Medtronic Engineering the extraordinary

Explant of Implantable Devices at End of Service

CRM Technical Services Standard Letter

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The guidance provided in this letter is for healthcare providers and Medtronic representatives and applies to the following Medtronic device types:

This Standard Letter, as of October 2022, addresses the Explant of Implantable Devices at End of Service:
IPG – Implantable Pulse Generators (Pacemakers), except Micra VR™ and Micra AV™
ICD – Implantable Cardioverter Defibrillators
CRT-P – Cardiac Resynchronization Therapy Pacemakers
CRT-D – Cardiac Resynchronization Therapy Defibrillators

This Standard Letter addresses the rationale behind the need to explant a device once it has reached the end of its effective service life – commonly known as End-of-Life (EOL) or End-of-Service (EOS)

BACKGROUND INFORMATION - Regulatory Approved Labeling
Projected service life is the estimated time from Implant to Recommended Replacement Time (RRT) or Elective Replacement Indicator (ERI). Each implantable device is released with a(n) instructions for use manual approved by local regulatory agencies (where applicable), and this approved labeling includes general estimates on the projected service life of a device based on a discrete subset of use conditions.

PATIENT MANAGEMENT GUIDANCE AT RRT/ERI/EOS/EOL
Once RRT/ERI has triggered, approved labeling also provides a general statement that replacement of the device should be scheduled within a certain number of months following the observation of these events. This is commonly known as the prolonged service period (PSP), or the time from RRT/ERI until EOS/EOL. This time period (generally 1-6 months depending upon the type of device – see examples below) is based on a very specific set of use conditions. The use conditions for achieving the prolonged service period are specified in the labeling for each device model.

For example:
Adapta/Versa/Sensia include the following statements:
The Recommended Replacement Time (RRT/ERI) warns when the device battery is nearing depletion.
Caution: When RRT/ERI is set and verified, the pacemaker must be replaced within three months.

Attesta/Sphera: When RRT is set and verified, the pacemaker must be replaced within six months. When ERI is set and verified, the pacemaker must be replaced within 3 months. For details, refer to “Prolonged service period” in the applicable device manual.
Revo: If the displayed battery voltage is at or below the displayed RRT value or if the RRT indicator is displayed, schedule an appointment to replace the device.

Table 42. Recommended Replacement Time (RRT)

Device status indicator: Quick Look screen displays an RRT message	
Possible cause	**Suggested corrective action**
The battery voltage measurement was lower than the RRT voltage threshold for 3 consecutive days.	Schedule an appointment to replace the device.

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EnRhythm: If the displayed battery voltage is at or below the displayed ERI value or if the ERI indicator is displayed, schedule an appointment to replace the device.
EOL indication – If the programmer indicates that the device is at EOL, replace the device immediately

Advisa/Azure/Percepta/Serena/Solara
If the Recommended Replacement Time (RRT) indicator or Elective Replacement Indicator (ERI) is displayed, or if the battery voltage is at or below the displayed RRT voltage, contact your Medtronic representative and schedule a replacement procedure with your patient.
RRT (Recommended Replacement Time) - battery status indicator displayed by the programmer to indicate when replacement of the device is recommended.
Warning: Replace the device immediately if the programmer displays an EOS indicator. The device may lose the ability to pace, sense, and deliver therapy adequately after the EOS indicator appears.

CRT-D and ICDs
RRT (Recommended Replacement Time) – The programmer displays the RRT battery status to indicate that replacement of the device is recommended.
EOS (End of Service) – The programmer displays the EOS battery status to indicate that the device should be replaced immediately and may not operate per specifications.
Warning: Replace the device immediately if the programmer displays an EOS indicator. The device may lose the ability to pace, sense, and deliver therapy adequately after the EOS indicator appears

EXPLANT
Consider the following information related to device explant

- Explant the implantable device postmortem.
- In some countries, explanting battery-operated implantable devices is mandatory because of environmental concerns; please check the local regulations.
- Medtronic implantable devices are intended for single use only. Do not re-sterilize and reimplant explanted devices.

In summary, as battery capacity depletes and voltage nears the end of its useful life (as defined by the RRT/ERI threshold), regulatory agencies require that devices be explanted as noted in each device manual and highlighted by the examples above.

RATIONALE FOR EXPLANTING A DEVICE AT RRT/ERI/EOS/EOL

- Generally speaking, the electronics within an implantable device require a certain level of battery capacity and minimum battery voltage in order to support the therapies, diagnostics and other features available.
- There are environmental, clinical and electrical reasons for requiring explant of a device. Most notably, as the battery continues to deplete, the performance of the transistors (electrical switches) within the device will become unpredictable due to lack of sufficient current being supplied to these components.
- These transistors control a host of features including (but not limited to) the lead/battery measurements, shock delivery and pacing and sensing functions.
- Explant of a device following RRT/ERI within the timeframe recommended reduces the risk for erratic or unanticipated therapies, pacing, loss of pacing, loss of sensing, or other potentially harmful behavior.

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Labeling

Consult the appropriate individual device manual for specific guidance related to Explant at End of Service.
www.medtronic.com/manuals

***Adapta ADAPTA® ADDR01/03/06, ADDRS1/L1 Implant Manual*.** Manual Document Number: M960723A001 2016-06-15 REV.A, **www.medtronic.com/manuals**

***Adapta ADAPTA® / VERSA® / SENSIA® / RELIA Reference Manual*.** Manual Document Number: M965319A001 2016-09-24 REV.C, **www.medtronic.com/manuals**

***ADVISA DR MRI™ / ADVISA SR MRI™ SURESCAN™ A3SR01 Clinician Manual*.** Manual Document Number**:** M986837A001 2019-06-13 REV. B, **www.medtronic.com/manuals**

ATTESTA™ MRI SURESCAN™ / SPHERA™ MRI SURESCAN™ Reference Manual: Manual Document Number: M967436A001 2017-02-23 REV. A, **www.medtronic.com/manuals**

***Azure™ XT DR MRI SureScan™ W1DR01 Device Manual*.** Manual Document Number: M994942A001 2019-04-15 REV. A, **www.medtronic.com/manuals**

Azure™ XT SR MRI SureScan™ W1SR01 W1SR01 Device Manual. Manual Document Number: M994943A00 2019-04-15 REV. A, **www.medtronic.com/manuals**

CLARIA MRI™/CLARIA MRI™ QUAD CRT-D Reference Manual. Manual Document Number: M963432A001 2019-12-02. REV. D, **www.medtronic.com/manuals**

ENRHYTHM® P1501 DR Reference Manual. Manual Document Number: M950679A001 2013-04-12 REV. B, **www.medtronic.com/manuals**

***EVERA MRI™ SURESCAN™ DR DDMB1D1 Device Manual*.** Manual Document Number: M963601A001 2019-11-27 REV. C, **www.medtronic.com/manuals**

PERCEPTA™ / SERENA™ / SOLARA™ Reference Manual. Manual Document Number: M968096A001 2017-05-09 REV B, **www.medtronic.com/manuals**

REVO MRI® SURESCAN® RVDR01 Reference Manual. Manual Document Number: M954625A001 2013-12-06 REV. A, **www.medtronic.com/manuals**

Additional comments

For further information please contact the following:

Technical questions: Medtronic Technical Services can answer additional questions regarding these device operations.

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Device labeling: For additional device-specific guidance**,** consult the labeling associated with the device available on the Medtronic Manual Library website at www.medtronic.com/manuals

How to contact U.S. CRM Technical Services: Email: tshelp@medtronic.com
Pacemakers: (800) 505-4636, ICDs: (800) 723-4636, Programmer Support: (800) 638-1991

This information is verified for devices approved in the U.S. and may differ by country. For product-specific information on device operation and indications for use, reference the appropriate product labeling.