

**URGENT FIELD SAFETY  
NOTICE**



Date of Letter Deployment

GE HealthCare Ref. # 85477

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: **Centricity PACS image limit leading to potential partial study acquisition**

**Safety  
Issue**

GE HealthCare has become aware of an issue where image storage is not possible when Centricity PACS reaches the maximum number of unique image identifiers (Ckeys). If this occurs, it can result in acquisition of a partial study. In an unlikely scenario that the partial study is unnoticed, it can lead to misdiagnosis. Centricity PACS is able to uniquely identify approximately 2.1 billion images (e.g. equivalent to 21 million exams with 100 images each). However, there is no notification to the user when the maximum number of unique image identifiers has been reached.

**Actions  
to be  
taken by  
Customer  
/User**

You can continue to use your device if it has not reached the maximum number of Ckeys. In order to determine the remaining number of available Ckeys:

- If GE HealthCare is remotely monitoring your Centricity PACS system as part of an existing service agreement, the number of available Ckeys is assessed routinely. If your device is close to maximum capacity, the GE HealthCare support team will contact you to discuss next steps.
- If GE HealthCare is not remotely monitoring your system, please contact the GE HealthCare support team who will help you check your Ckey status.

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

Please retain this document for your records.

Please complete and return the attached acknowledgement form to [recall.85477@gehealthcare.com](mailto:recall.85477@gehealthcare.com).

**Affected  
Product  
Details**

The following product versions of Centricity PACS are affected:

| Affected Product                   | UDI            |
|------------------------------------|----------------|
| All versions of Centricity PACS V2 | Not available  |
| All versions of Centricity PACS V3 | Not available  |
| All versions of Centricity PACS V4 | 00840682124430 |
| All versions of Centricity PACS V6 | 00840682104807 |
| All versions of Centricity PACS V7 | 00840682145572 |

Intended Use:

The Centricity PACS software product is intended for the storage, reading, diagnostic review, analysis, annotation, distribution, printing, editing, and processing of digital images and data acquired from diagnostic imaging devices.

**Product Correction** GE HealthCare will provide an updated manual with CKey monitoring instructions at no cost to you.  
A GE HealthCare representative will contact you with further information.

**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 per the contact information above.

Sincerely,



Laila Gurney  
Chief Quality & Regulatory Officer  
GE Healthcare



Scott Kelley  
Chief Medical Officer  
GE Healthcare

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

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: (recall.85477@gehealthcare.com)**

