



URGENT MEDICAL DEVICE CORRECTION

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

Date of Letter Deployment

GEHC Ref# 32064

To: Director of Biomedical Engineering
Director of Clinical/Radiology
Risk Manager/Hospital Administrator
Chairman Medical Board and Relevant Head of Departments for hospital”

RE: Giraffe OmniBed Carestation, Giraffe Incubator Carestation, Giraffe Warmer, Panda iRes Warmer, Panda Freestanding Warmer and Panda Wall Mount - Electrical Safety Testing Required

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issue

During an internal review of our manufacturing activities, we found an electrical safety test deficiency in some identified devices. The device design provides dual electrical safety protections. However, without performing the appropriate electrical safety test, the device could potentially lead to electric leakage affecting the user. There have been no complaints or injuries reported as a result of this issue.

Safety Instructions

You can continue to operate your device, consistent with good clinical practices. Until GE Healthcare performs the necessary testing, users should:

- 1) Disconnect devices that use the USB (Giraffe OmniBed Carestation and Giraffe Incubator Carestation only) and the RS232 Nurse call ports, see below pictures for location.
- 2) Inspect all power cords to ensure there is no damage to the cord or ground pin.

WARMERS RS232 PORT



CARESTATIONS RS232 PORT and USB PORT



Affected Product Details

Giraffe OmniBed Carestation, Giraffe Incubator Carestation, Giraffe Warmer, Panda iRes Warmer, Panda Freestanding Warmer and Panda Wall Mount. See the attached Appendix for affected serial numbers.

**Product
Correction**

GE Healthcare will perform necessary electrical safety test on all affected products and correct if required at no cost to you. A GE Healthcare representative will contact you to arrange for this test.

**Contact
Information**

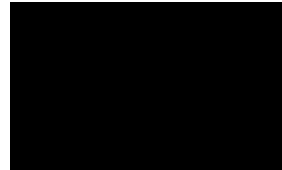
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.

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,



James W. Dennison
Vice President - Quality Assurance
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare