

URGENT FIELD SAFETY NOTICE

GE Healthcare 3000 N. Grandview Blvd. - W440

Waukesha, WI 53188, USA

GEHC Ref# 32066

<Date of Letter Deployment>

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.

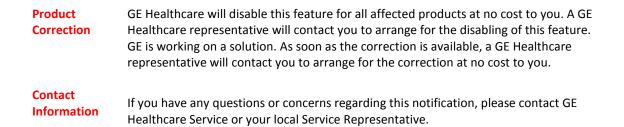
SafetyWhen using the Panda iRes Warmer ResusView heart rate feature, the heart rate dataIssuecould drop off or display incorrect, rapidly changing values. An incorrect ECG heart rate,
if used as the only heart rate source, can mislead the clinician and cause them to make
incorrect treatment decisions 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.

SafetyDiscontinue use of the ResusView heart rate featureuntil your system has beenInstructionscorrected. 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.

AffectedPanda iRes Warmer System with ResusView feature: PBWX72359, PBWX72362,ProductPBWX72360, PBWX72361, PBWX72554, PBWX72711, PBWX72712, PBWX72260,DetailsPBWX72263, PBWX72259, PBWX72262, PBWX72261



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



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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: <u>MIC.Recall@ge.com</u>

You may obtain this e-mail address through the QR code below:

