PHILIPS

URGENT - Field Safety Notice
Medical Device Correction

Brilliance BigBore Oncology CT, Brilliance BigBore Radiology CT
4D CT pulmonary phase issue

Dear Customer,

A problem has been detected in the Philips Brilliance BigBore Oncology CT, Brilliance BigBore 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.

When a respiratory gated 4D CT scan is performed with the Bellows pulmonary gating device, in some circumstances described in this letter, the CT images might be reconstructed at a single phase, while the annotations on the images incorrectly indicate that the reconstruction is from the requested specific phases (0% to 90%). Philips will release field change order (FCO) 72800660 to correct the affected systems.

If you need any further information or support concerning this issue, 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 the pulmonary toolkit option and software version 4.2.0 Brilliance BigBore Oncology CT Brilliance BigBore Radiology CT
PROBLEM DESCRIPTION	When a retrospective respiratory gated 4D CT scan is performed with the Bellows pulmonary gating device, the CT images might be reconstructed at a single phase, while the annotations on the images incorrectly indicate that the reconstruction is from the requested specific phases (0% to 90%). There are two scenarios that may result in misrepresentation of the 4D CT images with a respiratory gated 4D CT scan and reconstruction: Scenario 1: **'Start Final Recon'** button is clicked immediately after the 4D CT scan is completed but prior to the pulmonary waveform being displayed in the offline viewer, at the top of the screen. When this happens, the waveform information is not captured prior to sending the reconstruction request to the Common Image Reconstruction System (CIRS). This results in the CIRS defaulting all the CT image reconstructions to 0% pulmonary phase. Scenario 2: This happens during 4D CT scans that are approximately 100 seconds or more in duration. The issue is noticed with slow or irregular breathers, for example less than 8 breaths per minute. The breathing level may drop to a very low level or have a spike in the middle of the scan, and the breathing wave is lost. The console displays a message **'Respiratory Signal Lost'** in the scan ruler indicating that the breathing signal is lost. The scan continues as planned. The pulmonary waveform picks back up before the scan is finished. However, the CIRS ignores the pulmonary waveform. This results in all the images being reconstructed at the same phase.
HAZARD INVOLVED	Misrepresentation of CT images due to incorrect image pulmonary phase annotation; Or CT rescan if the patient is rescanned due to an incorrect image pulmonary phase.

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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
ACTION TO BE TAKEN BY CUSTOMER / USER	We recommend the customer take the following respective actions with two Scenarios that may cause the 4D CT images being reconstructed at the same phase. Scenario 1: • To avoid Scenario 1, ensure the pulmonary waveform is visible before selecting '**Start Final Recon**'; • If Scenario 1 does occur after performing a 4D CT scan, use the 4D CT raw data to perform offline reconstruction to generate images with correct phases. Scenario 2: • To avoid Scenario 2, complete a 4D CT study utilizing linear binning reconstruction. If the following error message '**Respiratory Signal Lost**' appears in the scan ruler during the 4D CT acquisition, edit the pulmonary waveform before selecting '**Start Final Recon**'. If amplitude binning reconstruction is desired, please use the 4D CT raw data to perform offline reconstruction to generate images with correct phases. • If Scenario 2 does occur after performing a 4D CT scan, use the 4D CT raw data in linear binning to edit the pulmonary waveform and perform offline reconstruction to generate images with correct phases. If amplitude binning reconstruction is desired, perform the second reconstruction using the edited waveform and choose amplitude binning option.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare is notifying the affected users of the issue via this Field Safety Notice.

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	Field Change Order (FCO) will be released to correct this issue in both scenarios by software usability interface redesign. For weak and slow pulmonary waveform signal that is considered "dropped" after scan starts, the system will mandate the user to review and edit the waveform if needed before the final reconstruction can be implemented. 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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