FIELD SAFETY NOTICE

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

<CUSTOMER NAME>
<CUSTOMER ADDRESS>
cc: Chairman Medical Board and relevant Department Heads

Date:	2023-SEP-04
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 – February 2023
Field Safety Notice Notice:	FSN-POZ-001-2023
Number of pages	3 & Customer Response Form

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

Dear Customer,

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

Arjo is releasing the Field Safety Notice to our customers in order to notify them of the risk attributed to issues reported in a number of received customer complaints.

Please note: Beds without the IndiGo module installed are completely free of the issue.

Description of the issue:

Arjo has confirmed through received customer complaints and subsequent manufacturer investigation that Arjo-branded medical beds assembled with the IndiGo modules may malfunction leading to the unintended movement of bed wheels.

The manufacturer investigation has revealed that the cause of the issue occurrence is multi-factorial, however the main factor is an issue with the IndiGo Printed Circuit Board Assembly (PCBA) located inside the module.
While a technical solution is still under development and will be available later in 2023, customers will be notified again when this solution is available. Prior to the solution release, Arjo would like to notify you of the identified risk and reiterate the contents of the IndiGo Instruction for Use provided along with the product.

As long as the Instruction for Use is followed, the risk of any health consequences is mitigated.

Clinical risk:

Arjo confirms that the issue has never led to any serious injury or other severe health consequences (either to patient or caregiver). Only in a projected event (that represents the worst case scenario), along with failure to follow the IFU, it could possibly lead to an outcome which might be assessed as a severe consequence / serious injury. According to our complaint data, the probability of occurrence for such an incident is remote. Your device(s) can remain in use, providing the following Risk mitigation factors are adhered to.

Risk mitigation factors:

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.**

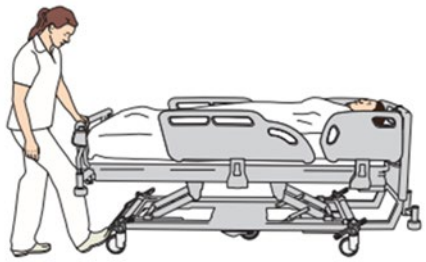

Fig. 17

- 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:

https://qbank.arjo.com/productdocumentation/416260-EN%20Rev%204.pdf

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 Arjo at *6202 7367* or via email at Mary.Ting@arjo.com
4. Reach out to your local Arjo organization if any product malfunction occurs.

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.

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.

Arjo will contact you separately as soon as the technical permanent solution to the issue is available.
The product service will be performed on-site, free of charge.

The notice has been submitted to the National Competent Authority in your country, Food and Drug Administration, Philippines.

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 +65 *6202 7367* or via email at Mary.Ting@arjo.com