

URGENT - FIELD SAFETY NOTICE**ArjoHuntleigh Entroy
Field Action**

Date:	2018-xx-xx
Product Issue:	Entroy Docking Procedure Failure
Affected Product:	298 ArjoHuntleigh Entroy of model number GAB1000-x1 – see list of affected serial numbers – Annex A.
Resolution:	<i>ArjoHuntleigh propose to hand out for the customers that own the devices a quick reference guide to make sure that the intended use of the device is followed.</i>
Affected Serial No.:	Please refer to list of affected serial numbers – Annex A.
Field Correction Notice:	FSN-POZ-001-2018
Pages:	3

Dear Customer

Our records indicate that you own one or more Entroys marked with a serial number listed as per Annex A.

This letter is to inform you of a corrective action that will be performed to ensure that failure described in this letter will not occur.

The issue we found with our device is related to seat/stretchers detachment from Entroy Pool Lift when not correctly paired. A trend analysis for the problem in question shows that ArjoHuntleigh has registered a number of reportable instances where the device user failed to dock the Entroy chair or stretcher correctly. When docking fails there is a risk of the stretcher or chair becoming detached and fall.

This potential for malfunction is caused by the fact that caregiver may suppose that the pin has been paired with the seat/stretcher, but there could be a misalignment that might be unnoticed by the caregiver so the seat/stretcher does not get paired. Instead, once the lift reaches certain height, the seat/stretcher falls off the lift. There are one or more possible reasons that can lead to such a situation to occur:

- Maintenance checks not performed properly
- Users do not recognize the poor connection
- Pool lift owners does not recognize that the product needs maintenance
- Wear on the docking connection causes the pin to hit the edge of the pairing cylinder instead of entering it

The device is *no longer produced* therefore we have developed Quick Reference Guide which is an illustration-based instruction that will allow users to perform the transfer safely. This action is to hand out this Quick Reference Guide free of charge to every customer that owns Entroy device and by doing so, to assure that the knowledge how to operate the device stays with the customer at all times.

Next Steps

1. Please make sure that all caregivers and users of the Entroy referenced on the previous page are made aware of this Field Notice and all listed devices at your facility are available to the Service Technician Visit who will place the Quick Reference Guide on the device.
2. Complete and sign the enclosed Customer Response Form and return this form to the local ArjoHuntleigh office.

Transmission of this Field Notice

This ArjoHuntleigh Entroy 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.

The undersigned confirms that the notice has been submitted to the Regulatory Agency *[insert name]*.

If you have any further questions or require assistance completing the Customer Response Form, please contact Arjo at *[insert local phone number]* or via email at *[insert email]*.

Customer Response Form

FSN-POZ-001-2018

Reference: Urgent Field Safety Notice, ArjoHuntleigh Entroy.

Our records indicate that the *Entroy* 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 *Entroy* 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 *Entroy* 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

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

CONTACT

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 Tel: <SSU contact phone number>
 Fax: <SSU contact fax number>