

URGENT – FIELD SAFETY NOTICE

Arjo Sara Plus lift – Risk of ignition

Date:	31 March 2022
Product Issue:	Risk of device ignition
Affected Product:	Sara Plus floor lifts
Resolution:	Product retrofit by Arjo service
Field Safety Notice:	FSN-POZ-001-2022
Pages:	5
Single registration number of manufacturer in EU:	SE-MF-000000696



Dear Customer,

Our sales and service records indicate that you may be in possession of one or more Sara Plus lifts equipped with a PCB (Printed Circuit Board) that is prone to damage during product use. The PCB is an electronic part located inside the lift underneath the cover, as shown below.

We are notifying you of a required corrective action on affected devices.

Note: Affected devices are Arjo Sara Plus floor lifts manufactured from 13 October 2016 with the HMX1350-1 PCB, and Arjo Sara Plus floor lifts on which a PCB was replaced to HMX1350-1 after that date. Other Arjo lifts are unaffected with the risk of PCB damage.

It has been found that internal damage of the affected HMX1350-1 PCB may lead to overheating of the part and excessive heat emission which could potentially damage the PCB cover or, in the worst case, cause its ignition.

Prior to this action launch, Arjo has received 2 (two) reports of Sara Plus lift ignition occurring but with no reports of any health consequences to either patients or caregivers due to that failure mode.

The technical evaluation of the failure showed that the likelihood of the issue occurrence is limited and dependent on multiple factors. Nevertheless Arjo is taking this issue seriously as customer satisfaction and safety are essential to us, so we have decided to undertake a corrective action to eliminate the identified failure.



Before an ignition may occur, it can be preceded by white smoke coming out of the lift. The emitted smoke is not harmful and unlikely to result in any health consequences. **However, as soon as you notice any smoke, stop using your Sara Plus lift immediately – push the Emergency Stop Button and remove the battery from the battery socket to prevent from any further failure (please refer to an image below).**

Next, contact Arjo Service on 01 809 8960 or via email to service.roi@arjo.com for further assistance. The smoke will phase out completely by itself after less than 3 minutes.



We will arrange a visit to your facility by an Arjo engineer to complete the Sara Plus correction with a service kit developed by the manufacturer to eliminate the issue.

Next Steps

1. Ensure that all caregivers and users of the Sara Plus floor lift(s) at your facility are made aware of this Field Safety Notice (FSN) and precautionary measures detailed below are followed until the device correction is made.
2. Complete and sign the enclosed Customer Response Form and return this form to us. We will then schedule the repair of your devices free of charge with the named contact from the customer response form.

Note: if your facility has sold or moved the Sara Plus lifts, please include the new facility's information in the Customer Response Form.



3. The manufacturer identified factors contributing to PCB damage. Several precautionary measures to reduce the potential for damage are recommended until the field action can be completed. These are detailed below. **Please follow all of them until your Sara Plus floor lift is corrected by Arjo.**

We regret any inconvenience that this Field Safety Notice may cause, however we greatly appreciate your understanding as we take actions to ensure the safety of patients and caregivers. The notice has also been submitted to the Regulatory Agency/National Competent Authority in your country (HPRA).

Additional Comment

If you have any further questions or require assistance completing the Customer Response Form, please contact us via email at fieldactions.uki@arjo.com.

**The following precautionary measures should be taken immediately by
Caregivers / users of the Sara Plus Lift:**

<p>DO NOT use the lift in humid areas and DO NOT spray the lift covers with any liquid. Accidental water ingress can contribute to the PCB failure.</p>	<p>ALWAYS clean your lift, equipment and accessories by wipe down with a damp cloth using warm water with a mild detergent added.</p> <p>To disinfect the device, clean the equipment first, then wipe it using a solution containing one of the compatible disinfectants. Please refer to the Sara Plus Instructions for Use supplied along with the product for a detailed guidance.</p>
<p>DO NOT overload the lift. Please remember that: When using the transfer and walking sling for the transfer, the Safe Working Load is 140 kg (308 lbs). When using the same sling for walking practice the Safe Working Load is 190 kg (420 lbs).</p>	<p>ALWAYS remove the battery from battery socket on a mast if your Sara Plus lift remains unused.</p>
<p>DO NOT use the lift with depleted, old (over 2 years old) or damaged batteries. Please note that a manufacturing month of your battery is visible on its sticker, as below.</p> 	<p>ALWAYS make sure that the lift battery is in a good working condition before you attempt to use the lift. Charge your battery as soon as battery discharge indicator (small battery symbol) situated on the lift display reaches 5 out of 8 filled segments, as below:</p> 
<p style="text-align: center;">DO NOT leave your patient unattended on the lift in any situation.</p>	

Customer Response Form

URGENT FIELD SAFETY NOTICE FSN-POZ-001-2022

Reference: Arjo Sara Plus lift – Risk of ignition

Our records indicate that you may have one or more Sara Plus floor lifts within your facility affected by this action. Please verify if you have any of the listed devices and complete the information below.

Record the total number of devices currently located at your facility here, please → _____.

Field Safety Notice Receipt and Customer Response Form Completion

- We have read the Field Safety Notice and we understand the communication and the required actions.
Please provide information where the affected devices are physically located now.

Current Facility Name			
Contact Name / Title			
Address			
City, Post Code			
Phone Number		Fax	
E-Mail Address			

- We have sold/moved our Sara Plus floor lift(s) to another facility.
If checked, please provide details of the new facility below:

New Facility Name			
Contact Name / Title			
Address			
City, Post Code			
Phone Number		Fax	
E-Mail Address			

- We have decommissioned our Sara Plus floor lift(s) permanently. No further action is required by Arjo.

Signature		Date	
------------------	--	-------------	--

Affected Arjo Sara Plus floor lifts at your facility:

SERIAL NO.	PLEASE CONFIRM LOCATION - ROOM / FLOOR / WARD

PLEASE send your completed forms to fieldactions.uki@arjo.com or you can mail or fax as detailed below:

MAIL

Arjo (Ireland) Ltd
EA House
Damastown Industrial Estate
Mulhuddart
Dublin 5

CONTACT

rachel.bowers@arjo.com
fieldactions.uki@arjo.com
Tel: 01 809 8960
Fax: 01 809 8971

THANK YOU