SIEMENS Healthcare

To users of SIEMENS Artis systems with Software Artis VC20x/VC21A/VD10x that have a DSA license installed

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Customer Safety Advisory Notice

UI-S AX010/13/S

Information regarding a field safety corrective action for Artis systems with Software Artis VC20x/VC21A/VD10x that have a DSA license installed.

Dear Customer,

This letter is to inform you of a potential issue on Artis systems with the software Artis VC20x/VC21A/VD10x that have a DSA license installed. Under certain preconditions, executing roadmap OGP (organ program) in the DSA overlay mode may lead to imprecise registration of the DSA mask image with the roadmap image displayed on the live monitor.

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

This potential malfunction may occur randomly after system installation or software upgrade to Artis VC20x/VC21A/VD10x. If the operator has moved the system (stand or table) between DSA taken and DSA used as mask when executing the OGP roadmap in the DSA overlay mode, the image visualizing the vessel tree and the roadmap image visualizing devices such as a catheter may not be registered precisely when displayed on the live monitor. This imprecise registration may imply danger to the patient since the operator may rely on incorrect visualization of the catheter relative to the vessel tree. A similar risk exists if the patient moves within the time window described above.

If this occurs, the system may not be functioning correctly until the service technician carries out the referred field update instruction.

For safe operation until a software patch eliminating this problem is installed, the operator shall follow the instructions below:

- The system (stand or table) is not to be moved between DSA taken and DSA used as mask when executing the OGP roadmap in the DSA overlay mode.

A similar risk exists if the patient moves within the time window described above. Therefore the operator shall consider the following:

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- The patient must be properly immobilized such that the relevant body region to be visualized is not displaced between DSA taken and DSA used as mask when executing the OGP roadmap in the DSA overlay mode.

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

The potential problem will be eliminated by a software patch that rejects a DSA selected as a mask image for the OGP roadmap in the DSA overlay mode, in case the system (stand or table) was moved after this DSA was taken.

To resolve this issue, the update AX011/13/S (VC20x/VC21A) respectively AX019/13/S (VD10x) will be made available approximately in April 2013. With the distribution of this Urgent Field Safety Notice we would highly recommend securing an appointment with our Customer Service organization in order to have the update implemented.

In order to make the operator aware of the necessity to properly immobilize the patient, an addendum to the user manual will be distributed.

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

There is no patient follow-up considered necessary regarding this subject.

We appreciate your understanding and cooperation in dealing with this Customer Safety Advisory Notice and would ask you to pass this information on to all those who need to be aware of it and to instruct your personnel accordingly. Please also forward this safety information to other organizations that could be affected by this action. Please also maintain awareness of this notice and resulting action until the update has been completed.

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. We would also ask you to inform us, where possible, of the new user's identity.

Best regards,

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