Medtronic
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URGENT MEDICAL DEVICE RECALL

EnTrust® <and Escudo®> VR/DR/AT ICDs

Model	Device Name
D154ATG	EnTrust
D153ATG	EnTrust
D154VRC	EnTrust
D153VRC	EnTrust
D144VRC	Escudo
D144DRG	Escudo

June 2018

Dear Physician or Healthcare Professional:

This letter is to inform you of the potential for loss of high voltage and anti-tachycardia pacing therapy in EnTrust <and Escudo> implantable cardioverter defibrillators (ICDs) as they near elective replacement indicator (ERI) voltage. Under certain circumstances, the device may display an immediate End of Life (EOL) Observation with no prior ERI alert. Though no ERI alert is triggered, there may not be enough remaining battery capacity to charge the high voltage circuits, resulting in an excessive charge time EOL Observation (refer to Image 1 in Appendix A), leading to a loss of high voltage and anti-tachycardia pacing therapy. Bradycardia therapies will continue to operate as expected.

Through June 15, 2018, Medtronic has confirmed 25 charge timeout events related to this issue, with no (0) patient deaths or complications. All events occurred during routine capacitor formation or in-clinic charge testing. Twenty-one (21) events occurred with no ERI alert; four (4) events followed an ERI alert. Time from implant to the devices experiencing the issue ranges from 7.9 – 11.7 years.

EnTrust <and Escudo> ICDs were last manufactured in 2010. Approximately 25,000 sold devices globally are in-scope of this advisory, with an estimated 2,770 of those devices remaining actively implanted worldwide (209 confirmed as active in the U.S.). The rate of occurrence in remaining active devices is estimated to be 0.00098 in single chamber ICDs and 0.00005 in dual chamber devices.

Patient Management Recommendations
We realize that each patient requires unique clinical considerations. In consultation with the Independent Physician Quality Panel, Medtronic recommends the following actions:

- Consider scheduling an in-office patient follow-up as soon as possible to assess the potential for this issue per the steps described below.
- Ensure the *Excessive Charge Time EOL…and the Low Battery Voltage ERI…* Patient Alerts have been programmed to "On-High" (Refer to Image 2 in Appendix A).
- Instruct patients to contact your office if they hear device alert tones. Consider utilizing the "*Demonstrate Tones. . .*" function to ensure patients recognize the audible tone.
- If this issue has occurred, an "*EOL: replace device immediately*" Observation will be displayed on the QuickLook report. Schedule device replacement immediately.

Additionally, Medtronic recommends the following actions to help ensure patient safety and effective high voltage therapy remain as the device battery voltage approaches its **2.61V ERI threshold**.

If Battery Voltage ≤ 2.64V:
Prophylactic device replacement should be strongly considered since the device is near its elective replacement and additional programming

would provide only minimal additional months of service. For patients for whom it is determined that delaying replacement is clinically desirable, contact Medtronic Technical Services.

If Battery Voltage > 2.64V:

Step 1: *If the* ***Auto-Cap Formation Interval*** *is set to "Auto", reprogram the value to "6" (Refer to Image 3 in Appendix A). Change from an "Auto" value to a fixed numeric value will ensure that an excessive charge time will trigger an audible patient alert.*

Step 2: *Conduct an in-clinic manual high voltage charge in "Tests – Charge/Dump" (Refer to Image 4a in Appendix A). DO NOT Dump the Test Charge as it will dissipate on its own and allow for capacitor reformation to occur.*

Step 3: *Retrieve Data after the Test Charge (Refer to Image 4b in Appendix A)*

- ***If Charge Time is less than 16 seconds,*** *no further action is required. Continue with routine follow-up per clinic practice (recommend 3-month follow-up sessions per labeling).*
- ***If Charge Time is 16 seconds or longer,*** *or an "EOL" Observation is displayed, schedule device replacement immediately.*

Medtronic will offer a supplemental device warranty for prophylactic replacements as defined under the patient management recommendations. Contact your Medtronic sales representative for terms and conditions. Medtronic will notify all applicable regulatory agencies about this matter. Please share this notification with others in your organization as appropriate.

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, 8am-5pm Central Time). If you have any questions, please contact your local Medtronic Representative or Medtronic Technical Services at 800-723-4636.

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

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

Sincerely,

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

APPENDIX A
PROGRAMMER OBSERVATION AND PROGRAMMING SCREENS

Image 1 - Excessive Charge Time EOL (Observation)

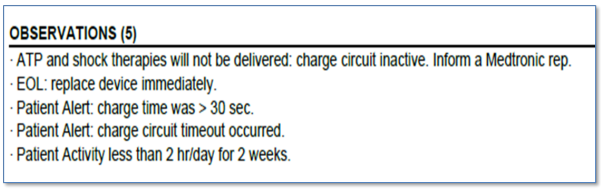


Image 2 – Excessive Charge Time EOL Alert (Programming Screen)

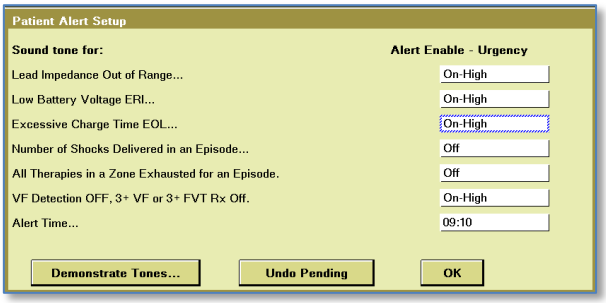
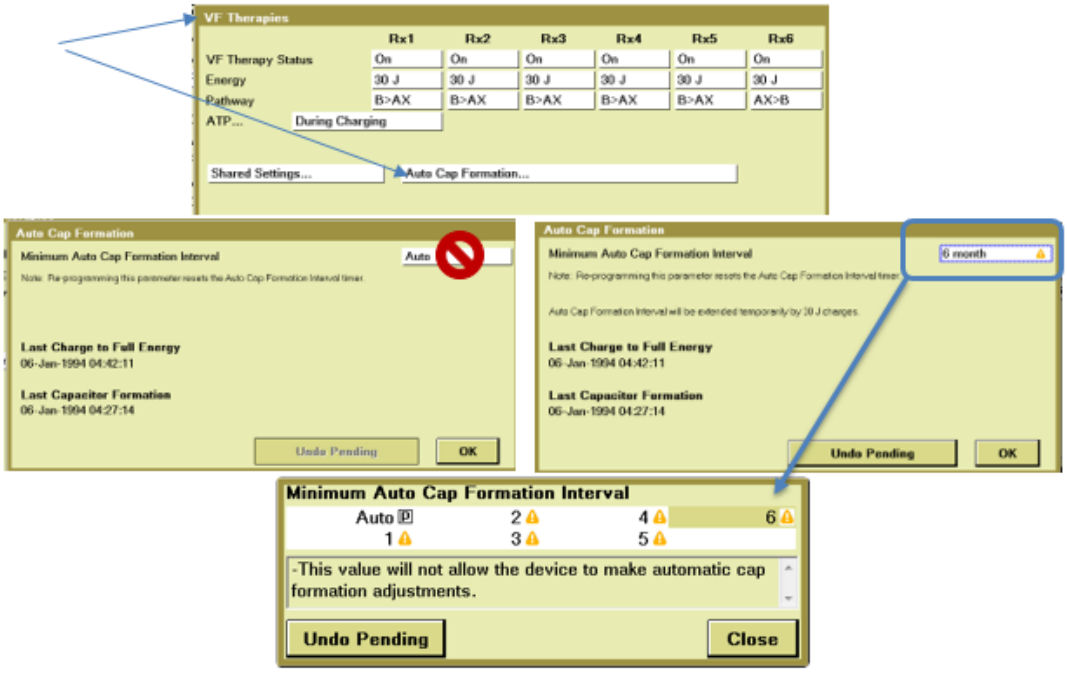


Image 3 – Programming Steps to Change Auto-Cap Formation Interval to Fixed value of 6-month intervals



Images 4a and 4b – Programming Screens to Conduct In-clinic High-Voltage Test Charge