

URGENT – FIELD SAFETY NOTICE

IndiGo Drive Assistance for Arjo beds

Date: 2021-May-DD

Product Issue: Potential failure of IndiGo Cabling

Affected Product: Arjo medical beds assembled with IndiGo module

Resolution: Product retrofit by Arjo service

Field Safety Notice: FSN-POZ-001-2021

Pages: 2 & Customer Response Form

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



Dear Customer,

Our records indicate that you have one or more Arjo medical bed(s) within your facility (ies) assembled with IndiGo Intuitive Drive Assistance.

We are contacting you to provide information of a safety-related corrective action that we would like to perform on the affected device(s) to address a recently detected potential failure of the IndiGo cabling.

Note: Beds without IndiGo installed are completely free of the issue.

Following continual monitoring of customer feedback, we have observed that the Indigo power cord might wear during use which could lead to its damage.

Arjo has received limited reports of this malfunction occurring and no reports of health consequences to either patients or caregivers. The probability of occurrence of harm is unlikely. In extreme cases, our investigations have projected, that there is a remote possibility for the transmission of current from the Indigo cabling throughout certain metal components of the bed base frame, which may result, in the worst case scenario, in electrocution.

We would like to reiterate that this scenario is projected only and no injury has ever occurred.

Arjo is taking this issue seriously as the customer satisfaction and safety are essential. We are contacting you to notify you of the risk and assist you in arranging a visit by an Arjo service engineer in order to complete the IndiGo correction at your facility, with no need to return the product to us.

Next Steps

1. Carefully verify the condition of IndiGo cabling. Check for any visible damage of the part – if any damage in the cabling is detected, remove the product from use until its retrofit is completed.



IndiGo cabling - location

2. Following the Warning in the Instruction for Use provided along with the product, make sure to disconnect the bed from the electricity supply before starting any cleaning and maintenance activity.
3. Ensure that all caregivers and users of the beds with IndiGo are made aware of this Field Safety Notice (FSN) and all listed devices at your facility are available to be corrected free of charge during an Arjo service technician visit that will be arranged.
4. Complete and sign the enclosed Customer Response Form and return this form to Arjo address given in Additional Comment section. This will allow us to contact you as soon as possible.

Note: if your facility has sold or moved the beds with IndiGo, 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.

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]**.