

IMPORTANT - FIELD SAFETY NOTICE**ArjoHuntleigh Akron Tilt Table
Field Action FSN-POZ-002-2018**

<Customer Name/ Address>

cc: Chairman Medical Board and relevant Head of Departments

Date: 25 May 2018

Product Issue: Akron Tilt table missing weld

Affected Product: Akron Tilt Table couches

Resolution: Perform a field correction with initial inspection and rework (if needed) of the middle frame section for affected devices in order to ensure that they are fully functional.

Affected Serial No.: [REDACTED]

Field Correction Notice: FSN-POZ-002-2018

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Dear Customer

Our records indicate that you purchased Akron Tilt Table couches which fall within the scope of this field action with serial numbers listed above. This letter is to inform you of a corrective action that will be performed to prevent a possible health hazard consequences.

As part of our post market surveillance (complaint reporting) monitoring, ArjoHuntleigh received a complaint related with Akron Tilt Table middle section frame brakage. The investigation showed that one of critical welds in the part was missing. There were no injury related to this incident. Please note that not all devices are affected by this defect, however we see the issue as potential hazard and want to prevent any related event occurring with our customers.

The issue is related with potential hazard for patient and if the affected device will be used it can lead to collapse during movement to the the vertical position. In the worst case scenario user can falls down with the upholstery (if not protected with belts). According to our simulation this situation is safety related therefore we would like to inform you about our actions.

Based on following we would like to visit your facility to verify condition of the middle section frames, continuity and completeness of welding joints. If defect would be found, exchange of part will be done, free of charge. It is not recommended to use the couch until action would be taken by ArjoHuntleigh.

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 Notice and all listed devices at your facility are available for the inspection during the service technician visit
2. Complete and sign the enclosed Customer Response Form and return this form to the local ArjoHuntleigh office. A ArjoHuntleigh Sales or Service person will contact the person you listed on the Customer Response Form to schedule service to verify and (if needed) rework your device, free of charge.

Transmission of this Field Notice

This ArjoHuntleigh Field 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.

Additional Comment

We deeply regret this inconvenience, but we greatly appreciate your understanding as we take actions to ensure correct product performance. If you have any further questions or require assistance completing the Customer Response Form, please contact ArjoHuntleigh.

Customer Response Form

FSN-POZ-002-2018

Reference: Urgent Field Safety Notice, ArjoHuntleigh Akron Tilt Table.

Our records indicate that the Akron Tilt Table device shown 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.

ArjoHuntleigh ORDER NO.	ITEM NO.	SERIAL NO.	MANUFACTURING DATE

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

Please check the appropriate boxes below:

- ☐ We have read the 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, State, Zip			
Phone Number		Fax:	
E-Mail Address:			

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

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

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

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