**Field Safety Notice**

PHILIPS

**Philips Healthcare**

**Advanced Molecular Imaging** -1/12- FSN88200490 17 June 2014

# URGENT – Field Safety Notice

## BrightView XCT and BrightView X- upgraded with the XCT Flat Panel Detector

### Flat Panel Detector (FPD) may pivot inward unexpectedly as the gantry is rotated, resulting in potential injury

### ACTION: CEASE USE of XCT Flat Panel Detector until the implementation of the appropriate field safety correction

Dear Customer,

Recently, a problem was reported from the field that the Flat Panel Detector (FPD) failed to remain securely locked in the deployed position. If the issue were to re-occur, it could pose a risk for a person who is in the direct path of the FPD.

This Field Safety Notice (FSN) 88200490 and Addendum is intended to inform you about the following:

- what the problem is and under what circumstances it 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 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 Healthcare 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 Agencies.

Sincerely,

Scott Christiansen
Director of Quality and Regulatory



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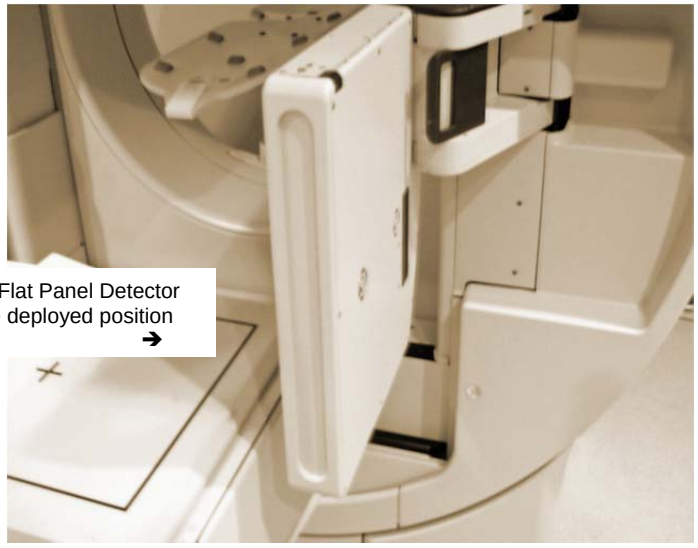
**Advanced Molecular Imaging** -2/12- FSN88200490 17 June 2014

# URGENT – Field Safety Notice

## BrightView XCT and BrightView X- upgraded with the XCT Flat Panel Detector

**Flat Panel Detector (FPD) may pivot inward unexpectedly as the gantry is rotated, resulting in potential injury**

**ACTION: CEASE USE of XCT Flat Panel Detector until the implementation of the appropriate field safety correction**

| | |
|---|---|
| **AFFECTED PRODUCTS** | • BrightView XCT<br>• BrightView X- upgraded with the XCT Flat Panel Detector (FPD) |
| **PROBLEM DESCRIPTION** | Philips received a report from the field that the FPD failed to remain securely locked in the deployed position.<br><br>During a daily XCT Quality Assurance phantom scan for image quality and Hounsfield Unit (HU) linearity an operator experienced resistance when engaging the locking handle of the FPD in the deployed position. With the locking handle in the locked position, the FPD locking mechanism was not locked, moved unexpectedly and contacted the imaging detector during system movement. Philips' investigation determined the internal linkage shaft broke preventing the FPD from being locked into its correct deployed position.<br><br>  <br>XCT Flat Panel Detector in the deployed position ➔ |
| **HAZARD INVOLVED** | If this problem were to re-occur the FPD could swing inward unexpectedly during gantry motion and come in direct contact with the patient, user or service personnel if they were in the path of the pivoting detector. |

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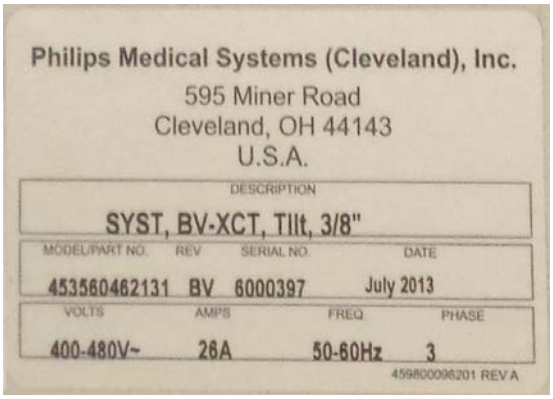
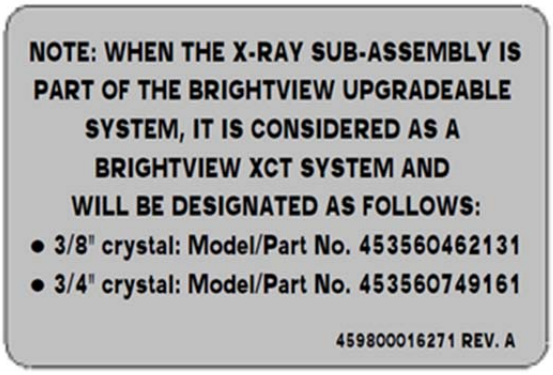
# URGENT – Field Safety Notice

## BrightView XCT and BrightView X- upgraded with the XCT Flat Panel Detector

**Flat Panel Detector (FPD) may pivot inward unexpectedly as the gantry is rotated, resulting in potential injury**

**ACTION: CEASE USE of XCT Flat Panel Detector until the implementation of the appropriate field safety correction**

| | |
|---|---|
| **HOW TO IDENTIFY AFFECTED PRODUCTS** | **<u>BrightView XCT system:</u>**<br>Refer to the System Label affixed to the bottom right rear of the gantry cover. The "Description" box identifies the affected system description: "BV-XCT"<br><br>BrightView XCT System Label Example<br><br>  <br><br><br>**<u>BrightView X system upgraded to a BrightView XCT system:</u>**<br>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.<br><br>BrightView X system upgrade to a BrightView XCT System Label Example<br><br>  <br> |

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**Advanced Molecular Imaging** -4/12- FSN88200490 17 June 2014

# URGENT – Field Safety Notice

## BrightView XCT and BrightView X- upgraded with the XCT Flat Panel Detector

### Flat Panel Detector (FPD) may pivot inward unexpectedly as the gantry is rotated, resulting in potential injury

### ACTION: CEASE USE of XCT Flat Panel Detector until the implementation of the appropriate field safety correction

| | |
|---|---|
| **ACTION TO BE TAKEN BY CUSTOMER / USER** | 1. **Immediately CEASE USE of the XCT Flat Panel Detector and stow the XCT FPD until the implementation of the appropriate field safety correction is completed by a Philips Healthcare Field Service Engineer (FSE) and the system is released for clinical use.**<br><br>**IMPORTANT:** Until your system has been released for clinical use: The customer/user is being advised to follow the "INSTRUCTIONS TO CONTINUE LIMITED USE" instructions described in the attached Addendum.<br><br>2. Read and understand this Field Safety Notice and Addendum. The Addendum is intended to provide the information required for the continued use of your system (prior to release by Philips FSE for clinical use of the Flat Panel Detector).<br><br>3. Complete the Customer Response Form provided, confirming that you have read and understand this Field Safety Notice and Addendum. Return your signed and dated response form WITHIN 10 DAYS OF RECEIPT via fax to number +1440-483-2950 or email to CTNM.QARA@philips.com.<br><br>4. This Field Safety Notice and Addendum must be placed in your User Documentation until otherwise notified. |
| **ACTIONS PLANNED BY PHILIPS** | Philips Healthcare is initiating this field correction consisting of:<br>• The distribution of this Field Safety Notice (FSN) FSN88200490 and Addendum informing the operator of the issue and required actions and<br>• An immediate field correction of your system conducted by a Philips Healthcare Field Service Engineer. |
| **FURTHER INFORMATION AND SUPPORT** | If you need any further information or support concerning this issue, please contact your local Philips representative or local Philips Healthcare office. For North America and Canada contact the Customer Care Solutions Center (1-800-722-9377: follow the prompts). |



