PHILIPS

URGENT Field Safety Notice

BrightView, BrightView X, BrightView XCT
Patient Extremity Entrapment Hazard while using Pre-Programed Motion

Philips previously issued this letter on 30-Nov-2023. This letter is being re-issued with additional statements and images in Section 1 and Section 4.

December 21, 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 that may present an extremity entrapment hazard to patients during setup. This URGENT Field Safety Notice is intended to inform you about:

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

While using Pre-Programmed Motion (PPM) in a non-clinical or quality control manner, a gap can be created between the patient support and the detector, which presents a potential hazard. The gap can occur if the External QA PPM is executed and the lower detector is raised up and the patient table is lowered, both using the hand controller. This gap presents a potential extremity entrapment hazard for patients while the system detectors and patient support are in motion.

Figure 1. Image of gap between the patient support and detector

Gap between the detector and patient support. During PPM, the gap may decrease creating the potential for extremity entrapment.

Figure 2. Side Image of gap between the patient support and detector

Philips has received one (1) report of an adverse event associated with this issue. In this reported event, the operator positioned a patient on the patient support and initiated the total body Pre-Programmed Motion (PPM). While the patient support and detectors were in motion, the patient straightened their leg due to a cramp, causing their foot to extend and become entrapped between the patient support and the detector. The patient sustained a foot fracture.

2. Hazard/harm associated with the issue

If extremity entrapment occurs, the risk to patients may include fracture, body part loss of function/debilitation, muscle or ligament sprain or strain, laceration, crush injury, abrasion, or contusion. Additionally, operational loss of function of the system may occur resulting in the need for a rescan and/or re-injection of radiopharmaceuticals.

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.

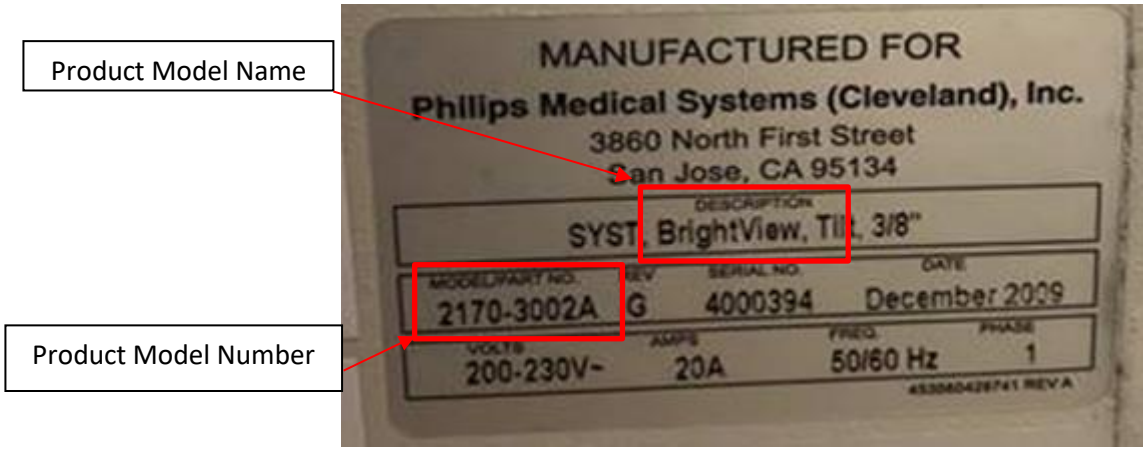
Table 1. Affected BrightView Systems

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 3. Figure 3 is showing 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 3. Equipment label



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.

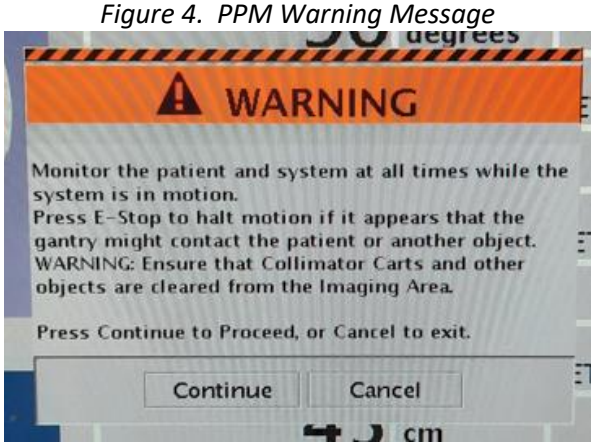
BrightView X-XCT Intended use:

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

Philips is working to provide a solution to remove this potential hazard identified with the use of the PPM. In the interim, initiate the "Patient Loading PPM" without the patient on the imaging table, prior to use and proceed in accordance with the guidance of the system warning as shown in Figure 4 and refer to the Instruction For Use guidance outlined below.

Figure 4. PPM Warning Message



- **Monitor the patient during system movement when the Pre-Programmed Motion is in use and review the warning and caution guidance information below, as outlined in *Section 2: Safety and Regulatory Agency Compliance* in the Instructions for Use:**
  - If the patient extends beyond the end of the imaging table, reposition the patient before starting any preprogrammed motion.
  - Vigilantly watch the patient to make sure that equipment or patient motion does not result in patient harm or equipment damage.
  - If you perform a PPM with the patient on the imaging table, monitor the equipment motion closely to avoid contact with the patient object.
  - If any part of the system looks as if it is going to collide with the patient, use an emergency stop button to immediately stop system motion.
  - When moving a patient using the Hand controller or the touchscreen, advise the patient not to move because they may be temporarily out of your line of view.
  - If you use PPM when a patient is on the imaging table, make sure that no part of the patient comes into contact with the gantry.
  - Do not use the Stop button on the Hand controller in an emergency. In an emergency, always use one of the four Emergency Stop buttons on the system. Although the Stop button on the Hand controller stops the acquisition, this button is not intended to immediately stop all system motions. See Figure 5 below for a photo of the Emergency Stop.

Figure 5. Emergency Stop

- Circulate this 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 a solution is installed on your system; 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 Field Safety Notice, understanding of the issue, and required actions to be taken.

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 install a technical solution to resolve this issue (refer to FCO88200537).

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 at the Philips Customer Care Service Centre by:

PHILIPS

Telephone: UKI : +448000260086
NI: +448000260430
ROI: +3531800832340

Email: ukisfco@philips.com

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

Cassandra Kocsis
Sr. Manager, Correction & Removals

PHILIPS

URGENT Field Safety Notice Response Form

Reference: 2023-PD-CTAMI-011 BrightView Detector Collision (FCO88200537)

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 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 Field Safety Notice.

We acknowledge receipt and understanding of the accompanying Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that handle the affected Philips CT System(s).

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

Please return this completed form to Philips at: **safetynoticeuki@philips.com**