FIELD SAFETY NOTICE, rev. 2

Technical Solution Availability

IndiGo Drive Assistance for Arjo Enterprise 5000x, Enterprise 8000X, Enterprise 9000X, Citadel medical beds

Date:	2023-DEC-DD
Product Issue:	Unintended movement of bed wheels
Affected Product:	Arjo medical beds Enterprise 5000x, Enterprise 8000X, Enterprise 9000X, Citadel assembled with IndiGo module
Manufacturing range of affected devices:	May 2018 – October 2023
Field Safety Notice:	FSN-POZ-001-2023
Single registration number of the manufacturer in the EU:	SE-MF-000000696
Number of pages	6

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

Dear Customer,

Thank you for your patience in awaiting for the availability of a technical solution.
We are pleased to inform you that a technical solution to the issue (unintended movement of bed wheels) has been developed and become available.

The product correction of your Arjo medical beds with IndiGo module can be completed free of charge at your facility, with no need to return the product to us.

As such, Arjo would like to arrange a service visit at your facility in order to address your Arjo medical beds with IndiGo module.

The solution consists of one additional part that will be installed inside the IndiGo module and a new software revision for the IndiGo Printed Circuit Board (PCBA) located in the module, as well.

It eliminates the risk of the issue occurence completely. Once your Arjo medical bed with IndiGo is corrected, the product will be returned to daily usage fully functional.
Any other beds functions remain unchanged.

<u>Please note:</u> All the IndiGo modules and Enterprise 5000X, Enterprise 8000X, Enterprise 9000X, Citadel medical beds manufactured before 2023-10-09 have been added to the scope of the correction – this is due to changes in IndiGo calibration procedure and to ensure the product consistency across the range of the marketed devices in case any service activity is needed in the future.

The following risk mitigation factors still apply until your devices is corrected. They shall be followed also (along with all the Instruction for Use contents) upon the correction completion:

To minimise the risk of any health consequences, always use the product correctly following the IndiGo Instruction for Use, in particular:

- Contact with a device needs to be maintained while operating at all times:

> **CAUTION**
>
> **When operating IndiGo, maintain contact with bed at all times.**

- Deactivate IndiGo and apply brakes by placing the pedal in the most downward position:

AFTER USING *IndiGo*

1. Deactivate *IndiGo* and apply brakes by placing the pedal in the most downward position. **See Fig. 17**
2. Charge *IndiGo* by connecting the bed's power cord to the wall outlet after every use.

> **NOTE**
>
> **Refer to IndiGo Activation / Deactivation and Brakes.**

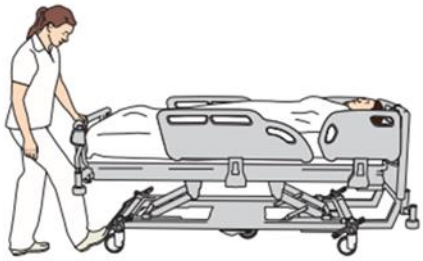

Fig. 17

- If the issue occurs accidentally, remember that each IndiGo module incorporates an Emergency Stop Switch that can be activated to stop bed motion at any time. The Switch is located at both, the head and foot ends of the bed. When the Emergency Stop Switch is activated (pushed down), an electric brake is applied to reduce momentum and slow the bed down until stopped.

For further information please refer to your copy of the Instruction for Use (IFU).

The IFU can be downloaded also at the following web link, free of charge. Press *Ctrl button* and click on the following link or copy and paste them to your browser: <link to the IndiGo IFU in a local language>

Next Steps

1. Ensure that all caregivers/personnel responsible for moving beds at your facility are made aware of this Field Safety Notice.
2. Use your device always following the Instruction for Use.
3. Fill in and return a Customer Response Form (Annex 1) to <local Arjo e-mail address>.
4. The Arjo representative will contact you to schedule a service visit at your facility.

5. Reach out to your local Arjo organization if any product malfunction occurs.
6. Whenever possible, please prepare your Arjo medical beds to facilitate their quick location at your facility for their prompt correction with minimal impact on product utilization.

Please note: if your facility has sold or moved the Arjo medical beds with IndiGo, please include the new facility's information in the Customer Response Form.

The notice has been submitted to the National Competent Authority in your country, <name of the local Competent Authority>

Additional Comment

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

ATTACHMENT 1

Customer Response Form

FIELD SAFETY NOTICE FSN-POZ-001-2023

Technical Solution Availability

Reference: IndiGo Drive Assistance for Arjo beds – Unintended movement of bed wheels

Our records indicate that you may have one or more Arjo medical bed(s) within your facility (ies) assembled with IndiGo Intuitive Drive Assistance. Please verify if you have any of the listed devices (refer to the table on page 7) 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 mark an appropriate box below and fill in also a table on the last page:

☐ We have read the enclosed Field Safety Notice and we understand the communication and the required next steps.

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

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 bed (s) with IndiGo Intuitive Drive Assistance 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			
Legible signature:		**Date:**	

☐ We have read the enclosed Field Safety Notice and we understand the communication and the required next steps. We had decommissioned our bed (s) with IndiGo Intuitive Drive Assistance permanently before the Field Safety Notice was received.

If marked : Please fill in the following table.

Legible signature:		**Date:**	

PLEASE RETURN YOUR COMPLETED FORM TO:

MAIL	**CONTACT**
<local Arjo address line 1>	*<contact address>*@arjo.com
<local Arjo address line 2>	Tel: *<Arjo contact phone number>*
<local Arjo address line 3>	Fax: *<Arjo contact fax number>*
<local Arjo address line 4>	

Arjo medical beds assembled with IndiGo module supplied to your facility (ies):

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