

URGENT – FIELD SAFETY NOTICE

Arjo Sara Plus lift – Risk of ignition

Date: 2022-Mar-DD

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: 3 & Customer Response Form

Single registration number of the manufacturer in the EU: SE-MF-000000696



Dear Customer,

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

Arjo is contacting you to advise of a required corrective action on identified affected device(s).

Note: The only affected devices are Arjo Sara Plus floor lifts manufactured from 2016-Oct-13 (originally assembled with an affected 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. The heat generated is unlikely to evolve into a flame that could damage the PCB cover or, in the worst case, cause its ignition.

Until the day of this action launch, Arjo has received 2 (two) reports of Sara Plus lift ignition occurring and 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 the customer



PCB location
in the lift

satisfaction and safety are essential for us, we have decided to undertake a corrective action to completely eliminate the identified failure.

The ignition 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 the smoke, stop using your Sara Plus lift immediately– push Emergency Stop Button and remove the battery from battery socket to prevent from any further failure (please refer to an image below). Next, contact Arjo at [insert local phone number] or via email at [insert email address] for further assistance.** The smoke will phase out completely by itself after less than 3 minutes.



We are contacting you to arrange a visit of an Arjo service engineer in order to complete the Sara Plus correction with a service kit developed by the manufacturer at your facility, with no need to return the product to us.



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).
2. Complete and sign the enclosed Customer Response Form and return this form to Arjo address given in Additional Comment section. This will allow us to contact you as soon as possible.

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 the damage of the affected PCB. Based on that, several precautionary measures mitigating the likelihood of the PCB failure are recommended as below. Please follow all of them until your Sara Plus floor lift is corrected by Arjo.

PRECAUTIONARY MEASURES TO BE TAKEN IMMEDIATELY BY CAREGIVERS/USERS OF 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 for cleaning your lift, equipment and accessories wipe down with a damp cloth using warm water to which a mild detergent has been added. 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 align="center">DO NOT leave your patient unattended on the lift in any situation.</p>	

Once your Sara Plus lift is corrected, the product will be returned to daily usage fully functional. Always when you use Sara Plus, please follow the Instructions for Use.

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 our patients and caregivers.

Additional Comment

If you have any further questions or require assistance completing the Customer Response Form, please contact Arjo at **[insert local phone number]** or via email at **[insert email]**. The notice has been submitted to the Regulatory Agency/National Competent Authority in your country **[insert name]**.