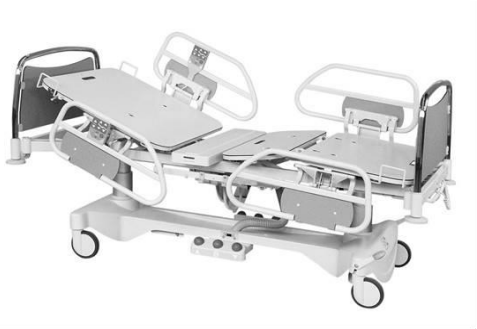
HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Eleganza de Luxe

Priority 2 – Warning



HPRA Safety Notice: SN2019(05) **Issue Date: 1st February 2019**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Linet spol. S.r.o.	V36009

ISSUE

Certain models of Eleganza de Luxe hospital beds are equipped with footswitches for height adjustment of the mattress area. The footswitch is lockable by the operator to prevent unintended use of the footswitch. Linet, the manufacturer, has become aware of users not using the footswitch locking function, which can lead to unintended activation of the bed and potential injury to the operator or patient.

Due to the passage of time, changes in the service providers and distribution network of the beds, Linet does not have full visibility of the locations and/or users of the beds in Ireland. The HPRA is issuing this Safety Notice to raise awareness of the field safety notice (FSN).

ACTION OR RECOMMENDATIONS

The HPRA advises that healthcare professionals:

1. Refer to the accompanying FSN and follow the recommendations provided.
2. Acknowledge receipt of the FSN to the supplier / service provider for this bed.

3. Forward a copy of this safety notice and the FSN to all relevant personnel within your organisation and to any other organisations/persons to which/whom these devices have been transferred.

4. Report any concerns regarding these devices and this issue to the manufacturer and the HPRA.

TARGET GROUPS

Hospital Managers / CEOs
Supplies Managers
Risk Managers
All Nursing Staff
Relevant Wards
Clinical Directors
Purchasing Managers
Clinical/Biomedical Engineers
Public and Private Nursing Homes
Medical Device Distributors

BACKGROUND

Through customer complaints Linet has become aware of improper use of the locking function of the height adjustment mechanism of the bed. When the bed is being used by a patient, such improper use, may cause unintended activation of the bed and in the worst case scenario, injury to a patient or user.

MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Linet spol s.r.o.
Želevčice 5,
274 01 Slaný
Czech Republic

Telephone: +420 312 576 451
E-mail: info@linet.cz

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie