

URGENT – FIELD SAFETY NOTICE

Nimbus 4 & Nimbus Professional mattress – risk of over-inflation

Date: 2021-Apr-20

Product Issue: Mattress over-inflation

Affected Product: Arjo Nimbus 4 & Nimbus Professional mattress

Affected Serial No.: Attachment A

Resolution: Deactivate mattress grommet membrane

Field Safety Notice: FSN-SUZ-001-2021

Pages: 3 & Customer Response Form

Single registration number of the manufacturer: SE-MF-000000696



Dear Customer,

Our records indicate that you have one or more Arjo Nimbus 4 and/or Nimbus Professional pressure injury prevention mattress (es) within your facility (ies).

We are contacting you to provide information regarding safety-related corrective action initiated by our company to address a recently detected potential product failure.

Note: This notice applies to the Nimbus 4 and Professional mattress systems only. No other Arjo mattresses systems are affected by this potential issue.

Arjo has received limited reports of the Nimbus 4/Professional mattress over-inflating which requires an unusual set of circumstances to occur. This is a very rare occurrence and there have been no reports of health consequences to either patients or caregivers due to this issue.

Our investigation has concluded that there is a remote possibility that a patient could fall from the mattress if the issue was to occur and was not detected by care givers. The issue is caused by inner mattress components that may fail after a certain period of time, however this is extremely rare and unfortunately cannot be detected until the product is disassembled.



Malfunctioning
mattress

Although Arjo acknowledges there may be a potential risk related to the issue, it has never led to any patient fall.

Please be assured that Arjo is taking this matter very seriously and therefore contacting to notify you of the potential risk and provide an instruction how to remove the risk immediately and completely – please refer to a provided video recording.

Next Steps

1. Transfer the patient to another appropriate surface
2. Turn off and unplug the pump.
3. Perform grommet membrane deactivation as instructed in the video to allow the accumulated air to freely vent out. Use a screw driver with a diameter of 2 – 3 mm. Make sure that the membrane is punctured through.

The video is available at the following link and QR code:

<https://arjo.qbank.se/mb/?h=3b5cf4b6d59bd1940c8c9d369877394c>



In order to get access to the video please enter a PIN: NimbusPIP0876!

Google Chrome web browser is recommended.

NOTE: The grommet membrane restricts the volume of excess air escaping. Removing the membrane will not affect mattress functionality in any way other than to allow excess air to escape at a slightly higher rate. This process does not introduce any new risks.

4. Reinstall the mattress following information outlined in the Instruction for Use.
5. Place patient back on the mattress once the installation process is completed.
6. In order to confirm the completion of this process, please complete and sign the enclosed Customer Response Form and return it to the Arjo address given in Additional Comment section.

7. Note: if your facility has sold or moved the Nimbus 4 or Professional mattress, please include the new facility's information in the Customer Response Form.

We deeply 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.

Additional Comment

If you have any further questions or require assistance in the procedure, please contact Arjo at *[insert local phone number]* or via email at *[insert email]*.

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

Customer Response Form

URGENT FIELD SAFETY NOTICE FSN-SUZ-001-2021

Reference: Nimbus 4 & Nimbus Professional mattresses – risk of over-inflation



Our records indicate that you may have one or more Arjo Nimbus 4 and/or Nimbus Professional mattress (es) within your facility (ies).

Please verify if you have any of the listed devices (table on page 2) and complete the information below.

Please mark one of boxes below:

- ☐ **We have read the Field Safety Notice and we understand the communication and the required actions.**
We confirm that we have completed the grommet membrane puncture following the provided video.

Customer Response Form

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 Arjo Nimbus 4 and/or Nimbus Professional mattress 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:	

☐ We have already decommissioned/removed the product from service permanently.

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>