Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 109 **dated** 29/5/23 **Regarding NCMDR Field Safety Notice of Ultraview SL (UVSL) Command Module from (mfr: Spacelabs Healthcare Inc).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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سلطنة عُمان
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مسقط

Circular No. 109 **/ 2023**

09 -11-1444 H
29 -05-2023

Field Safety Notice of Ultraview SL (UVSL) Command Module from Spacelabs Healthcare Inc.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19540
Product	Ultraview SL (UVSL) Command Module.
Description	Detector and alarm, arrhythmia.
Manufacturer	Spacelabs Healthcare Inc.
Local agent	Bahwan Healthcare Center LLC.
The affected products	Model 91496 Software version 2.03.06 and earlier and software version 2.04 and later.
Reason	User confusion associated with the Suspend Processing feature of the Ultraview SL (UVSL) Command Module that may have contributed to a patient death.
Action	1. Users must be adequately trained on all versions of the product that will be used. Please provide the attached FSN 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. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

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P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
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SPACELABS
HEALTHCARE

31/March/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 UltraView 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

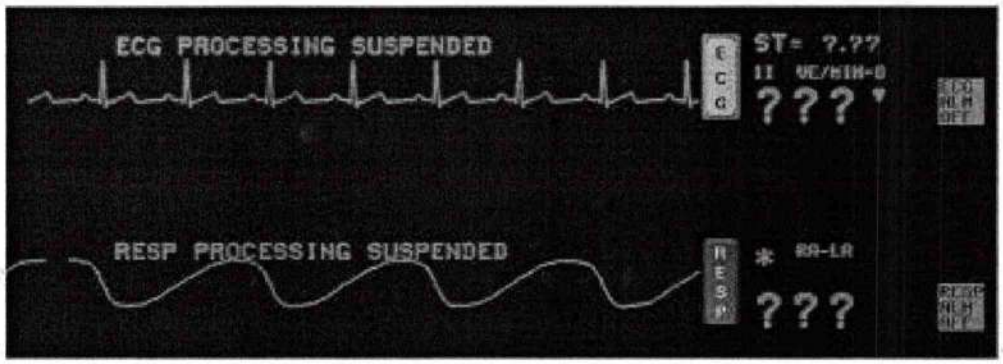
The Suspend Processing feature is designed to allow the users of the device to temporarily pause alarms and analysis of the patient without the need to discharge and readmit each patient. This can be used when a patient who is connected to the device needs to be taken to another location for testing 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.

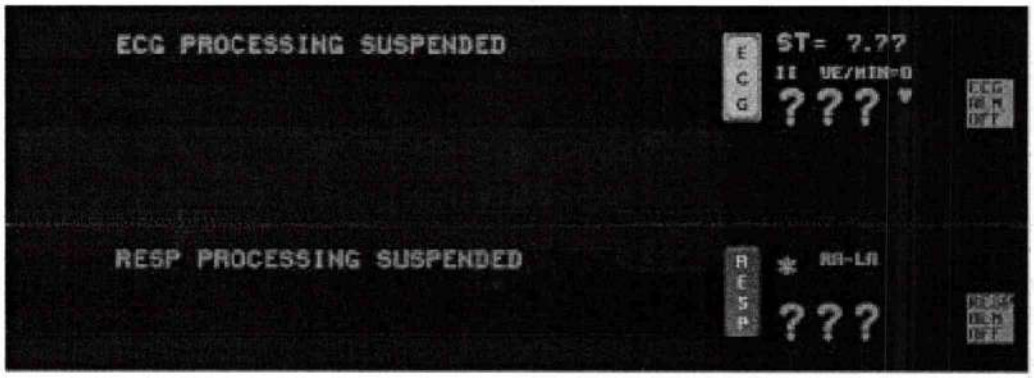
Shown below is an example of the display while processing for ECG and Respiration is suspended.



Suspended Processing in versions up to and including 2.03.03

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 2.03.03 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 requests that all customers acknowledge receipt and understanding of this notification by either mailing the included PDF copy of the response form or by completing the online form which can be accessed by using the URL below:

https://spacelabshealthcare.com/support/recall-reply-form/2023-00001-c/

Please pass this notice on to those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Questions regarding this correction can be directed to Spacelabs Healthcare Technical Support at 1-800-522-7025 and select option 2.

Sincerely,

Zachary Orlowski

Zachary Orlowski

Head of Product Management

Spacelabs Healthcare, Inc.

SPACELABS
HEALTHCARE

NON-EU Distributor/Importer Reply Form

1. Recall information	
Reference number*	Z-1503-2023
Recall Date*	3rd May 2023
Product/ Device name*	Ultraview SL (UVSL) Command Module
Product Code(s)	91496 software 2.03.06 & 2.04

2. Distributor/Importer Details Distributor	To be completed by the
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	brian.mcclorey@spacelabs.com
EMEA FCA Helpline	+49 163 75234 81
Deadline for returning the Distributor/Importer reply form*	31.05.2023

4. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	**MANDATORY**
☐	I confirm that my local Competent Authority will be informed	Customer letters sometimes contain a statement that the authorities have been informed. This statement is for EU Distributors only
☐	I confirm that I will identify all affected Customers, and document their acknowledgments locally	Spacelabs maybe required to provide evidence that your affected Customers have been informed.
☐	Neither I nor any of my customers has any affected devices in inventory	Spacelabs maybe required to provide evidence that Customers are not affected.
Print Name*		
Signature*		
Date *		

Mandatory fields are marked with *
Strike through all N/A questions

It is important that your organization takes the actions detailed in the recall notification and confirms that you have received the recall notification.

Your organization's reply is the evidence we need to monitor the progress of this corrective action.