

## Physician Communication

### Important Device Upgrade Information – Epic & Atlas Family of ICDs

January 16, 2008

Dear Doctor,

St. Jude Medical is making a programmer software upgrade available to resolve and eliminate a very rare occurrence (incidence of 8 in 143,000 devices) that could lead to a ventricular sensing anomaly in our Epic and Atlas families of Implantable Cardioverter Defibrillators (ICDs). The new programmer software (version 6.4.1 for Merlin PCS and version 6.5.1 for Model 3510) will allow a programmer to automatically identify a device that can benefit from a firmware upgrade to resolve and eliminate the potential issue with a simple, one time device software upgrade.

St. Jude Medical Field Sales Staff and Field Clinical Engineers will install this software upgrade in Merlin PCS and Model 3510 programmers in the field. Thereafter, upon initial interrogation of an Epic or Atlas family ICD, the Merlin or 3510 programmer will automatically identify implanted devices that require a firmware upgrade and will inform the clinician with a message that an upgrade should be performed. The programmer will complete the device upgrade in approximately 10-20 seconds. During the upgrade process the device continues to function as programmed, with all bradycardia and tachycardia functions fully available.

Approximately 143,000 Epic and Atlas family ICDs have been implanted worldwide since July 2002; approximately 123,000 of these devices remain in service. To date, 8 out of 143,000 of the subject device population (an incidence of 0.00006) have been found to exhibit a loss of ventricular sensing, with a risk of patient harm estimated to be on the order of 1 in 1 million (0.000001).

The loss of ventricular sensing has been attributed to a well defined, yet extremely rare timing sequence that occurs in a very small (61 microsecond) timing window. No patient injuries or deaths have been reported to St. Jude Medical as the result of a device entering the described loss of sensing state. As mentioned above, the potential issue can be fully resolved and eliminated by a programmer initiated upgrade to the device.

In summary:

- A simple programmer software/device firmware upgrade will resolve the issue and prevent a future occurrence. Patients who are followed on a routine basis with scheduled follow-up visits every three to six months should continue with their scheduled visit. Upon interrogation of one of the subject devices, the Merlin and Model 3510 programmers with the newly provided software will automatically identify a device that can benefit from a firmware upgrade and will instruct the clinician that an upgrade is available.
- St. Jude Medical along with our independent Medical Advisory board members have determined that no other action is recommended.

If you have any questions or would like to discuss this topic in greater detail, please do not hesitate to contact your local Sales Representative or Technical Services at 800.722.3774.

Sincerely,

A handwritten signature in cursive script that reads "Kathleen M. Chester".

Kathleen Chester  
Vice President, Regulatory Affairs and Quality Assurance