

## URGENT – FIELD SAFETY NOTICE

### IndiGo Drive Assistance for Arjo beds

**Best Contact Sdn Bhd**  
 No.73-1, Jalan Equine 10,  
 Taman Equine, Seri Kembangan  
 Malaysia

**Date:** 2021-May-27

**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



**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 and sparks emission. We would like to assure you that there is no possibility of ignition of the device, nor heat transmission to the mattress or mattress platform. Our devices are made from fire retardant materials.

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. As projected in technical investigations, the subsequent risk of electrocution could not be excluded completely.

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. 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.
2. 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.
3. 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 Malaysia.

### **Additional Comment**

If you have any further questions or require assistance completing the Customer Response Form, please contact Arjo at +65 6202 7367 or via email at Michael.Perez@arjo.com.