URGENT FIELD SAFETY NOTICE

Date of Letter Deployment

GE HealthCare Ref. # 30123

To: HealthCare Administrator / Risk Manager
Director of Cardiology Department

RE: **MAC VU360 v3.0 – Preview/Review Screen Does Not Close After 2 Minutes of Inactivity**

Safety Issue

GE HealthCare has become aware of a potential safety issue with the MAC VU360 v3.0 system. Specifically, after selecting the order refresh icon, an open preview or review screen might fail to close automatically after 2 minutes of inactivity. As a result, data from a previous patient may remain on the screen and could be incorrectly associated with a subsequent patient. This can lead to delayed or incorrect diagnosis and/or treatment.

There have been no injuries reported to GE HealthCare as a result of this issue.

Actions to be taken by Customer/User

You can continue to use your device.

Pending corrections from GE HealthCare, after pressing the **Order Refresh** icon do not rely on automatic closure of the **Preview** and or **Review** screen when:

- patient has been disconnected, and
- at least 2 minutes of system inactivity

If this occurs, do the following to clear all patient information data:

- On the **Preview** screen, select **Reject > Start New Patient**
- On the **Review** screen, select **Done > Start New Patient**

NOTE: Be certain **Start New Patient** is selected to clear all patient information data.

Please ensure all potential users 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 electronically via FMI 30123 Digital Response Form or print, fill out manually, scan, and email to DCAR.Recall@gehealthcare.com

Affected Product Details

Product Name: MAC VU360
Software Version: v3.0 (V3.00)
Affected Units: All MAC VU360 devices with v3.00 software installed

Table 1: Product details

Product	Ref# part number	GTIN Number
MAC VU360	2030361-023	00198953107263

Intended Use:
The MAC™ VU360 is intended to be a high-performance, multichannel resting electrocardiograph. As a resting electrocardiograph, the MAC VU360 simultaneously acquires data from each lead. Once the data is acquired, it can be analyzed, reviewed, stored, printed or transmitted. It is a device primarily intended for use in hospitals but may be used in medical clinics and offices of any size. The MAC VU360 is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility.

Product Correction

GE HealthCare will correct 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.

Service Centre UK - Patient Care Solutions :
Phone : 0800 387 377
Email : askuktechnicalsupport@gehealthcare.com

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact GE HealthCare per the contact information above.

Sincerely,

GE HealthCare

GE HealthCare Ref. # 30123

FIELD SAFETY 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 Field Safety 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 Field Safety Notification, and that we have informed all potential users 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): _____

To complete this form electronically, please scan the QR Code below or click this link: https://gehealthcare-svc.my.site.com/publicForm/s/?formId=aGjUr000003QZbV	**To complete this form via email, scan or take a photo of the completed form and email to: DCAR.Recall@gehealthcare.com**