Rev 1: September 2018

FSN Ref: 079-0297-02, Rev A FSCA Ref: 3010157426-05042026-003-C

Date: <Date>

Urgent Field Safety Notice
Xhibit Central Station, Model 96102
Audio/Video Loss With Splitter use

For Attention of*: All users of the Xhibit Central Station, model 96102, utilizing a display port splitter, model 010-1975-00.

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
FRANCE **SPACELABS HEALTHCARE FRANCE** Confidential business information **GERMANY** **SPACELABS HEALTHCARE GMBH (GERMANY)** Confidential business information **ITALY** **SPACELABS HEALTHCARE SRL (ITALY)** Confidential business information **OTHER EUROPEAN COUNTRIES: EUROPE,** Confidential business information

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1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Xhibit Central Station provides clinicians with central monitoring of adult, pediatric, and neonatal patient data from networked Spacelabs Healthcare patient monitors and telemetry transmitters, and to generate visible and audible alarms when atrial or ventricular arrhythmia, such as premature contraction or ventricular fibrillation, and other physical monitoring parameters when breech in occurs. A four-way display port splitter allows local display signal replication for up to three remote displays. Remote displays connected to the splitter can also replicate the audio and video from the local display.
1.	2. Commercial name(s)
	Xhibit Central Station
1.	3. Unique Device Identifier(s) (UDI-DI)
	10841522100345, 10841522127069, 10841522102882, 10841522100536, 10841522107832, 10841522107160, 10841522120244, 10841522120220, 10841522117688, 10841522131141, 10841522129780, 10841522127052, 10841522127045, 10841522127038, 10841522127021
1.	4. Primary clinical purpose of device(s)*
	Xhibit Central Station provides clinicians with central monitoring of adult, pediatric, and neonatal patient data from networked Spacelabs Healthcare patient monitors and telemetry transmitters, and to generate visible and audible alarms when atrial or ventricular arrhythmia, such as premature contraction or ventricular fibrillation, and other physical monitoring parameters when breech in occurs. A four-way display port splitter allows local display signal replication for up to three remote displays. Remote displays connected to the splitter can also replicate the audio and video from the local display.
1.	5. Device Model/Catalogue/part number(s)*
	Xhibit Central Station Model Number 96102. Display port splitter 010-1975-00
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	No affected serial number range.
1.	8. Associated devices
	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Spacelabs Healthcare has concluded that the use of the previously distributed splitter (model number 010-1975-00) can have an adverse effect on product performance, specifically around audible and visible alarms. Splitters may fail to perform as intended and result in degraded or complete loss of alarm audio and video. Additionally, the use of unqualified splitters may pose the same risks. Spacelabs Healthcare does not support the use of third-party equipment that has not been approved by Spacelabs Healthcare.
2.	2. Hazard giving rise to the FSCA*
	If the system experiences the associated issue, audio and video may fail, resulting in distorted tones or complete loss of audio and video for the alarms. The clinical staff may be unable to detect the alarm condition if the alarms are not visible, do not sound and / or do not sound as expected

	and may fail to respond to a medical condition requiring clinical intervention. It is foreseeable that failed clinical response could result in serious injury or death.
2.	3. Probability of problem arising
	The probability of occurrence has been determined to be Improbable. The clinical staff may be unable to detect the alarm condition if the alarms are not visible, do not sound, and / or do not sound as expected and may fail to respond to a medical condition requiring clinical intervention. However, as revealed by complaint data, component failure is extremely rare – especially to the extent it would prevent full audio or visual alarms. While failure leading to harm is possible, it is extremely unlikely that it will occur.
2.	4. Predicted risk to patient/users
	If the system experiences the associated issue, audio and video may fail, resulting in distorted tones or complete loss of audio and video for the alarms. The clinical staff may be unable to detect the alarm condition if the alarms are not visible, do not sound and / or do not sound as expected and may fail to respond to a medical condition requiring clinical intervention. It is foreseeable that failed clinical response could result in serious injury or death.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	The problem was identified through a review of product complaints.
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 Spacelabs requests that all customers acknowledge receipt and understanding of this notification and provide the information outlined in the included acknowledgement form.	
3.	2. By when should the action be completed?	As soon as possible, but no later than 30-Aug-2026.
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes

3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Spacelabs Healthcare has isolated the issue to the use of the Xhibit Central Station with AV Splitter model number 010-1975-00. Additionally, Spacelabs Healthcare cannot guarantee the performance of unapproved third party AV Splitters. Customers who purchased the affected splitter component from Spacelabs Healthcare will receive a free of charge replacement of a new model splitter. Customers utilizing unapproved splitters are required to cease use and contact an Authorized Spacelabs Healthcare representative to acquire the appropriate splitter solution.	
3	6. By when should the action be completed?	Customers should return the acknowledgement form and contact their local Spacelabs Healthcare service representative no later than 30-Aug-2026.
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? *	No
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	Confidential business information.
	b. Address	Confidential business information
	c. Website address	Confidential business information
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *Yes	
4.	9. List of attachments/appendices:	**Customer Letter**
4.	10. Name/Signature	Personal information Personal information Personal information

	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..*

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