ST. JUDE MEDICAL

Field Safety Notice

Information on Device Software Upgrade Procedure for Fortify ST™ ICD Models CD1235-40, CD1235-40Q, CD2235-40, CD2235-40Q

18th April 2013

The Merlin PCS Programmer software Model 3330 versions 14.2.2, 16.2.1 and 17.2.1.1 provide new features for St. Jude Medical pacemakers, ICDs and CRT-Ds, including an option to enhance the ST diagnostic features in St. Jude Medical Fortify ST™ ICD models CD1235-40, CD1235-40Q, CD2235-40 and CD2235-40Q via a device software upgrade. During a device software upgrade, implanted devices are temporarily placed into the back-up pacing (BVVI)* and back-up defibrillation only (BDFO) mode. The back-up mode parameter settings will be in effect for the two minute upgrade process. Once the upgrade successfully completes, the device will revert to the previously programmed parameter settings. This letter is being provided to ensure that the operation of these devices during backup operation is clearly understood.

During backup mode operation, the device will function in BVVI/BDFO mode with the following settings:

Parameter	Setting	Parameter	Setting
Pacing Rate	67 min^{-1}	V. Post Sense Threshold Start	50%
Low Frequency Attenuation Filter	Off	V. Post Paced Decay Delay	0 ms
Ventricular Pace Refractory	321.5 ms	V. Post Paced Threshold Start	1.0 mV
Pacemaker Max Sensitivity	2.0 mV	SVT Discrimination	Off
Defib Max Sensitivity	0.3 mV	VF Detection Rate	146 min^{-1}
V. Post Sense Decay Delay	0 ms	HV Output Energy	36 J
*Upon entry into BVVI, up to 3 second pacing pause			

Depending on the individual patient, this temporary change in parameter values could make the device susceptible to oversensing and potentially deliver high voltage therapy during the upgrade procedure.

In order to prevent the potential for inappropriate therapy during the software upgrade process, **consider programming the "Tachy Therapy Enabled/Disabled" function to <u>Disabled</u>** prior to proceeding with the software upgrade. It is imperative to re-interrogate the device and program the **"Tachy Therapy Enabled/Disabled" function to Enabled** after the upgrade has been successfully completed.

As with any device evaluation and programming, ECG monitoring and availability of back up external defibrillation equipment is recommended during the entire software upgrade process.

St. Jude Medical remains committed to keeping customers informed about product performance. If you have any questions about the information above, please contact your local St. Jude Medical representative or our Technical Support Department at +46-8474-4147.

Sincerely,

Philip Tsung

Philip Tsung
Vice President, Quality Assurance

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