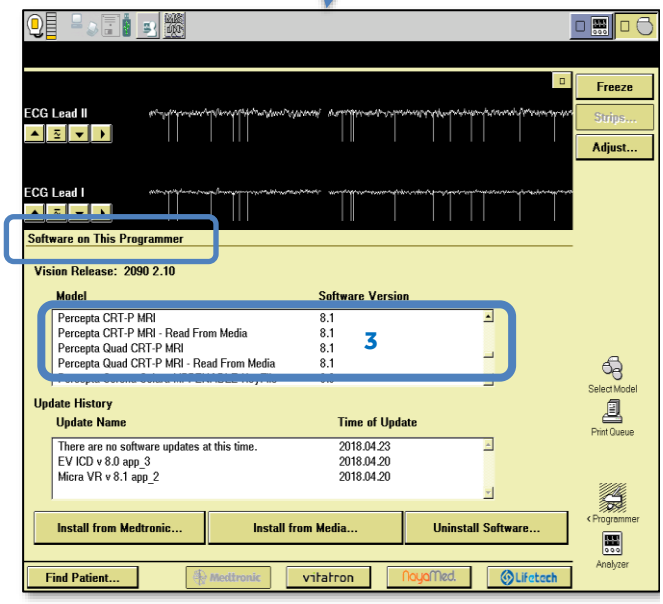


Image 1b



Parameters Report- Device ID Information
Image 2a

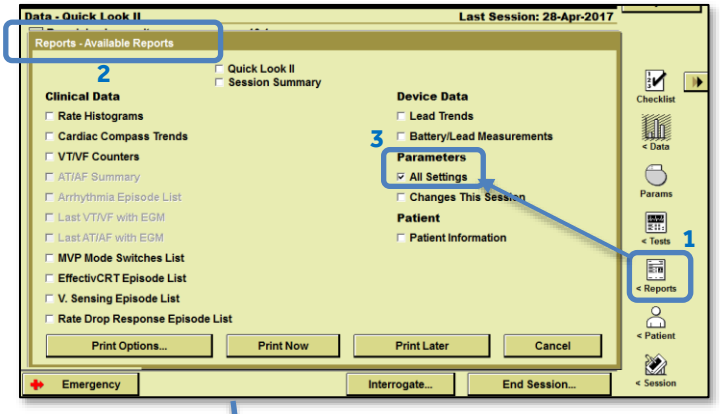


Image 2b