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

AMENDED –
URGENT FIELD SAFETY NOTICE

<Date of Letter Deployment>

GEHC Ref# 32067-A

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

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

This is a supplement to a previous notification you may have received and provides additional Safety Instructions.

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 or latch areas on the warmer can become cracked, broken, or damaged if the unit is moved using the bedside panels instead of the front handle or the maneuvering handle on the back of the warmer. If an infant makes contact with a bedside panel with a cracked or broken latch or a damaged panel, the panel can disengage and fall open, no longer protecting the infant from falling from the warmer.

Safety Instructions

BEFORE EACH USE OF THE DOOR PANEL: Visually inspect for any cracks or damage to the beside panels, the latch area, and the area connecting the panel to the bed (see below Figure 1B). If any portion of the bedside panels or latches is damaged or cracked (see below Figure 1C)**, stop use of the warmer**.

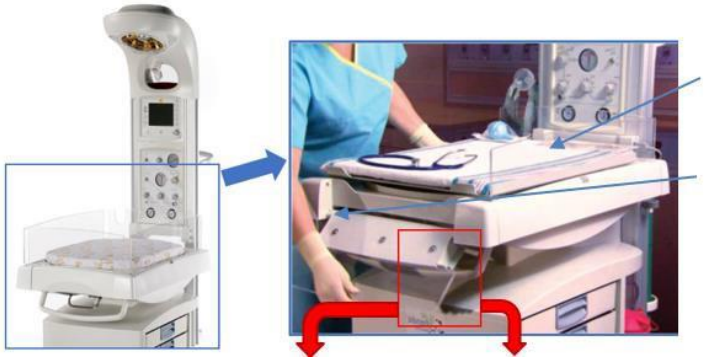


Figure 1A: Bedside panels

Figure 1B: Area connecting panel to bed

Figure 1C - Broken Latch

Figure 1D - Good Latch

- If the Warmer bedside panels or latches have no cracks or damage, you may continue to use your warmer.
- Before every patient use and every time the walls are raised and lowered during routine patient care by all staff who interact with warmers, complete the following additional check:
    - Inspect the operation of all three bedside panels: front (furthest away from the Healthcare Provider Control Panel) and both side panels and confirm that they lock securely in the upright position. Lowering a bedside panel should be possible only by pulling it up and then pulling the top edge away from the bed.
- If any of the beside panels do not lock securely, replace bedside panel(s) before placing an infant inside the warmer. Move the infant to a warmer with fully functioning bedside panels. Do not place or leave an infant in a warmer with non-functioning bedside panels. Remove the warmer with non-functioning bedside panels from service until the bedside panel(s) can be replaced.
- Ensure the bed side panels are securely latched following each opening/closing of the bedside panels during patient care.

PRIOR TO AND DURING USE OF THIS DEVICE:

- **Do not leave the patient unattended while any bedside panels are lowered or removed** when using the Giraffe or Panda iRes Warmers.
- If any of your bedside panels are damaged and you have not already sent back the reply form as part of the original FMI32067 recall letter instructions, please complete and send back the original reply form indicating parts needed. If you have questions, contact GE Healthcare (1-800-437-1171).
- Review the enclosed revised Addendum (5821739 **Rev 3**) remove and destroy any previous Addendums that you may have received related to GEHC reference #32067 (destroy previous Addendum Reference # 5805715 **Rev 1**).
- Review the enclosed "Device Correction Instructions" and affix the three provided labels to each of your warmers. These labels supplement the labels provided with the earlier recall notice. Your warmers should now have both sets of labels (the 3 additional white labels within this recall letter (FMI32067A) and the green and red labels in original recall 32067). If you have requested replacement walls as part of the original recall notice, ensure that all additional labels (white, red and green) are applied to the replacement walls.
- Post the provided posters in prominent locations for your staff, as described in the enclosed "Device Correction Instructions," and ensure they remain posted for the lifetime of the warmer(s).
- Confirm that the information from this recall letter and attached addendum is properly disseminated to all users that handle the warmers. Confirm that all staff (Clinicians, Biomeds, and Cleaning staff) are properly trained on the handling of the devices and will take appropriate actions in accordance with this Notification.
- Ensure that Biomedical Engineering staff routinely check the device for damaged bedside panels or latches and include this check as part of their preventive maintenance for this product.

PLEASE REMIND USERS TO NOT USE THE BEDSIDE PANELS TO HANDLE OR MOVE THE WARMERS. COMMUNICATE TO ALL USERS THE CORRECT METHOD OF USING THE HANDLES. The previously provided red and green labels, which should be attached to the warmer panels, show the proper way to handle and move the warmers, and also remind users to check for broken, cracked or damaged panels and latches before every use of the panels.

