December 8th, 2020

# URGENT MEDICAL DEVICE CORRECTION

## Spacelabs Healthcare Ltd.

## Sentinel V10.x & V11.x, Models: 98200 & 98201

Dear Sir or Madam,

Spacelabs Healthcare would like to inform you about a potential concern regarding Sentinel. 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

Please circulate this notification to all persons affected by the information it contains.

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

The Regulatory (Competent) Authority of your country has been informed about this communication.

Please also complete and return the attached customer reply form or use the below link to acknowledge receipt of this letter.

- https://www.spacelabshealthcare.com/support/recall-reply-form/

If you have any questions about this Customer Alert, please contact Spacelabs at +44 (0) 1992 507740 and ask for Global Technical Support, or email gtsdc@spacelabs.com

Sincerely,

Roger Moldon
Director, Quality and Regulatory, Cardiology
Spacelabs Healthcare Ltd.

SPACELABS
HEALTHCARE

An OSI Systems Company

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Sentinel, Models: 98200 & 98201

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| **Affected Systems** | Sentinel systems that have been upgraded from Version 9 or below to Version 10 or above. |
| **Description of Problem** | During upgrade from Sentinel V9 or below to any later version, incorrect comments may be added to existing reports stored in the system. |
| **Identification of Risk** | Our investigation has concluded that any system that has been upgraded from Version 9 or below to a later version is at risk. In such instance:<br><br>• **Resting ECG** reports which <u>did not contain comments</u> at the time of the upgrade, may have unrelated comments added. Existing comments will not be overwritten or removed. This will affect ECG tests from the following devices.: **CD12USB, CardioExpress (All Models), Voyager (All Models), CardioCollect, CD12**<br><br>• **ABP** reports which <u>did not contain comments</u> at the time of the upgrade, may have unrelated comments added. Existing comments will not be overwritten or removed. This will affect ABP tests from the following devices.: **TR NIBP II, 90207, 90217, 90217A, 90227**<br><br>• **Holter** test reports which <u>did not contain comments</u> at the time of the upgrade, may have unrelated comments added. Existing comments will not be overwritten or removed. This will only affect Holter test reports that were analysed by the following analysers.: **Lifescreen, Impresario**<br><br>    o  If a **CardioNavigator+** database was imported into Sentinel V9 prior to the upgrade then all test comments associated with imported tests would be removed. *Note that CardioNavigator+ only supported Impresario and no other test types*<br><br>• **Stress** tests <u>which did not have comments</u> added within the Sentinel "Review Report" screen prior to the upgrade, may have unrelated comments appended to the stress report PDF. Existing comments will not be overwritten or removed. This will affect Stress tests from the following devices.: **CH2000, HearTwave II**<br><br>• **Imported PDF** files <u>which did not have comments</u> added within the Sentinel "Review Report" screen prior to the upgrade, may have unrelated comments appended to the PDF report. This will not affect comments already within the imported PDF file. Existing comments previously added within Sentinel will not be overwritten or removed.<br><br>• **Rhythm ECG** Tests may have comments overwritten with unrelated comments. This will affect ECG tests from the following devices.: **CD12USB, CardioCollect, CD12**<br><br>The exception to this is where a database was imported from **CardioNavigator** into Sentinel V9 prior to the upgrade then the tests listed above will be affected even if the comments are not blank.<br>No other data such as ECG waveforms, blood pressure values, or statistics are affected in any way. The issue only occurs at the time of the upgrade; any tests created after the upgrade are not affected. |

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| **Actions to be Implemented by Users** | Any comments associated with reports from the above tests that existed in your system prior to the date of your upgrade should be re-reviewed for accuracy before being used to inform any clinical decision.<br><br>We at Spacelabs are committed to customer care and clinical satisfaction. Please weigh the benefits versus the risks when deciding whether to use the comments associated with these tests which existed in your system prior to the date of your upgrade of Sentinel.  We recommend that you brief your staff regarding the issue listed above. |
| **Information and Technical Assistance** | For additional information or technical assistance, please contact:<br><br>Global Technical Support<br>Spacelabs Healthcare, Ltd<br>Unit B, Foxholes Centre,<br>John Tate Road, Hertford SG13 7DT<br>+44 (0) 1992 507740 and ask for Global Technical Support<br>Or email: gtsdc@spacelabs.com |

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