Medtronic

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Urgent Field Safety Notice
Programmer Software Update
Supporting the Micra™ Transcatheter Pacing System

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Model
2090 CareLink™ Programmer
29901 Encore™ Programmer
CareLink Network Application Software 2491

January 2019

Medtronic reference: FA856

Dear Risk Manager or Healthcare Professional,

This letter is to inform you of the availability of a software update for Medtronic 2090 CareLink and 29901 Encore programmers. The update is specific to the programmer software that supports the Micra Transcatheter Pacing System (TPS) device and is released under the **application software ID: Model SW022 version 8.1**. This software update corrects an error in how the programmer calculates and displays the remaining longevity value during a period of time (up to 2 years) prior to the device reaching its Recommended Replacement Time (RRT).

The software display error does not reflect any issues with the Micra TPS device battery, its ability to deliver therapy and to function as designed. The observed performance of the Micra TPS remains within published expectations.[1] No other Medtronic implantable device models are affected by this software display issue.

Software update Model SW022 version 8.1 is required to ensure that the correct remaining longevity estimate is displayed at all times during the life of the device. Without the software update, the displayed value during this period may remain static and reflect an over-estimation of the remaining longevity. Once the RRT voltage threshold is reached the correct remaining longevity estimate is once again displayed. Per labeling the time from RRT trigger to End of Service (EOS) is 180 days. The software display error was discovered internally. Through December 19, 2018 there have been zero (0) reports of this issue being observed in the field.

Through the end of calendar year 2019, it is estimated that 0.5% of early clinical devices would encounter an inaccurate longevity estimate during this period. The larger population of commercially implanted devices are not projected to encounter the issue until calendar year 2020. Updating programmers will eliminate this issue.

Note: A corresponding update to the CareLink Network Device Data Management Application Software was activated January 17, 2019 (coincident with the initiation of this communication). Therefore, any remote transmissions will already contain the software fix and the correct remaining longevity will be displayed through CareLink Network reports as of that date.

Customer Recommendations

- Work with your local Medtronic Representative and schedule installation of the programmer software update, **Micra Application Model SW022 version 8.1,** onto all CareLink Model 2090 and Encore Model 29901 programmers to eliminate this issue.
- Newly acquired programmers (including those received directly from Medtronic) must be checked prior to use to ensure they have the most up to date software and updated if needed.
- **No updates to a patient's device are required** since the issue resides only in the displayed value on the programmer.
- Refer to Appendix A for instructions on how to determine if your clinic programmers have been updated with software application model SW022 version 8.1 (Image 1) and how to identify if the programmer reports are reflecting the updated remaining longevity value (Image 2a and 2b).

[1]El-Chami, Michael F., et al. Updated performance of the Micra transcatheter pacemaker in the real-world setting: A comparison to the investigational study and a transvenous historical control. *Heart Rhythm.* 2018. DOI: https://doi.org/10.1016/j.hrthm.2018.08.005

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

The Competent Authority of your country has been notified 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

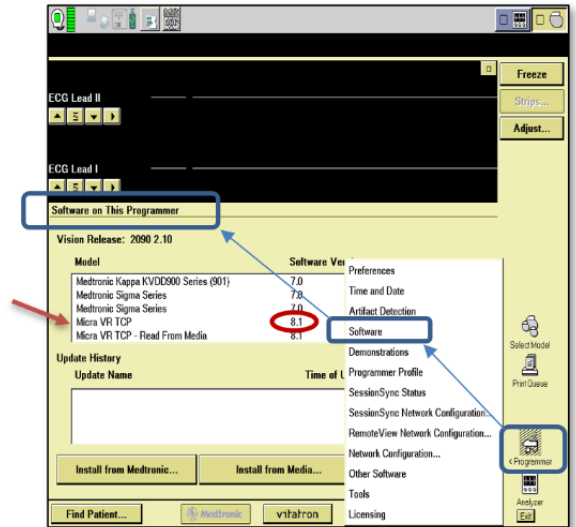## APPENDIX A: PROGRAMMER USER SCREENS

Software Installation History Screen
Correct software: Micra VR TCP version 8.1 (or higher)

From the Programmer start-up screen CANCEL out of the Find Patient window and Select the Programmer icon along the right-hand side of the programmer display:

- Select Software (see image 1)
- Scroll through the list of available Software Models in the top selection box until you locate the Micra selection
- Verify the Software Micra VR TCP Version is 8.1

Image 1

Battery/Device Measurements Report Software ID Information

Any CareLink transmission completed after January 17, 2019 will report the updated remaining longevity estimate. For in-clinic patients who have been interrogated via a programmer, the clinician can view the Battery and Device Measurements Report (Images 2a and 2b) and verify that the Software Application Model ID located in the lower-left corner of the report indicates "SW022 Software Version 8.1".

- Select Reports (see image 2a)
- Select Battery/Device Measurements
- Click Print Now
- Verify the software version printed on the lower left-hand corner is "SW022 Software Version 8.1"

Images 2a and 2b