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URGENT Field Safety Notice

BrightView, BrightView X, BrightView XCT (Product Codes 882480, 882478, 882482)

Potential Detector Fall could Result in Injury to the Patient

December 14, 2023

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 this letter for your records.

Dear Customer,

Philips has become aware of a potential safety issue affecting BrightView systems where the detector may unexpectedly fall due to a component failure. This URGENT Field Safety Notice is intended to inform you about:

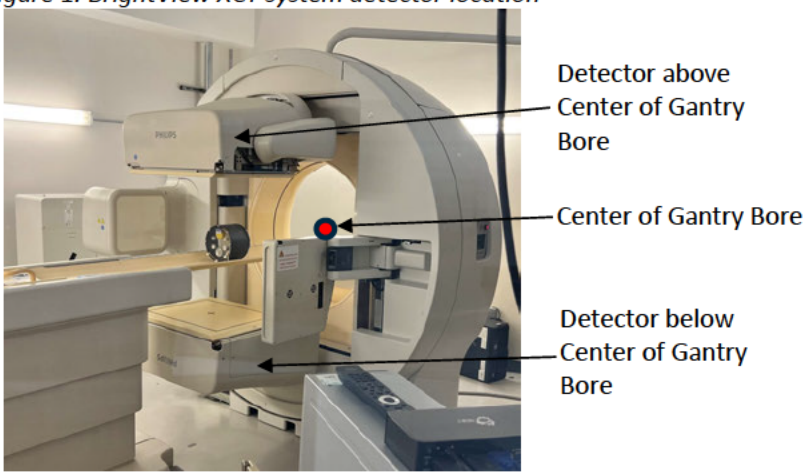
1. What the problem is and under what circumstances it can occur

A detector support component may fail due to unexpected wear:

- **Scenario 1:** If the detector is below the center of the gantry bore and the detector support component fails, the detector may descend downward unexpectedly and potentially contact the patient.
- **Scenario 2:** If the detector is above the center of the gantry bore and the detector support component fails, the detector will not be able to move to complete the imaging.

Refer to Figure 1 for the location of detectors relative to the gantry bore.

Figure 1. BrightView XCT system detector location



Philips has received a complaint associated with this issue; however, there are no reports of injury or serious harm.

2. Hazard/harm associated with the issue

Scenario 1, Detector positioned below center of gantry: If the patient's lower limb(s) is directly below the lower detector and the support component fails, the detector may descend downward in an uncontrolled manner and contact the patient. There is a potential for abrasion, contusion, laceration, and/or fracture to the patient's lower limb(s). Additionally, there will be an interruption to normal system operation. A rescan or re-injection of radiopharmaceutical to the patient may be required.

Scenario 2, Detector above center of gantry: If the support component fails, the detector will remain in place, and will not move as intended for clinical imaging, resulting in an interruption to normal system operation. A rescan or re-injection of radiopharmaceutical to the patient may be required.

3. Affected products and how to identify them

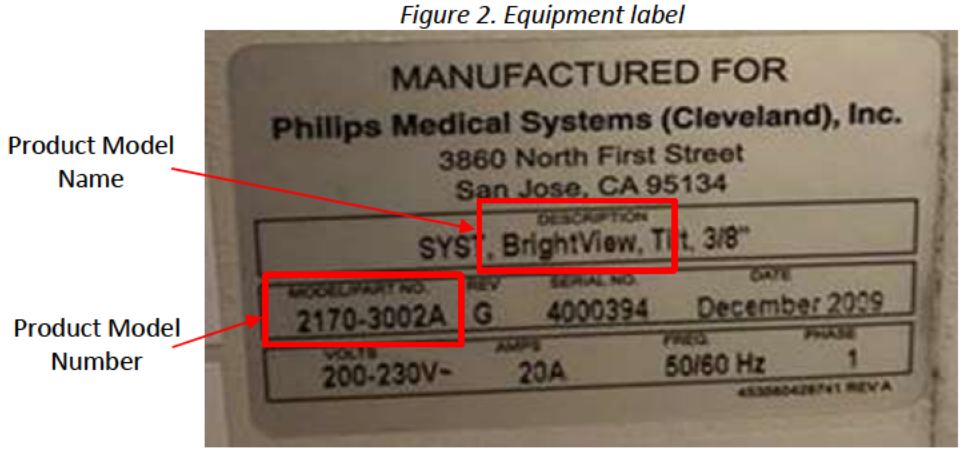
To identify if your system is affected:
This issue affects all BrightView systems with model numbers listed in Table 1.

Table 1. Affected BrightView Systems

Product Model Name	Product Model – 6 Digit Format	Product Model – 12 Digit Format	Product Model – 4x4 Digit Format
BrightView	882480	453560279781 453560279791 453560279811 453560279801	2170-3000A 2170-3001A 2170-3002A 2170-3003A
BrightView X	882478	453560824741 453560829261	N/A
BrightView XCT	882482	453560462131 453560749161	N/A

To locate the product model name and product model number, locate the equipment label on the back of the gantry near the bottom right as shown in Figure 2. Figure 2 shows a sample label for BrightView product model 2170-3002A (882480) as an example. Note: The system label may not have the same digit format as the example shown below.

Figure 2. Equipment label



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Intended Use:
BrightView Intended use:
The BrightView Gamma Camera System is intended to produce images depicting the anatomical distributions of single photon emitting radioisotopes within the human body for interpretation by medical personnel.

BrightView X-XCT Intended use:
BrightView XCT is a gamma camera for Single Photon Emission Computed Tomography (SPECT) and integrates with an attenuation device consisting of flat panel x-ray imaging components. BrightView XCT produces non-attenuation corrected SPECT images and attenuation corrected SPECT images with x-ray transmission data that may also be used for scatter correction. The nuclear medicine images and the XCT images may be registered and displayed in a fused format (overlaid in the same orientation) to provide anatomical localization of the nuclear medicine data. The BrightView XCT Imaging System should only be used by trained healthcare professionals.

4. Actions that should be taken by the customer / user in order to prevent risks for patients or users

- **Do Not** position a patient's lower limbs directly under the detector below the Center of Gantry bore (refer to Figure 3), for example while performing dual head (DH) hand (left/right) procedure.

Figure 3. Avoid positioning a patient's lower limbs under the detector below Center of Gantry

- After following the above referenced action, you may continue to use your system(s) in accordance with the intended use.
- Circulate this Urgent Field Safety Notice to all users of this device so that they are aware of the issue. Please retain this letter with your system(s) until the system is corrected; ensure the letter is in a place likely to be seen/viewed.
- Please complete and return the attached response form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice, understanding of the issue, and required actions to be taken.

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5. Actions planned by Philips to correct the problem

Philips will contact you to schedule a time for a Philips Field Service Engineer (FSE) to visit your site and to inspect and correct the system if necessary (FCO 88200538).

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information or support concerning this issue, please contact your local Philips representative.

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

[redacted]

[redacted]
Sr. Manager, Corrections and Removals

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URGENT Field Safety Notice Response Form

Reference: BrightView, BrightView X, BrightView XCT Potential Detector Fall could Result in Injury to the Patient, 2023-PD-CTAMI-019 (FCO88200538)

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Refer to the instructions provided in section 4 of the Urgent Field Safety Notice.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that handle the BrightView, BrightView X, BrightView XCT imaging systems.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please return this completed form to your local Philips representative.