Field Safety Notice

PHILIPS

Philips Healthcare

Advanced Molecular Imaging -1/13- FSN 88200481 March 10, 2014

URGENT – Field Safety Notice

ADAC Vertex Classic, Vertex Plus, Solus and Vertex V60 Systems

Detector head may drift, resulting in potential patient injury or death

ACTION: CEASE USE of Relative 180 SPECT scans and procedures using the Pinhole Collimator
LIMITED SYSTEM USE described in Addendum

NOTE: The ADAC Cardio System is NOT affected by this Field Safety Notice

Dear Customer,

Recently, a problem was reported from the field of radius drive belt slippage in an ADAC Vertex System. If the issue were to recur it could pose a risk of a potential serious injury or death for a patient if he or she is directly under the detector.

The affected systems are labeled ADAC Laboratories, not Philips Healthcare.

This Field Safety Notice 88200481 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 customer / user in order to prevent risks for patients or users
- the actions planned by Philips Healthcare 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, Option 5: Enter site ID or follow the prompts).

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

[redacted]
Director of Quality and Regulatory

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NOTE: The ADAC Cardio System is NOT affected by this Field Safety Notice

AFFECTED PRODUCTS	• ADAC Vertex Classic • ADAC Vertex Plus • ADAC Vertex V60 • ADAC Solus **Please note that the ADAC Cardio is not affected by this Field Safety Notice. The Cardio system can be identified by:** • **The word "Cardio" on the system's label;** • **By the fixed 90 degree orientation of the detector heads; and,** • **Vertex "Cardio" printed on the detector bonnet.** The affected systems are labeled ADAC Laboratories, not Philips Healthcare.
PROBLEM DESCRIPTION	Philips Healthcare received a report from the field about an ADAC Vertex Plus system. During clinical use in the relative 180 degree configuration of the detector heads, the radius drive belt in the superior positioned head slipped off the idler pulley, allowing the detector head to drift down slowly (approximately 1 cm per minute) towards the patient. This resulted in the operator having to perform an emergency removal of the patient from the system. There have been no reports of serious injury or death as a result of this situation.
HAZARD INVOLVED	In the relative 180 degree configuration, the superior positioned detector head radius drive belt slipped off the idler pulley, allowing the detector head to drift down slowly (approximately 1 cm per minute). If this problem were to recur a drifting detector head could potentially come in direct contact with the patient. Without immediate intervention a patient may become entrapped between the detector head and the patient pallet due to the operator's inability to engage the Manual Override mode*. This override mode becomes inoperable when the software detects unrequested motion, as designed, triggering a permanent E-Stop. The permanent E-stop cannot be cleared by an operator, rendering the system inoperable without Field Service Engineer intervention. Therefore, should the Manual Override become inoperable, the patient pallet cannot be lowered. This situation has the potential to cause serious injury or death from the weight of the detector coming to rest on the patient. ***Note:** Normally, the proper function of the Manual Override mode allows the operator to recover the basic system motions when a system is in a collision state.

Field Safety Notice

PHILIPS

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Advanced Molecular Imaging -3/13- FSN 88200481 March 10, 2014

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ACTION: CEASE USE of Relative 180 SPECT scans and procedures using the Pinhole Collimator
LIMITED SYSTEM USE described in Addendum

NOTE: The ADAC Cardio System is NOT affected by this Field Safety Notice

HOW TO IDENTIFY AFFECTED PRODUCTS	• ADAC Vertex Classic • ADAC Vertex Plus • ADAC Vertex V60 • ADAC Solus *** Please note that the ADAC Cardio is not affected by this Field Safety Notice.** The system name can be identified by the system serial label which is located on the gantry by the input power.

ACTION TO BE TAKEN BY CUSTOMER / USER	• **CEASE use of "Relative 180 degree SPECT" procedures until implementation of the Field Change Order (FCO) (See Addendum for complete details).**
	• **CEASE use of the "pinhole collimator" procedures until implementation of the FCO (See Addendum for complete details).**
	• **Continue use of Total Body Planar and Planar Static and Dynamic studies with workflow modifications and/or detector modifications as described until implementation of the FCO (See Addendum for complete details).**
	• 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.
	• A Customer Response Form has also been provided. Please confirm by signing the attached form that you have read and understand this Field Safety Notice and Addendum.
	  • **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.**
	• This Field Safety Notice and Addendum must be placed in your User Documentation until otherwise notified.

