SPACELABS
HEALTHCARE

13/April/2023

URGENT MEDICAL DEVICE CORRECTION

UltraView SL (UVSL) Command Module

Suspend Processing Feature

Introduction

Spacelabs Healthcare has been made aware of an instance of user confusion associated with the Suspend Processing feature of the Ultraview SL (UVSL) Command Module that may have contributed to a patient death. The potential confusion may be exacerbated by customers using multiple versions of the device software. We are sending this notification to make our customers aware of this potential misunderstanding and/or misuse and to explain how the Suspend Processing feature functions with all software versions on the UItraView SL Command Module to reduce any risk of user confusion or misuse. Spacelabs has received no additional reports of relevant misunderstanding, misuse, or adverse events.

Please make sure all product users are made aware of this potential for confusion and misuse to reduce the risk of serious injury or death.

Device Indication for Use

The Spacelabs USVL Command Module is intended for use with the Patient Care Management System (PCMS) to acquire, monitor, and process various clinical parameters from an adult or neonate/infant populations in any type of clinical environment other than home use. Physiological parameters that may be monitored include ECG with arrhythmia detection, respiration, invasive and noninvasive blood pressure, temperature, oxygen saturation (SpO2), and cardiac output. Acquired data may then be communicated to an information network for display, recording, and analysis.

Background of the Problem

Spacelabs has received a customer complaint that expressed that user confusion regarding alarm status may have contributed to the death of a patient. The user had suspended parameter processing and alarms. During the time the parameter processing and alarms were suspended, the patient had suffered an undetected cardiac event that resulted in the death of the patient. As ECG/Respiration

processing and alarms were suspended, no alarm occurred. The user did not detect the patient's cardiac event and did not medically intervene in a manner that may have prevented the patient's death.

Spacelabs investigated the medical device software and concluded that user misunderstanding and error may occur and result in serious injury or death when 1) a user places the product in Suspend status AND they or another user fails to recognize the device alarms are not active, and 2) An unmonitored patient becomes unstable (i.e. rhythm or vital signs deteriorate) requiring urgent medical response AND the medical response is not provided.

Spacelabs has determined that this field notification is necessary and appropriate to ensure that all customers and users are made aware of this potential for confusion and error that could result in an adverse event.

Spacelabs has received no additional reports of relevant misunderstanding, misuse, or adverse events.

Discussion of the Potential User Error

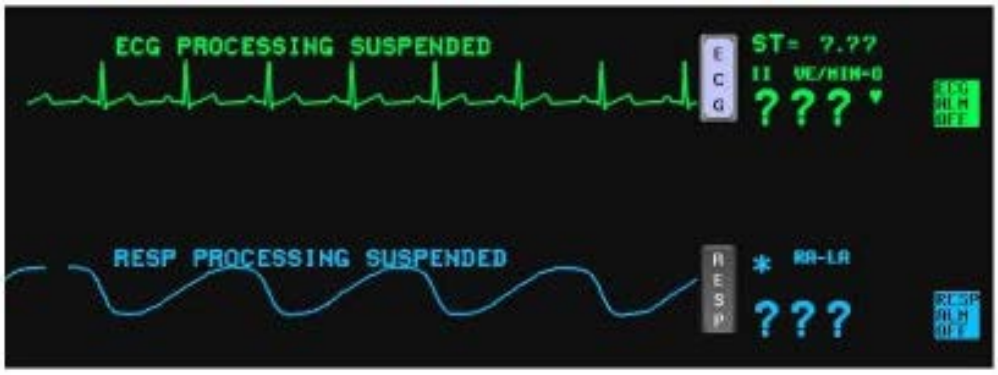
The Suspend Processing feature is designed to allow the users of the device to temporarily pause alarms and analysis of the patient without the need to discharge and readmit each patient. This can be used when a patient who is connected to the device needs to be taken to another location for testing or if the electrodes are needed to be replaced without triggering a lead off alarm. **Regardless of the version of software, when a parameter is suspended by the user, all alarms for that parameter are disabled.**

There are two possible display formats for the user interface of the device when Suspend Processing is engaged, depending on the version of the software.

