

**URGENT FIELD SAFETY  
NOTICE  
UPDATE**



Date of Letter Deployment

GE HealthCare Ref# 85477-2

To: Director/Manager of Radiology  
Risk Manager/Hospital Administrator  
Head of Radiology Department  
PACS Administrator  
Director of IT Department  
Head, Biomedical Engineering  
Head of Imaging Informatics

RE: **Update to the previous Urgent Medical Device Correction Communication (attached) regarding the Centricity PACS product line.**

Dear Customer,

As a follow up to the attached GE HealthCare Urgent Medical Device Correction Letter Ref# 85477, we are providing a user manual addendum that provides an overview of Image CKey, including the technical limitations that could lead to the potential acquisition of a partial study, and instructions for monitoring the CKey usage on Centricity PACS.

There are three steps to mitigate the potential issue:

Step 1: A GE HealthCare representative will contact you to enable CKey monitoring on your Centricity PACS.

Step 2: Upon completion of Step 1, please follow the instructions below to download the user manual addendum.

1. Access the GE HealthCare Customer Documentation Portal page at: <https://www.gehealthcare.com/support/manuals>
2. In the search field stating, "Enter Product Info", enter the Part number: **5970708**
3. Press **Enter** or click the **Magnifying Glass** icon in the search field to initiate the search. "Centricity PACS Image CKey Usage Instructions Manual" will be displayed as the search result.
4. Click the **Download** button  that is to the right of "Centricity PACS Image CKey Usage Instructions Manual".
5. Click **Accept** to acknowledge the copyright restrictions. The "Centricity PACS Image CKey Usage Instructions Manual" document now displays.
6. Click either the **Save** icon or **Download** icon depending on the browser being used.
7. **Save** the "Centricity PACS Image CKey Usage Instructions Manual" to the local system as well as to a suitable central location available to all users.

Step 3: Follow the instructions in the addendum to monitor the CKey usage.

**Contact  
Information**

If you have any questions or concerns regarding this notification, please contact GE HealthCare Service or your local Service Representative.

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

**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT  
RESPONSE REQUIRED – ACTIONS COMPLETED FORM**

Please either complete this form and return it to GE HealthCare promptly upon receipt within 30 days from receipt or complete the online response form through the link at the bottom of the page. This will confirm receipt and understanding of the Medical Device Correction Notice.

\*Customer/Consignee Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

City/State/ZIP/Country: \_\_\_\_\_

\*Customer Email Address: \_\_\_\_\_

\*Customer Phone Number: \_\_\_\_\_

We acknowledge receipt and understanding of the accompanying Medical Device Notification. We have downloaded the CKey monitoring manual and are aware of the image CKey technical limitations and the monitoring options.

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

Signature: \_\_\_\_\_

\*Printed Name: \_\_\_\_\_

\*Title: \_\_\_\_\_

\*Date (DD/MM/YYYY): \_\_\_\_\_

\*Indicates Mandatory Fields

**Please either return completed form by scanning or taking a photo of the completed form and email to [Recall.85477Resolution@gehealthcare.com](mailto:Recall.85477Resolution@gehealthcare.com) or complete the online response form.**



QR Code for email:



Online response form:

Online response form link: <https://app.sc.ge.com/esurveys/takesurvey/18446744073711653720>