

URGENT – FIELD SAFETY NOTICE
Concerto & Basic shower trolley



Customer Name
Customer Address

Cc: Chairman Medical Board and relevant Head of Departments

Date:	2019-AUG-16
Product Issue:	Concerto & Basic shower trolley – Potential unintentional drop of safety side panel
Affected Product:	<p>✓ Concerto & Basic shower trolleys manufactured between November 2018 and June 2019; [REDACTED]</p> <ul style="list-style-type: none"> Concerto & Basic shower trolleys fitted with the affected spare parts (safety catch) part no. 8451622, 8546608, S8533571-031, S8533572-031, S8533570-031 S8542201-014, S8523559-031, 100-805-03, 100-806-03 during service between 2018-Nov-27 and 2019-Jun-14
Affected Serial No.:	Attachment A
Resolution:	Safety catches replacement in order to ensure the device is operating safely
Field Safety Notice:	FSN-POZ-002-2019
Pages:	3 & Customer Response Form

Dear Customer,

Our records indicate that you may have one or more Arjo Concerto or Basic shower trolley(s) within your facility(ies). This letter is to inform you of a safety-related corrective action that will be performed on the affected device(s).

Each Concerto & Basic shower trolley is equipped with two Side Supports, one on each side of the shower trolley (Image 1). Each side support is secured by two (2) Safety Catches (Image 2) which are used to fold down the supports as well as secure the support in the raised position.

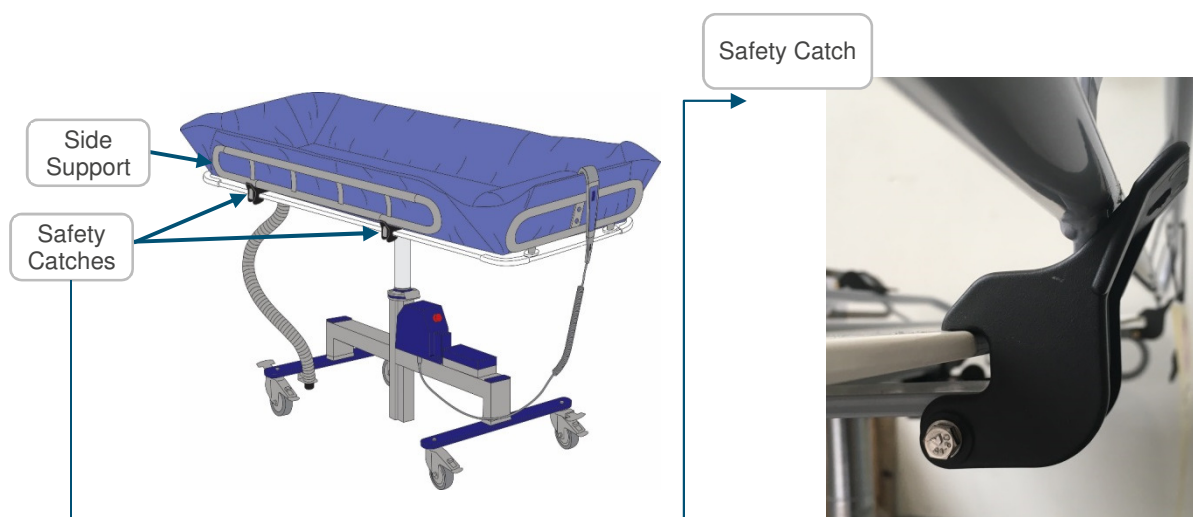


Image 1

Image 2

Arjo has become aware that any of the 4 Safety Catch(es) may exhibit a mechanical failure (break in one of the arms of Safety Catch), which in certain circumstances may contribute to the Side Support unintentionally opening and may lead to a potential risk of patient fall, leading to possible injuries to patient and/or caregiver.

Until the day of the safety-related corrective action launch, Arjo has received six incidents with this failure mode where one (1) out of four (4) Safety Catches broke. Although the likelihood of an adverse injury or event is limited, Arjo is taking this matter very seriously and intends to perform corrective action on the affected units.

