Effective: 18 July 2014. *See approved document for rationale and signatures.*

Advanced Molecular Imaging FSN 88200486 2014 November 04

URGENT - Field Safety Notice
Medical Device Correction
BrightView SPECT, BrightView X and BrightView XCT

Software Issues identified on the BrightView SPECT, BrightView X and BrightView XCT Systems

Dear Customer,

Recently, Philips Healthcare notified you through Field Safety Notice (FSN) 88200455 of software issues identified on the BrightView SPECT, BrightView X and BrightView XCT Systems and that Philips would be installing a software update to all of the BrightView Family systems to correct those issues. Prior to the implementation of the previous Field Change Order (FCO) on your system, additional issues were identified, therefore the release of the previous Field Change Order 88200455 was put on hold.

Philips identified a solution that resolved these additional issues and will deploy an updated correction by installing a BrightView Family software version update 1.2.4/2.5.4. Field Change Order 88200486 will replace the software version released in the previous FCO 88200455.

This Field Safety Notice 88200486 is intended to inform you about:

- what the issues are and under what circumstances they can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the issues.

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.

Philips is advising the customers/users to retain a copy of this Field Safety Notice with the equipment Instruction for Use, until further notice.

If you need any further information or support concerning these issues, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

This notice has been reported to the appropriate Regulatory Agencies.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Daniel R. Brown
Director, AMI/CT Quality and Regulatory

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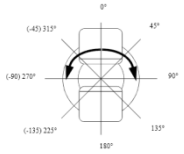
AFFECTED PRODUCTS	• BrightView SPECT • BrightView X • BrightView XCT Systems
PROBLEM DESCRIPTION	**Problem 1:** Following a cardiac scan and when using SmartStep* to setup the camera for a Relative 180 procedure, it is possible for Detector 1 to collide with the head holder when moving from the position at which the flat panel is deployed. The issue was not reported by the field but was identified during in-house testing on a BrightView XCT system. This issue only affects BrightView XCT systems. Refer to the "**ACTION TO BE TAKEN BY CUSTOMER / USER" section of this Field Safety Notice for additional information in reference to this problem.** *SmartStep is the automatic acquisition workflow of the JETStream acquisition station to assist in camera setup and positioning. **Problem 2:** During a patient SPECT lung acquisition, the clinical scan acquisition protocol commanded the gantry rotation to move from the 45 degree to the 90 degree position. Refer to Figure 1 below. However, in the middle of a clinical scan acquisition, the detector heads moved away from the patient (center of rotation) in an uncommanded motion and subsequently the gantry unexpectedly rotated to the 240 degree position. The movement form 90 degree to the 240 degree may take approximately 7 seconds.  ←Center of Rotation Figure 1: Detector and gantry orientation, viewed facing the front of the gantry.

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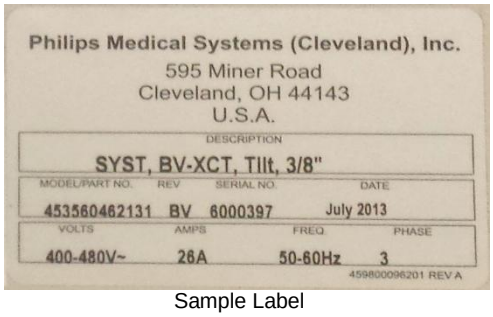
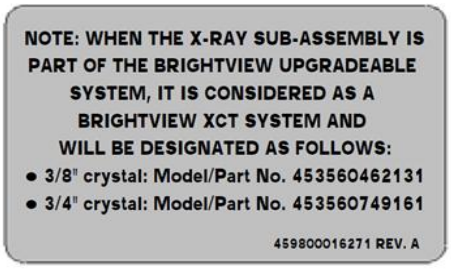
HAZARD INVOLVED	In addition to the previous Field Safety Notice 88200455, this notice FSN 88200486 is being provided to our customers informing you of additional issues(s) that may result in unintended contact with a detector or gantry. **There have been no reports of any injury as a result of the two situations described in this notice.**
HOW TO IDENTIFY AFFECTED PRODUCTS	Refer to the System Label affixed to the bottom right rear of the gantry cover. The "Description" box will identify the system description: Refer to the Sample Label below:  ← "Description" box Sample Label • <u>BrightView X system upgraded to a BrightView XCT system:</u> At the time of a BrightView X system upgrade to a BrightView XCT system, an additional label is added to the bottom right rear of the gantry cover, which considers the system has received the upgrade kit: "BrightView X to BrightView XCT". Refer to the additional system label affixed at the time of the upgrade.  BrightView X system upgrade to a BrightView XCT System Label Example

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ACTION TO BE TAKEN BY CUSTOMER / USER	Philips is advising the customers/users to retain a copy of this Field Safety Notice with the equipment Instruction for Use, until further notice. **Problem #1:** Philips is advising the customer/user to perform the following workaround prior to the implementation of the field safety correction, to avoid contact between the detector and the head holder as describe above in Problem #1: **ONLY** if the system is positioned in a Relative-90 configuration with one of the detectors below the pallet level **and** the table in in the patient load position: Follow the sequence of operations prior to performing a study utilizing the head holder: - Deploy or store the x-ray panel if necessary; - Run the patient load PPM; - Install the head holder; and - Position the patient on the table and proceed with the study In addition, take the following preventative actions: • Monitor the patient during any and all system motions. • Know locations of the multiple E-Stop button(s) to halt all system motion. (Emergency Stop: where the system immediately stops all detector and gantry motions by disconnecting power to the motors that control system motion)
ACTIONS PLANNED BY PHILIPS	Philips Healthcare is initiating a corrective action consisting of : • Distribution of this Field Safety Notice 88200486, • Conducting the appropriate field safety correction will address the above issues that have been identified. This field safety correction will consist of the installation of BrightView Family software version 1.2.4/2.5.4 update through Field Change Order (FCO) 88200486.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.