

July 22, 2008

**URGENT - MEDICAL DEVICE CORRECTION**

Spacelabs Medical Telemetry Receiver – Model 90478

Dear Hospital Administrator/Biomedical Manager:

This letter is to inform you of a potential hazard associated with the use of Spacelabs Medical Telemetry Receiver, Model 90478. We have received a report from a hospital in the United States that a telemetry receiver module failed to alarm for low rate and asystole. The hospital reported that the patient later died. There were five reports in the Netherlands in 2004 and 2006 of telemetry receiver modules failing to alarm for high rate, low rate, VFIB or asystole, in one instance involving the death of a Do Not Resuscitate (DNR) patient.

We at Spacelabs Medical recognize and share your concern for patient safety. If you decide to continue to use the device, we have a way to mitigate the risk in the interim:

If you test each module for high rate alarm prior to each patient use, this will detect if the above alarm failure has occurred. If the failure exists, you can remove the module from the housing for 15 minutes to clear the failure. The failure will be cleared. Although the rate of occurrence is very low, the failure could reoccur. Thus we recommend testing the module prior to each patient use.

We have a software solution that will detect when the fault occurs. Once installed, the fault will trigger a high priority audio and visual alarm including a warning message on the screen warning you of the situation. By pressing a button on the screen, you will clear the fault by resetting the module. Module Configuration Manager (MCM) defaults will be restored and arrhythmia history will be lost.

We will be contacting you to schedule a mutually agreeable time to come to your hospital and update your module software at no cost to the hospital.

If you have any questions about this corrective action, please contact Spacelabs Medical at +49 9128 9160.