

URGENT – FIELD SAFETY NOTICE
Concerto & Basic shower trolley



Date:	2019- MMM-DD
Product Issue:	Concerto & Basic shower trolley – Potential unintentional drop of safety side panel
Affected Product:	<ul style="list-style-type: none"> ✓ Concerto & Basic shower trolleys manufactured between November 2018 and June 2019; Serial number ranges: P0512263 to P0551621 ✓ 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, Attachment A & 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.

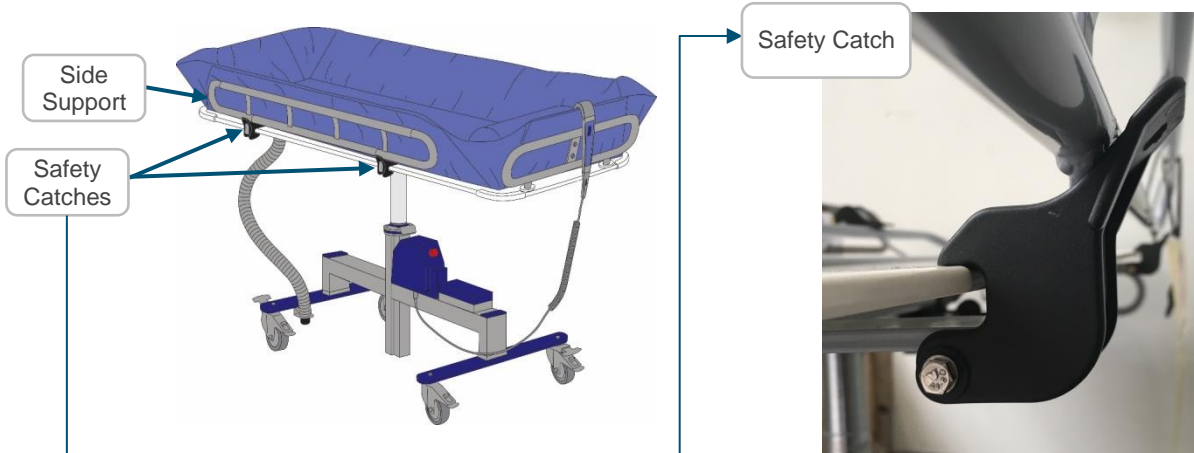


Image 1

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 your country **[insert name]**.

Additional Comment

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]**.

Attachment A - Affected Devices

No	Serial Number	Customer Facility Name
1		
2		
3		
4		
5		
6		