URGENT FIELD SAFETY NOTICE

Date of Letter Deployment

GE HealthCare Ref. # 32095

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

RE: **Incomplete Electrical Safety Testing for Certain Giraffe Warmers and Panda iRes Warmers**

Safety Issue

GE HealthCare has become aware that complete electrical safety testing was not conducted during manufacturing of certain Giraffe and Panda iRes Warmers. There are multiple electrical safety protections included in the product design. However, because the electrical safety testing in manufacturing was incomplete for these devices, there's the potential for leakage current to exceed IEC 60601 limits. In the unlikely scenario that this occurs, it could potentially lead to adverse impact to the user or patient.

There have been no complaints or injuries reported as a result of this issue. GE HealthCare identified this issue internally.

Actions to be taken by Customer/ User

Prior to GE HealthCare inspecting and testing your systems, you can continue to use the affected Warmers by taking the following actions before each clinical use:

a. Inspect all power cords. Replace power cords with any damage.
b. Confirm proper grounding at your facility.

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

Please retain this document for your records.

Please complete and return the attached acknowledgement form to **MIC.FMI32095@gehealthcare.com**.

Affected Product Details

Giraffe Bedded Warmers (GTIN:00840682103923), Panda iRes Warmers (GTIN:00840682103893), See the attached Appendix for serial numbers of the affected devices.

Intended Use
Infant radiant warmers provide infrared heat in a controlled manner to neonates who are unable to thermo-regulate based on their own physiology. Infant radiant warmers may be used to facilitate the neonate's transition to the external environment or to provide a controlled open environment. An optional integrated SpO2 monitoring feature may be used for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 sensor). An optional integrated resuscitation system may be used to provide the basic equipment required for pulmonary resuscitation of infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures and/or manual ventilation to the infant. For professional use only, by trained clinicians.

Product Correction

GE HealthCare will inspect all affected products at no cost to you. A GE HealthCare representative will contact you to arrange for the correction.

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 per the contact information above.

Sincerely,

[redacted]

Chief Quality & Regulatory Officer
GE HealthCare

[redacted]

Chief Medical Officer
GE HealthCare

APPENDIX

AFFECTED SERIAL NUMBERS

GBW24230381SA	PBW23482092SA	PBW24112150SA	PBW24192278SA
PBW23242000SA	PBW23482093SA	PBW24112151SA	PBW24192279SA
PBW23242001SA	PBW23482099SA	PBW24112152SA	PBW24202292SA
PBW23242002SA	PBW23482100SA	PBW24112153SA	PBW24202293SA
PBW23242003SA	PBW23482103SA	PBW24112154SA	PBW24202294SA
PBW23320035SA	PBW23482104SA	PBW24112155SA	PBW24202308SA
PBW23320041SA	PBW23482105SA	PBW24112156SA	PBW24202309SA
PBW23320042SA	PBW23492139SA	PBW24112157SA	PBW24202310SA
PBW23340090SA	PBW23492140SA	PBW24112158SA	PBW24202311SA
PBW23390175SA	PBW23492142SA	PBW24112159SA	PBW24202312SA
PBW23420278SA	PBW23492144SA	PBW24122189SA	PBW24202313SA
PBW23462025SA	PBW23492145SA	PBW24122190SA	PBW24202314SA
PBW23462035SA	PBW23492149SA	PBW24122195SA	PBW24202315SA
PBW23462036SA	PBW23502154SA	PBW24122197SA	PBW24212323SA
PBW23462038SA	PBW23512155SA	PBW24122198SA	PBW24212324SA
PBW23462039SA	PBW24052060SA	PBW24132200SA	PBW24212327SA
PBW23462040SA	PBW24052062SA	PBW24132201SA	PBW24212328SA
PBW23472043SA	PBW24052063SA	PBW24132202SA	PBW24241063SA
PBW23472049SA	PBW24052064SA	PBW24132203SA	PBW24241064SA
PBW23472050SA	PBW24052065SA	PBW24132204SA	PBW24241065SA
PBW23472051SA	PBW24052066SA	PBW24132205SA	PBW24241066SA
PBW23472056SA	PBW24062069SA	PBW24142209SA	PBW24241067SA
PBW23482075SA	PBW24062070SA	PBW24152225SA	PBW24241068SA
PBW23482078SA	PBW24062072SA	PBW24152226SA	PBW24241069SA
PBW23482079SA	PBW24062078SA	PBW24152227SA	PBW24241070SA
PBW23482081SA	PBW24062081SA	PBW24152229SA	PBW24241071SA
PBW23482082SA	PBW24062087SA	PBW24152231SA	PBW24241072SA
PBW23482083SA	PBW24062101SA	PBW24172250SA	PBW24241075SA
PBW23482085SA	PBW24110390SA	PBW24172251SA	PBW24241076SA
PBW23482086SA	PBW24112144SA	PBW24172252SA	PBW24241078SA
PBW23482087SA	PBW24112145SA	PBW24172253SA	PBW24241079SA
PBW23482088SA	PBW24112146SA	PBW24172254SA	PBW24241084SA
PBW23482089SA	PBW24112147SA	PBW24172255SA	PBW24241085SA
PBW23482090SA	PBW24112148SA	PBW24192258SA	PBW24241086SA
PBW23482091SA	PBW24112149SA	PBW24192277SA	PBW24241087SA

GE HealthCare

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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.

Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Email Address: _____

Customer Phone Number: _____

By signing this form, we acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed all potential staff and have taken and will take appropriate actions in accordance with that Notification.

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

Signature: _____

Printed Name: _____

Position/Job Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and email to: (MIC.FMI32095@gehealthcare.com)