

Customer Safety Advisory Notice

To all users of *syngo* Imaging with versions: V20, V25 or systems upgraded from these versions with a network file system (NFS) connected archive ("MountPoint Solution").

Name	[REDACTED]
Department	H IM IKM QM pro
Telephone	+49 (9131) 84-[REDACTED]
Fax	+49 (9131) 84-[REDACTED]
E-mail	[REDACTED]
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syngo Imaging: Potentially defective stored image data on long term storage.

Dear customer,

This letter is to inform you of a potential malfunction and hence a potential hazard to patients when using *syngo* Imaging under certain circumstances in the versions listed above.

When does this malfunction occur and what are the potential risks ?

The issue can occur when *syngo* Imaging is configured to archive image data via a network file system (NFS) connected archive ("MountPoint Solution"). A defective behavior in the data transport layer of the NFS connection between *syngo* Imaging and the long term storage (LTS) could cause that series are marked as successfully archived even though the content of the archived image data is saved sporadically with either defective pixel or header data.

Impact to the users of *syngo* Imaging:

- When prior patient examinations are dearchived from the LTS and the patient series is loaded to *syngo* Imaging or any other DICOM viewer:
 - in case of defective stored pixel data the affected images of a series will be displayed distorted
 - in case of defective stored header data the complete series will be loaded as black segment without patient demographic data and with a yellow exclamation mark and in the upper right corner.

In both cases it is obvious to the user that image data is defective (see screenshots below). The defective stored image data on the LTS is not recoverable if the image data is available only on the LTS.

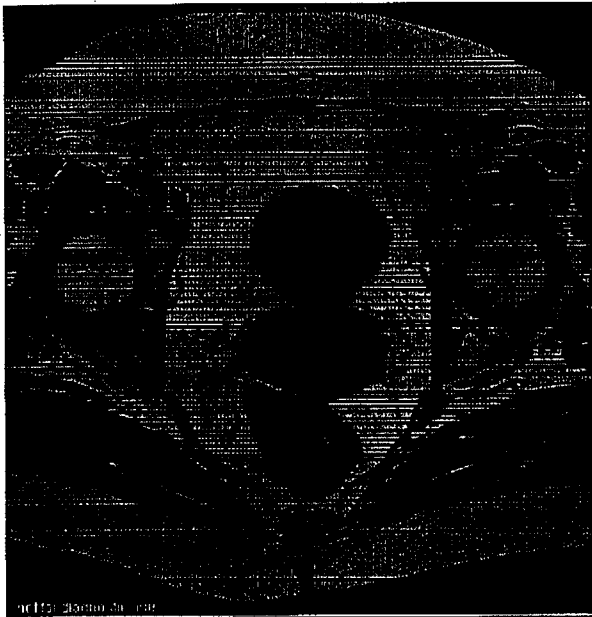
There is a potential risk of a patient harm when prior image data is not available for the reporting/review workflow.

Siemens AG
Healthcare Sector
Head: Jim Reid-Anderson

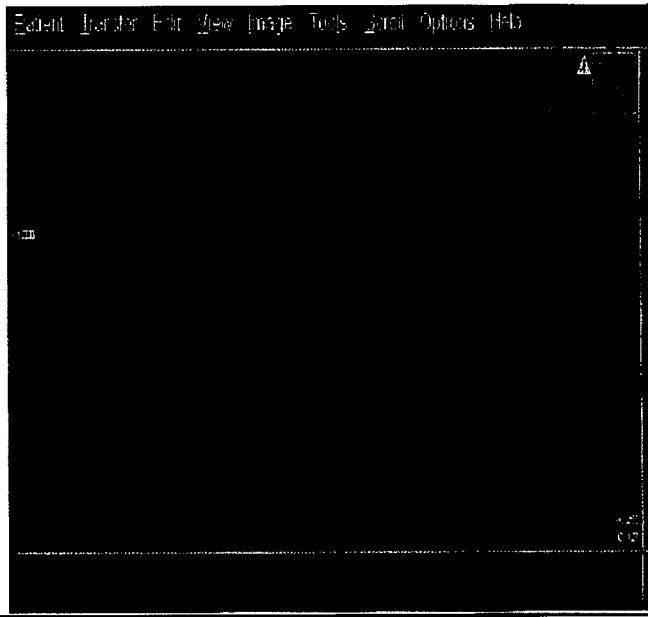
Postal address:
Siemens AG
MED IKM IQ
P.O. Box 32 60
91050 Erlangen

Office address:
Hartmannstr. 16
91052 Erlangen
Tel: +49 (9131) 84 0

Siemens Aktiengesellschaft: Chairman of the Supervisory Board: Gerhard Cromme
Managing Board: Peter Loeschner, Chairman, President and Chief Executive Officer; Wolfgang Dehen, Heinrich Hiesinger, Joe Kaeser, Jim Reid-Anderson, Hermann Requardt, Siegfried Russwurm, Peter Y. Solmssen
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Example for distorted images



Example for black segments

Affected are all *syngo* Imaging systems :

- prior to V30A with a NFS connected archive ("MountPoint Solution").
- since V30A when upgraded from a *syngo* Imaging version where a NFS connected archive ("MountPoint Solution") was configured previously.
(Potentially defective data could have been archived on the long term storage with prior versions)

Not affected are all net new *syngo* Imaging installations (V30A, V31A and V30B and related hotfixes). These versions have implemented enhanced checks for the integrity of the archived image data on the LTS.

What steps can the user take to avoid the potential risk of this issue ?

1) Preventive actions:

Customers with V20/V25 versions shall contact their local service organization to schedule the update of their systems to version V31A to mitigate the risk of potentially defective stored image data. A respective update from version V20/V25 to version V31A is available.

Please consider additionally 2)

2) Corrective actions:

Customers who experience distorted image data or black segments after dearchiving from LTS shall immediately contact their local service organization.

How will the issue finally be resolved ?

For customers who identify distorted image data or black segments we have defined following corrective actions which will be performed by service organization:

- a) Identify all affected image data in the LTS (defective header and/or pixel data)
- b) In case of distorted images no correction is possible.
- c) In case of black segments the affected images within an affected series will be replaced by an empty image containing a text which makes the user aware off that the image data is not available.
This ensures that the not affected images within a series can be loaded.
- d) These marked images will be checked in a next step if only header data is corrupted.
In this case the images can be recovered.
In case the header and pixel data is affected the image can be recovered but remains as distorted image as the pixel data is not recoverable.

-> These corrective measures must be scheduled case by case together with the customer and the service organization.

We appreciate your understanding and cooperation with this Safety Advisory and ask you to immediately instruct your personnel accordingly.

Please ensure that this Safety Advisory is placed in the system's instructions for use.

Your personnel should maintain awareness until upgrade of your system.

If you have sold this device/equipment and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this device/equipment. Please inform us about the new owner of the device/equipment.

If you have further questions regarding this issue do not hesitate to contact your SIEMENS Uptime Service Center.

Sincerely Yours

09.02.09 :U

Date /

IKM CEO

2009-02-09

Date /

IKM Vice President Quality