

URGENT - FIELD SAFETY NOTICE

**Arjo System 2000 Bath
Field Safety Action FSN-POZ-001-2019**

Date: 21-MAY-2019

Product Issue: Potential Risk of electrocution for service personnel: Assembly error in manufacturing - an additional live cable in System 2000 bath control box

Affected Product: Arjo System 2000 of model number: AR01800GB1000

Resolution: Removal of AH1000536 cable from MPA Power Box in System 2000

Field Correction Notice: FSN-POZ-001-2019 rev.1

Dear Customer

Arjo is contacting you as our records indicate that you are the owner of one System 2000 Rhapsody bath marked with a serial number listed as above.

This letter is to inform you of a corrective action that our company is initiating to prevent a potential risk of electrocution for service technicians inspecting the bath control box.

An unnecessary additional live cable was plugged into a control box, due to an assembly error during manufacturing process, of a specific range of System 2000 baths. **One out of the affected devices has been shipped to Republic of Ireland.**

Please note that the cable is enclosed behind two plastic covers, so that caregivers or residents or users do not have any contact with this part, therefore they are not directly exposed to any risk of harm.

Please note: Your device(s) are safe to be used by the users, including nurses and patients/residents at full capacity. The device can remain in use before and after the correction is carried out.

The potential risk of electrocution is present during maintenance / service of the bath, if the inside of the control box is inspected.

The hazardous situation only occurs if the bath is still connected to the mains power supply during maintenance / or service operations and the control box is uncovered.

Following results of the manufacturer's investigation, it was concluded that the likelihood of the harm occurrence is low. The harm might occur only if the following unfortunate sequences of events takes place:

- the cable AH1000536 is present in the control box,
- the cable AH1000536 is connected to the 230 V through the PCB inside the control box,
- the bath control box is inspected by service personnel,
- the bath is not disconnected from the main power before service activities
- and service personnel touch the cable AH1000536 or inner metal parts of the control box being in direct contact with the cable.

Corrective actions at the manufacturing site have been implemented immediately upon the problem detection to prevent it from reoccurring.

Based on the above, we would like to perform a correction on the affected devices at your facility. The action is to remove the cable from the control box by a qualified Arjo service technician, so that a potential hazard will be eliminated.

Next Steps

1. Please make sure that all caregivers or users of the System 2000 bath referenced on the previous page are made aware of this Urgent Field Safety Notice and the device at your facility is available to be reworked during an Arjo service technician visit that will be arranged with you.
2. Complete and sign the enclosed Customer Response Form and return it to the local Arjo office.

Note: An Arjo Sales or Service person will contact the person you listed on the Customer Response Form to schedule service to repair your device, free of charge.

Transmission of this Field Notice

This Arjo System 2000 Urgent Field Safety Notice needs to be distributed to those individuals who need to be aware within your organization - or to any organization where the potentially affected devices have been transferred.

Please maintain awareness of this notice and resulting action for the use period of the device to ensure effectiveness of the corrective action.

The field safety action we are initiating has been reported to the National Competent Authority in your country.