

Siemens Healthcare GmbH, SHS DI XP RMT PRM, Siemensstr. 3, 91301 Forchheim

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

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

Dear customer,

This letter is to inform you about a change regarding a previously announced field update.

With field safety notice XP028/19/S Siemens Healthineers has announced to resolve two issues in the mentioned products with a modified software version (update XP029/19/S).

For technical reasons the rollout of this software version has been stopped. It will be superseded by a new software version (update XP008/20/S) that will finally resolve the issues described in the original field safety notice. The new software version is planned to be available beginning of the third quarter of 2020.

Both issues addressed in update XP029/19/S only occur under very rare conditions.

The first issue (using the override function in case of blocked system movements) is only relevant when the bypass key that overrides the collision control is used inappropriately. The second issue (incorrectly assigned image) may only occur in the unlikely event of an interrupted connection to a MAX static detector during examination.

In the isolated cases worldwide reported to Siemens Healthineers regarding these issues, no patients or other persons have been harmed. Your system is safe to use when observing the instructions provided with the original field safety notice until your system is updated.

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

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.

Do not use the system continuously in the "bypass" mode.

Siemens Healthcare GmbH
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Sitz der Gesellschaft: München, Deutschland; Registergericht: München, HRB 213821
WEEE-Reg.-Nr. DE 64872105

2. **Incorrectly assigned image**

(Ysio Max, Luminos dRF Max, Luminos Agile Max, with detector MAX Static)

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.

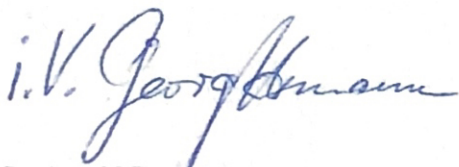
Apart from the corrections for the described issues, the updated software contains further stability and performance improvements and is provided free of charge.

Our service organization will contact you for an appointment to perform the corrective action update
– XP008/20/S when it is available.

We apologize for the change of schedule and appreciate your understanding and cooperation with this customer notice. 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 letter to the new owner of this device/equipment. Please inform us about the new owner of the device/equipment.

Sincerely yours,



Georg Wittmann
Head of Research and Development
X-Ray Products



Michael Zeus
Head of Marketing and Sales Operations
X-Ray Products