

URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# 32051

To: Nurse Managers, Labor & Delivery/NICU Bio-Medical Engineering Department Managers Risk Management Directors

RE: CarePlus Incubator, Giraffe Exam Light, Giraffe Incubator, Giraffe OmniBed, Giraffe Spot PT, IWS, Panda Warmer, Giraffe Bedded Warmer - Potential Power Cord Overheating

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

Safety Issue GE Healthcare has become aware of a potential safety issue where certain power cords could overheat. The affected power cords were manufactured by Electri-Cord and are referred to as "Taller Bridge" power cords. The overheating of the power cord could result in fire, charring, smoke, or sparking where the power cord connects to the wall outlet which could cause thermal injury. There have been no injuries reported as a result of this issue.

Safety Instructions GE Healthcare will provide a correction for all Electri-Cord "Taller Bridge" power cords used on GE affected products which match the configuration shown in Figure 1 below.

Figure 1 - Affected Power Cord Plug (includes a black bridge connecting the terminal prongs on the plug)

Black Bridge
Design (Black
surrounding
prongs)

Figure 2 - Not Affected Power Cord Plug (does not include a black bridge connecting the terminal prongs on the plug)



Check to determine if you have any of the Electri-Cord "Taller Bridge" power cords in use with any of the GE products listed in the Affected Product Details section below.

During your check, also inspect the power cord for damage or excessive wear and tear. If you find any power cords with bent or cracked prongs, burnt plastic, or excessive wear and tear, immediately discontinue use and dispose of the power cord. If there are no signs of damage, you can continue use the power cord until a replacement arrives.

In order to receive your corrected power cords, complete the attached Medical Device Correction Confirmation Form (attached to this letter). See form for instructions for completion and directions for

sending to GE Healthcare. Please send the form to GE Healthcare within 2 weeks of receiving this letter.

Affected Product Details

Affected products are the following, only if they have the affected Electri-Cord "Taller Bridge" power cord:

- Giraffe Exam Light shipped by GEHC between February 2003 and April 2010. Waldmann Lighting manufactured the Giraffe Exam Light for GEHC.
- CarePlus Incubator, Giraffe Incubator, Giraffe OmniBed, Giraffe Spot PT, IWS, Panda Warmer, Giraffe Bedded Warmer shipped between August 2008 and April 2010.

Product Correction GE Healthcare will correct all affected power cords at no cost to you. Follow the Safety Instructions

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provided above to identify and obtain your corrected power cords.

Contact Information

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 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 & Regulatory GE Healthcare



Jeff Hersh PhD, MD Chief Medical Officer GE Healthcare