



Medtronic

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URGENT FIELD SAFETY NOTICE

Medtronic approval to enable “Rate Profile Optimization” (RPO) with Micra® TPS Software Version 1.1 Software Update

8 May 2015

Medtronic Reference: FA643

Dear Micra Transcatheter Pacing Study Investigator,

Medtronic is announcing approval to enable RPO where Micra® Transcatheter Pacing System software version 1.1 is available.

Background:

- Previously, RPO was required to be programmed to OFF per the Micra Clinical Investigation Plan (CIP), Version 2.0, Table 16.
- With commercially released Micra devices, it is left to the discretion of the Investigator whether to enable RPO in existing or new patients.
- The updated Micra software (Version 1.1) corrects an RPO firmware anomaly and revises nominal sensing settings. Refer to the updated Clinician manual for details.

Action Required:

1. All Micra 2090 programmers at your study site must be updated with software version 1.1 . Version 1.1 will be available via the Software Distribution Network (SDN) or via USB device. Your Medtronic Micra clinical representative will assist you in updating the Micra Clinical programmer(s).
Note: the protocol requires the investigational software to be updated prior to study closure if an updated version of software is commercially available prior to study closure (page 19 and 64).
2. When version 1.1 is downloaded on the programmers, please ensure any USB device with previous software (version 1.0) is returned to Medtronic or destroyed.
3. The Micra TPS Clinician Manual is available electronically at <http://manuals.medtronic.com>
4. Update the Software Device Disposition Log to: “Software overwritten with updated version” or “Software overwritten with commercially available/approved version” if you are an active Micra site.
5. Once RPO is enabled, CIP requirements for short exercise testing decrease; however, please continue to evaluate your subjects for postural sensitivity.
 - Pre-Hospital Discharge: Short exercise testing is no longer required at Pre-Hospital Discharge: per page 49 of the CIP, which indicates, “Once Medtronic announces approval to enable RPO, short exercise testing and manual adjustment of set points is not required at pre-hospital discharge.”
 - 1 Month Visit: Short exercise testing is only required for one vector (one short exercise test) at 1 month, per page 49 of the CIP, which indicates, “Once Medtronic announces approval to enable RPO, only one short exercise test is required at 1 month (on one vector), and manual adjustment of set point parameters is no longer required.”

Medtronic has notified the Competent Authority of your country of this action.

Contact your Medtronic Micra clinical representative with any questions.

Sincerely,

Keith Taverner Regulatory Affairs Manager UK and Ireland on behalf of: Mr Stephen John Allen Senior Clinical Research Specialist.