SIEMENS **Healthcare**

Siemens AG, H CP XP MK, Allee am Röthelheimpark 2, 91052 Erlangen

<To the person in charge of the unit where the SIEMENS product is operated, and the administrative head of organization>

Contact person of the Regional Unit Department

Telephone
Fax
E-Mail

Date

Safety Advisory Notice

To all users of the SIEMENS Ysio Max, Luminos dRF Max, Luminos Agile Max, Uroskop Omnia Max with software version VE10A to VE10C

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Date

Re: Malfunctions in Ysio Max, Luminos dRF Max, Luminos Agile Max, Uroskop Omnia Max

Dear customer,

This letter is to inform you of two malfunctions and hence potential risks to patients:

1. Images might get lost due to an automatic RIS worklist update and thus be missing in the examined patient folder.

2. Labels (L, R) and annotations may be displayed incorrectly, when images are transferred to PACS or hardcopy/filming.

1. Loss of images

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

If an automatic RIS worklist update is performed while a patient is already selected for examination, the subsequently acquired images of this patient might get lost under certain circumstances and cannot be recovered.
This malfunction is not detectable to the user during the examination. Only after the patient study is opened in the "Examined Patients" list, the user will be able to recognize that the acquired images are not available and irreversibly lost.

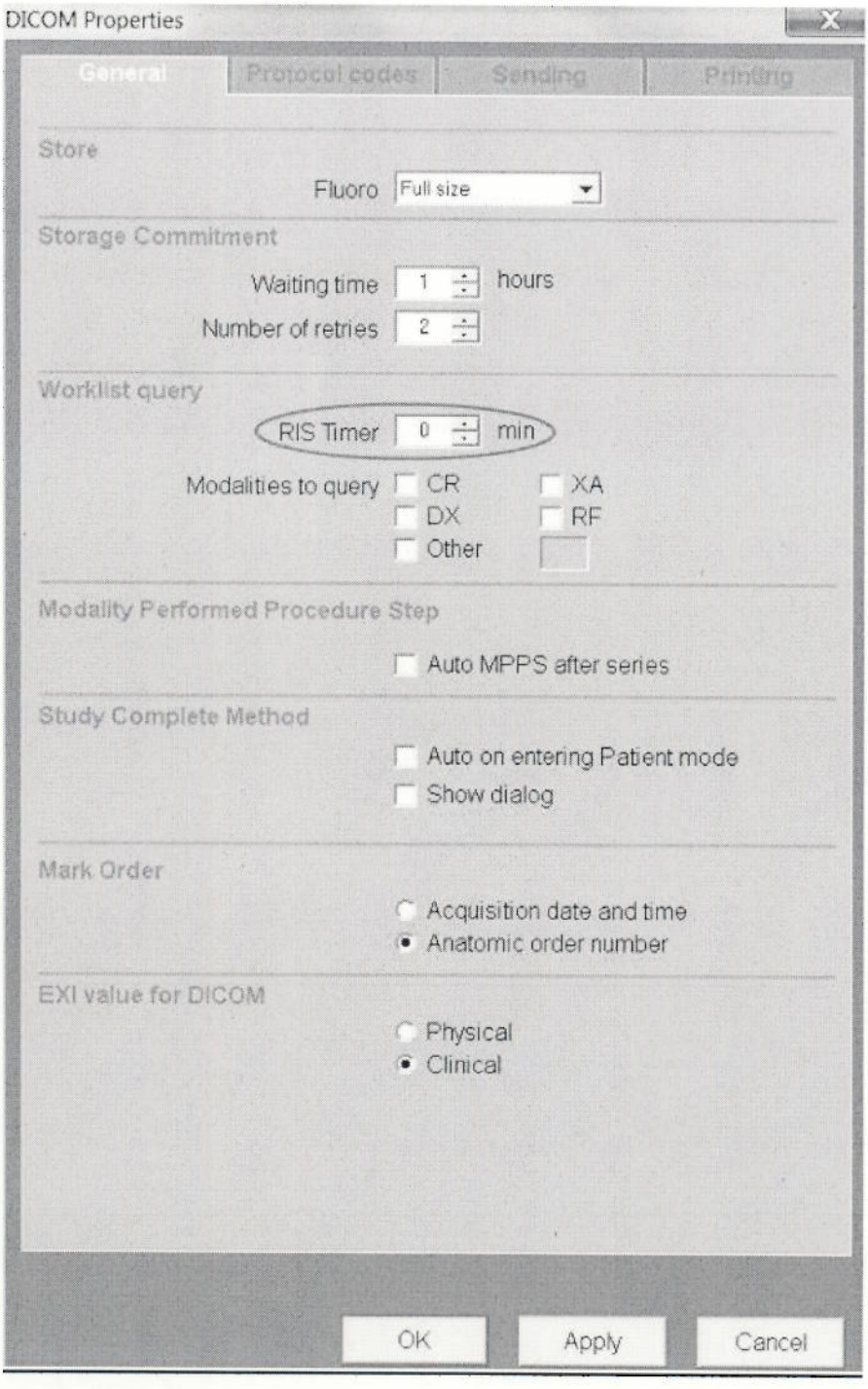
In the described scenario the images would need to be acquired again which will results in additional radiation exposure to the patient.

