Field Safety Notice – Supine 2 and Multistander 2

Please contact Jiraffe on the below contact information if you have a Jenx Multistander 2 or Jenx Suine 2 with the following serial number:

JX10017SUP02FP
JX10009SUP02FP
JX10209MUS2FP08
JX10018SUP02FP
JX10026SUP02FP
JX10316SUP02FP
JX10007SUP3-01
JX20069SUP02FP
JX20024MUS2FP08
JX20025MUS2FP08

Please see full FSN-015A information listed below.

Territory	Contact name	Contact email	Contact telephone
UK and ROI	Jiraffe	hello@jiraffe.org.uk	0114 285 3376

Jenx Limited, Wardsend Road, Sheffield S6 1RQ, United Kingdom
Tel: +44 (0) 114 285 3376
Email: export@jenx.com
www.jenx.com

Field Safety Notice – Supine 2 and Multistander 2

FSN-015A

10th April 2024

For the attention of: All users, carers, prescribers, healthcare organisations, and distributors.

1. Products affected

The affected products were manufactured between 5th April 2022 and 14th November 2023.

Product Code	Description	UDI-DI	Size	Compatible with
GS068	LA40 Actuator	NA	One size	Supine Stander Size 2 Multistander Size 2
RPRT167	Lithium Battery Actuator Kit	5056235221746	One size	Supine Stander Size 2 Multistander Size 2
MUS02-FP-08	Multistander Size 2 (powered)	5056235200451	One size	NA
SUP-02FP	Supine Stander Size 2 (powered)	5056235221739	One size	NA

Images of affected items are included in Appendix I.

2. Description of the identified issue

A small number of products have been identified in which the actuator extends and/or retracts beyond its intended range of operation. Repeated operation beyond the intended range places additional strain on the actuator which can cause it to fail. Failures have been identified in a small number of products which are apparent because the angle adjustment of the support surface ceases to work. No injuries have occurred in relation to any affected product, however it has been identified that if the actuator were to fail while the product is in use there are two possible outcomes:

- Pressure in the lifting arm is lost, which means the upper frame can be pulled up and down by hand. Whilst this is unlikely to cause injury, it may be unpleasant for the user.
- Because of the above, the product may be stuck in the vertical position and cannot be returned to a horizontal position for ease of transferring the user. This means the user would need to be removed from the product while in a standing position which may increase the manual handling risks to both the user and carers.

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3. Actions taken by the manufacturer

- Investigations conducted with Linak (the supplier of this part) have shown that the issue has been caused by the actuators being supplied with the incorrect operation limits installed in the operating software.
- Testing of a Beta version of the proposed new firmware supplied by Linak have been successful.
- Jenx will arrange for the control box on all products manufactured within the affected time period to be updated and operate on the new firmware with the correct operation limits set. The actuator will also be replaced.

4. Actions to be taken by the user/user's representative

The product is safe to continue to use in most instances, however please incorporate the additional information provided in this FSN into your risk assessment to determine the suitability for individual users while awaiting the software update and new actuator. Please do not continue to press the handset buttons once the product is in a full vertical or horizontal position as this puts further strain on the actuator arm.

Please contact us immediately with the information below, using the contact details given in section 6 so we can arrange for the software updates to be installed on your affected product/s and have the actuator replaced.

- Location of the product
- Phone number of the person who can grant access to the product
- Email address of the person who can grant access to the product

5. Action to be taken by organisations and distributors

Continued awareness and vigilance is important to ensure the corrective action identified in this FSN is effective.

i. Distribute this FSN to any person within your organisation and/or to any customer where the affected parts may have been allocated or sold.
ii. Continue to monitor responses to ensure that all affected products in your supply chain have been identified.
iii. Contact us with details of the location of the product

6. Contact Details

Territory	Contact name	Contact email	Contact telephone
UK and ROI	Jiraffe	hello@jiraffe.org.uk	0114 285 3376
Rest of World	Export	export@jenx.com	0114 285 3376 (or account manager)

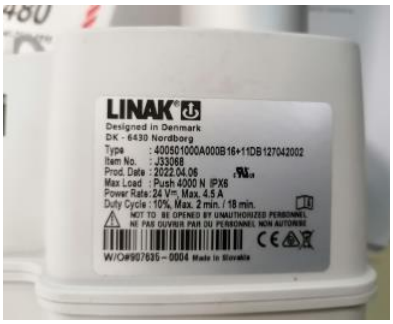
Manufacturer Contact Reference Person

Daniel Limb - Director
Jenx Ltd, Herries Road, Sheffield,
+44 (0)114 285 3376
daniel.limb@jenx.com

To confirm this notice has been forwarded to the appropriate Regulatory Agencies for and on behalf of Jenx Ltd.

Signed: 

Appendix I



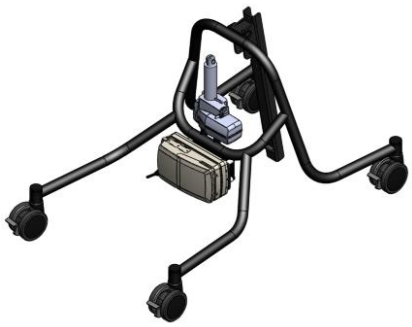
GS068



MUS02-FP-08



RPRT167



SUP-02-FP