



IMPORTANT PHYSICIAN ADVISORY

October 6, 2005

Dear Doctor:

This letter is written to provide you with important safety information regarding a memory chip component supplied to us and used in a limited number of St. Jude Medical ICD products within the Photon and Photon Micro device families and in certain Atlas devices.

Specifically, we have identified that a particular vendor-supplied memory chip can be affected at a low frequency rate by background levels of atmospheric ionizing cosmic radiation ("background cosmic radiation"). The anomaly can trigger a temporary loss of pacing function and permanent loss of defibrillation support. Our records indicate that you may have implanted or are monitoring patients with impacted devices.

There have been no serious patient injuries or deaths reported to St. Jude Medical that are attributable to this low frequency anomaly found in the subject memory chip component. To date, an incidence of only 0.00167 of the devices at issue (60 out of 36,000) have been found to have been affected by background cosmic radiation. Although this incidence level is low, we are taking a conservative approach in advising you and the medical community about this issue.

Affected Devices

This low frequency anomaly relates to a vendor-supplied static random access memory (SRAM) chip component found in the following St. Jude Medical ICDs:

Photon DR (Model V-230HV) (*certain serial numbers*)
Photon Micro VR/DR (Models V-194/V-232)
Atlas VR/DR (Models V-199/V-240)

Unaffected Devices

As part of a new ICD product platform introduced in 2002, and prior to our having any knowledge of this particular anomaly, St. Jude Medical began using a different vendor and a different design of the SRAM memory chip component. Laboratory testing and clinical experience indicate that this newer generation memory chip component does not share the same susceptibility to background cosmic radiation as the earlier generation. **Consequently, other St. Jude Medical ICDs and all models of CRT-D devices, including the Atlas DR model V-242 and all Epic, Epic HF, Epic +, Epic + HF, Atlas + and Atlas + HF product families, are not affected by this issue.**



Root Cause

As you may be aware, background cosmic radiation bombards the earth constantly. While the earth's atmosphere acts as a shield and absorbs much of the cosmic radiation, some amount of high energy particles do arrive at the earth's surface.

St. Jude Medical has determined that when the subject static access memory (SRAM) chip component is exposed to background levels of atmospheric ionizing cosmic radiation it can trigger a high current drain condition. St. Jude Medical has been able to replicate this condition in a nuclear laboratory. This has also been independently confirmed by the manufacturer of this component. St. Jude Medical has not identified any tests to predict if a particular device's memory chip component will exhibit this specific anomaly.

Clinical Manifestation

In the unlikely event that a device chip is affected by background cosmic radiation, the high current drain condition will deplete the battery voltage rapidly. This can result in loss of output for a period up to approximately 48 hours. During this period, the patient would be without pacing or defibrillation therapy. After this initial period, the battery will reach a voltage level at which the device will enter its "Hardware Reset Mode." This safety mode is designed to preserve the device's ability to provide VVI pacing support. A device that has been reset to the Hardware Reset Mode will operate in the VVI mode at 60 ppm, but will not be capable of providing tachycardia detection or therapy. This will be noted by a warning message on the programmer screen upon device interrogation.

Low Probability of Occurrence

Approximately 36,000 of the devices listed above have been implanted worldwide with approximately 26,000 of these devices still remaining in service. About 8,000 of these are in service in markets outside the United States.

The estimated incidence of an anomaly of this type in the listed devices is 0.00257 over the five year projected life of each device. To date, there have been 60 reported observations (an incidence of 0.00167) of the anomaly with 53 of these being observed following device implant (i.e. 7 devices were found to have been affected by background cosmic radiation prior to device implant). The nature of the anomaly is random and constant over time.

As depicted in the Table below, once implanted, the risk of a future occurrence decreases commensurately with the passage of time over the life of the ICD product.

Time From Implant	Estimated Incidence Rate*
0 days	0.00257
1 year	0.00209
2 years	0.00157
3 years	0.00102
4 years	0.00046

* Assumes five year projected life for device.

Overall reliability information about the affected ICDs, as well as about other St. Jude Medical products, can be found on our web site at www.sjm.com.

It is important to note that the opportunity for early detection will increase with more frequent follow-up intervals. As shown in the Table below, increasing monitoring frequency would reduce relative patient risk.

Follow-up Frequency	Probability of Occurrence**
6 months	0.0000163
3 months	0.0000082
1 month	0.0000027

* Predicted risk of patient requiring VT/VF therapy and not receiving therapy due to this anomaly during the indicated follow-up period. The analysis assumes that a typical ICD patient will experience a VT/VF event rate of 4.8% per year based on an analysis of observed event rates in major published ICD clinical trials.

Recommendations

We realize that each of your patients is unique and we support your clinical judgment in caring for your patients. To assist in your patient care and following discussions with our independent Medical Advisory Board, St. Jude Medical recommends:

- If it is not already your current practice, physicians should perform routine device monitoring every 3 months for patients with the affected models listed above.
- In determining whether additional patient management or follow up may be needed, consider the low failure rate for the anomaly and the unique medical needs and situation of each individual patient, including whether the patient is pacemaker dependent or at high risk for life-threatening arrhythmias.
- If a patient's device is found in the Hardware Reset Mode, you should arrange for device replacement as soon as possible.
- You should continue to provide the patients with the usual admonitions to keep scheduled appointments and to report all changes in symptoms.

Should you elect to replace a subject device in a specific patient (e.g. patients who are pacemaker dependent or receive frequent VT/VF therapy), St. Jude Medical will provide a replacement device at no cost.



St. Jude Medical Contact Information

Every employee at St. Jude Medical is dedicated to providing safe, reliable and sophisticated medical devices. We strive for perfection and are disappointed when any anomaly like this occurs. ICDs and pacemakers save thousands of lives each year, and we at St. Jude Medical will continue to do all we can to provide the tools that help people live longer, healthier, more productive lives.

-----If you have questions or comments, please feel free to contact your local St. Jude Medical sales representative or Technical Support at +46 8 474 41 47 (24-hours-support number).-----

Sincerely,

A handwritten signature in black ink, appearing to read 'Gabriel Kohanyi', set against a light gray grid background.

Gabriel Kohanyi
Vice President,
Quality Assurance
St. Jude Medical CRMD

A handwritten signature in black ink, appearing to read 'Eric S. Fain', set against a light gray grid background.

Eric S. Fain, M.D.
Executive Vice President,
Development and Clinical/Regulatory Affairs
St. Jude Medical CRMD