Software v. 2.03.06 and earlier

In software versions up to and including version 2.03.06, as in the case of the Complaint discussed above, "Processing Suspended" messaging overlays the waveforms, question marks (?) replace the typically found numerical data, and there is an "alarm off" symbol on the far right of the parameter zone while the product in in Suspend status. The patient's ECG and Respiratory waveforms remain displayed in the parameter zone of the user interface while the product is in Suspend status.

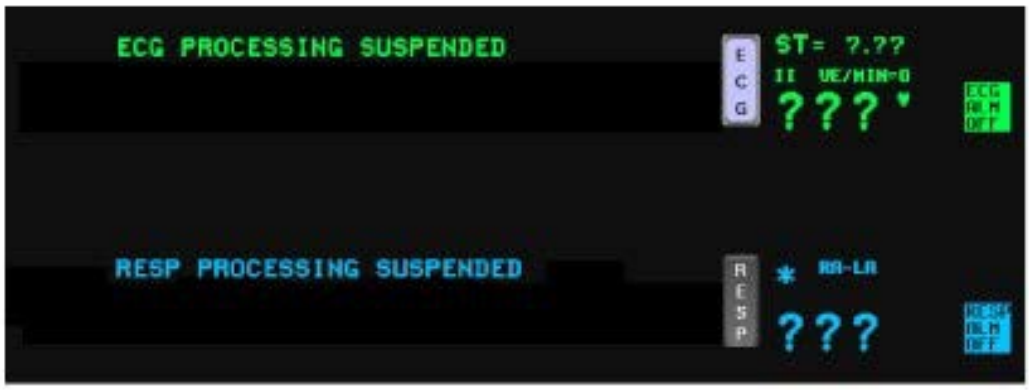
Shown below is an example of the display while processing for ECG and Respiration is suspended.



Suspended Processing in versions up to and including 2.03.06

Software v. 2.04 and later

Similarly, in software version 2.04 and later, “Processing Suspended” messaging overlays the waveform zone, question marks (?) replace the typically found numerical data, and there is an “alarm off” symbol on the far right of the parameter zone while the product in in Suspend status; however, the active patient waveforms are no longer displayed. We believe that the halted display of parameter waveforms more clearly communicate that the product is in Suspend status. For example:



Suspended Processing in versions up to and including 2.04 and higher

Exacerbated Risk when using both 2.03.06 or earlier AND 2.04 and later software

We believe the risk of confusion and potential for error is most significant when a customer simultaneously uses multiple versions of the product software, notably 2.03.06 and earlier (displaying active ECG and Respiratory waveform during Suspend status) with software 2.04 and above (no waveform displayed during Suspend status). With such mixed version use, a user accustomed to seeing no active waveform during

Suspend status (versions ≥ 2.04) may be confused when seeing the active patient waveforms while in Suspend status (versions ≤ 2.03.06) and mistakenly believe that the product is actively processing parameter data and alarms are active when they are not. Again, in such cases, any triggering physiological alarm conditions would not result in an alarm and the failure to detect the condition could result in serious injury or death.

Recommendations

It is Spacelabs Healthcare's recommendation that users must be adequately trained on all versions of the product that will be used. Please provide this notification and/or communicate correct and appropriate use to all users. Ensure that all users are aware that Suspend Processing status means that all parameter processing and alarms are stopped and will not function. The Suspended state must be manually re-engaged by pressing the "Resume Processing" button to return to active processing and return the alarms to the intended operation.

Acknowledgment Requested

Spacelabs requires that all customers and distributors acknowledge receipt and understanding of this notification by returning the included reply form.

Please pass this notice on to those who need to be aware within your organization or to any organization where the potentially affected devices are being used.

Questions regarding this correction can be directed to your Spacelabs Service Representative at the contact information listed below.

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Sincerely,

Zachary Orlowski

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Head of Product Management

Spacelabs Healthcare, Inc.