

URGENT MEDICAL DEVICE CORRECTION



Date of Letter Deployment

GE HealthCare Ref. # 30117

To: HealthCare Administrator / Risk Manager
Director of Cardiology Department

RE: **MAC VU360 Acquisition Module Holder**

Safety Issue

GE HealthCare has become aware that if a user incorrectly places the Acquisition Module into the Acquisition Module Holder, it can result in excessive bending and wear of the Acquisition Trunk Cable. This is visible as exposed wires or damaged sheaths. If a damaged Acquisition Trunk Cable is not recognized and removed from service, the cable can overheat with continued use. In the event of prolonged contact with the heated cable this could cause a partial thickness thermal injury.

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

Actions to be taken by Customer/ User

You can continue to use your device in accordance with the instructions in the MAC VU360 Operator Manual and the actions described below:

1. Inspect all potentially affected devices for the presence of damage to the Acquisition Trunk Cable per the MAC VU360 Operator Manual (P/N 2088531-202, Section 11). You can download the latest version of the MAC VU360 Operator Manual (P/N 2088531-202) from the GE HealthCare Customer Documentation Portal at <https://www.gehealthcare.com/support/manuals>.
2. Please ensure the Acquisition Module is being placed correctly in the Acquisition Module Holder and that the Acquisition Trunk Cable is not pinched during insertion. See section 1.3 of the MAC VU360 V1.03 Setup and Configuration Manual (P/N 2088531-204).

Please complete and return the attached acknowledgement form to DCAR.Recall@gehealthcare.com

Please make sure all potential users in your facility are made aware of this safety notification and the recommended actions.

Please retain this document for your records.

Affected Product Details

Product	Device Product Code
MAC VU360	VU2, VU4

Product Correction

GE HealthCare is currently working on and will provide a customer-installable kit containing the redesigned Acquisition Module Holder and Acquisition Trunk Cable for the affected devices at no cost to you within the next following months.

If you need support to install the Acquisition Module Holder and or the Acquisition Trunk Cable, please contact your GE HealthCare representative.

Contact Information

If you have any questions or concerns regarding this notification, please contact GE HealthCare Service at 1-800-437-1171 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,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical & Safety Officer
GE HealthCare

DRAFT

**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 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): _____

Please return completed form by scanning or taking a photo of the completed form and email to: DCAR.Recall@gehealthcare.com