Next Steps

1. Verify the condition of all 4 Safety Catches attached to your device. If you notice the break (as shown in Image 3) withdraw the trolley from use.



Image 3



Image 4

IMPORTANT: The device may stay in use until the upgrade is performed, providing that the following instructions are carefully followed:

- ✓ It is recommended that the Safety Catches on the shower trolley Side Supports be inspected daily to ensure any of the catches are not broken as show on the Image 3.
- ✓ The patient is not left unattended at any time.
- ✓ The patient is fully assisted so that he/she does not grab, push or lean against the Side Supports during showering activities.
- ✓ Caregivers should limit pulling and pushing of the Side Supports with excessive force.
- ✓ **Note:** always adhere to the Safe Working Load as outlined in the IFU.

2. Ensure that all caregivers and users of Arjo Concerto & Basic shower trolleys are made aware of this Field Safety Notice (FSN) and all listed devices at your facility are available to be retrofitted free of charge during the service technician visit.
3. Complete and sign the enclosed Customer Response Form and return this form to your local Arjo office. Once returned, Arjo will contact the designated facility representative listed on the Customer Response Form to schedule the service call on all devices at your facility.

Note: if your facility has sold or moved affected Concerto & Basic shower trolley, please include the new facility's information in the Customer Response Form.

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 from your facility.

We regret any inconvenience that this Field Safety Notice may cause, however we greatly appreciate your understanding as we take actions to ensure the safety of our patients/residents.

Please note that the possibility of the described failure occurring is limited only to the specific range of serial numbers (as presented on page 1).

The notice has been submitted to the Regulatory Agency/National Competent Authority in Singapore.

Additional Comment

If you have any further questions or require assistance completing the Customer Response Form, please contact Arjo at 6202 7367 [REDACTED].

Customer Response Form

URGENT FIELD SAFETY NOTICE FSN-POZ-002-2019

Reference: Concerto & Basic shower trolley – Potential unintentional drop of safety side panel

Our records indicate that the Concerto & Basic shower trolley(s) listed below was/were delivered to your facility. Please verify if you have any of the listed devices (table on page 2) that are potentially affected and complete the information below.

Record the total number of affected devices currently located at your facility here → ____.

Please mark the appropriate boxes below:

- ☐ We have read the Concerto & Basic shower trolley Field Safety Notice and we understand the communication and the required actions.

If marked: please provide information where the affected devices are physically located now.

Field Safety Notice Receipt and Customer Response Form Completion

Current Facility Name			
Contact Name / Title			
Full Address			
City, State/Province, Zip/Post Code			
Phone Number		Fax:	
E-Mail Address			
Signature		Date:	

- ☐ We have sold/moved our Concerto & Basic shower trolley(s) to another facility.

If marked: please provide new facility information below.

New Facility Name			
Contact Name / Title			
Full Address			
City, State/Province, Zip/Post Code			
Phone Number		Fax:	
E-Mail Address			
Signature:		Date:	

PLEASE RETURN YOUR COMPLETED FORM TO:

MAIL

Arjo South East Asia Pte. Ltd.
31 Kaki Bukit Road 3
#05-06/07 Techlink Lobby B
Singapore 417818

CONTACT

Michael Ryan Falceso Perez
Quality & Regulatory Compliance Officer, SEA
Tel. No.: +65 6202 7367

Fax No.: +65 6747 0994

Concero & Basic shower trolley(s) delivered to your facility:

SERIAL NO.	FACILITY CURRENT OR NEW (mark a correct one)		ROOM / FLOOR / WARD
<XXXX>	CURRENT	NEW	
<YYYY>	CURRENT	NEW	
	CURRENT	NEW	
	CURRENT	NEW	
	CURRENT	NEW	
	CURRENT	NEW	
	CURRENT	NEW	
	CURRENT	NEW	