URGENT FIELD SAFETY NOTICE

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

GEHC Ref# 30098-2

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

RE: CASE and CardioSoft-CS ECG systems – Incorrect PDF reference in manually exported XML report

> **This document contains important information for 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.**

Safety Issue

CASE™ and CardioSoft-CS™ systems can export test reports in both XML and PDF file formats, which can then be viewed on the hospital Electronic Medical Records (EMR) or other similar system.

In the unlikely event that each of the steps below occur in sequence:

1. The system is configured with Automatic Export enabled, with both PDF and XML options selected,
2. Patient A's test is completed,
3. The user does not reboot the system.
4. The user goes to the database, manually selects a different patient (Patient B) and exports the XML for Patient B,
5. The EMR or similar system uses the PDF file path in the exported XML of Patient B to import the PDF test report,

the PDF test report that belongs to Patient A will appear in Patient B's record when viewed in an EMR or a similar system. This issue could result in a potentially delayed or inappropriate treatment.
There have been no injuries reported as a result of this issue.

Safety Instructions

You can continue to use the automatic export option.

1. If you switch from automatic export to manual export, you must reboot the CASE or CardioSoft system before export.

2. CASE or CardioSoft-CS systems that run Microsoft Windows Server 2008 R2, Windows XP, or Windows 7 must be rebooted before manually exporting tests. Microsoft ended support for these operating systems in April 2014 and Jan 2020, respectively. This action will prevent an incorrect XML to be sent from CASE and CardioSoft-CS. A software patch cannot be made available to these systems since these operating systems are not supported by Microsoft. Refer to the links below for more details:

Windows XP or Windows 7
https://support.microsoft.com/en-us/windows/windows-7-support-ended-on-january-14-2020-b75d4580-2cc7-895a-2c9c-1466d9a53962

Microsoft Windows Server 2008-R2

https://docs.microsoft.com/en-us/troubleshoot/windows-server/windows-server-eos-faq/end-of-support-windows-server-2008-2008r2

Make sure to follow these best practices for each exam:

- When reviewing CASE and CardioSoft-CS PDF reports on another system (for example an EMR) always confirm that the patient demographics information in the CASE and CardioSoft-CS PDF report is consistent with the patient medical record you are reviewing.
- If a test must be manually exported in the XML format, the system should be rebooted prior to each manual export.

Affected Product Details

All CASE™ or CardioSoft™ Systems used with the software versions listed below (* Identify this in your software application):

Product	Versions*	GTIN
CASE™	V6.6x	Not applicable
	V6.7x	00840682105088
	V7.0	00840682144179
CARDIOSOFT™	V6.6x	Not applicable
	V6.7x	00840682105170 00840682105156
	V7.0	00840682123679

The primary clinical purpose for CASE and CardioSoft systems is to acquire and analyse 12 and 15 Lead ECG data during physiologic stress/ exercise, or while resting, and generate reports. These systems can also acquire data from ancillary devices, such as Spirometry and Ambulatory Blood Pressure devices.

Product Correction

GE Healthcare will correct all CASE and CardioSoft systems that are at Windows 8.1 and above at no cost to you. Complete the attached acknowledgement form by checking box 1.

Note: For all units that are running Microsoft Windows Server 2008-R2, Windows XP, and Windows 7, complete the attached acknowledgement form by checking box 1 and 2.

Contact Information

If you have any questions or concerns regarding this notification, 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 provide relevant information regarding this software correction, as they become available.

☐ 1   We acknowledge receipt and understand the accompanying Medical Device Notification, and that we have informed the appropriate staff and have taken and will take appropriate actions in accordance with that Notification.

☐ 2   We acknowledge that the CASE and/or CardioSoft-CS systems running on Microsoft Windows Server 2008 R2, Windows XP or Windows 7 will not be updated with the software patch.

Please provide the name of the individual with responsibility who completed this form.

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return the completed form.
Scan or take a photo of the completed form and email it to:
Recall reply DCAR.30098@ge.com
You may obtain this e-mail address through the QR code below: