To all user of the following systems with software version VE20C

Product/Trade Name:	ARTIS pheno, ARTIS icono biplane, ARTIS icono floor
Model number:	10849000, 11327600, 11327700

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Date	October, 2021
Corrective Action ID	AX046/21/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Four potential software issues and a missing information in the Operator Manual on all ARTIS icono and ARTIS pheno systems with software version VE20C

Dear Customer,

We would like to inform you about the following potential issues with your ARTIS icono/pheno system and a corrective action that will be performed.

This customer letter is addressing four potential issues

Issue 1 Updated calibration data not saved with measurement after scene+/-

What is the issue and when does it occur?

For a scene with measurements, measurement values and image text displaying the calibration factor are immediately updated and displayed after applying and confirming Auto TOD Calibration (Table Object Distance Calibration) or Distance Calibration. After closing and reopening the same scene during review, the previously displayed change of distance measurements is lost, i.e. the image text shows the updated calibration factor although it was not applied to the distance measurement values.

What is the impact on the operation of the system and what are the possible risks?

The measurement values are not based upon the displayed calibration factor and will be inaccurate. This might cause a falsified diagnosis and an inappropriate treatment of the patient.

How was the issue identified and what is the root cause?

The problem was identified during inhouse testing at manufacturer site. The root cause is that during recalibration of images, the updated distance measurements values are not saved to the system's database.

Which steps have to be taken by the user to avoid the possible risks associated with this issue?

To avoid inaccurate measurement values, repeat the distance measurements after changing the Auto TOD Calibration or Distance Calibration of the scene.
Additionally, before closing the image after performing the calibration, create a screenshot/secondary capture image for post review.

What actions are being taken by the manufacturer to mitigate possible risks?

The operator manual of the affected systems will be updated according to the information mentioned above. This is regarded as an interim solution until the next software update is available.

What is the efficiency of the corrective action?

The operator manual update will draw attention to the issue.

What risks are there for patients who have previously been examined or treated using this system?

This issue might have caused a falsified diagnosis and an inappropriate treatment of the patient. However, considering the complete workflow which includes: scene calibration – measurement – review – recalibration of same scene – measurement – review – switch to another scene – switch back to the previous scene and check measurement again, it could be expected that significant deviations from first measurement in the respective scene will have become obvious. I.e. we consider the risk of falsified diagnosis and an inappropriate treatment of the patient as inconceivable.
As all the results of the treatment are finally assessed by the physician, it is not expected that any follow-up treatment will be necessary. In case of doubt please verify the results and diagnostic evaluation if applicable.

Issue 2 No x-ray possible, system shutdown/restart might be required during intervention

What is the issue and when does it occur?

In very rare cases a regular operation of the system might not be possible any more due to a software error in the Image Visualization System (IVS). However, "Bypass fluoroscopy" mode is still available

What is the impact on the operation of the system and what are the possible risks?

In case of "Bypass fluoroscopy" mode a limited imaging functionality (non-subtracted, continuous fluoroscopy with reduced power and without acquisition and storage of images functionality) is available.

This may result in a situation where it is necessary to cancel clinical treatment or to continue treatment on an alternative system.

How was the issue identified and what is the root cause?

The problem was identified by regular field observation. The root cause is a software issue.

Which steps have to be taken by the user to avoid the possible risks associated with this issue?

If "Bypass fluoroscopy" message is displayed permanently (message does not disappear after more than two minutes) the standard operation mode of the system might be recovered by shutting down and restarting the system.

What actions are being taken by the manufacturer to mitigate possible risks?

The software in the affected systems will be updated to correct the issue.

What is the efficiency of the corrective action?

The software update will mitigate the occurrence of the issue.

Issue 3 Corrupted Image during Roadmap

What is the issue and when does it occur?

After using the zoom out functionality during DSA roadmap (DSA RDMP), the subsequent roadmap might potentially be corrupted.

What is the impact on the operation of the system and what are the possible risks?

In this case the location, nature and extent of pathologies may not be identified correctly and may not be appropriate for clinical diagnosis. Therefore, it might be necessary to unselect/stop and restart the DSA RDMP workflow. This could cause a medium-term delay in procedure and additional exposure to low-level radiation and contrast medium.

How was the issue identified and what is the root cause?

The problem was identified by regular field observation. The root cause is a software issue.

Which steps have to be taken by the user to avoid the possible risks associated with this issue?

Do not zoom out during roadmap or unselect/stop and restart the DSA RDMP after zooming out to avoid image corruption.

What actions are being taken by the manufacturer to mitigate possible risks?

The software in the affected systems will be updated to correct the issue.

What is the efficiency of the corrective action(s)?

The software update will mitigate the occurrence of the issue.

Issue 4 Unintended shutdown of Imaging System with UPS (Uninterruptable Power Supply) option (only for customer with UPS who are already informed with CSAN AX019/21/S are affected)

What is the issue and when does it occur?

In very rare cases the imaging system UPS sporadically forces a shutdown of the imaging system PC without a true power supply problem.
After implementation of the measure AX020/21/S the UPS is disconnected and the issue cannot occur.

What is the impact on the operation of the system and what are the possible risks?

There is currently no risk or impact on the operation of the system, provided that UPS is disconnected as previously implemented by AX020/21/S.

How was the issue identified and what is the root cause?

The issue was detected by regular field observation. According to the investigation the existing non-conformity could be identified as a combination of software and hardware behavior. Normally the operating system can cover sporadically malfunctions of the image system UPS but in this case the operation system fails, and this may result in a hardware-initiated shutdown of the IVS.

What actions are being taken by the manufacturer to mitigate possible risks?

The Windows software settings for emergency power operation will be updated to avoid the issue.
The affected UPS will be reconnected to reestablish the complete functionality.

What is the efficiency of the corrective action(s)?

The software update will mitigate the occurrence of the issue.

How will the corrective action be implemented?

Our service organization will get in contact with you for an appointment to perform the corrective action (covering issues 1 to 4 above). Please feel free to contact our service organization for an earlier appointment.
This letter will be distributed to affected customers as update AX047/21/S.

What risks are there for patients who have previously been examined or treated using this system?

We do not consider it necessary to re-examine any patients in relation with the issues (issue 1 to 4) described above. If measurement have already been performed in the past for diagnostics, please verify the results and diagnostic evaluation if applicable.

Please ensure that all users of the affected products within your organization and others who may need to be informed will receive the safety relevant information provided with this notice and will comply with the recommendations therein.

We appreciate your understanding and cooperation with this safety advisory and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory is retained in your product related records appropriately. Please keep this information at least until the measures have been finalized.

Please forward this safety information to any other organizations that could be affected by this measure.

If the device has been sold and is therefore no longer in your possession, please forward this safety notice to the new owner. We would also request you to inform us of the identity of the device's new owner where possible.

With best regards,

Siemens Healthcare GmbH

Business Area Advanced Therapies (AT)

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