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**Field Safety Notice**

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# URGENT – Field Safety Notice

## BrightView XCT and BrightView X- upgraded with the XCT Flat Panel Detector

**Flat Panel Detector (FPD) may pivot inward unexpectedly as the gantry is rotated, resulting in potential injury**

**ACTION: CEASE USE of XCT Flat Panel Detector until the implementation of the appropriate field safety correction**

## FIELD SAFETY NOTICE 88200490 CUSTOMER RESPONSE FORM

HOSPITAL/CENTER NAME:_____

ADDRESS: _____

CITY:_____STATE/PROVINCE:_____ZIP CODE:_____

SYSTEM NAME:_____SYSTEM SERIAL NUMBER:_____

DEPARTMENT CONTACT NAME:_____

DEPARTMENT CONTACT PHONE NUMBER:_____

**SYSTEM STILL IN USE: yes _____ no_____**

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- I have received, read and understand the content within the Field Safety Notice (FSN) 88200490 and Addendum, "**ADDENDUM-INSTRUCTIONS TO CONTINUE LIMITED USE**"
- I acknowledge Philips Healthcare's information and instructions in the Addendum, "**INSTRUCTIONS TO CONTINUE LIMITED USE**" for the continued use of the system until a Philips Healthcare Representative conducts the appropriate field safety correction.

NAME:_____
PRINT

TITLE:_____
PRINT

SIGNATURE:_____

DATE:_____

**** IMPORTANT: Please complete this "Field Safety Notice 88200490 Customer Response Form"**
**IMPORTANT: For United States: Return the signed and dated response form WITHIN 10 DAYS OF RECEIPT via fax to number +1440-483-2950 or email to CTNM.QARA@philips.com.**

**For other countries, please follow your local office contact information.**

**Complete this form regardless of whether your system is still in use at your facility**



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# URGENT – Field Safety Notice

## BrightView XCT and BrightView X- upgraded with the XCT Flat Panel Detector

**Flat Panel Detector (FPD) may pivot inward unexpectedly as the gantry is rotated, resulting in potential injury**

**ACTION: CEASE USE of XCT Flat Panel Detector until the implementation of the appropriate field safety correction**

## ADDENDUM
## INSTRUCTIONS TO CONTINUE LIMITED USE

| Study Type | Action Required |
|---|---|
| 180 & 90 SPECT LOC | • CEASE USE IMMEDIATELY until implementation of the appropriate field safety correction. |
| 180 & 90 SPECT AC | • CEASE USE IMMEDIATELY until implementation of the appropriate field safety correction. |
| 180 & 90 SPECT NON AC / NON LOC | Unaffected |
| Total Body Planar | Unaffected |
| Planar Static & Dynamic | Unaffected |
| Cardiac 90 & Relative 90 SPECT | Unaffected |

**IMPORTANT:** Continued use of the BrightView XCT and BrightView X (Post Upgrade to XCT) systems requires modification of acquisition protocols to remove XCT work steps.

- The following instructions will permit users to perform standard SPECT studies using the system in all head configurations associated with factory default protocols.
- 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.
- Total impact to patient throughput and technologist workflow will vary per department. Careful consideration must be taken in scheduling, and desired image results must be understood regarding the limitations of NON AC & NON LOC SPECT acquisitions.

