IMPORTANT PHYSICIAN ADVISORY
Vitatron T and C series pacemakers

February 2007

Dear Doctor,

This letter is to advise you about a software anomaly affecting Vitatron dual chamber C-series and T-series pacemakers. If these devices are programmed to specific parameters, this issue may present clinically as a reset of the pacemaker or inhibition of pacing if the patient’s intrinsic rate falls below the programmed lower rate. To date, we have received 28 reports of this anomaly out of approximately 77,000 devices sold (0.04%). There have been no reported patient injuries or deaths due to this issue.

Issue Summary
The issue can only arise with dual chamber Vitatron C-series and T-series pacemakers that are programmed to:

1. DDD(R) or DDI(R) mode with the Atrial Blanking on Ventricular Pace parameter set at less than 150 milliseconds (The nominal setting for this parameter is 150 milliseconds) or
2. VDD(R) mode, regardless of parameter settings

The issue cannot arise if the device is at nominal (factory) settings or programmed to any other mode. Vitatron estimates that approximately five percent of Vitatron dual chamber C-series and T-series pacemakers worldwide are programmed to susceptible parameters.

In rare instances under the parameters specified above, a software anomaly related to automatic retrograde conduction testing can inhibit the device from pacing if the patient’s intrinsic rate falls below the programmed lower rate. If the patient’s intrinsic heart rate drops to 24 beats per minute or less, restoration of pacing at programmed parameters or back-up pacing will occur automatically. However, if the issue occurs in a patient with an intrinsic heart rate greater than 24 beats per minute, the device will not reset unless interrogated and the patient may experience a return of bradycardia symptoms.

Affected Devices
The potentially affected Vitatron C-series models are C50A1, C50A2, C50A3, C60A1, C60A2, C60A3 and C70A3. The potentially affected Vitatron T-series models are T60A1 and T70A1. Not all device models have been distributed in all countries.
There are approximately 67,000 worldwide active dual chamber Vitatron C-series and T-series implants.

**Issue Resolution**

Vitatron has developed a programmer software update that will correct the anomaly automatically during device interrogation and prevent it from occurring in the future. The programmer software update (Suite VSE02 release 3.0 for 2090 programmers) has been approved by our Notified Body and will be distributed to you by your sales representative as soon as possible.

**Recommendations**

To assist physicians in their patient care and with input from our physician advisors, Vitatron offers the following recommendations:

- Review patient records and consider scheduling follow-up visits for patients with devices programmed to susceptible parameters (see Issue Summary) earlier than otherwise planned. Once the updated programmer software is installed, routine interrogation of the device during patient follow-up will correct the anomaly and prevent the issue from occurring in the future.

- **Vitatron does not recommend replacement of these devices prior to normal elective replacement.** Re-programming potentially affected devices to non-susceptible parameters will prevent the issue from occurring, and the anomaly is automatically corrected upon device interrogation after installation of the updated programmer software.

Vitatron is communicating this information to the appropriate regulatory agencies. The information in this letter will be posted on Vitatron.com on February 12, 2007.

We regret any difficulties this may cause you and your patients. If you have any questions, or if we can be of assistance, please contact your local Vitatron representative.

Sincerely,

Vitatron B.V.

Lucien van Os
Vice President and General Manager