Affected Product Details	Giraffe Warmers (GTIN:00840682103923*), Panda iRes Warmers (GTIN:00840682103893*) (All serial numbers starting with GBW, PBW and HDJ) *NOTE: Some products were shipped prior to implementation of UDI and may not contain a GTIN #. This notice does not apply to free-standing and wall mount warmers which do not include a bed. GE Healthcare is including with this notice a kit that contains additional labels and wall posters.

Product Correction GE Healthcare is including with this notice an additional addendum, labels and wall posters.

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

GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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,

James W. Dennison
Vice President - Quality Assurance
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

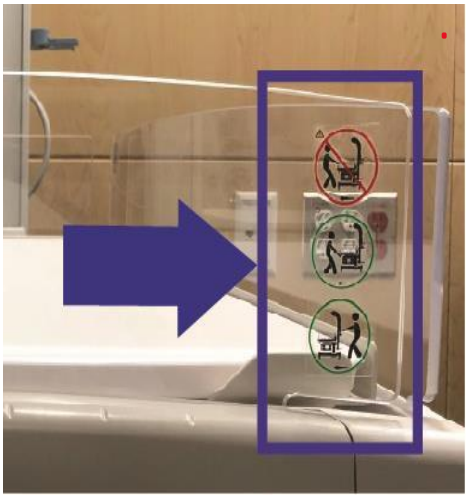
DEVICE CORRECTION INSTRUCTIONS

FMI Kit Contents

Part	Part Number	Qty
Giraffe and Panda Warmer Bedside Panel Letter	N/A	1
Giraffe and Panda Warmer Bedside Panel Poster	5829537 Rev 1	4
Giraffe and Panda Warmer Bedside Panel Addendum	5821739 Rev 3	1
Giraffe and Panda Warmer Bedside Panel Labels	5829539	Set of 3

Actions:

1. Make sure all procedures in the initial recall (FMI32067 Revision 2 Addendum) are complete. Warmers with that FMI applied will have the labels shown below on the 3 bedside panels.



2. Make sure the procedures below and in the enclosed Giraffe and Panda Warmer Bedside Panel Addendum have been completed (5821739 Rev 3).

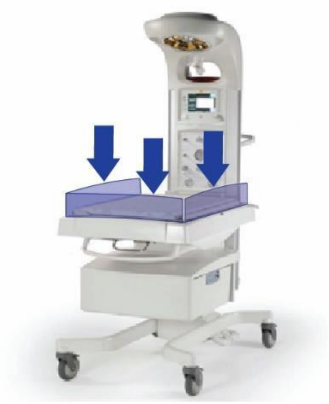
Procedure

Posters:

Post the 4 copies of the Giraffe and Panda Warmer Bedside Panel Poster in appropriate locations, as applicable:

1. Biomed or service area
2. Environmental service (EVS) or cleaning area
3. Clinical area (2 if needed)

Additional Labels:

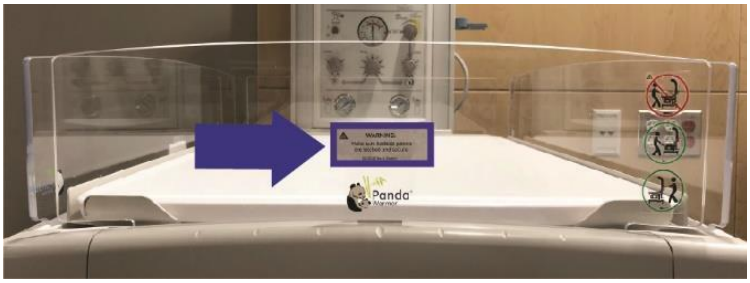


Each warmer has 4 bedside panels. Do the procedure listed below for each of the 3 movable bedside panels. One label must be applied to each bedside panel.

Note: A Panda warmer is shown above. Giraffe iRes warmers have higher bedside panels, but the labels are applied in the same locations, as shown by the blue arrows above and specified below.

Attach the Giraffe and Panda Warmer Bedside Panel Label at the locations shown below.

Side bedside panels: Attach the label .25 inches (6 mm) above the level window at the bottom of both side panels.



End bedside panel: Attach the label 0.25 inches (6 mm) above the logo sticker.

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-A.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

Please read the following section and check the box to confirm acknowledgement and completion:

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification and confirm that the information from this recall letter and addendum is properly disseminated to all users that handle the warmers. We confirm that all staff (Clinicians, Biomeds, and Cleaning staff) are properly trained on the handling of the devices and will take appropriate actions in accordance with this Notification.

Customer actions:

- Apply 3 labels provided with this notification to each warmer as specified in the Labeling Instructions;
- Place the provided revised Addendum in Warmer Operator Manual (enclosed 5821739 **Rev3**) and destroy any previous Addendums (5805715 **Rev1**) that you may have received related to GEHC reference #32067;
- Post the provided 4 Posters in specific areas as listed in the Labeling Instructions; and
- Ensure hospital staff are properly trained on the handling of the devices and detection of broken wall panels/latches.

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

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

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: