SPACELABS HEALTHCARE

Date: 27 MAY 2022

Urgent Field Safety Notice
Xhibit Telemetry Receiver

For Attention of*:All the customers who are using Xhibit Telemetry Receiver along with

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

Company Name/Logo

Urgent Field Safety Notice (FSN)
Xhibit Telemetry Receiver (XTR)
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The Xhibit 96280 Telemetry Receiver is intended to provide the Spacelabs Healthcare monitoring system with adult, paediatric and neonatal patient data of patients connected to Spacelabs Healthcare telemetry transmitters. Data includes physiological waveforms and calculations, cardiac arrhythmia and ST data, and patient demographic information to monitor adequacy of treatment or to exclude causes of symptoms.
1.	2. Commercial name(s)
	Xhibit 96280 Telemetry Receiver
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	The Xhibit Telemetry Receiver is intended to provide the Spacelabs Healthcare monitoring system with adult, paediatric and neonatal patient data of patients connected to Spacelabs Healthcare telemetry transmitters. Data includes physiological waveforms and calculations, cardiac arrhythmia and ST data, and patient demographic information to monitor adequacy of treatment or to exclude causes of symptoms.
1.	5. Device Model/Catalogue/part number(s)*
	96280
1.	6. Software version
	Xhibit v1.5, XTR v1.4
1.	7. Affected serial or lot number range
	See appendix A
1.	8. Associated devices
	96102 Xhibit® Central Station.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	After approximately 25 days of continuous use, technical alarm escalation does not occur in the Xhibit 96280 receiver as specified. Expected technical alarms that may be set to escalate will not do so. These include Signal loss, all leads off, low battery, SpO2 sensor off, and signal interference. Alarms set to escalate will enunciate at the configured priority level and will not escalate to the product escalation maximum.
2.	2. Hazard giving rise to the FSCA*
	An error associated with the operating system causes this defect condition. After approximately 25 days of continuous use, technical alarm escalation does not occur as specified and expected. All clinical alarms function as intended and initial technical alarms initiate as intended, but the technical alarm escalation, which occurs after a technical alarm continues for an additional time, does not occur. The fact that this involves technical alarms and not clinical alarm drove the difficult in more timely recognition of the potential safety risk associated with this defect. The safety concern is based upon the potential that a caregiver may not respond to the initial alarm and is not made aware of the continuing technical failure because of the failure of the secondary (the escalating) alarm. A patient event could occur and without the escalation to indicate a higher severity, the delayed or lack of response from the caregiver could result in injury

	or death of the patient. In addition, if the alarm acknowledge feature is used, there would be no breakthrough reminder to the caregiver in the form of an alarm escalation. Technical alarms include: (1) all leads off, (2) low battery, (3) signal lost, (4) signal interference, and (5) Sp02 sensor off. As notable from the associated complaints, many customers have detected the issue, but no occurrence have led to any harm.
2.	3. Probability of problem arising
	Low – Remote risk of harm.
2.	4. Predicted risk to patient/users
	Caregivers may not respond to initial or low-level alarms, waiting for the escalating alarm to communicate that the unaddressed technical issue continues. If the escalating alarm does not occur, then the caregiver may not detect the malperforming technical condition. This could lead to a failure of detection of a clinical condition that could cause harm or death due failure of alarm
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Several complaints were received, and investigation determined a failure mode exists within version 1.4 software.
2.	7. Other information relevant to FSCA
	Xhibit Telemetry Receiver (XTR) 96280 v.1.4.0

	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 We at Spacelabs recognize and share your concern for patient safety. Please weigh the benefits versus the risks when deciding whether to continue to use the alarm escalation feature within XTR 1.4. Suggestions from Spacelabs to mitigate the risk: • Set the priority to the same level as the “escalation max” on the product. This will ensure that the highest priority alarm is triggered for the technical alarm. • Do not run the XTR 1.4 for more than 24 days consecutively. Restarting the XTR after 24 days will mitigate the issue for another 24 days.	
3.	2. By when should the action be completed?	Immediately

3.	3. Particular considerations for: Diagnostic Imaging device Is follow-up of patients or review of patients' previous results recommended? No N/A	
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 Currently working to correct version 1.4 with subsequent software release.	
3	6. By when should the action be completed?	Immediately
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	**Spacelabs Healthcare, Inc.**
	b. Address	**35301 SE CenterSt. Snoqualmie, WA 98065 United States**
	c. Website address	https://www.spacelabshealthcare.com/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	**N/A**
4.	10. Name/Signature	**xxx**

	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.