SPACELABS HEALTHCARE

FSN Ref: Manufacturer's ref number FSCA Ref: Manufacturer's ref number

Date: 11 Apr 2023

Urgent Field Safety Notice
Ultraview SL (UVSL) Command Module, Model 91496

For Attention of all the customers who are using software versions prior to 2.04 used in combination with software versions 2.04 and above of the Ultraview SL (UVSL) Command Module, Model 91496.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Spacelabs Healthcare, Inc.35301 SE Center St, Snoqualmie, WA 98065, United States of America

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Urgent Field Safety Notice (FSN)
Ultraview SL (UVSL) Command Module, Model 91496
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The Spacelabs Multi-parameter 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.
1.	2. Commercial name(s)
	Spacelabs Ultraview SL Command Module, Model 91496
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	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, editing and analysis.
1.	5. Device Model/Catalogue/part number(s)*
	91496
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	343 Affected Sites
1.	8. Associated devices
	96102 Xhibit® Central Station 91393 Xprezzon® Bedside Monitor 91390 Qube® Compact Monitor 91389 Qube® Mini Transport Monitor

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	None
2.	2. Hazard giving rise to the FSCA*
	The severity was determined to be "Catastrophic," as the failure to detect a cardiac event could lead to patient death.
2.	3. Probability of problem arising
	The probability of occurrence was determined to be "remote." It was conclude that users may occasionally use multiple versions of the product without adequate training and encounter the potential for the described user error. Improving user awareness of the various display states will reduce the probability of occurrence of the user error
2.	4. Predicted risk to patient/users
	The severity was determined to be "Catastrophic," as the failure to detect a cardiac event could lead to patient death.
2.	5. Further information to help characterise the problem
	Include any further relevant statistics to help convey the seriousness of the issue.

2.	6. Background on Issue
	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.
2.	7. Other information relevant to FSCA
	N/A

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☒ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None	
3.	2. By when should the action be completed?	N/A
3.	3. Particular considerations for: Diagnostic Imaging device Is follow-up of patients or review of patients' previous results recommended? No Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None ***Improving user awareness of the various display states and training on the version of software***	
3	6. By when should the action be completed?	As soon as possible
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	
4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Spacelabs Healthcare, Inc.**
	b. Address	**35301 SE CenterSt. Snoqualmie, WA 98065 United States**
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	**Customer Letter**
4.	10. Name/Signature	**Thomas Faris** **Vice President RA/QA**

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

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Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.