
Urgent Field Safety Notice

Commercial name of the affected products: Eleganza 5
FSCA-identifier (assigned by manufacturer) : RN-2019-02
Type of action: Device correction

Date: 22.11.2019

Attention: CEO, COO, Facility Risk Manager, Vigilance Manager, Product management, Sales management

Details on affected devices:

Electrically operated hospital beds

Eleganza 5, model number: 1GE5xxxxx-xx

Serial numbers: 20160023029 - 20180197688

Manufactured : 2017 – 03/2019

Description of the problem:

Eleganza 5 Beds manufactured between the dates specified above may experience a problem with the side rails. A component used within the side rail mechanism may malfunction, resulting in the side rail either not locking properly in the upper position or the side rail becoming stuck in the upper position. If the clicking sound of the side rail mechanism (mentioned in the User Manual) is not heard when the side rail is lifted into the upper position, this may indicate that there is a problem. If the side rail is not securely locked in the upper position, there is a risk for unwanted side rail release, which could possibly result in patient or user injury.

Advice on action to be taken by the user:

Linet has developed a correction for the side rail mechanism. We will contact you to schedule a Linet or partner technician to update your affected Eleganza 5 Beds with this correction.

Until your affected beds are updated, we ask that you follow the safety information as outlined in the Eleganza 5 User manual (D9U001GE5-0101, version: 11, Publication date: 2019-11 (available at your local distributor)) when operating the side rails.

Section 11.1 Side rails

Chapter MANIPULATION

To raise siderails up:

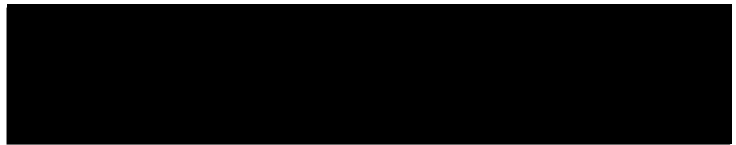
- ▶ Grab side rail by Side rail Handle.
- ▶ Pull side rail up until it latches. You will hear audible “click”.

If you raise the side rails to the upper position and you find the side rail is not secured and/or no audible click is heard during this operation, take the bed out of service until the bed has been updated.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be notified within your organisation or to any organisation where the potentially affected devices have been transferred.

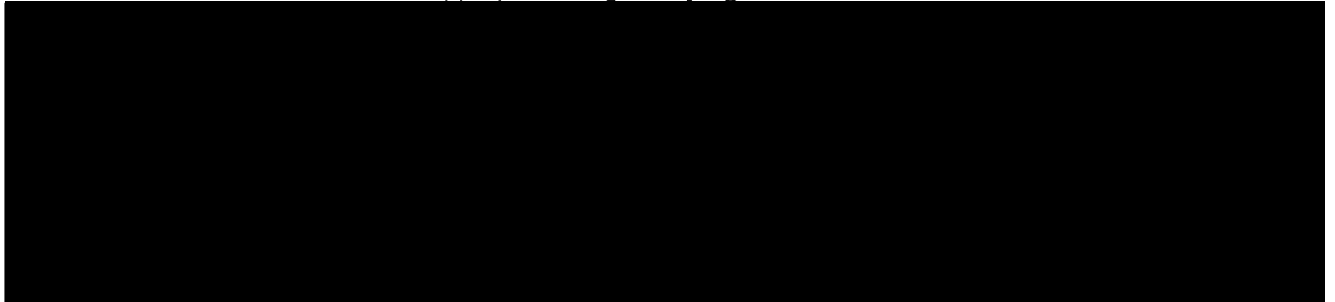
Please transfer this notice to other organisations on which this action has an impact.



Contact reference person

If you have any questions concerning this Field Safety Corrective Action, please contact Jakub Polasek, Quality manager at regulatory@linet.cz or your local Linet representative directly.

The undersigned confirms that the appropriate Regulatory Agencies have been notified.





Template for a Field Safety Notice Customer Reply Form

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	RN-2019-02
FSN Date*	22.11.2019
Product/ Device name*	Eleganza 5
Product Identification:	Hospital Beds Manufactured : 2017 – 03/2019
Batch/Serial Number (s)	NA

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation		
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A
<input type="checkbox"/>	No affected devices are available for correction	Customer to complete or enter N/A
<input type="checkbox"/>	Other Action (Define):	



<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender (address of the Distributor/ Importer)	
Email	
Customer Helpline	
Postal Address	
Web Portal	
Fax	
Deadline for returning the customer reply form*	

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.