SIEMENS Healthcare Sector

To all users of the SIEMENS AXIOM Luminos TF/ Sireskop SD **Systems**

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Urgent Field Safety Notice

Customer Safety Information

UI-S AX 030/10/S

Information regarding a corrective measure for AXIOM Luminos TF and Sireskop SD where potential malfunction or unintended reaction of the system will be solved upon performing UI-S AX 030/10/S

Dear Customer,

This letter is to inform you of a potential malfunction and hence hazard or potential hazard to patients when using the AXIOM Luminos TF / Sireskop SD, system material number 10093902 / 3111668, 3111676, 8890407 and 8890415. To resolve this issue, a corrective measure UI-S AX 030/10/S is available. With the distribution of this Urgent Field Safety Notice we would highly recommend securing an appointment with our service organization.

When does this malfunction occur and what is the potential risk?

Details about this issue have been distributed with UI-S AX 029/08/S and UI-S AX 069/08/S including information to take precaution when performing interventional procedures.
The corrective measure addresses the potential malfunction or unintended reaction of the system caused by fluid entering the multi functional handle (Opti Grip). Additionally, the risk associated with this issue is potential unintended movement, increased radiation or useless image.

What steps will be taken to eliminate the potential risk of this issue?

Customers have been informed to take specific precautions when performing interventional procedures and to avoid fluids penetrating the system.

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The potential risk will be eliminated by a replacement of the multifunctional Handle (OptiGrip). The modified version of the handle resists fluid from entering the OptiGrip and prevents malfunction.

What is the risk associated to patients previously processed/treated with this system?

There are no risks associated to patients previously processed or treated with this system.

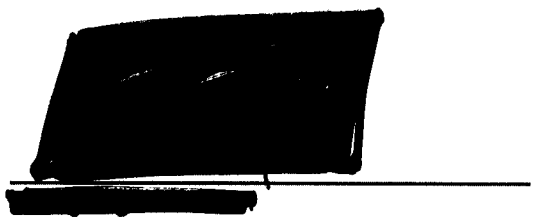
We appreciate your understanding and cooperation with this Customer Safety Information and ask you to immediately pass this information to all those who need to be aware and instruct your personnel accordingly. Please transfer this notice to other organisations on which this action has an impact. Please also maintain awareness on this notice and resulting action unless the problem is solved by performing UI-S AX 030/10/S.

The manufactures National Competent Authority has been informed accordingly.

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

Best regards,
SIEMENS AG Healthcare Sector
Business Unit AX

CEO H IM AX



Safety Officer Medical Devices