



Field Safety Notice

January 2009

To: Hospital Administrator
Head of Biomedical Engineering
NICU Nursing Manager/Labor & Delivery Nursing Manager

RE: **Elevated Patient Temperature**

Dear < Salutation >:

GE Healthcare (GEHC) has recently received customer reports of elevated body temperature in some babies cared for on the Panda iRes or Giraffe Warmers. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

We have recently received customer reports of elevated body temperature in some term or near term babies cared for on the Panda iRes or Giraffe Warmers. Specifically, some customers have reported an issue in Baby Mode where the temperature measured at a remote site such as the axilla, rectum or ear has been up to 2.4°C higher when compared to the abdominal skin temperature. Since the warmer skin temperature probe reading matched the warmer Set Temp, there was no warmer alarm. We also have one report where the patient received a first degree burn, and was treated using topical ointment.

Affected Product Details



Panda iRes Bedded Warmers and Giraffe Bedded Warmers shipped prior to July 31, 2008.

Affected Serial Numbers are in the range of HDJL50001 – HDJL50543 and HDJM50001 – HDJM51383. Not all serial numbers in this range are affected.

Safety Instructions

The following information has been released as an addendum to the Operator's Manual for the Panda iRes and Giraffe Warmers:

To increase detectability of this issue and provide optimal thermal care for all patients:

- 1. Observe the patient frequently, looking for signs of heat stress such as skin redness, warmth to touch, diaphoresis, or increased heart rate.*
- 2. Check the patient's temperature frequently (at least every two hours) with an independent temperature measurement at a remote site such as the axilla, rectum or ear.*
- 3. Pay special attention to the warmer heater power settings during the admission process. Allow the warmer to complete the Warmup Mode and press the Admit*

Baby key only when the baby is physically on the bed.

4. *Once the patient is admitted, do not keep the warmer in manual mode at 100% power for extended periods of time.*

If the patient shows more than a typical 0.5°C difference between the warmer abdominal skin temperature and a remote site such as the axilla, rectum or ear, consider the following actions:

1. *Verify the warmer temperature probe has good skin contact using a reflective patch;*
2. *Move the warmer temperature probe to another site, such as the axilla, and continue to monitor the patient's temperature;*
3. *Adjust the warmer Set Temp as needed to meet the desired temperature at the independent measurement site (such as axillary, rectal or ear); or*
4. *Place the warmer in Manual Mode and adjust the heater power as needed to meet the desired temperature per independent measurement (such as axillary, rectal or ear).*

Additional safety labeling information is being sent to your Head of Biomedical Engineering. This safety labeling contains two items: (1) a **Manual Addendum**, and (2) a **Quick Reference Card**. Customers are instructed to place the Manual Addendum with the device operation instructions, and attach the Quick Reference Card to each of their Panda or Giraffe warmers.

Customers may Request additional copies of this Labeling information by contacting the GE Healthcare Customer & Technical Support line listed below.

**Contact
Information**

For more information please contact your local GE Healthcare representative.

Please be assured that maintaining a high level of safety and quality is our highest priority. We apologize for any inconvenience caused by this action and thank you for your continued cooperation and support.

Sincerely,



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