



URGENT FIELD SAFETY NOTICE

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

Date of Letter Deployment

GEHC Ref# 30097

To: Director of Biomedical Engineering
Chief of Nursing
Healthcare Administrator / Risk Manager

RE: MAC VU360™ ECG systems - Incorrect patient identification and/or patient demographic errors

This document contains important information for your product. 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.

Safety Issue #1

After a patient exam has been completed on the MAC VU360 device, if the user selects "Start New Patient" before disconnecting the current patient from the device, and if the Auto-ECG feature is enabled, this can result in the device automatically capturing an ECG from the patient and storing this in the background, without the user's knowledge. When the next patient is connected to the MAC VU360 device, the ECG that was automatically captured and stored in the background from the previous patient can get incorrectly assigned to this next patient. This could lead to an incorrect diagnosis, unnecessary treatment and/or a delay in treatment for this next patient. There have been no injuries reported as a result of this issue.

Safety Issue #2

During our internal investigation, GE Healthcare identified another potential issue. The MAC VU360 allows an unsaved Preview ECG or opened Review ECG to remain on the screen until a user saves or rejects the Preview ECG or closes the Review ECG.

If the Preview ECG is not saved or rejected or the Review ECG is not closed, and a user expands the demographics banner, this banner would cover the ECG's and they would not be visible to the user.

If a user then enters patient information and is not aware that there is an ECG behind the expanded banner, it could result in the ECG being assigned to the incorrect patient. This could lead to an incorrect diagnosis, unnecessary treatment and/or a delay in treatment. There have been no customer complaints or injuries reported as a result of this issue.

Safety Instructions

You can continue to use your MAC VU360 system:

At system setup:

- Disable Auto-ECG in System Settings until the software has been upgraded.

When performing ECGs:

- Ensure the current patient lead wires are disconnected **before** selecting the Start New Patient workflow in the user interface.
- Verify there are live scrolling waveforms on the screen **before** acquiring an ECG on the patient.
- Verify the date and time of the ECG report corresponds to the patient for whom you are acquiring the ECG.
- Always enter patient demographic data for each patient **before** acquiring an ECG.

**Affected
Product
Details**

All MAC VU360 Systems P/N: 2030360-001 GTIN: 00840682125499

**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 MAC VU360 software to be updated.

Providing GE Healthcare with an email address in the attached customer response form, allows us to deliver this software update to you electronically and provide you with notifications of future software updates, as they become available.

Note: After the MAC VU360 has been updated, discontinue usage of and destroy any media containing MAC VU360 V1.01 SP06 and any prior versions of MAC VU360 software.

**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,



Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare



**MEDICAL DEVICE CORRECTION CONFIRMATION
CUSTOMER 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.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Phone Number: _____

Email Address*: _____

*Providing GE Healthcare with an email address allows us to deliver this software update to you electronically and provide you with notifications of future software updates, as they become available.

Affected Device Serial Numbers (attach additional sheets if needed):

We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed appropriate 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: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and email to:

Recall reply DCAR.30097@ge.com

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