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

- Please disable the automatic RIS worklist update and perform this procedure manually.

  The automatic RIS worklist update is disabled by setting the **RIS Timer** to **0 min**.

  This setting can be found under **Patient** mode → **Settings** → **DICOM Properties** → **General** tab card (also to be found in FLUORSPOT Compact Operator Manual chapter 4.9.3):



2. ***Incorrect labels and annotations*** *(Ysio Max is not affected)*

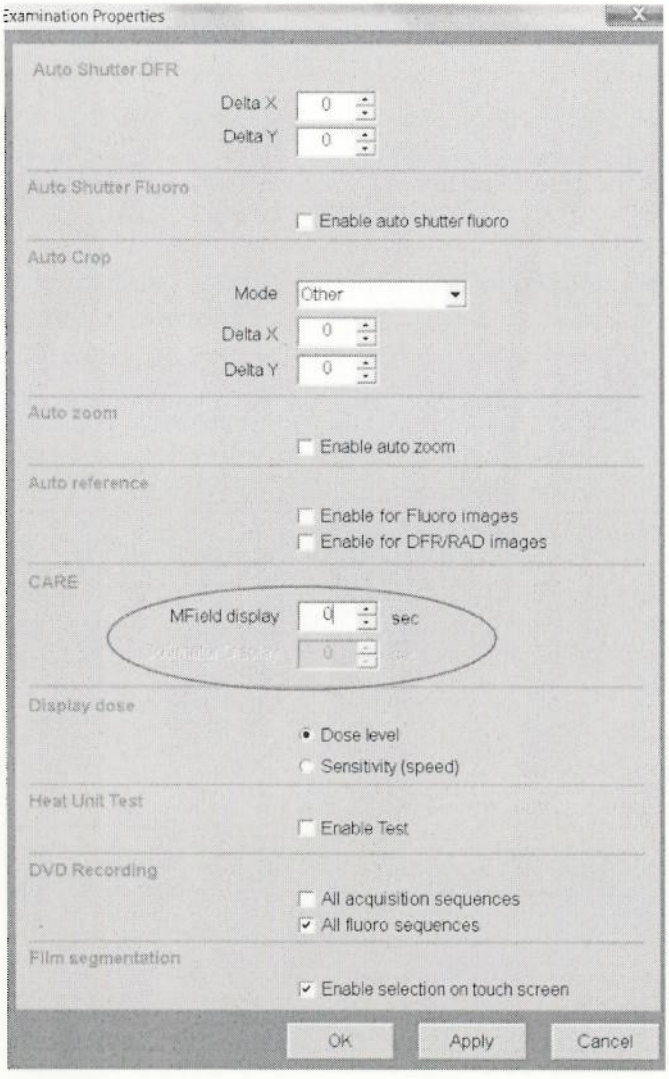
When does this malfunction occur and what are the potential risks?

Under certain circumstances the image label (L, R) and annotations are displayed incorrectly after images have been sent to PACS or hardcopy/filming. This might lead to potentially incorrect diagnosis.

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

- Please disable the **Measurement Field Display** and **Collimator Display** by setting the display time for both settings to **0 sec** (if editable).

  This setting can be found under **Patient** mode → **Settings** → **Examination Properties** (also to be found in FLUORSPOT Compact Operator Manual chapter 4.9.4):



- It is always recommended to use lead letters to indicate the patient orientation on the X-ray image.

How will the issue finally be resolved?

We are working intensely on a new software version that will permanently resolve all described malfunctions. This improved software version will be rolled out free of charge to all affected systems within the next weeks.

We appreciate your understanding and cooperation with this safety advisory notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory notice is placed in the System's instructions for use. Your personnel should maintain awareness until the modification has been implemented.

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

Sincerely Yours

Andre Hartung
CEO H CP XP

i. V.

Jürgen Buckow
H CP XP QM

SIEMENS Healthcare

Acknowledgement of receipt

Customer address:

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_____

_____

I hereby confirm as the owner / responsible operator of the <*product name*> with the Serial number _____(optional) that I received the following document:

Safety Advisory Notice

<product name> with <short description of the malfunction>

Place, Date _____

Name _____

Signature _____