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Contact the company for a copy of any references, attachments or enclosures.

**Health Canada Endorsed Important Safety Information on
VENTAK PRIZM AVT[®], VITALITY[®] AVT and CONTAK RENEWAL[®] AVT**



June 17, 2005

Subject: Important Safety Information on VENTAK PRIZM AVT[®], VITALITY[®] AVT and CONTAK RENEWAL[®] AVT implantable cardiac defibrillators

Dear Health Care Professional,

This letter is intended to inform you of important safety information regarding all serial numbers of VENTAK PRIZM AVT[®], VITALITY[®] AVT, and CONTAK RENEWAL[®] AVT. Our records indicate that you have implanted or are monitoring patients that have these devices. This letter is intended to fully advise physicians and their patients about the problem and to limit adverse events.

Guidant's Cardiac Rhythm Management Quality System has determined that the atrial therapy (AVT) subgroups of certain Guidant ICD and CRT-D product families are subject to a condition in which a random memory error causes functional "latching" that limits available therapy. Engineering analysis has determined that latching can only occur when storing tachy detection/therapy episode information to affected memory. Two occurrences have been confirmed out of approximately 20,950 devices implanted to date; none have resulted in patient injury beyond device replacement. A software solution is expected by the end of this year.

Clinical Implications

Latching of AVT devices will suspend detection and treatment of atrial and ventricular arrhythmias. Telemetry and programming are not available. Brady pacing may continue, but will not be programmable and may not match programmed settings. In a latched state, battery usage may increase, but battery status indicators will not be available. In the event that latching occurs during delivery of ATP therapy, ATP therapy delivery could continue independent of patient need. Device replacement is required if latching occurs.

Guidant has developed a predictive engineering model to generate rate-of-occurrence probabilities described in Table 1. This table is based on Guidant's understanding of root cause, in conjunction with bench testing of returned product. If no programming actions are

taken, Guidant's model predicts that one additional latching event would occur worldwide before implementation of a software solution, which is expected by year-end.

Recommendations

Currently, programming options are available to further diminish the already very low probability of even one more latching event. Guidant recommends the following actions at the next regularly scheduled office visit:

- Verify normal device function using routine clinical follow-up procedures
- Program Atrial Tachy Episode Data Storage to 0% (Option B in Table 1)
- Review the rate of occurrence estimates in Table 1 to evaluate the additional risk reduction benefit of temporarily programming ATP therapy OFF (Option C in Table 1)

Table 1. Estimated Probability of Device Latching Prior to Software Solution (year end)

Programming options	Probability of latching	Probability of latching with continuous ATP therapy
A) No programming mitigation	0.005% (1 per 20,000 devices)	0.000265% (1 per 377,000 devices)
B) Program Atrial Tachy Episode Data Storage to 0%	0.000066% (1 per 1,520,000 devices)	0.00000352% (1 per 28,400,000 devices)
C) Program Atrial Tachy Episode Data Storage to 0% and program all ATP therapies to OFF	0.000066% (1 per 1,520,000 devices)	Zero ⁽¹⁾
Following implementation of a software solution (year-end)	Zero Return to normal programming	Zero Return to normal programming

(1) Although functional latching may still occur, it will not result in continuous ATP therapy.

Devices Impacted

Only atrial therapy AVT subgroups of Guidant ICD and CRT-D product families are impacted by this anomaly.

This issue does not impact standard ICDs and CRT-Ds.

Table 2. AVT Models Impacted Worldwide

Device Family	Model Numbers	Population Worldwide	Confirmed Events
VENTAK PRIZM AVT	1900	714	0
VITALITY AVT	A135, A155	19,446	2
CONTAK RENEWAL 3 AVT*	M150, M155	125	0
CONTAK RENEWAL 3 AVT HE*	M157, M159	37	0
CONTAK RENEWAL 4 AVT*	M170, M175	255	0
CONTAK RENEWAL 4 AVT HE*	M177, M179	369	0

*Under clinical investigation in some geographies.

Table 3. AVT Models Impacted in Canada

Device Family	Model Numbers	Population Canada	Confirmed Events
VENTAK PRIZM AVT	1900	16	0
VITALITY AVT	A135, A155	2	0
CONTAK RENEWAL 4 AVT*	M170, M175	6	0
CONTAK RENEWAL 4 AVT HE*	M177, M179	1	0

*Under clinical investigation.

To date, there have been no reported failures in Canada. A list with patients implanted with affected devices will be provided to physicians with this communication if applicable.

Future Actions By Guidant

Guidant is currently developing a non-invasive software solution for VITALITY AVT and all RENEWAL AVT devices. This solution is expected by year-end, pending regulatory approval. Upon first interrogation with new programmer software, VITALITY AVT and all RENEWAL AVT devices will no longer be subject to this anomaly. At that time, memory may be re-allocated as desired for atrial episode data storage and normal programming can be resumed.

While programming options discussed above will significantly reduce the risks of functional latching in a PRIZM AVT, estimates of normal service life for remaining PRIZM AVTs indicate that few will be in service by the time a software solution can be developed and approved. Accordingly, no software update will be developed for PRIZM AVT.

Further Information

We recognize the impact of this communication on both you and your patients, and want to reassure you that patient safety remains Guidant's primary concern. As always, if you have any questions regarding this communication, please contact:

- Your local Guidant representative;
- Guidant Technical Services USA at 1-800-CARDIAC (1-800-227-3422); or
- Scott Kadwell (Guidant Canada, CRM Country Manager at 1-800-268-4487, extension 75828.

The identification, characterization, and management of medical device-related adverse incidents are dependent on the active participation of health care professionals in adverse incident reporting programmes. Any occurrences of a specific adverse incident or other serious and/or unexpected adverse incidents in patients implanted with VENTAK PRIZM AVT®, VITALITY® AVT or CONTAK RENEWAL® AVT defibrillators should be reported to Guidant Canada Corporation or Health Canada at the following addresses:

Guidant Canada Corporation

505 Apple Creek Boulevard, Unit #4
Markham, Ontario L3R 5B1
(800) 268-4487
(905) 947-5800

Any suspected adverse incident can also be reported to:

Health Products and Food Branch Inspectorate
HEALTH CANADA
Address Locator: 3002C
Ottawa, Ontario K1A 0K9
Tel: The Inspectorate Hotline 1-800-267-9675

For other inquiries, please refer to contact information:

Marketed Health Products Directorate (MHPD)

MHPD_DPSC@hc-sc.gc.ca

Tel: (613) 954-6522

Fax: (613) 952-7738

The [Medical Devices Problem Report Form](#) and [Guidelines](#) can be found on the Health Canada web site.

http://www.hc-sc.gc.ca/hpfb/inspectorate/md_pro_rep_form_tc_e.html

http://www.hc-sc.gc.ca/hpfb/inspectorate/man_vol_pro_rep_md_entire_e.html

Sincerely,

original signed by

Scott Kadwell
Country Manager, Cardiac Rhythm Management
Guidant Canada Corporation