Recall Notification for Regulatory Authorities

05 March 2026

Medical Device Authority
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II, Block 3547,
Persiaran APEC, 63000 Cyberjaya, Selangor,
Malaysia

Subject : Voluntary Field Safety Corrective Action

Company field safety action reference number: FSN_3502261

Manufacturer Name: ArjoHuntleigh Polska Sp. z o.o.

Importer/Distributor Name: Best Contact (M) Sdn Bhd

Product: Tenor mobile passive patient lift

Dear Sir/Madam,

This letter is to inform you of our intention to perform a Voluntary Field Safety Corrective Action involving the Tenor mobile passive patient lifts and associated lifting actuators (part number TEN.107), which have been distributed across a number of markets.

Outlined below and on the following pages is the summary of information with regards to this corrective measure.

1. Correction Number and Identification of the product involved

Correction Number:	Internal Arjo no. FSN_3502261
Brand Name:	Tenor – mobile passive patient lift
Model Number:	KHA10xx-xx
Product Code:	KHA10xx-xx
Product Class:	Class A Medical Device
Intended use:	The Tenor is a mobile passive patient hoist intended for lifting and transfer of adult patients and residents in healthcare and long-term care environments. The device is intended to be used by trained caregivers in accordance with the Instructions for Use and has a Safe Working Load of up to 320 kg.
Is product sterile?	No
Is product controlled by software?	No
Is this a trackable device?	No
Is this an implantable device?	No
Total quantity manufactured:	252 Tenor lifts and 4 spare lifting actuators (TEN.107)
Quantity distributed:	175 Tenor lifts and 1 spare lifting actuators (TEN.107)
Distribution Date ranges:	2025-Mar-06 and 2025-Nov-17
Amount of product quarantined:	79
CAPA ref. no.:	3511308
Recall initiation date:	2026-03-09

2. Range of the affected product

- 252 Tenor mobile passive patient lifts (Model Number: KHA10xx-xx) released from the manufacturing facility between 2025-Mar-06 and 2025-Nov-17, incorporating lifting actuators originating from the affected supplier batch.
- 4 spare lifting actuators TEN.107 (also within spare part RKT.560) distributed through Arjo service channels.

3. Firm information

Recalling Firm:	ArjoHuntleigh Polska Sp. Z o.o.		
Address:	ul. Ks. Piotra Wawrzyniaka 2		
City:	62-052 Komorniki, Poland		
Country:	Poland		
Type of firm:	Manufacturer of the recalled medical device		
Top Firm Official:	Mr. Andréas Elgaard	**Title:**	CEO
Address:	Hans Michelsensgatan 10		

City:	Malmo 211 20, Sweden		
Phone:	+46 10 335 4899		
Email:	Andreas.Elgaard@arjo.com		
Manufacturer:	ArjoHuntleigh Polska Sp. z o.o.		
Address	ul. Ks. Piotra Wawrzyniaka 2		
City	62-052 Komorniki, Poland		
Country	Poland		
Recall Contact:	Tagudin Madeline	**Title:**	Quality and Regulatory Compliance Officer
Address:	31 Kaki Bukit Road 3, 05-06/07 Techlink Lobby B		
City, State, Zip	Singapore		
Phone:	+65 6202 7366		
Owner/Operator Number:	+65 8268 8184		
Email	Madeline.Tagudin@arjo.com		
Corporate Recall Contact (Public Contact):	Justyna Kiełbowska	**Title:**	VP Corporate Quality Systems, Complaints and Vigilance.
Address:	Hans Michelsensgatan 10		
City:	Malmo 211 20, Sweden		
Phone:	+48 61 664 5463		
Email:	vigilance@arjo.com		

4. Reason for field corrective action /recall

A. Detail of how product is defective.

The Tenor is a mobile passive patient hoist intended for lifting and transfer of adult patients and residents in healthcare and long-term care environments. The identified issue concerns the lifting actuator (part number TEN.107) used in the Tenor lift.

During final product testing at the manufacturing site, abnormal behaviour of the lifting actuator was identified, which prompted a detailed investigation involving the actuator supplier. The investigation confirmed a manufacturing deviation affecting an internal brake component of the actuator, originating from a specific sub-supplier batch. The affected brake component exhibits excessive porosity and reduced mechanical strength, resulting in insufficient braking torque. As a consequence, the actuator may lose its self-locking function when subjected to load.

In the event of brake failure, the actuator push tube may collapse rapidly and uncontrollably during patient lifting or transfer. This failure mode is mechanical in nature and cannot be detected through normal pre-use checks, preventive maintenance, or routine functional testing. The defect becomes evident only at the moment of the failure and cannot be mitigated by any precautionary measures.

The affected Tenor lifts and spare actuators were manufactured and distributed across a number of markets. The issue was identified through internal quality controls and supplier investigation, and not as a result of complaints or adverse events reported from the field.

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

Although no complaints, incidents, or injuries related to the identified actuator issue have been reported from the field to date, the Health Hazard Evaluation has demonstrated that the issue has a potential to lead to severe health consequences. The supplier manufacturing deviation affecting the internal brake component of the actuator may result in a loss of the actuator's self-locking function under load. In such a

scenario, the actuator push tube may collapse rapidly and uncontrollably during patient lifting or transfer, which directly compromises the intended performance and safety of the device.
Based on the Health Hazard Evaluation, the most serious reasonably foreseeable outcomes include:

- For patients/residents: patient fall, head injury, major trauma;
- For caregivers: musculoskeletal injury, fractures, or other serious physical injury.

While the probability of occurrence based on post-market surveillance data is currently considered remote, the potential severity of harm is high as the defect cannot be detected prior to failure.

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

The problem originated from a supplier-related manufacturing deviation affecting an internal brake component used in the lifting actuator (part number TEN.107). During the production of a specific sub-supplier batch, an uncontrolled process variation introduced excessive material porosity, resulting in reduced mechanical strength of the brake component. This defect has the potential to compromise braking torque and the actuator's self-locking capability under load.
The manufacturing deviation is understood to have occurred at the time this batch was produced by the sub-supplier. No actuator collapse or similar event has occurred in the field or during Arjo's final product testing. The presence of the deviation was later confirmed by the actuator supplier on 2025-Dec-22 through their testing and batch analysis.

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

The issue was initially identified during final product testing at the Arjo manufacturing site, when abnormal actuator behaviour prompted an internal problem notification. At that time no actuator collapse, nor any symptom leading to its eventual collapse was observed. The affected actuator (TEN.107) was returned to the supplier for analysis. In 2025-Dec-22 the supplier confirmed to Arjo a manufacturing deviation affecting an internal brake component originating from a specific batch. These investigative findings established the defect and initiated Arjo's risk evaluation process.

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

At the time of initiating this Field Safety Corrective Action, no customer complaints related to the identified actuator issue affecting the Tenor lift have been received. There have been no reports of actuator collapse, loss of braking function, or any performance failure in distributed units. The issue was not identified through the Post Market Surveillance.

Complaint Summary:

- Deaths: 0
- Complaints claiming injuries: 0
- Number of units involved in complaints: 0

5. Health Hazard Assessment

Describe risk to resident/caregiver:

Arjo confirms that the identified actuator issue has not resulted in any injuries (serious or non-serious), or other adverse health consequences to date, either for patients/residents or caregivers.

Based on the Health Hazard Evaluation, in the event of brake failure, the actuator push tube may collapse rapidly and uncontrollably during patient lifting or transfer. In such a scenario, the most serious reasonably foreseeable outcomes include:

-For patients/residents: patient fall, head injury, major trauma;
- For caregivers: musculoskeletal injury, fractures, or other serious physical injury.

While the probability of occurrence based on Post Market Surveillance data is currently considered remote, the potential severity of harm is high, and the defect cannot be detected prior to the failure occurrence.

6. Volume of recalled product

A. Total quantity produced worldwide: 252 Tenor lifts and 4 spare lifting actuators (TEN.107)

B. Quantity distributed worldwide: 175 Tenor lifts and 1 spare lifting actuators (TEN.107)

C. Quantity distributed to Malaysia: 1 Tenor lifts and 1 spare lifting actuators (TEN.107)

7. Strategy

A. Level to which you are extending the recall:

End user

B. Method of notification:

Field Safety Notice and Customer Response Form (please refer to Appendix 1 & 2) are to be mailed/distributed via common carrier, to the affected customers.

C. How notification will be sent:

Customers identified as owners of the affected Tenor mobile passive patient lifts (Model KHA10xx-xx) and/or spare lifting actuators (part number TEN.107) will be notified of the identified risk through the Field Safety Notice (FSN_3502261) issued by Arjo.

Affected customers are requested to ensure that all caregivers, clinical personnel, and other users of the affected devices are informed of the Field Safety Notice and to forward a copy of the notice to all relevant departments within their organization, as well as to any third parties to whom the affected devices may have been transferred.

A total of four documented contact attempts will be made before a customer is considered non-responsive to the Field Safety Notice (FSN). This includes one initial outreach followed by up to three subsequent follow-up attempts.

D. Instructions to customers:

Customers will be requested to acknowledge receipt of the Field Safety Notice, complete and sign the enclosed Customer Response Form, and return it to Arjo using the contact details provided in the notice.

Upon receipt of the Field Safety Notice, all affected Tenor lifts must be immediately withdrawn from use and remain quarantined out of service until the corrective action has been completed. No temporary precautionary measures, additional checks, or changes in use practices can mitigate the identified risk.

The corrective action consists of on-site replacement of the affected actuator (TEN.107) with a compliant component by authorized Arjo service personnel and will be performed free of charge.

Affected devices may be returned back to service only after completion of the corrective action. The devices do not require destruction or return, as the correction can be performed directly at the customer's facility.

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

The effectiveness of the Field Safety Corrective Action will be monitored through confirmation of Field Safety Notice reception and completion of the corrective action.

Dissemination of the Field Safety Notice (FSN_3502261) will be considered completed when 100% of identified customers have either returned a completed Customer Response Form or have not responded after four documented contact attempts. These attempts include one initial notification followed by up to three subsequent follow-up contact attempts.

For customers who do not respond after the documented contact attempts, the status will be recorded as non-responsive in accordance with internal field action procedures.

Regardless of whether a completed Customer Response Form is received, all identified customers will be informed of the Field Safety Notice and the required corrective actions. Follow-up activities will continue until all affected devices have been corrected.

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

Sincerely,

Tagudin Madeline
Quality Regulatory Compliance Officer
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Madeline.Tagudin@arjo.com

CC: J Kiełbowska, E Coffin, N Sahaj, K Urbaniak, Anna Nowotna,

Enclosures:

Appendix 1 –Field Safety Notice
Appendix 2 – Customer Response Form
Appendix 3 – Consignee List (Malaysia)