

FIELD SAFETY NOTICE**Arjo Symbliss Bath Chair**

Date:	2025-mm-dd
Product Issue:	Welds in the base frame were applied contrary to specification, which may lead to progressive cracking and structural failure.
Affected Product:	Symbliss Bath Chair without scale, models SYBCB001-XX and SYBCS001-XX potentially affecting 13 Symbliss Chair devices shipped to EU markets (end customers). Refer to list of the affected serial numbers at the end of this notice.
Resolution:	Temporary withdrawal from use and replacement of base frame with compliant part. Rework to be performed by Arjo technicians.
Field Safety/Correction Notice:	FSN_3340453
Pages:	3 & Customer Response form
Single registration number of the manufacturer:	SE-MF-000000696

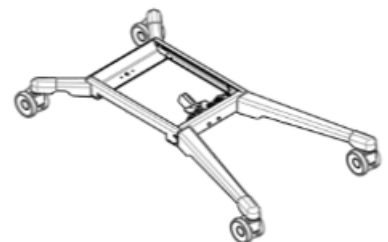
Attention: Clinical Personnel, Caregivers, Risk Managers, Nursing Managers, Biomedical Personnel

Dear Customer,

Our records indicate that your facility may have received one or more Arjo Symbliss Bath Chairs affected by a manufacturing deviation in the base frame welds. This Field Safety Notice is issued to inform you of a potential safety risk and the corrective action required.

Description of the issue:

During final product testing at Arjo manufacturing site, a deviation was identified in the welds of the base frame used in Symbliss Bath Chair models without scale. Specifically, the welds were applied in a manner inconsistent with the technical specification, which may affect the long-term structural integrity of the frame.



The weld defect is not externally visible due to the presence of a cover on the base frame and may develop progressively during use.

Although no failures or injuries have occurred in the field, Arjo is initiating this Field Safety Notice as a preventive measure to address all potentially affected units and ensure continued safe use of the product.

Figure 1 Base frame assembly

Clinical risk:

If the weld were to fail during use, the chair may become unstable and tip over. This could result in unintended movement or tipping, posing a risk of injury.

If a weld is not applied according to specification in the base frame, the bath chair may become unstable and tip over. This poses serious safety risks:

- For residents: In the event of a tip-over while the chair is occupied, the individual may be exposed to a risk of falling, which could potentially result in head injury, fractures, or other serious trauma.
- For caregivers: If the chair collapses during handling or movement, it may strike the caregiver, potentially causing musculoskeletal injury, such as contusions, sprains, fractures, or in severe cases, internal injury.

This action is being taken proactively to mitigate any possible risk and maintain the highest safety standards.

Solution to the issue:

Arjo will provide replacement base frames that meet all applicable technical specifications. Prior to any corrective action, the weld joints in the base frame will be inspected by authorized Arjo service technicians.

If the inspection confirms that a weld does not meet the required criteria, the affected chair will be disassembled and the base frame will be replaced to restore full structural integrity and ensure continued safe use of the device.

Note: Until the correction is completed, the affected chairs should be withdrawn from use.

Next Steps:

1. Remove the affected Symbliss Bath Chairs from use and quarantine them until the corrective action is completed. This will ensure the devices are not used for patient/resident hygiene care or transfer.
2. Ensure that all caregivers and users of Symbliss Bath Chairs are made aware of this Field Safety Notice (FSN), and that all listed devices at your facility are available for inspection and correction by Arjo service personnel.
3. Complete and sign the enclosed Customer Response Form and return it to your local Arjo office. Once received, Arjo will contact the designated facility representative listed on the form to schedule the corrective action visit.

Please note: if your facility has sold or moved the Symbliss bath chair, please include the new facility's information in the Customer Response Form.

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 and caregivers and to resolve the issue as quickly and effectively as possible.

The notice has been submitted to the Regulatory Agency/National Competent Authority in your country [insert name of the Competent Authority].

Additional Comment

If you have any further questions or require assistance in completing the Customer Response Form, please contact Arjo at <local SSU contact phone number> or via email at <local SSU email address>.

The list of the affected serial numbers of Symbliss Bath Chair:

1. P0885581
2. P0885837
3. P0886839
4. P0895823
5. P0897849
6. P0905984
7. P0905985
8. P0906088
9. P0906096
10. P0906390
11. P0906408
12. P0906627
13. P0917515

Customer Response Form

FIELD SAFETY NOTICE FSN_3340453

Reference: Symbliss Bath Chair - base frame weld failure

Our records indicate that you may have one or more *Symbliss Bath Chair* within your facility (ies). Please verify if you have any of the listed devices (table on page 2) that are potentially affected and complete the information below. Return the completed and signed-off Customer Response Form as soon as possible.

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

Please check the appropriate box below:

- ☐ We have read the *Symbliss Bath Chair* Field Notice and we understand the communication and the required Next Steps.

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

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			
Legible signature		Date:	

- ☐ We have read the enclosed Field Safety Notice and we understand the communication and the required Next Steps. We have sold/moved our *Symbliss Bath Chair* to another facility.

If marked : Please provide new facility information below. If your devices have been transferred to more than one facility, please write down their serial numbers and new addresses at the bottom of the last page.

New Facility Name			
Contact Name / Title			
Full Address			
City, State/Province, Zip/Post Code			

Phone Number		Fax:	
E-Mail Address			
Signature:		Date:	

☐ We have read the enclosed Field Safety Notice and we understand the communication and the required next steps. We had decommissioned our *Symbliss Bath Chair* permanently before the Field Safety Notice was received.

If marked: Please fill in the following table.

Legible signature:		Date:	
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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

BRAND NAME	SERIAL NO.	FACILITY ROOM / FLOOR / WARD
	<XXXX>	
	<YYYY>	