

Advanced Molecular Imaging (AMI)

CIL 88200496 Rev01

22 Dec 2015

Customer Information

Philips BrightView, BrightView X, BrightView XCT, and BrightView XCT Upgrade

Version 1.2.3 (and higher) and 2.5.3 (and higher) Software Upgrade Issues

Dear Customer,

Philips has discovered four potential issues 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.

If you need any further information or support concerning this issue, please contact your local Philips representative.

Philips apologizes for any inconveniences caused by these problems.

Sincerely,



Adam Hoff
Business Analyst CT-AMI Field Actions
Quality & Regulatory

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AFFECTED PRODUCTS	<ul style="list-style-type: none">▪ 882480: BrightView▪ 882478: BrightView X▪ 882482: BrightView XCT▪ 882454: BrightView XCT Upgrade
PROBLEM DESCRIPTION	<p><u>Issue 1:</u> During a cardiac non-Auto Body Contouring (ABC) scan, using Cardiac High Resolution (CHR) collimators, the collimator may come in contact with the bottom edge of the patient pallet. If this occurs, collision sensors would pause the scan.</p> <p>Advice on actions for customer/user: The operator can recover from this condition by clearing the collision (reference Instructions For Use (IFU) documents BrightView Family v1.2.3 /2.5.3) and adjusting the orbit to prevent contact with the patient pallet. There have been no reports of any injuries associated with this event.</p> <p><u>Issue 2:</u> During a scan, the gantry motion may halt prematurely. This causes the scan sequence to pause. Incidences of scan sequence pause have been reported to occur more often after installation of the following software:</p> <ul style="list-style-type: none">▪ Version 1.2.4 for BrightView.▪ Version 2.5.4 for BrightView X, BrightView XCT and BrightView XCT Upgrade <p>Advice on actions for customer/user: The operator can choose to resume the scan by acknowledging the message on the touch screen or acquisition station.</p> <p>There have been no reports of any injuries associated with this issue.</p> <p><u>Issue 3:</u> The operator will receive a warning message indicating that the scan may not complete when defined with the following scan parameters:</p> <ul style="list-style-type: none">• Detector Relative Angle: 90 AND• Head first supine OR feet first prone

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This message further instructs the operator to re-mark the points used to define the orbit.

Advice on actions for customer/user:

When this message is received while using the scan parameters listed above, re-marking is not necessary and the scan may be continued.

There have been no reports of any injuries associated with this issue.

Issue 4:

The Resolved Defects section of the User Release Document 1.2.4/2.5.4 for BrightView, BrightView X and BrightView XCT (45980022532 Rev A) listed two Pre-Programmed Motions (PPMs) whose motion sequences were changed by the release of software version 1.2.4/ 2.5.4. The software has been updated so that the patient table is extracted before detectors are in motion.

In addition to the two PPMs in the User Release Document, the following 31 PPMs have also changed motion sequence:

- DH Hands Left
- DH Hands Right
- DH Sitting
- DH Standing
- Install Head Holder*
- Remove Head Holder*
- Anterior Oblique 30
- Posterior Oblique 30
- Anterior Oblique 60
- Posterior Oblique 60
- Anterior Oblique 45
- Posterior Oblique 45
- Seated Plantar
- SH Posterior Det 1
- SH Posterior Det 2
- Planar
- Pallet Change
- Outerroom Det 1 Left
- Outerroom Det 1 Right
- Outerroom Det 2 Left

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	<ul style="list-style-type: none"> • Outerroom Det 2 Right • Bed Imaging • Rel 90 Test Spin** • Rel 180 Test Spin** • PinHole*** • PinHole Anterior* • PinHole Posterior* • Lung -Pallet In • Lung -Rotate CW 45° • Lung -Rotate CCW 45° • Lung -Pallet Out <p>*Applicable only to BrightView X and BrightView XCT</p> <p>** Applicable only to BrightView XCT</p> <p>***Applicable only to BrightView</p> <p>Advice on actions for customer/user: Be aware that the new behavior of the Pre-Programmed Motion (PPM) is for the patient table to move before the detectors. There is no action required by customer/user.</p> <p>There have been no reports of any injuries associated with this issue.</p>
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HOW TO IDENTIFY AFFECTED PRODUCTS	<p>All BrightView Family systems that have had the following software installed:</p> <ul style="list-style-type: none"> • Version 1.2.3 or 1.2.4 for BrightView • Version 2.5.3 or 2.5.4 for BrightView X, BrightView XCT and BrightView XCT Upgrade <p>To find the most recent software version that is loaded on your system:</p> <ol style="list-style-type: none"> 1. From the Windows desktop, double-click . This is the BrightView JETStream icon. 2. Select Help > About JETStream to view the splash screen information. For example, software version 1.2.4 or 2.5.4 <div data-bbox="581 1018 1291 1312">  </div> <p style="text-align: center;">Figure 1 Current Software Version Information</p>
ADVICE ON ACTIONS BY CUSTOMER / USER	<p>Refer to Advice on actions for customer/user in the problem description section of this Customer Information Letter (CIL).</p>
ACTIONS PLANNED BY PHILIPS	<ol style="list-style-type: none"> 1. Philips has paused further deployment of the version 1.2.3 (and higher) and 2.5.3 (and higher) software upgrades. 2. Philips is notifying the affected BrightView Family system customers about these issues via this Customer Information Letter (CIL). 3. A Field Change Order (FCO) will be deployed for Field Service Engineers (FSE) to upgrade the system software, to correct these issues.
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning these issues, please contact your local Philips representative.</p>