Advanced Molecular Imaging (AMI) CIL CLE16-013 26 May 2016

Customer Information

Philips BrightView X, BrightView XCT, and BrightView XCT Upgrade

Rel-180 Workflow Software Issue

Dear Customer,

Philips has discovered a potential issue with your BrightView system. This letter is to inform you:

- what the problem is and under what circumstances it can occur
- the actions that you as a customer can take to minimize the effect of the problem
- the actions planned by Philips to correct the problem

Please retain this Customer Information Letter with your system Instructions for Use for future reference.

If you need any further information or support concerning this issue, please contact your local Philips representative Technical Support Line: 1-800-722-9377.

Sincerely,

Holly Wright Lee
Senior Manager, Post Market Surveillance
Philips Healthcare
595 Miner Road
Highland Heights, OH 44143
Office: (440) 483-2015
Mobile: (440) 264-3237

Advanced Molecular Imaging (AMI) CIL CLE16-013 26 May 2016

Customer Information

Philips BrightView X, BrightView XCT, and BrightView XCT Upgrade

Rel-180 Workflow Software Issue

AFFECTED PRODUCTS	▪ 882478: BrightView X ▪ 882482: BrightView XCT ▪ 882454: BrightView XCT Upgrade
PROBLEM DESCRIPTION	**Issue:** During a non-Auto Body Contouring (ABC), non-circular, rel-180 scan, the detector may come in contact with the patient. If this occurs, contact sensors would pause the scan. All of the following conditions are required to create the situation. 1. Patient being scanned on a BrightView X or XCT camera 2. Performing a non-circular rel-180, non-ABC acquisition 3. During anterior/posterior setup, operator adjusts the detector radii, and then selects "Mark" to mark the orbit points 4. During lateral setup, the operator adjusts only the patient table height, moving it upward 5. The system displays a warning message that detector radii were not adjusted, as follows: **"Marking of one or both detectors not completed. Image quality may be compromised.** **Press Retry to re-mark orbit, or press Continue to proceed as marked."** 6. The operator chooses the "Retry" option 7. The operator adjusts the detector radii without readjusting the patient table height, and then selects "Mark" 8. The system displays a warning message that table height was not adjusted, as follows: **"The table height was not changed for patient centering. Select Retry to adjust the table height or Continue to use the current height."** 9. The operator chooses the "Continue" option 10. The software fails to apply the table height adjustment (marked in step 4) to the radius positions defined in step 3 11. The system moves to the start position, and a detector comes in contact with the patient during the scan

Customer Information

Philips BrightView X, BrightView XCT, and BrightView XCT Upgrade

Rel-180 Workflow Software Issue

	12. Contact sensors activate and stop system motion upon contact with the patient There have been no reports of any injuries associated with this issue.
HOW TO IDENTIFY AFFECTED PRODUCTS	All BrightView X and XCT systems are affected.
ADVICE ON ACTIONS BY CUSTOMER / USER	**Advice on actions for customer/user:** The operator can avoid this condition by completing the following sequence: 1. Select "Retry" described in step 8 above. • By choosing "Retry", the system will return to step 7 by displaying the informational prompt for step 7: **"Center the patient vertically by adjusting table height Adjust the radius to position the detectors close to the patient. Then select Mark to proceed or select Cancel to end the study."** 2. Select "Cancel" to end the study. 3. The operator can then start and follow the workflow to setup the study by adjusting both the table height AND the detector radii in step 4. 4. Select "Proceed" to start and complete an acquisition. There have been no reports of any injuries associated with this issue.
ACTIONS PLANNED BY PHILIPS	1. Philips is notifying the affected BrightView Family system customers about the issue via this Customer Information Letter (CIL). 2. A Field Change Order (FCO) will be deployed for Field Service Engineers (FSE) to upgrade the system software, to correct the issue.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning the issue, please contact your local Philips representative Technical Support Line: 1-800-722-9377.