

URGENT - FIELD SAFETY NOTICE**ARJOHUNTLEIGH FLOWTRON ACS900**

Date:	xx-yyy-2017
Product Issue:	Continuous high pressure provided to the garment and not deflating
Affected Product:	Flowtron ACS900 pumps manufactured between 26 Sep 2014 and 20 Dec 2016 with the software V1.099 Serial Numbers range from 1400028031 to 1600048470
Resolution:	Upgrade the devices via software upgrade to version V2.0 in order to make sure the device is operating safely and effectively.
Affected Serial No.:	Attachment A
Field Correction Notice:	FSN/SUZ/001-2017
Pages:	3

Dear Customer

Our records indicate that you may have within your facility(ies) one or more consigned or purchased ArjoHuntleigh Flowtron ACS900 pumps used for the prevention of Deep Vein Thrombosis (DVT).

This letter is to inform you of a corrective action that we will be performing on the ArjoHuntleigh Flowtron ACS900 pump.

It has been identified that in some instances the pump will constantly deliver pressure to the garment without triggering the alarm. ArjoHuntleigh has investigated the symptom encountered and has concluded that the consistent flow of pressure to the garment without deflation may lead to a potential risk of injury to patients. ArjoHuntleigh has received a limited number of complaints regarding this specific state.

Although the likelihood of this occurring is remote, ArjoHuntleigh takes this matter seriously and is advising you on the following steps:

Upgrading the ACS900 pump to the software revision V2.000 in order to ensure a more resilient Flowtron systems.

The device may stay in use until the upgrade will be performed, on the condition that the patient's limbs are monitored frequently and the garments are checked to ensure that they are correctly fitted to the patient and that deflation of the garments is occurring on a regular basis.

It is also recommended that the pump LCD display is regularly checked to ensure that it shows that the garments are inflating and deflating correctly. In the limited number of complaints, the LCD display was blank.

Next Steps

1. Ensure that all caregivers and users of the ArjoHuntleigh Flowtron ACS900 pump are made aware of this Field Safety Notice (FSN) and all listed devices at your facility are available to be upgraded during the service technician visit.
2. Complete and sign the enclosed Customer Response Form and return this form to the local ArjoHuntleigh office.

Note: ArjoHuntleigh will contact the designated facility representative listed on the Customer Response Form to schedule service to upgrade the software on all listed devices at your facility, free of charge.

Distribution of this Field Safety Notice

This Field Safety Notice must 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.

We deeply regret any inconvenience that this Field Safety Notice may cause, however we greatly appreciate your understanding as we take actions to ensure patient safety and correct product performance.

The undersigned confirms that the notice has been notified to the appropriate Regulatory Agency.

Additional Comment

If you have any further questions or require assistance completing the Customer Response Form, please contact ArjoHuntleigh at _____ or via email at _____

ATTACHMENT A

Affected Serial Nos.:

NO	SERIAL NUMBER	COUNTRY
1		
2		
3		
4		
5		
6		

Customer Response Form

FSN/SUZ/001-2017

Reference: Urgent Field Safety Notice, ArjoHuntleigh Flowtron ACS900

Our records indicate that the Flowtron ACS900 pump was delivered to your location. Please review your inventory and the Urgent Field Safety Notice, Attachment A, to determine if you have any of the potentially affected products. The version of software on the device can be determined by power cycling the Flowtron ACS900. On the start-up screen, the version will display briefly. See image below:



Next, complete the information below and return completed form to the ArjoHuntleigh address (please see at the bottom of this page).

Note: Provide information where the affected Flowtron ACS900 pumps are currently physically located.

ArjoHuntleigh ORDER NO.	MODEL NO.	SERIAL NO.	MANUFACTURING DATE

In case of limited space, use the table on page 2

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

Please check the appropriate boxes below:

- We have read the Flowtron ACS900 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 Flowtron ACS900 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:			

