

May 12, 2011

URGENT - MEDICAL DEVICE CORRECTION

Spacelabs Medical Capnography Module, Model 91517

Dear Hospital Administrator/Biomedical Manager:

This letter is to inform you of a potential hazard associated with the use of Spacelabs Medical Capnography Module, Model 91517. During internal testing we discovered the Capnography module resets 20 seconds after power failure, instead of after three minutes as specified. This reset clears the RAM and the module returns to default settings. Any changes from default alarm settings will be lost. No one has been injured as a result of this failure.

We at Spacelabs Medical recognize and share your concern for patient safety. To mitigate this issue, we recommend you set all your Capnography Module Configuration Manager (MCM) alarm settings to ON.

Please weigh the benefits versus the risks when deciding whether or not to continue to use your Capnography modules until they can be upgraded. We recommend that you brief your staff about the possibility of losing changes to the default settings and to restore them after a power interruption.

Your field service engineer will be contacting you to schedule a mutually agreeable time to come to your hospital and upgrade your affected modules at no cost to the hospital.

If you have any questions about this corrective action program, please call Spacelabs Medical at 1-800-522-7025 and select 2 for Technical Support or, outside the United States, 1-425-657-7200 x5089.