

Safety Notice

Medical Devices

Giraffe Bedded Warmer, Panda iRes Warmer

Priority 2 – Warning



HPRA Safety Notice: SN2019(12)

Issue Date: 29th April 2019

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Ohmeda Medical / GE Healthcare	V39486

ISSUE
GE Healthcare has become aware that the bedside panels, and latch areas on Giraffe Bedded Warmers and Panda iRes Warmers can crack or break if the unit is moved using the bedside panels instead of the front handle or the manoeuvring handle. If an infant impacts a bedside panel with a cracked or broken latch, the panel can disengage and fall open, no longer protecting the infant from falling from the warmer.

ACTION OR RECOMMENDATIONS
The HPRA advises that users: <ol style="list-style-type: none"> 1 Read the accompanying field safety notice (FSN) carefully. 2 Promptly inspect warmer bedside panels, latch areas and areas connecting the panel to the bed for any cracks or damage. Discontinue use of the warmer immediately if any

damage is found and contact GE Healthcare as detailed in the Product Correction section of the FSN.

- 3 If no damage is found, follow Safety Instructions 2) and 3) as detailed in the FSN.
- 4 Acknowledge receipt of the FSN if you have not already done so.
- 5 Forward a copy of this Safety Notice and the FSN to all relevant personnel within your organisation or to any other organisations/persons to which/whom these devices have been transferred.
- 6 Report any adverse events/incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Hospitals
Clinics
Neonatologists
Paediatricians
Midwives
Paediatric nurses

Maternity units
Neonatal intensive care units
Clinical engineers
Patient Transport Managers
Clinical Nurse Managers
Risk Managers

BACKGROUND

Ohmeda Medical / GE Healthcare has indicated that there is the potential for infants to fall from warmers in which the panels / latches have been damaged, resulting in serious injury.

GE Healthcare will replace all cracked or damaged bedside panels / latches free of charge. Safety labels and an addendum to the operation and maintenance manual have been provided by GE Healthcare to customers together with the FSN, to ensure the ongoing safe operation of undamaged warmers.

MANUFACTURER / AUTHORISED REPRESENTATIVE / DISTRIBUTOR CONTACT INFORMATION

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

Datex-Ohmeda, Inc.
9900 Innovation Drive
Wauwatosa, WI 53226
USA

Enquiries to the **authorised representative** should be addressed to:

GE MEDICAL SYSTEMS SCS
283 Rue De La Miniere
78530 Buc

E-mail: CoE.Postmarket@ge.com

France.

Website:
<https://corporate.gehealthcare.com>

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

Oxygen Care Ltd.,
2 Holfield Business Park
Kilmacanogue
Co. Wicklow.

Telephone: 01 2769700
E-mail: sales@oxygen-care.ie
Website: www.oxygen-care.com

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
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie