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

27 June 2018

Dear Physician or Healthcare Professional:
CC: The Chairman Medical Board and Relevant Head of Departments
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. This notice must be passed to all those who need to be aware within your organization or to any organization.

Medtronic will notify all applicable regulatory agencies about this matter.

Please complete the attached Customer Confirmation Form in its entirety and return it as directed to confirm your receipt and understanding of this information.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your local Medtronic Representative.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required. We request that you contact Medtronic if you experienced quality problems or adverse events.

Sincerely,

[redacted]

Diana Teo
Quality System Manager
Medtronic

APPENDIX A

PROGRAMMER OBSERVATION AND PROGRAMMING SCREENS

Image 1 - Excessive Charge Time EOL (Observation)

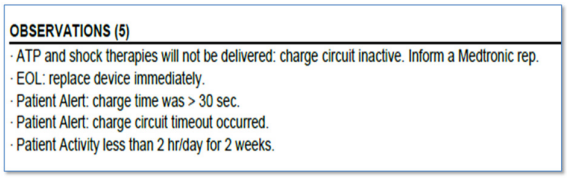


Image 2 – Excessive Charge Time EOL Alert (Programming Screen)

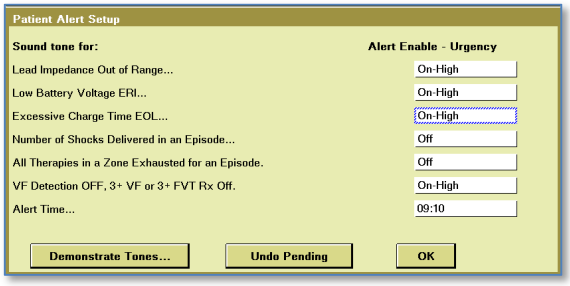
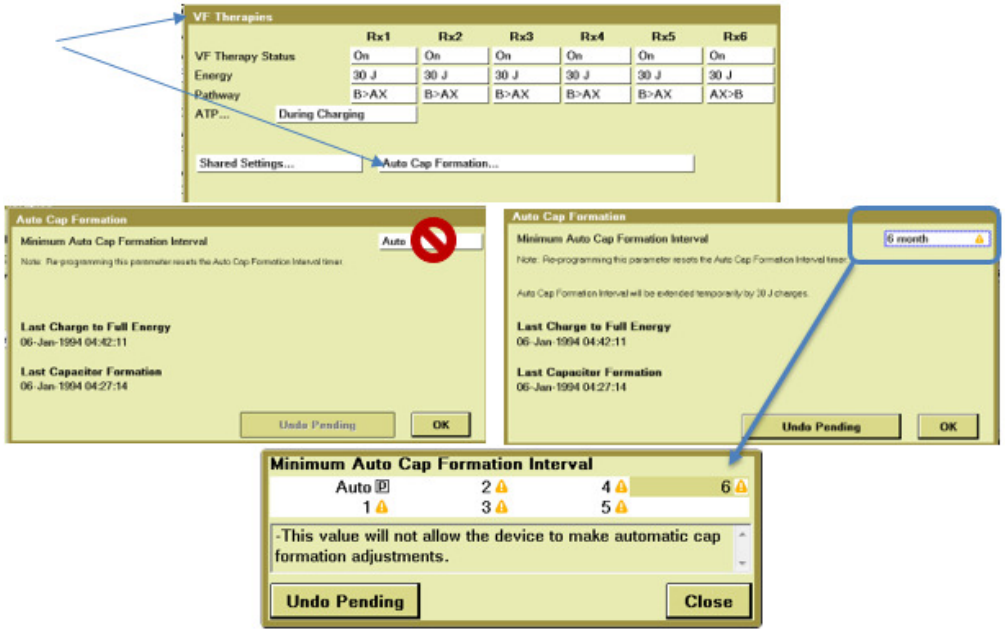
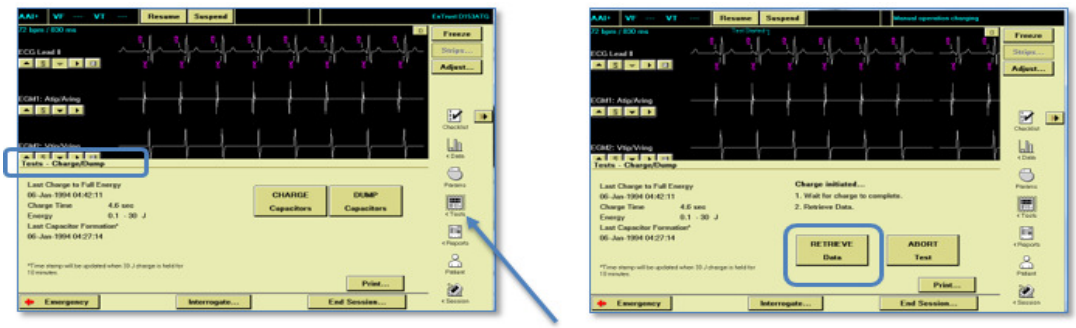


Image 3 – Programming Steps to Change Auto-Cap Formation Interval to Fixed value of 6-month intervals



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



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D144DRG	Escudo

Customer Contact Details	Medtronic Contact Details
Hospital / HCP/Patient:	**Name/Tel:**
	By E-mail:
Address:	**By Post:**
Telephone no:	
Fax no:	
E-mail:	

Product code	**Serial # of unit**

By signing this form, I confirm that I have read the ***Urgent Medical Device Recall*** **Notification Letter, dated 27 June 2018, from Medtronic regarding the EnTrust® and Escudo® VR/DR/AT ICDs, and taken appropriate action.** I also agree to further distribute and communicate this important information within my facility as required.

Name: _____ (print) Signature: _____ Stamp: _____ Date: _____