SIEMENS Healthineers

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Contact person of the Regional Unit Department

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

URGENT - Field Safety Notice

To all users of the SIEMENS Healthineers Systems Ysio Max, Luminos dRF Max, Luminos Agile Max and Uroskop Omnia Max

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Software update for Ysio Max, Luminos dRF Max, Luminos Agile Max and Uroskop Omnia Max

Dear customer,

This letter is to inform you of two potential hazards to patients or users and a software update addressing these issues. The potential hazards are different but are included in this single Field Safety Notice because the issues will be addressed by the same software update.

1. Using the override function in case of blocked system movements (Luminos dRF Max, Luminos Agile Max, Uroskop Omnia Max)

What is the problem, when can it occur and what are the potential risks?

We have received a report of a system collision (without any injuries) due to inappropriate use of the bypass key which is overriding the built-in collision control. The bypass key is intended to enable moving an otherwise blocked system only to avert an immediate hazard, e.g. to rescue a patient after a device error. It is not meant to be used permanently.

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Does this problem impact already examined patients?

No.

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

After a device error, the user should use the bypass key exclusively for averting an immediate hazard, and contact customer service immediately to fix the problem.

How will the issue finally be resolved?

With the field safety corrective action, a modified software version (update XP029/19/S) will be installed by Siemens Healthineers. After the software installation, potentially hazardous situations like that described above will trigger an acoustic signal to alert the user. The update is planned to be available by end of January 2020.

2. Incorrectly assigned image
(Ysio Max, Luminos dRF Max, Luminos Agile Max, with detector MAX Static)

What is the problem, when can it occur and what are the potential risks?

We have received a report of an image which was assigned to two different patients. In the unlikely event of an interrupted connection to a MAX Static detector during an examination, the previously acquired image (possibly belonging to the previous patient) could be stored again in the current patient's data set. If this error remains undetected by the user, it could have an influence on diagnosis.

The prior examination is not affected by this issue.

Does the problem impact already examined patients?

We have no knowledge of any case where this behaviour has had an influence on diagnosis. In the reported event the users have noticed the error.

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

The user should check to ensure that the image displayed after acquisition is a newly acquired one and belongs to the current patient. If this is not the case, the user should delete the image and call customer service.

How will the issue finally be resolved?

With the field safety corrective action, a modified software version (update XP029/19/S), will be installed by Siemens Healthineers. This software update will correct the described issue and prevent its reoccurrence. The update is planned to be available starting end of January 2020.

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Apart from the described corrections, the updated software contains further stability and performance improvements and is provided free of charge.

Our service organization will get in contact with you for an appointment to perform the corrective action update XP029/19/S. Please feel free to contact our service organization for an earlier appointment.

This letter will be distributed to affected customers as update XP028/19/S.

We appreciate your understanding and cooperation with this Field Safety Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this Field Safety 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 notice to the new owner of this device/equipment. Please inform us about the new owner of the device/equipment.

Sincerely yours,

i.V. C. Bertram

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