

URGENT - Field Safety Notice Medical Device Correction

BrightView, BrightView X, BrightView XCT, Precedence 6, Precedence 16

Collimator Fall during Collimator Exchange Process

Dear Customer,

A problem has been detected with the Philips BrightView, BrightView X, BrightView XCT, Precedence 6 and Precedence 16, that, if it were to reoccur, could pose a risk to operators, service users and patients. 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 user in order to prevent risk to patients
- the actions planned by Philips to correct the problem.

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

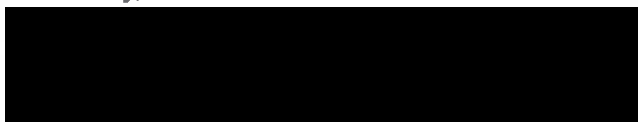
Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

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

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,



Rebecca Leaper
Head of Quality & Regulatory
CT/AMI



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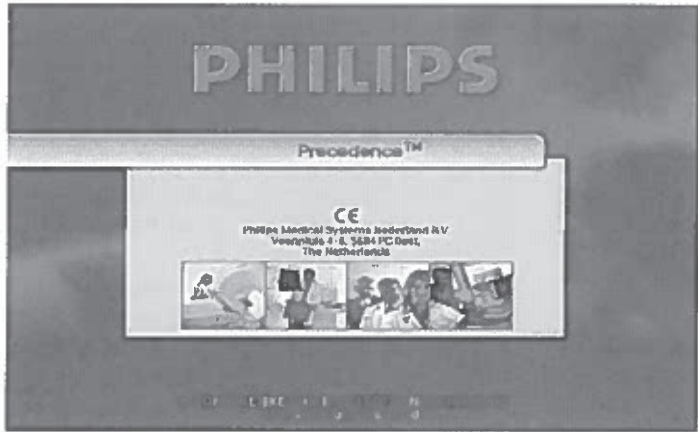
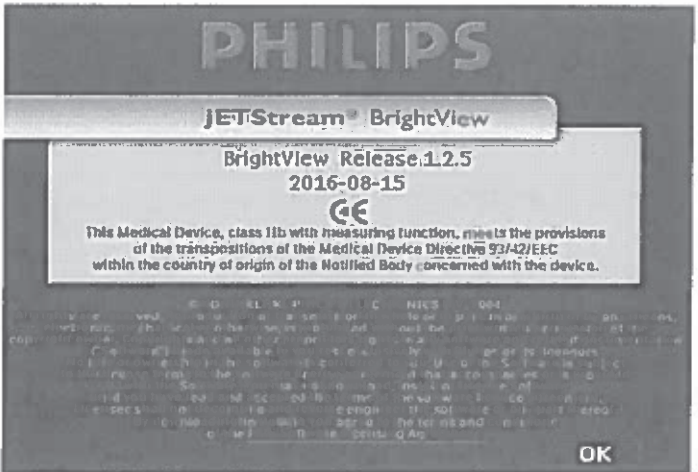
AFFECTED PRODUCTS	BrightView, BrightView X, BrightView XCT, Precedence 6, Precedence 16
PROBLEM DESCRIPTION	Philips has identified an issue during collimator exchange that may result in the collimator falling from the detector head or collimator cart.
HAZARD INVOLVED	<p>There may be times when the alignment of the collimator cart and detectors are such that a collimator exchange fails, and fails in such a way that a collimator drops to the floor beside the collimator cart. In some cases, the collimator may be partially supported by the cart (e.g. leaning against the cart), and in others it may fall/slide all the way to the floor.</p> <p>Hazard 1: There is a potential that a user / operator, who may be next to the collimator cart when the collimator falls, may have or place a limb in harms way [unintendedly, to try to stop the collimator from falling, or to minimize damage to the equipment].</p> <p>Hazard 2: There is a potential that a patient may incur an additional injection of radiopharmaceutical if the system becomes unusable due to the collimator falling, the patient has already received their injection, and the acquisition cannot be completed.</p>
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>All Precedence Family and BrightView Family systems are affected.</p> <p>To verify the product name for a Precedence system:</p> <ul style="list-style-type: none"> ➤ From the Windows desktop, click on the Precedence Processing button ➤ Click on Help, then select Product information to view the splash screen information with product model name.



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	 <p>The screenshot shows the Philips Precedence splash screen. At the top is the Philips logo. Below it is the word 'Precedence™'. In the center, there is a CE mark and the text 'Philips Medical Systems Nederland N.V. Voerstraat 1-2, 3824 PC Dordrecht, The Netherlands'. Below this is a small image showing a person in a clinical setting. At the bottom, there is a row of small icons.</p>
	<p>To verify the product name for a BrightView system:</p> <ul style="list-style-type: none">➤ From the Windows desktop, double click on the BrightView JETStream icon➤ Select Help > About JETStream to view the splash screen information with product model name.
	 <p>The screenshot shows the Philips JETStream BrightView splash screen. At the top is the Philips logo. Below it is the text 'JETStream® BrightView'. In the center, it says 'BrightView Release.1.2.5' and '2016-08-15'. Below this is a CE mark and the text 'This Medical Device, class IIb with measuring function, meets the provisions of the transpositions of the Medical Device Directive 93/42/EEC within the country of origin of the Notified Body concerned with the device.' At the bottom right, there is an 'OK' button.</p>



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ACTION TO BE TAKEN BY CUSTOMER / USER	<p>It is recommended that the technologist stay clear of moving parts during collimator exchange, other than the interaction required to dock / undock collimator carts with the system.</p> <p>It is recommended that the technologist keep their feet out from under the collimator carts while docking / undocking them with the camera.</p> <p>It is further recommended that the technologist observe the system during collimator exchange, and press an E-stop button if something occurs that is unexpected / not as described in the IFU.</p> <p>Follow the Warning, provided in the Instructions for Use (IFU) for BrightView as referenced in 459800422482 Rev B, Section 2 pg. 25-26 and 110 that states:</p> <p>“WARNING During collimator exchange, the detector latches engage the collimator; the system then moves the detector away from the collimator cart and pauses so you can examine the detector and collimator to make sure that the operation is proceeding normally. If any problems occur during collimator installation, press an E-Stop button, and call your Philips representative immediately.”</p>
ACTIONS PLANNED BY PHILIPS	<p>Preventative Maintenance procedures will be updated to check for and correct any misalignment and/or loose parts associated with collimator exchange.</p>
FURTHER INFORMATION AND SUPPORT	<p>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, follow the prompts).</p>

