ARJOHUNTLEIGH
GETINGE GROUP

July 17, 2017

Dear Sir/ Madam
Cc: Chairman Medical Board and relevant Head of Departments
Medical Device Branch
Health Sciences Authority, Singapore
11 Biopolis Way, #11-01 Helios
Singapore 138667
Delivery Method: Email

SUBJECT: Notice of Field Safety Corrective Action
Legal Manufacturer: ArjoHuntleigh AB, Malmo, Sweden
Product: Flowtron ACS900 Medical Pump

Dear Sir/ Madam
This letter is to inform you of a Voluntary Product Field Correction involving the Flowtron ACS900 Medical Pump. The Flowtron ACS900 medical devices manufactured by Getinge (Suzhou) Co., Ltd., Suzhou, Jiangsu, P. R. China.
Outlined below is the information with regards to this corrective action.

1. **Correction Number and Identification of the product involved**

Correction Number:	FSN/SUZ-001-2017
Brand Name(s):	Flowtron ACS 900
Generic Name(s):	SLEEVE, LIMB, COMPRESSIBLE
Model Number(s):	525000-xx*,526000-xx* *xx denotes country code
Regulation Class:	II
Intended use:	The intended use of the Flowtron ACS 900 system is to prevent the occurrence of Deep Vein Thrombosis (DVT) in at-risk patients. The system must be used as part of a prescribed plan of care under the supervision of trained medical and/or Clinical staff. The system is intended for use only in professional healthcare facilities. It is not intended to be used in the home healthcare environment (e.g. private dwellings). The nature of the therapy delivered is fixed by the device and is not readily configurable by the user.

2. **Serial Numbers of affected product or Serial Number Range of affected product.**

All Flowtron ACS 900 medical pumps manufactured by Getinge (Suzhou) Co., Ltd. since Sep 26, 2014 through December 20, 2016. Refer to Appendix A for a complete list of affected serial numbers.

3. **Recalling firm information.**

Manufacturer:

Name:	ArjoHuntleigh AB
Address:	Hans Michelsesngatan 10

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City:	Malmo	**Zip/Postal Code:**	21120
Country:	Sweden		
Type of firm:	Legal Manufacturer		
Recall Contact:	Kinga Stolińska	**Title:**	Sr. Director Complaint Handling & Vigilance
Phone:	(48) 61 664 5444	**Email:**	vigilance@arjohuntleigh.com

Importer/Distributor:

Name:	[ArjoHuntleigh Singapore Pte Ltd]
Address:	[20 Bendemeer Road, BS Bendemeer Centre, 06-03, Singapore 339914]
City:	[Singapore]
Country:	[Singapore]
Establishment Registration Number:	[ES0001568]
Contact:	

5. Firm responsible for problem.

Name: ArjoHuntleigh AB

6. REASON FOR FIELD CORRECTION/RECALL:

A. Detail of how product is defective.

It has been identified that in the unspecified circumstances (still being subjected to extensive investigation), the pump continues to deliver pressure to one of the garments without raising an alarm.
ArjoHuntleigh investigated the problem and concluded that a continuous high pressure provided to the garment and not deflating symptom may occur on the Flowtron ACS900 pumps providing a potential for risk to the patient.
At this time, despite of extensive investigation it could not have been determined what is causing this symptom to occur. The alleged failures are still being comprehensively investigated.

B. How the defect affects the performance and safety of the product.

The issue that was recognized may cause the appropriate therapy not to be provided to the patient as defined in the device labelling due to the alleged failure. The pump provides continuous/high pressure to the garment and not deflating as intended which may affect blood flow of vascular system.

C. Explain how the problem occurred and the date(s) it occurred.

In April of 2016 a complaint was received from an Australian hospital in which it was reported that a Flowtron ACS900 pump had a garment that remained inflated while the other garment remained deflated. Additional details supplied indicated that the pump in this state was found with the LCD off, the compressor running, and the status LEDs lit green. At that time a thorough investigation was started and a CAPA process was initiated. Devices returned from the field where this failure mode was reported were tested and run for many hours without failure. The condition

reported in complaints was never replicated and CAPA was closed inconclusive in October 2016. Despite comprehensive testing performed on returned samples, the failure could not have been reproduced until late April 2017 when the system involved in one of the latest complaints was isolated, kept in the failure state and made available for ArjoHuntleigh evaluation.

D. Explain how the problem was discovered and the date it was discovered.

The actual failure with the product have been discovered during the on-site visit on April 28th 2017,at Kaiser Permanente – Downey, where for the first time the ArjoHuntleigh R&D representative have been able to evaluate pump kept in this "failed" state.

All previous attempts to replicate reported problems have been unsuccessful since the evaluated pumps were turned off and on which cleared the failure.

To date, the failure investigation of the system hardware and software has not revealed a root cause. The investigation has however, with a high degree of confidence, shown that software version 2.000 will handle the failure state in a more resilient manner. If the failure state occurs in a device with software version 2.000, the device will reset, restart, and therapy will continue. The specific symptom observed in the field may, with a high degree of confidence, be addressed by upgrading devices to software version 2.000.

E. Provide detailed information on all complaints associated with the product problem.

Until today there have been 23 customer complaints on Flowtron ACS900 alleging that during use with patients the pump continues to deliver pressure to one of the garments and do not deflate. The customer complaints have been reported in United States, Australia and Austria. There have been total of 5 reports of serious injury occurrence.

7. Health Hazard Assessment.

The severity of harm associated with the pump providing continuous/high pressure to garment and not deflating has been assessed as high – Critical. The malfunction might contribute to Impaired Circulation, Tissue Ischemia / Deep Tissue Injury. The probability of its occurrence is considered to be relative to the patient monitoring scheme. In majority of reported issues (18 out of 23 reports) the problem was mitigated through frequent patient monitoring (as advised in the product IFU). The serious injury occurrence (5 out of 23) was reported in circumstances where the garments were not inspected for over 6 hours. The probability of occurrence of serious injury is considered to be remote. It is worth noting that the device is intended to be used in acute care environments only where patient condition shall be frequently monitored – as required per the device labelling.

8. VOLUME OF RECALLED PRODUCT:

A. Total quantity produced:	40 675 units manufactured with software V1.099
B. Date(s) produced:	from Sep 26, 2014 to December 20, 2016
C. Quantity distributed:	40 675 worldwide

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9. DISTRIBUTION PATTERN:

A. Number of direct accounts: [1 Customer]

B. Consignee list (include both ship-to and bill-to customers, if possible):

Refer to Appendix A for customer list.

10. STRATEGY:

A. Level to which you are extending the recall: End user

B. Method of notification:

A Field Safety Notice and Customer Response form will be mailed to affected customers.

C. How notification will be sent: Registered mail, signature required

D. Instructions to customers:

1. Affected customers need to ensure that all caregivers and users of the ArjoHuntleigh Flowtron ACS900 pump are made aware of the Field Safety Notice and all listed devices at their facility are available to be upgraded to software version V2.000 during the service technician visit. Affected customers need to review the Field Safety Notice and to acknowledge receipt and understanding of the Field Safety Notice and the required actions by completing, signing and returning the Customer Response Form to the local ArjoHuntleigh office.

2. Note! 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.

E. Effectiveness check strategy (incl. for non-responders):

1. Customers will be asked to complete and sign the Customer Response Form and return it to the local ArjoHuntleigh office.
2. Customers will be required to confirm (via the Customer Response Form or an ArjoHuntleigh Service Call Report) that the required corrective actions noted in the Field Safety notice were completed.
3. A total of three notices, with original notification documentation, will be sent to non-responding customers.

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11. Name and Telephone number of the firm's official contact concerning the Field Correction

ArjoHuntleigh Representative: ArjoHuntleigh Singapore Pte Ltd
[20 Bendemeer Road, BS Bendemeer Centre, 06-03]
[Singapore 339914]
[Singapore]
Contact: [Chris Tan Weng Lin, Senior Product Specialist]
Phone: [+65 9823 7989]
Fax: [+65 6293 3389]
Email: [chris.tan@getinge.com]

If you have any questions or require additional information regarding this submission, please do not hesitate to contact us.

Sincerely,

[Chris Tan] [redacted]

cc: K. Bobrow, K Stolinska, E Coffin, K Urbaniak, D Qin, J Crist, Chairman Medical Board and relevant Head of Departments

Enclosures: Refer to the enclosed list of appendices and attachments.