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 and Luminos Agile Max with software version VE10 including SmarthOrtho license

Contact person of the Business Unit Department: Felix Müller-Witt, X-ray Products, Marketing

Telephone: +49 9131 84-3115
Fax: +49 173 2978782
E-Mail: felix.mueller-witt@siemens.com

Date

Re: Ysio Max, Luminos dRF Max and Luminos Agile Max with incorrect flipping of composed images

Dear customer,

This letter is to inform you of a potential malfunction and potential risk to patients when composed images are flipped on the integrated imaging system *FLUOROSPOT Compact* (FLC). This malfunction affects all Ysio Max, Luminos dRF Max and Luminos Agile Max systems with software version VE10 including *SmartOrtho* license.

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

When composed images are flipped (vertically or horizontally) on the FLC the image information might become corrupted. Thus flipped images and associated annotations such as labels (R/L) may show incorrectly.

In general composed images are acquired via scanning or ortho technique which require the *SmartOrtho* license and are typically used for long leg or spine examinations.

The corrupt image information of flipped composed images might lead to potentially incorrect diagnosis.

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

Please do not flip composed images on the FLC. Generally there are two possibilities to flip composed images on the FLC:

a) As default setting in corresponding organ programs which can be adjusted via PEX editor. This setting must be disabled for all organ programs with composed images (FLUOROSPOT Compact Operator Manual: Chapter 5.6).

b) As part of the postprocessing of a composed image. To avoid the described malfunction, please ensure that flipping is deactivated during postprocessing (FLUOROSPOT Compact Operator Manual: Chapter 3.2.10).

After an export of the composed images from FLC to a target system (e.g. PACS) the composed images can be flipped without any restrictions according to the software functionality of the target system.

Additionally 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 on a new software version that will permanently resolve the described malfunction. This improved software version will be rolled out free of charge to all affected systems in a timely manner.

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 follow the instruction in this notice 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:

_____

_____

_____

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 _____