PHILIPS

URGENT - Field Safety Notice
Medical Device Correction

Brilliance Big Bore Oncology CT, Brilliance Big Bore Radiology CT
Version 4.2 release related issues

Dear Customer,

A problem has been detected in the Philips Brilliance Big Bore Oncology CT, Brilliance Big Bore Radiology CT products with software version 4.2.0 that, if it were to re-occur, could pose a risk for patients or users. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem.

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

If you need any further information or support concerning these issues, please contact your local Philips representative. For North America and Canada, contact the Customer Care Solutions Center (1-800-722-9377)

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,

[redacted]

Holly Wright Lee

Sr. Manager, Quality & Regulatory

Philips Medical Systems (Cleveland), Inc.
595 Miner Road, Highland Heights, Ohio 44143 U.S.A

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AFFECTED PRODUCTS	The following products with software version 4.2.0 and the associated Pinnacle³ Tumor LOC server (P14) that was installed on Brilliance Big Bore Oncology CT Brilliance Big Bore Radiology CT
PROBLEM DESCRIPTION	Philips became aware of issues with Brilliance Big Bore CT systems running software version 4.2.0. The most significant issues are: **1, EFOV (extended field of view) check message does not display when FOV is set >600mm for a paused scan** There are three scenarios that can cause the issue with Big Bore 4.2 RFLD software, 1. After enabling Extended Field of View (EFOV) in Preferences, the operator starts scanning with Field of View (FOV) less than 600mm and pauses the scan. After the scan is performed and then paused, in preview, the operator increases the FOV to more than 600mm, no EFOV check message window is displayed. The EFOV check message window should display with options "Add a duplicate result with FOV 600" and "Proceed without a duplicate result [Not recommended]" for the operator to select. 2. If FOV is increased to more than 600mm after recon is completed in 'edit results', no EFOV check message window is displayed. 3. If the operator has chosen "Duplicate a result with FOV=600" option, pause the scan and does final recon, duplicate result with FOV=600 is not created. In all three cases, the consequence is failure to create the duplicate result with FOV=600, or failure to warn the operator that the created FOV result is > 600 mm. **2, Prefer "center x/y 0" and "disable result rotation" checkboxes checked automatically when checking the "CT Simulation"** It is preferred to have improved usability such that the system can automatically turn on the "center x/y 0" setting and the "disable result rotation" setting when turning on the "CT simulation Exam Card". **3, Tumor LOC allows POI (Point of Interest) locking when a non-isocenter slice is displayed** During internal clinical simulation testing of Pinnacle³ Tumor LOC version 14.0, it was discovered that an isocenter could be marked even when it was not displayed in an MPR (multi-planar reconstruction) image plane.

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	4, Tracker scan completed, no images were generated The bolus tracking scan can appear completed, but no images are generated and the raw data file is not available for offline reconstructions. **5, Continuous Link plans the clinical scan outside the Surview** When planning a Chest and Abd/Pelvis scan, the Chest scan is normally planned and acquired first. However, if the Abd/Pelvis scan is planned prior to the Chest, check the plan length of the Chest scan closely before starting the acquisition. The planned Chest may extend beyond the Surview boundary. **6, Applying tilt on first mpr result, when the other axial results are unplanned causes change in scan length and number of cycles of scan** If the first result is a Multi-Planar Reconstruction (MPR) result such as Sagittal or Coronal and tilt is applied to it, when the remaining result gets planned (either while pressing Go or when selecting an unplanned axial result), there is a change in the scan length and number of cycles of scan. **7, "System is still initializing. Please wait..." error** While canceling an exam after all the scans included in one study were completed, the system may display a "still initializing..., please wait..." message and appear unresponsive. **8, Auto locations not functioning as expected** When using auto location to plan a scan exam including multiple acquisitions and each acquisition having multiple results, the auto location may not function as expected. If the user cannot recognize the auto location failed to plan the same Z coverage for the selected results, the wrong scan location may result. **9, System ended exam before completion** If a scan is canceled by the Gantry in the last 200ms of a scan, the Console may become unresponsive due to a software error that results in the Gantry software not notifying the Console the scan was cancelled. The operator may have to restart the Host computer to recover. **10, System Freeze-Up After Pause is Pressed** A software error may occur when the Pause/Cancel button is pressed at the end of an axial scan. The scan pause may cause the Console to freeze requiring the operator to restart the Host computer.
HAZARD INVOLVED	The hazard is Incorrect treatment due to issue 1~3; CT rescan due to issue 4~10.

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HOW TO IDENTIFY AFFECTED PRODUCTS	Determine whether you have a potentially affected system, then determine your software version. To identify the software version of your product: • Click the "Help" button • Select "About" and the software version is then displayed The products affected will display the following software version V4.2.0 The affected Pinnacle^3 Tumor LOC server version is 14.0
ACTION TO BE TAKEN BY CUSTOMER / USER	We recommend the customer take the following respective actions with regard to these issues: **1, EFOV (extended field of view) check message does not display when FOV is set >600mm for a paused scan** Identify the image labeling with Extended FOV, and the clear difference in the image quality beyond 600mm FOV. If desired, use offline reconstruction to generate the result FOV<=600. **2, Prefer "center x/y 0" and "disable result rotation" checkboxes checked automatically when checking the "CT Simulation"** For "CT simulation exam card", manually enable 'Force X/Y to 0/0' and 'Disable result rotation'. **3, Tumor LOC allows POI (Point of Interest) locking when a non-isocenter slice is displayed** Only lock a POI if you are showing at least one 2D viewing window and the POI that you intend to lock is shown in all of the 2D windows that are visible. **4, Tracker scan completed, no images were generated** There is no action could be taken by user to avoid this issue. **5, Continuous Link plans the clinical scan outside the Surview** Use the zoom feature to reduce the size of the Surview to confirm the planned area is accurate. **6, Applying tilt on first mpr result, when the other axial results are unplanned causes change in scan length and number of cycles of scan** The first result of an axial scan should always be an axial result and planned first. If MPRs are included they should follow the axial result. **7, "System is still initializing. Please wait..." error** In situations where the system may freeze near the end of a scan, restart the system. After the restart, the results may be available under the patient

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	directory and/or may be reconstructed from the raw data under the reconstruction folder. If the data is not present a rescan may be required. **8, Auto locations not functioning as expected** User may manually plan the same Z locations for the results with auto location. **9, System ended exam before completion** Perform a shutdown and startup of the host computer, as recommended in the systems Instructions for Use. Perform a host computer shutdown at least once per day to avoid this issue. **10, System Freeze-Up After Pause is Pressed** It is essential to comply with the routine system shutdown recommendations outlined in the system's Instructions for Use.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare is notifying the affected users of these issues via this Field Safety Notice. Field Change Order (FCO) will be released to correct these issues. A Philips Field Service Engineer will contact you to schedule the FCO updates at your site. Reference Field Change Order (FCO) 72800660.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or local Philips Healthcare office. For North America and Canada, contact the Customer Care Solutions Center (1-800-722-9377).

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