

## URGENT FIELD SAFETY NOTICE

### Arjo Akron Tilt Table Couch Field Corrective Action FSN-POZ-003-2019

**Customer Name**

**Customer Address**

cc: Chairman Medical Board and relevant Department Heads

**Date:** 09-OCT-2019

**Product Issue:** Risk of a middle section frame collapse

**Affected Product:** [REDACTED] manufactured between 2012 and 2018

**Resolution:** Middle section frame replacement

**Affected Serial No.:** Serial nos. within range P0151552 - P0500645 ([REDACTED] manufactured by ArjoHuntleigh Polska, distributed globally)

**Field Correction Notice:** FSN-POZ-003-2019

**Pages:** 33

---

#### Dear Customer

This letter is to inform you of a safety related corrective action to address a potential failure of the middle section frame on the Arjo Akron Tilt Table Couch. Our records indicate that you have purchased one or more of these Arjo couches within the serial number range referenced above and would like to provide you with the following solution.

It has been identified that the affected couches (outlined above) could potentially have a fault with the frame which in a very small number of cases has caused the frame to collapse. This failure may occur during movement of the frame to a vertical position. Consequently, there is a risk that a patient could fall down with the upholstery which has been confirmed in simulations.

Based on recent investigation results, it is not possible to determine which frames are at fault by visual inspection and as such Arjo has determined that due to the potential hazard all middle frames will be replaced to ensure no adverse event can occur, regardless of their visual inspection results. We would also like to note that there has been no injury reported due to the failure occurrence in the market. As is it not possible to visually inspect the frames for this fault Arjo recommends that, where possible, the unit/s are removed from use until the replacement frame can be fitted.

Due to this we would like to arrange a visit to your facility in order to exchange the middle section frame, free of charge.

Although the likelihood of this issue occurring is limited, Arjo takes this matter seriously and is moving forward with the following plan as outlined in the **Next Steps** section.



## Customer Response Form

FSN-POZ-003-2019

**Reference: Urgent Field Safety Notice, Akron Tilt Table Couch**

Our records indicate that the Akron Tilt Table device showed below was delivered to your location. Please verify if you have any of the listed devices that are potentially affected and complete the information below.

**Record the total number of affected device currently located at your facility here please → \_\_\_\_.**

Please check the appropriate boxes below:

- ☐ We have read the Akron Tilt Table Field Safety Notice and we understand the communication and the required actions.  
**If checked : please provide information where the affected devices are physically located.**

### Field Safety Notice Receipt and Customer Response Form Completion and Certification

<b>Current Facility Name</b>			
<b>Contact Name / Title</b>			
<b>Address (no PO boxes, please)</b>			
<b>City, Postcode</b>			
<b>Phone Number</b>		<b>Fax:</b>	
<b>E-Mail Address:</b>			

- ☐ We have sold/moved our Akron Tilt Table couch to another facility.  
**If checked : please provide new facility information below.**

<b>New Facility Name</b>			
<b>Contact Name / Title</b>			
<b>Address*</b>			
<b>City, Postcode</b>			
<b>Phone Number</b>		<b>Fax:</b>	
<b>E-Mail Address:</b>			

**PLEASE RETURN YOUR COMPLETED FORM TO:**

**MAIL**

Arjo South East Asia Pte. Ltd.  
 31 Kaki Bukit Road 3  
 #05-06/07 Techlink Lobby B  
 Singapore 417818

**CONTACT**

Michael Ryan Falceso Perez  
 Quality & Regulatory Compliance Officer, SEA  
 Tel. No.: +65 6202 7367

**[REDACTED]**  
 Fax No.: +65 6747 0994

**[REDACTED]**

SERIAL NO.	FACILITY CURRENT OR NEW (mark a correct one)		ROOM/FLOOR
	CURRENT	NEW	
<XXXX>	CURRENT	NEW	
<YYYY>	CURRENT	NEW	
	CURRENT	NEW	
	CURRENT	NEW	
	CURRENT	NEW	