

17 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:

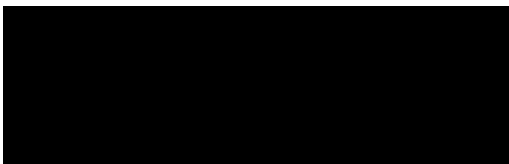
Spacelabs Healthcare would like to inform you about a concern regarding certain CardioCall ECG Event Recorders installed at your facility. The information contained in this notice is intended to inform you about:

- 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.



Al Van Houdt
Sr. Mgr. Regulatory Affairs & Compliance

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| <p>Affected Systems</p> | <p>CardioCall ECG Event Recorder, Models VS20, VS20x4, ST80, & ST80x4 PCBAs – PN: 670-1670-00 Devices or PCBAs shipped between 02/Mar/2015 and 19/Aug/2015.</p> |
| <p>Description of Problem</p> | <p>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.</p> |
| <p>Actions to be Implemented by Users</p> | <p>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.</p> |
| <p>Corrective Actions conducted by Spacelabs</p> | <p>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.</p> |
| <p>Information and Technical Assistance</p> | <p>For additional information or technical assistance, please contact:</p> <p style="padding-left: 40px;">Global Technical Support Spacelabs Healthcare, Ltd. 1 Harforde Court, John Tate Road Hertford SG13 7NW United Kingdom + 44 (0) 1992 507700</p> <p>For USA Technical Support call 1-800-522-7025 and select 2 for Technical Support</p> |

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