

URGENT FIELD SAFETY NOTICE

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

Date: <DD-MMM-YYYY>

Product Issue: Risk of a middle section frame collapse

Affected Product: 508 units manufactured between 2012 and 2018

Resolution: Middle section frame replacement

Affected Serial No.: P0304140

Field Correction Notice: FSN-POZ-003-2019

Pages: 2

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.

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

Please note: Arjo recommends the device be withdrawn from use until the middle section frame is replaced.

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.

Next Steps

1. Please make sure that all caregivers and users of the Akron Tilt Table referenced in this letter are made aware of this Field Safety Notice.
2. Complete and sign the enclosed Customer Response Form and return it to Arjo <add contact information> to help us initiate the process of replacement.
 - a. Note: if your facility has sold or moved an affected couch(es) to another facility, please include the new facility's information in the Customer Response Form.
 - b. Once the form is returned, Arjo will contact the designated facility representative listed on the Customer Response Form and schedule a service call to perform the replacement on all listed devices at your facility, free of charge.

3. Ensure all affected devices at your facility are available for the middle section frame replacement during the Arjo Technician's visit.

Transmission of this Field Notice

This Arjo Akron Tilt Table 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 within your facility.

This field safety notice has been reported to the National Competent Authorities in your country.

Additional Comment

We deeply regret this inconvenience but greatly appreciate your understanding as we take actions to ensure your products expected performance. If you have any further questions or require assistance completing the Customer Response Form, please contact Arjo via **<add contact information>**.

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

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

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

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

PLEASE RETURN YOUR COMPLETED FORM TO:

MAIL

<local SSU address line 1>
 <local SSU address line 2>
 <local SSU address line 3>
 <local SSU address line 4>

CONTACT

<contact address>@arjo.com
 Tel: <SSU contact phone number>
 Fax: <SSU contact fax number>

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

	CURRENT	NEW	
	CURRENT	NEW	
	CURRENT	NEW	