URGENT FIELD SAFETY NOTICE

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

<Date of Letter Deployment>

GEHC Ref# 32066

To: Director of Biomedical Engineering
Director of Clinical/Radiology
Risk Manager/Hospital Administrator

RE: **Panda iRes Warmer with ResusView Heart Rate Feature - Dropping / Inconsistent Heart Rate.**

This document contains important information for the continued safe and proper use of 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

When using the Panda iRes Warmer ResusView heart rate feature, the heart rate data could drop off or display incorrect, rapidly changing values. An incorrect ECG heart rate, if used as the only heart rate source, can mislead the clinician and cause them to make incorrect treatment decisions or withhold treatment during neonatal resuscitation which may lead to irreversible changes in the clinical status.
There have been no injuries reported as a result of this issue.

Safety Instructions

Discontinue use of the ResusView heart rate feature until your system has been corrected. Do not connect ECG trunk cable into the plug pictured below.

Note: You can continue to use the Warmer thermal, resuscitation, and Pulse Oximetry features.

Affected Product Details

Panda iRes Warmer System with ResusView feature: PBWX72359, PBWX72362, PBWX72360, PBWX72361, PBWX72554, PBWX72711, PBWX72712, PBWX72260, PBWX72263, PBWX72259, PBWX72262, PBWX72261

Product Correction	GE Healthcare will disable this feature for all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the disabling of this feature. GE is working on a solution. As soon as the correction is available, a GE Healthcare representative will contact you to arrange for the correction at no cost to you.
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

GE Healthcare

GEHC Ref# 32066

FIELD SAFETY NOTICE 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 Ref# 32066.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have taken and will take appropriate actions in accordance with that Notification.

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: