Urgent Field Safety Notice

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

GE Healthcare Ref: FMI 30080

<Date of Letter Deployment>

To: Health Care Administrator / Risk Manager
Biomedical Engineering / Device Administrators
Chief of Nursing

RE: Potential Issue with printing previously acquired Diagnostic Resting Electrocardiograms (ECGs) for use as current ECG on patient

GE Healthcare has become aware of a potential workflow issue with GE electrocardiographs that display and print diagnostic resting electrocardiograms (ECGs). Specifically, when consecutive ECGs are acquired without any patient information, a previously acquired ECG can be printed and mistakenly used as the patient's current ECG. Please ensure that all potential users in your facility are made aware of this notification and the recommended actions.

Safety Issue

If in clinical usage all of the following actions occur, the report for the first patient will be printed without patient specific identifiers on the report and could be mistakenly used for a second patient:

- Consecutive ECGs are acquired without any patient information being entered, *and*
- The device is left powered on and not returned to the main menu or next patient, *and*
- The user mistakenly uses the print/copy button instead of taking an ECG for a second patient.

Safety Instructions

The device can continue to be used. All ECG reports are stamped automatically with the acquisition date/time. When no patient information is entered, the acquisition date/time should always be checked to confirm it belongs to the relevant patient because that is the only unique identifier for that report. The acquisition date/time of a freshly acquired ECG report should match the current date/time displayed on the device. If not, the user may have inadvertently printed an ECG stored from the device's memory. In addition, any of the following actions will prevent occurrence of the issue:

- Pushing the ECG button to record an ECG, or
- Pushing "Next Patient", "Same Patient", or "Main Menu" after ECG test is complete, or
- Turning the device off between use, or
- Entering patient information for each patient.

Included with this notice are training materials and information on the suggested workflow to eliminate instances of a printed ECG being associated with the wrong patient. Please make this information available to all those responsible for acquiring ECGs at your facility.

Affected Product Details

MAC 600, MAC 800, MAC 1200, MAC 1600, MAC 2000, MAC 3500, MAC 5000, MAC 5500, MAC 5500 HD

Product Correction

All personnel responsible for acquiring ECGs should be trained to check the date/time stamped on the printed ECG report to verify it matches when they believe they acquired the ECG. The attached training materials provide more detailed information on the suggested workflow to eliminate instances when a printed ECG may be associated with an incorrect patient. No modifications to any of the listed devices are needed.

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 communicated to the appropriate Regulatory Agencies.

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.

Sincerely,

James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare

Jeff Hersh, M.D.
Chief Medical Officer
GE Healthcare