  **NOTE**: XCT is available only for Nuclear Medicine SPECT studies.

# URGENT – Field Safety Notice

## BrightView XCT and BrightView X- upgraded with the XCT Flat Panel Detector

**Flat Panel Detector (FPD) may pivot inward unexpectedly as the gantry is rotated, resulting in potential injury**

**ACTION: CEASE USE of XCT Flat Panel Detector until the implementation of the appropriate field safety correction**

- XCT Quality Assurance (QA) phantom studies as defined in the BrightView XCT User's Manual are affected.
- Collimator exchange functions as defined in the BrightView XCT User's Manual remain unaffected.
- These instructions may supersede portions of the current BrightView XCT User's Manual.

**Selecting a protocol:**

- To see the factory and custom Attenuation Correction and Localization protocols that are supplied with your system, from the acquisition console click Tools – Protocols, or:
- Enter required patient data for a new study or select an existing patient study.
- Click Proceed. The Patient Information tab now includes the Protocols tab and the Optional Visit Information tabs.
- Do one of the following:
  - Click the protocol shortcut button of the desired protocol.
  - Click the All Protocols button and select a protocol from the list. Select a protocol without the LOC or AC designation.
  - The selected protocol appears in the Patient Study panel.
  - If an orange dot appears next to the protocol name appearing in the patient study panel this denotes an XCT component has been applied. This may be altered from within the study by performing the following:
  - In the SPECT acquisition page locate the drop down menu for XCT parameters located in the top right hand side of the page. The drop down menu allows for the selection of :
    - NONE
    - AC FAST
    - AC SLOW
    - LOCALIZATION FAST
    - LOCALIZATION SLOW

# URGENT – Field Safety Notice

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**ACTION: CEASE USE of XCT Flat Panel Detector until the implementation of the appropriate field safety correction**

- Select NONE and this will remove the XCT parameters associated with the present protocol in use “On the Fly” without amending the factory or custom protocols in the protocol list.
- The visual indicator (Orange Dot) next to the protocol name will be removed and the XCT acquisition parameters setup page will disappear.
- Proceed with the acquisition setup and patient study.

**IMPORTANT** When you change a parameter in an acquisition setup form, you must click Update for the system to accept the new value.

**WARNING** Do not attempt to deploy or stow the FPD without first performing the Deploy Panel PPM or Stow Panel PPM. Do not press the release button to deploy the Flat Panel X-ray Detector in any position other than the Stow Panel PPM final position (+90 degrees).

# URGENT – Field Safety Notice

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**ACTION: CEASE USE of XCT Flat Panel Detector until the implementation of the appropriate field safety correction**

**To stow the FPD:**

1.) Touch the Stow Panel PPM on the touchscreen to move the system into the proper position.

2.) Pull the locking handle (Figure1) out and push it away from you 180 degrees.

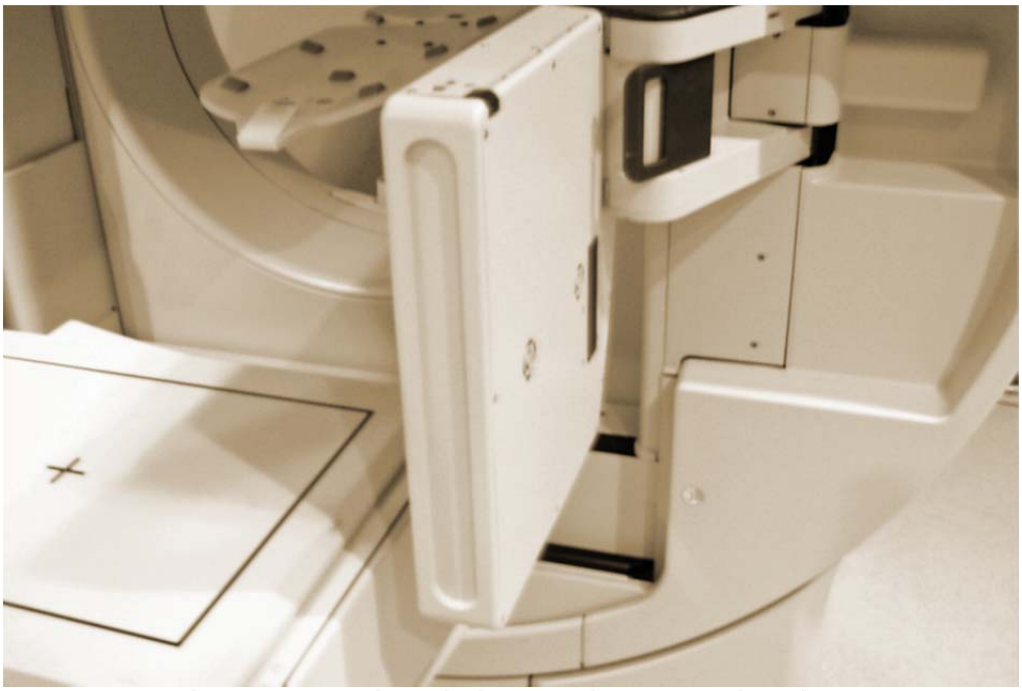

**Figure 1 – Deployed Flat Panel Detector (FPD)**

**IMPORTANT** Be careful not to rotate the FPD too far or it will collide with the gantry cover.

3.) Using the handle extend the FPD and the arm that supports it away from you to the right 90 degrees so that the entire assembly is parallel to the gantry.
4.) Extend the FPD towards you to the left 180 degrees and push it into the stowed position as shown in Figure 2.

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**ACTION: CEASE USE of XCT Flat Panel Detector until the implementation of the appropriate field safety correction**

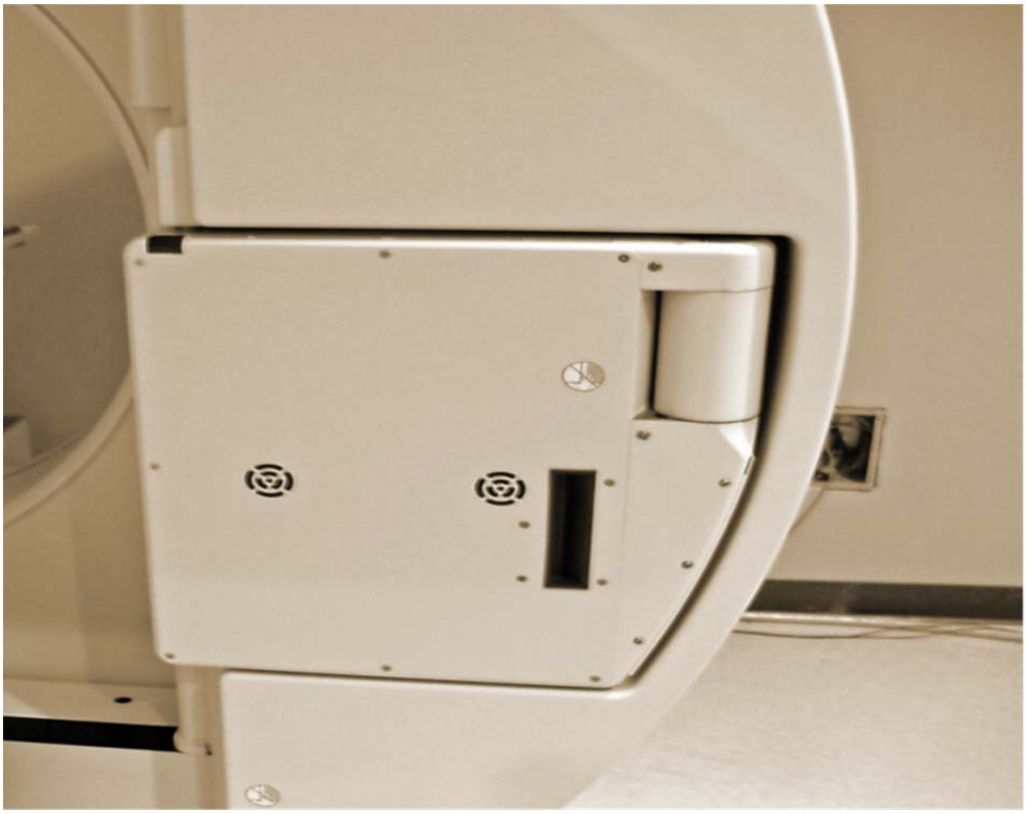

**Figure 2 – Stowed Flat Panel detector (FPD)**

- When you push the FPD into the locked position, you will hear a clicking sound and the FPD icon on the touchscreen displays the stowed position.

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# URGENT – Field Safety Notice

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**ACTION: CEASE USE of XCT Flat Panel Detector until the implementation of the appropriate field safety correction**

| 180 & 90 SPECT LOC —CEASE USE IMMEDIATELY | |
|---|---|
| **Justification** | Justification SPECT LOC procedures require the deployment of the FPD. |
| **Factory Protocols** | Fast (Body) Localization<br>Slow Localization |
| **Studies Affected** | • Dual Isotope Tc-Ga LOC<br>• Extremity Bone LOC<br>• Indium SPECT LOC<br>• Parathyroid SPECT LOC<br>• TB SPECT LOC<br>• Total Body Bone LOC |
| **Instruction** | Per this FSN # SPECT LOC is to be ceased until implementation of Field Change Order (FCO) 88200490. |

| 180 & 90 SPECT AC —CEASE USE IMMEDIATELY | |
|---|---|
| **Justification** | SPECT AC procedures require the deployment of the FPD. |
| **Factory Protocols** | Cardiac Attenuation Correction<br>Fast (Body) Attenuation Correction |
| **Studies Affected** | • Brain SPECT AC<br>• Cardiac One Day AC<br>• Cardiac Two Day AC<br>• Thallium SPECT AC<br>• Gated SPECT AC<br>• Cardiac Dual Isotope AC |
| **Instruction** | Per this FSN 88200490 SPECT LOC is to be ceased until implementation of Field Change Order (FCO) 88200490. |



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**Field Safety Notice**

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**Advanced Molecular Imaging** -12/12- FSN88200490 17 June 2014

# URGENT – Field Safety Notice

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**Flat Panel Detector (FPD) may pivot inward unexpectedly as the gantry is rotated, resulting in potential injury**

**ACTION: CEASE USE of XCT Flat Panel Detector until the implementation of the appropriate field safety correction**

| Cardiac 90 & Relative 90 SPECT NON AC / NON LOC – UNAFFECTED | |
|---|---|
| **Justification** | Cardiac 90 & Relative 90 SPECT NON AC / NON LOC procedures DO NOT require the deployment of the FPD. |
| **Factory Protocols** | N/A |
| **Studies Affected** | NONE Affected |
| **Instruction** | Continue normal use. |

| 180 SPECT NON AC / NON LOC – UNAFFECTED | |
|---|---|
| **Justification** | 180 SPECT NON AC / NON LOC procedures DO NOT require the deployment of the FPD. |
| **Factory Protocols** | N/A |
| **Studies Affected** | NONE Affected. |
| **Instruction** | Continue normal use. |

| Total Body Planar – UNAFFECTED | |
|---|---|
| **Justification** | Total Body Planar procedures DO NOT require the deployment of the FPD. |
| **Factory Protocols** | N/A |
| **Studies Affected** | None Affected. |
| **Instruction** | Continue normal use. |

| Planar Static & Dynamic - UNAFFECTED | |
|---|---|
| **Justification** | Planar Static & Dynamic procedures DO NOT require the deployment of the FPD. |
| **Factory Protocols** | N/A |
| **Studies Affected** | NONE Affected. |
| **Instruction** | Continue normal use. |



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