To all user of the following systems with software version VE20B

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|---|---|---|---|
| Product/Trade Name: | ARTIS pheno,<br>ARTIS icono biplane,<br>ARTIS icono floor | E-mail | advancedtherapies-fsca.team@siemens-healthineers.com |
| Model number(s): | 10849000,<br>11327600,<br>11327700 | Date | November, 2020 |
| | | Corrective Action ID | AX070/20/S |

# Customer Safety Information (CSI) for Field Safety Corrective Action

**Subject: Four potential software issues and a gap in the Operator Manual on all ARTIS icono and ARTIS pheno systems with software version VE20B**

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 software issues and a gap in the Operator Manual coverage.

## Issue 1 (System error management):

### What is the issue and when does it occur?

The ARTIS system is provided with a dedicated error management mechanism. In rare cases of specific X-ray tube failures, the system is intended to automatically switch over to “Bypass fluoroscopy” mode. However, in case such a failure occurs while the “Block Radiation” functionality is active, the “Block Radiation” functionality cannot be unlocked, and the system will not switch over to “Bypass fluoroscopy” mode. In “Bypass fluoroscopy” mode a limited imaging functionality (non-subtracted, continuous fluoroscopy with reduced power and without acquisition and storage of images) would remain available.

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

In that case (specific X-ray tube failure while “Block Radiation” is active), the operator is unable to release X-ray in “Bypass fluoroscopy” mode which remains permanently inhibited. 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 during inhouse testing at manufacturer site. The root cause is a software issue in the error management.

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

In any case, please make sure that patient treatment can be continued in other ways if there is any possible danger for the safety of the patient.

**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 2 (Erroneous error messages):**

**What is the issue and when does it occur?**

In rare cases system communication issues may lead to certain incorrect error signals in the high voltage generator. This eventually leads to the display of erroneous error messages, most likely “NO XRAY - TUBE TOO HOT. Please wait.”.

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

Misleading error messages might prevent the operator from identifying and implementing the appropriate recovery procedure. This may result in a delay in the examination.

**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 such an error message right after startup does not occur under the corresponding conditions (i.e. without extensive tube load, without pre-warning messages), the normal operation of the system might be recovered by shutting down and starting up the system again.

**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 (Zoom/Pan Function):**

**What is the issue and when does it occur?**

After using the Zoom/Pan function and panning the zoomed image, the shift parameter applied to the image will be saved even after closing the patient, i.e. the imaging system will not reset the shift parameter for displaying graphics and annotations upon performing measurements as part of the next examination with the next patient.

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

Measurement graphics and annotations might be displayed at the wrong location. Depending on the workflow the issue impacts either the control room or both the exam and control room monitors. The error might also affect the stored images.

This might cause derived data (graphical or alphanumerical overlay) displayed incorrectly, so that location, nature, extent of pathologies may be identified incorrectly.

**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?**

Following actions will reset and correct the graphics and annotation position:

a) zooming in or out the image,
b) switch to any other layout in control room, or
c) restart the system between the examination of different patients.

**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 (Grid Indication):

### What is the issue and when does it occur?

The current Operator Manual of the system does not contain information about the grid indication. This means the following information is missing: When no grid is inserted, no icon is displayed in the Info Area on the display in the control room. When a grid is inserted, an icon is displayed (for each plane separately for biplane systems).

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

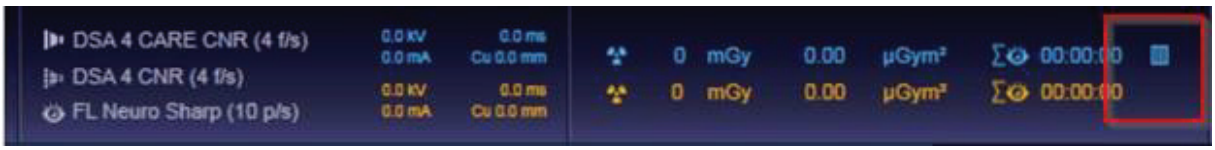
When the grid is not inserted, the user might miss to insert the grid back which may result in decreased image quality. This could result in the need to acquire another image after putting the grid back.

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

The problem was identified by regular field observation. The root cause of this issue is an inadequate operating instruction.

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

The user should know of the following information about the grid indication:




When a grid is inserted, an icon is displayed in the Info Area on the display in the control room (for each plane separately for biplane systems). When no grid is inserted, no icon is displayed. In the examination room, the user may check whether the grid is inserted in the FD housing.

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

The Operator Manual addendum to the Instruction for Use for VE20 had been updated and will be sent to the affected systems.

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

The addendum will include the missing information about the grid indication.

## Issue 5 (Coolant Level):

### What is the issue and when does it occur?

If the coolant level in the cooling circuit becomes low, this may result in a situation in which the X-ray tube is no longer sufficiently cooled, and the system will display the message “TUBE HOT - Please wait for tube to cool down”. Several minutes later the system will block X-ray to prevent further damages and displays the message “NO XRAY - TUBE TOO HOT. Please wait.” or “XRAY aborted: Tube too hot”

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

In case the issue occurs, the system cannot be operated normally. 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 issue was detected by regular field observation. The root cause is a coolant loss of the tube cooling unit which occurs over time.

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

As also described in the System Owner Manual, we recommend that the system operator checks the water level of the cooling circuit at least every three months and refills water, if necessary:

1) Open the filling gland of the cooling unit. The water surface must be clearly visible above the cooling ribs.
2) Replenish with water (drinking water quality) if cooling liquid is lacking.

Please also inform the service technician in case of lacking cooling liquid.

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

The software will be updated and in case the coolant level falls below a certain level one of following message will be displayed:

a) "The tube cooling water level is low in plane A. Refill water according to the operating manual."
b) "The tube cooling water level is low in plane B. Refill water according to the operating manual."

**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 5 above). Please feel free to contact our service organization for an earlier appointment.

This letter will be distributed to affected customers as update AX080/20/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 5) described above. If measurement graphics and annotations have already been used 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,

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