

FIELD SAFETY NOTICE***Arjo Carevo shower trolley***

Date:	dd-mmm-2026
Product Issue:	Carevo shower trolley torsion spring defect that may increase likelihood of incomplete handle locking potentially contributing to side support opening.
Affected Product:	The scope of potentially affected products includes all Carevo devices manufactured between 01-Aug-2025 – 29-Oct-2025
Resolution:	Reminder of the warnings already included in the Instructions for Use (IFU) supplied along with the device. Torsion spring replacement in affected devices to eliminate the identified contributing factor to unintentional side support opening.
Field Safety/Correction Notice:	FSN_2980188-3
Pages:	6 & Customer Response Form
Single registration number of the manufacturer:	SE-MF-000000696

Attention: Clinical Personnel, Caregivers, Nurses, Risk Managers, Nursing Managers, Biomedical Personnel

Dear Customer,

Arjo is contacting you because our records indicate that your facility may have received one or more Arjo Carevo shower trolleys. Over recent years, Arjo has received number of events where the side support opened unintentionally during use. This Field Safety Notice (FSN) aims to inform you about this risk and the actions introduced to support safe device operation.

Description of the issue

Unintentional side support opening does not occur spontaneously. Such situations may arise when the handles are not fully locked and additional force is applied to the handle during patient handling (for example by the caregiver's thigh or knee).

The internal investigation confirmed that the primary factor leading to unintentional side support opening and therefore a potential risk of patient fall is incorrect or incomplete handle locking combined with user (caregiver) movement during handling the trolley.

To address this issue, the Instructions for Use (IFU) were updated to reinforce proper handle engagement and recommended ergonomic practices.

Please note: Your device was supplied with an IFU that already includes these warnings.

Additional investigation showed that a supplier-related batch of torsion springs may not always support full return of the handle to its locked position. This may cause the handle to remain partially engaged, making the sequence of events that leads to unintentional opening more likely if other conditions occur.

Important note: The torsion spring deviation does not cause the side support to open by itself.

Unintentional opening requires a combination of incomplete handle locking and force applied to the handle.

Clinical risk

If the side support is not fully locked and additional force is applied by the caregiver on the handle (e.g., during turning or repositioning), the panel may open unintentionally, which can lead to a resident/patient fall and serious injury, such as head injury, fractures, or other trauma resulting from a fall.

Users may continue to use the Carevo shower trolley. Caregivers should handle the device carefully following the Instructions for Use.

Solution to the issue

This Field Safety Notice addresses the issue through two measures:

1. **User awareness** - Your device has been already supplied to your facility with the updated IFU containing warnings added to reinforce correct handle engagement and safe operating posture. Please ensure that all caregivers remain familiar with these warnings.
2. **Torsion spring replacement** on affected devices to remove the identified contributing factor (dimensional non-conformity in the affected supplier's batch), performed by Arjo Service. Although the spring deviation does not cause the side support to open by itself, Arjo will replace the torsion springs in affected devices to remove this additional contributing factor.

As a reminder, please review the following points to support safe operation:

1. When the side panels snap into place, a characteristic "click" sound can be heard.



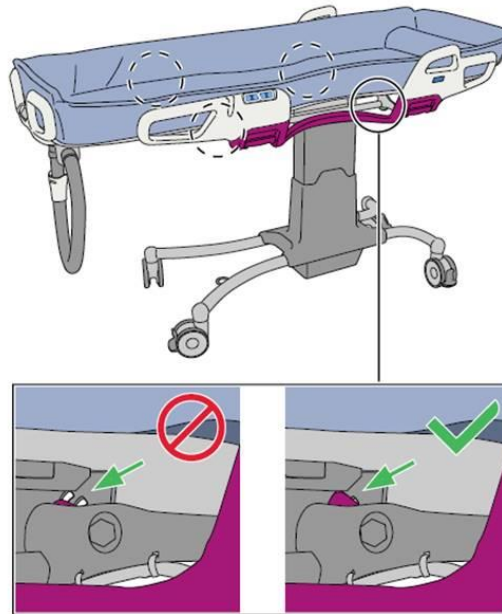
Pic. 1. Fold up the side support from the down folded position..

2. **Ensure both latches on each side support are in the locked position.** Failure to comply may result in unintentional side support opening while handling a patient/resident, posing their fall risk. Refer to picture 2.

Latches in the correct locked position – actual device photo



Illustration from the IFU



Pic. 2 Latches in the correct and incorrect locked position and their location on the device (actual device photo vs. illustration from IFU)

3. **Avoid hitting or pushing the side support handle with your thigh or knee when handling the patient.** Failure to comply may result in unintentional side support opening while handling a patient, posing a fall risk. Refer to Pic.3.



Pic. 3. Warning regards to knee hitting the handle.

Unintentional opening of the side support is very unlikely when the device is used according

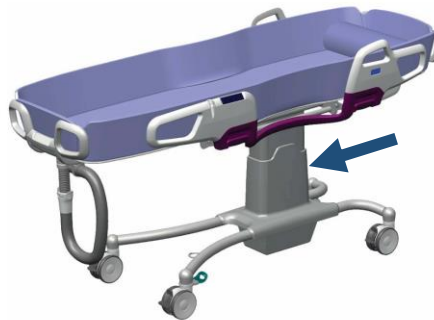
to the Instructions for Use (IFU), including fully locking both handles and maintaining the recommended ergonomic working posture.

Although Arjo will replace the torsion springs in the affected devices to remove a contributing factor, proper handling of the device remains essential.

Potential Risks: Failure to follow these instructions may result in patient fall, which can lead to a serious injury.

How to identify whether your device is in the scope:

To determine whether the Carevo shower trolley in your facility is affected, please check its serial number. The serial number label is located on the lower frame (chassis) of the shower trolley, between the leg, from the head-end side of the device, as shown in the reference photo below. Please compare the serial number on your device with the list of affected units provided by your local Arjo representative along with this letter.



Next Steps:

1. Continue using the device, following the warnings and instructions in the IFU provided with your Carevo shower trolley.
2. If your facility has lost the IFU, it can be downloaded here:
<https://documents.arjo.com/detail/252810/71>
or please contact your local Arjo representative to obtain a copy of the IFU.
3. Complete and return the Customer Response Form to your local Arjo representative, including details of any devices that have been sold or transferred to another facility. (Form attached to this notice.)
4. Ensure availability of all affected devices for the torsion spring replacement and designate a facility contact person. Arjo will contact this representative to schedule the corrective action visit.
5. Maintain awareness of this notice and the applicable IFU at your site. If you have any questions or concerns regarding the safe operation of the side supports, please contact your Arjo representative.

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.

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]**.

Customer Response Form

FIELD SAFTY NOTICE FSN_2980188-3

Reference: Carevo shower trolley – increased likelihood of incomplete handle locking, which may contribute to unintentional side support opening.

Our records indicate that the Carevo shower trolleys were delivered to your facility. Please verify if you have any of the potentially affected devices and complete the information below for each Carevo.

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

Please check the appropriate boxes below:

☐ We have read the *Carevo* Field Safety Notice and we understand the communication and the required actions.

Signature	Date

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

Field Safety Notice Receipt and Customer Response Form Completion

<u>Current</u> 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 *Carevo shower trolley(s)* to another facility.

Signature	Date

If checked : please provide new facility information below.

<u>New</u> Facility Name			
Contact Name / Title			
Full Address			

City, State/Province, Zip/Post Code			
Phone Number		Fax:	
E-Mail Address			
Signature:		Date:	

☐ Our Carevo shower trolley(s) had been decommissioned prior to the Field Safety Notice reception.

Signature	Date

☐ Our Carevo shower trolley(s) cannot be located despite numerous attempts.

Signature	Date

PLEASE RETURN YOUR COMPLETED FORM TO:

MAIL

<local SSU address line 1>

<local SSU address line 2>

<local SSU address line 3>

<local SSU address line 4>

CONTACT

<contact address>@arjo.com

Tel: <SSU contact phone number>

Fax: <SSU contact fax number>

List of devices delivered to your facility

SERIAL NO.	FACILITY CURRENT OR NEW (mark a correct one)		ROOM / FLOOR / WARD	COMMENT (e.g not located, decommissioned, sold/moved etc)
<XXXX>	CURRENT	NEW		
<YYYY>	CURRENT	NEW		
	CURRENT	NEW		
	CURRENT	NEW		
	CURRENT	NEW		
	CURRENT	NEW		
	CURRENT	NEW		
	CURRENT	NEW		