



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# 32067

To: Director of Biomedical Engineering
Director of Neonatology/ L and D/ Nurse Manager
Risk Manager/Hospital Administrator

RE: Giraffe Bedded Warmer/Panda iRes Warmer - Bedside panels, latch areas may be cracked, broken or damaged.

This document contains important information for your product. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions. Please retain this document for your records.

Safety Issue

GE Healthcare has become aware that the bedside panels, and latch areas on the warmer can crack or break if the unit is moved using the bedside panels instead of the front handle or the maneuvering 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.

Safety Instructions

1) Inspect the warmer bedside panels (see below Figure 1A) latch areas and the areas connecting the panel to the bed (see below Figure 1B) for any cracks or damages per the addendum included in this mailing. **If any portion of the bedside panels or latches are cracked or broken (see below Figure 1C), stop use of the warmer.** Complete and return the attached response form in Table 1-1, indicating what components require replacement. If the Warmer bedside panels or latches (see below Figure 1D) have no cracks or damage, continue to Safety Instruction 2.

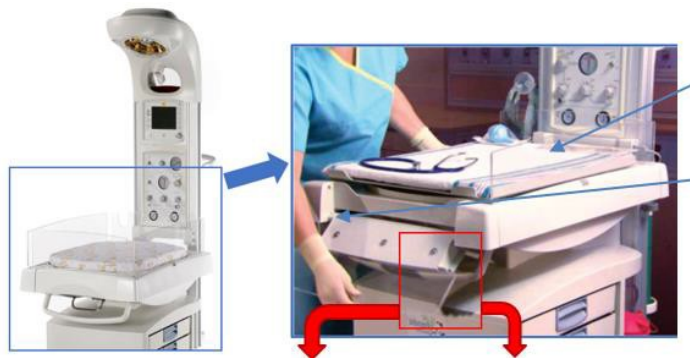


Figure 1A: Bedside panels

Figure 1B: Area connecting panel to bed



Figure 1C - Broken Latch



Figure 1D - Good Latch

2) If the Warmer bedside panels or latches have no cracks or damage, you may continue to use your warmer. Apply Safety labels included in this mailing to the warmer by following the below instructions:

- a) Clean area with a cleaning solution recommended in the Operation and Maintenance Manual.
- b) Wait for the area to dry.
- c) Peel off label 1 and apply it to the front (south) bedside panel at the location shown in the illustration below.
- d) Peel off label 2 and apply it to the left (west) bedside panel at the location shown in the illustration below.
- e) Peel off label 3 and apply it to the right (east) bedside panel at the location shown in the illustration below.



3) Review the attached Addendum and place it with your Warmer Operation and Maintenance Manual.

Affected Product Details

Giraffe Bedded Warmers (GTIN:00840682103923), Panda iRes Warmers (GTIN:00840682103893) (All serial numbers starting with GBW, PBW and HDJ)

Product Correction

GE Healthcare will replace all cracked or damaged bedside panels/latches at no cost to you. Complete and return the attached "Customer Response" form via e-mail to MIC.Recall@ge.com and a GE Representative contact you to arrange for a replacement.

Contact Information

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,

Vice President - Quality Assurance
GE Healthcare

Chief Medical Officer
GE Healthcare



**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED**

Please complete this form and return it to GE Healthcare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice and required actions to be taken Ref# 32067.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have taken and will take appropriate actions in accordance with that Notification.

Customer action:

- Inspect warmer, stop use if needed and complete table 1-1 below for replacement parts.
- Apply labels if warmer is not cracked or damaged.
- Place addendum in Warmer Operator Manual.

Please provide the name of the individual with responsibility who has completed this form.

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Table 1-1 Replacement Needed:

Part description	Part number	Broken bedside panel quantity
Rear bed side panel assy., Giraffe	6600-1655-500	
Rear bed side panel assy, Panda	6600-2063-500	
Rear bed side panel assy, tube management, Giraffe	6600-2146-500	
Rear bed side panel assy, tube management, Panda	6600-2145-500	
Left/right bed side panel assy, Giraffe	M1092331	
Left/right bed side panel assy, Panda	M1092338	
Left/right HFOV sidepanel assy, Giraffe	M1092332	
Left/right HFOV side panel assy, Panda	M1092340	
Front bed side panel assy, Giraffe	M1092335	
Front bed side panel assy, Panda	M1092342	
Front bed side panel assy, tube management, Giraffe	M1092337	
Front bed side panel assy, tube management, Panda	M1092506	
Front bed side panel assy, tall wall, Giraffe, Panda	M1183772	
Left/right large panel side wall assy, Giraffe, Panda	M1183770	

Please return completed form to FAX NUMBER: +1-410-630-5579, or scanning or taking a photo of the completed form e-mailing to: MIC.Recall@ge.com

You may obtain this e-mail address through the QR code below:

