

**URGENT - FIELD SAFETY NOTICE**

**ARJOHUNTLEIGH ECHO 2 COUCHES WITH DEFECTIVE STEP MODULES**

**Date:** Please provide with issue date

**Product Issue:** Possible defective step module, with missing weld, which can break during use.

**Resolution:** ArjoHuntleigh propose to inspect the step module and if needed replace it to make sure all devices present in the market are working effectively and safely.

**Affected Product:** (quantity of affected device) Akron Echo 2 Couches of model A5962 and A5972 manufactured between February 2013 and November 2015 were identified to be affected. The affected serial numbers are (list the serial numbers)

**Field Correction Notice:** FSN/POZ/001-2016

**Pages:** 2

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**Dear user:**

Our records indicate that you purchased Akron Echo 2 couch with step module accessory (part no.A5911) with one of the serial numbers above from ArjoHuntleigh.

This letter is to inform you about the corrective action that will be performed to prevent occurrence of possible hazardous situation related with breakage of step module accessory during use of our couch. The defect can lead to patients falling down from the step module.



We have received a very small number of customer complaints related to this issue and fortunately none of them was related to injury. However, based on risk analysis and potential of the hazardous situation occurrence decision about the field action was taken.

This potential for malfunction is caused by a manufacturing error at our supplier. We implemented corrective action in production and tightened quality control of the involved supplier. The problem is prevented from recurring and we can ensure that step modules supplied after December 2015 are in accordance to specification.

Please note that the defect cannot be detected by the user, however presence of welds can be verified by appropriately trained person. Please note that step module breakage does not cause couch malfunction and the main product can still be used after removal or exchange for the accessory for correct one.

**Next Steps**

1. Please make sure that all caregivers and users of the Echo 2 Couch devices referenced on the previous page are made aware of this Field Safety Notice (FSN) and all listed devices at your facility are available for inspection and (if needed) part replacement during the ArjoHuntleigh service technician visit.
2. Please make sure that all devices addressed by this FSN are correctly marked and excluded from the usage until the replacement.
3. Complete and sign the enclosed Customer Response Form and return this form to the local ArjoHuntleigh Regulatory Department. **Note:** An ArjoHuntleigh Sale and Service Unit will contact the designated facility representative listed on the Customer Response Form to schedule service to inspect and if defected would be detected replace affected part in your device, free of charge.

**Transmission of this Field Safety Notice:**

This FSN 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 an appropriate period to ensure effectiveness of the corrective action.

**Additional Comment**

We deeply regret this inconvenience that this Field Safety Notice may cause. However, we ask that you please see this corrective action as a resident/patient related safety action. We greatly appreciate your understanding as we take actions to ensure not only patient and customer safety, but also satisfaction.

Please also be informed this Field Safety Correction Action has been notified to the appropriate Regulatory Agency.

If you have any further questions or require assistance completing the Customer Response Form, please contact ArjoHuntleigh.

**(Please provide the contact address, phone etc. of the ArjoHuntleigh facility)**