ANZCDACC Product Defect Correction Notice 17th Jan 2019

Device: Programmer Software Update supporting the Micra Transcatheter Pacing System (TPS)

Medtronic 2090 Carelink Programmer, 29901 Encore Programmer, Carelink Network Application software 2491

ARTG: 116038 & 213024

TGA Reference: RC-2019-RN-00079-1

Advisory grade TGA: TBA

ANZDACC Advisory Grade: Routine

Number of CIEDs affected in Australia and New Zealand: ~ 400

Description:

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 Micra TPS. Without the software update, the displayed value during this period may remain static and reflect an over-estimation of the remaining longevity. Once the Recommended Replacement Time (RRT) voltage threshold is reached the correct remaining longevity estimate is once again displayed. Per labelling, the time from RRT trigger to End of Service (EOS) is 180 days, after which the device will switch to 'Device Off' mode.

No updates to a patient's device are required since the issue resides only in the displayed value on the programmer.

Any CareLink transmission completed after 17 January 2019 will report the correct remaining longevity estimate.

Risk:

The software display error was discovered internally. Through 19 December 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 trial 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.

Presentation:

If the 2090 CareLink or the 29901 Encore Programmer is used to interrogate a Micra TPS and the software version is 8.0 or less, the displayed 'remaining longevity' may be overestimated up to 2 years

Advice:

1. Ensure any 2090 or 29901 Programmers are updated with software application model SW022 version 8.1 prior to interrogating a Micra TPS. See Appendix A for detail on how to do this.

2. Review data from the most recent check on all Micra TPS implanted prior to 6th of December 2016 (TGA approval date). If the remaining longevity was reported as anything less than 3 years using the old software, ensure the patient is checked again within 180 days from the last interrogation to re-check the battery remaining longevity estimate. This can be done by either a remote monitor transmission through CareLink or an in-clinic check following the software update.

The ANZCDACC encourage you to report any adverse event or near (potential) adverse event associated with the use of a medical device including any abnormal CIED or lead function. We encourage reporting to ANZCDACC directly via the Committee chair Dr Paul Gould drpgould@gmail.com and to the following regulators.

In Australia, report to the TGA;

Online   https://www.tga.gov.au/reporting-problems

In New Zealand, report to Medsafe;

Post   Compliance Management Branch, Medsafe, PO Box 5013, Wellington 6145.

Email   devices@moh.govt.nz

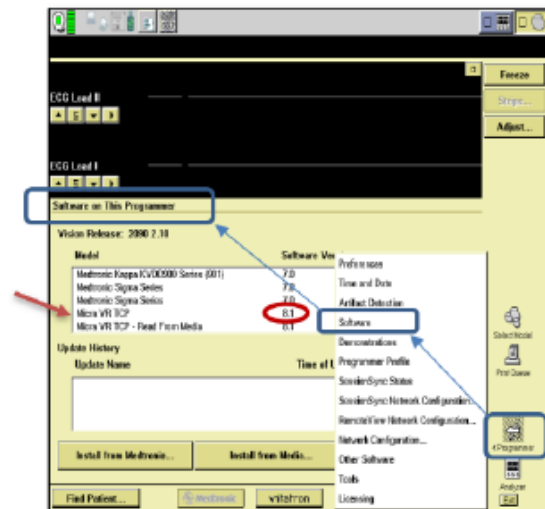Fax   04 819 6806

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 17 January 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