



SPACE LABS
HEALTHCARE

1 Harforde Court, John Tate Road
Hertford, SG13 7NW
United Kingdom

Tel +44 (0) 1992 507700
Fax +44 (0) 1992 501213
www.spacelabshealthcare.com

25 September 2015

URGENT - MEDICAL DEVICE CORRECTION

Spacelabs Healthcare Ltd.

CardioCall ECG Event Recorder Models VS20, VS20x4, ST80, ST80x4 PCBA PN: 670-1670-00

Dear Hospital Administrator/Biomedical Manager/Office Manager:

Spacelabs Healthcare would like to inform you about a concern regarding certain CardioCall ECG Event Recorders installed at your facility. The information contained in this notice is intended to inform you about:

- The nature of the problem and the circumstances in which it can occur
- Actions the customer / user can take to minimize risk to patients or users
- Actions implemented by Spacelabs to correct the problem

Please circulate this notification to all persons concerned by the information it contains and add a copy to the appropriate system user manuals until such time as corrections have been implemented by Spacelabs.

As always, patient safety is a top priority at Spacelabs Healthcare as we partner with you to provide the best care experience to patients and their families.

We confirm that this notice has been sent to the appropriate regulatory agencies.

Sincerely,

Al Van Houdt
Sr. Mgr. Regulatory Affairs & Compliance



SPACE LABS
HEALTHCARE

An OSI Systems Company



Affected Systems	CardioCall ECG Event Recorder, Models VS20, VS20x4, ST80, & ST80x4 PCBAs – PN: 670-1670-00 Devices or PCBAs shipped between 23/Dec/2014 and 19/Aug/2015.
Description of Problem	This letter is to inform you of a potential issue with the CardioCall ECG Event Recorder. We have reports that when the battery is inserted into the device, the device beeps twice and is followed by a continuous ringing sound that only stops when battery is removed. The device has a self-test failure and will not operate normally. No one has been injured as a result of this issue.
Actions to be Implemented by Users	We at Spacelabs recognize and share your concern for patient safety. Please weigh the benefits versus the risks when deciding whether or not to continue to use your CardioCall ECG Event Recorders until they can be replaced. We recommend that you brief your staff regarding the failure mode listed above.
Corrective Actions conducted by Spacelabs	To correct this situation, Spacelabs Healthcare will send you a replacement CardioCall ECG Event Recorder(s) at no cost to you. We will provide a prepaid method to ease the return of the affected CardioCall device(s) back to Spacelabs.
Information and Technical Assistance	If you have any questions about this corrective action program, please contact Corona Vitas at Falkevej 22, Køge, call +45 (46) 15 54 08 or email support@coronavitas.dk for Technical Support.