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Field Safety Notice

PHILIPS

Philips Healthcare

Advanced Molecular Imaging -4/13- FSN 88200481 March 10, 2014

URGENT – Field Safety Notice

ADAC Vertex Classic, Vertex Plus, Solus and Vertex V60 Systems

Detector head may drift, resulting in potential patient injury or death

ACTION: CEASE USE of Relative 180 SPECT scans and procedures using the Pinhole Collimator
LIMITED SYSTEM USE described in Addendum

NOTE: The ADAC Cardio System is NOT affected by this Field Safety Notice

ACTIONS PLANNED BY PHILIPS HEALTHCARE	Philips Healthcare is initiating this field correction consisting of:
	• The distribution of:
	  ○ A Field Safety Notice 88200481 informing the operator of the issue.
	  ○ An Addendum, "Instructions to Continue Limited Use" to provide the information required for the continued use of your system, and
	  ○ A Customer Response Form requiring customer action.
	• Philips Healthcare will conduct the appropriate field correction through a Field Change Order. The FCO will include the replacement of two (2) radius drive belts and the two (2) idler Pulleys.

FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips Healthcare representative or local Philips Healthcare office. For North America and Canada contact the Customer Care Solutions Center (1-800-722-9377, option 5: Enter Site ID or follow the prompts).

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Field Safety Notice

PHILIPS

Philips Healthcare

Advanced Molecular Imaging -5/13- FSN 88200481 March 10, 2014

URGENT – Field Safety Notice

ADAC Vertex Classic, Vertex Plus, Solus and Vertex V60 Systems

Detector head may drift, resulting in potential patient injury or death

ACTION: CEASE USE of Relative 180 SPECT scans and procedures using the Pinhole Collimator
LIMITED SYSTEM USE described in Addendum

NOTE: The ADAC Cardio System is NOT affected by this Field Safety Notice

ADDENDUM
INSTRUCTIONS TO CONTINUE LIMITED USE

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

WARNING: CEASE use of Relative 180 SPECT detector configuration.
CEASE use of the pinhole collimator

Study Type	Action Required
Pinhole Collimator	CEASE USE IMMEDIATELY
Relative 180 SPECT	CEASE USE IMMEDIATELY
Total Body Planar	Continue use with workflow modifications noted below.
Planar Static & Dynamic	Continue use with detector configuration and workflow modifications noted below.
Cardiac 90 & Relative 90 SPECT	Unaffected

IMPORTANT: Continued use of the ADAC Vertex family of systems requires modification of detector head configurations and workflow not common to most Planar Static & Dynamic, and Total Body Planar protocols.

- The following instructions will permit users to perform standard static and dynamic planar studies using the system in a Relative 90 degree detector head configuration instead of the Relative 180 degree configuration most commonly 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 outcomes must be understood regarding the limitations of detector configurations.
- Quality Assurance (QA) studies as defined in the Cardio, Solus, Vertex, and Vertex PLUS User's Manual remain unaffected.
- Collimator exchange functions as defined in the Cardio, Solus, Vertex, and Vertex PLUS User's Manual remain unaffected.
- These instructions may supersede portions of the current Cardio, Solus, Vertex, and Vertex PLUS User's Manual.

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Field Safety Notice

PHILIPS

Philips Healthcare

Advanced Molecular Imaging -6/13- FSN 88200481 March 10, 2014

URGENT – Field Safety Notice

ADAC Vertex Classic, Vertex Plus, Solus and Vertex V60 Systems

Detector head may drift, resulting in potential patient injury or death

ACTION: CEASE USE of Relative 180 SPECT scans and procedures using the Pinhole Collimator
LIMITED SYSTEM USE described in Addendum

NOTE: The ADAC Cardio System is NOT affected by this Field Safety Notice

Pinhole Collimator – CEASE USE IMMEDIATELY	
Justification	**Pinhole procedures require the detector heads to remain in the Relative 180 detector configuration.**
Factory Protocols	• **SH Planar**
Studies Affected	Including but not limited to the following: • Thyroid
Instruction	**Per this FSN 88200481 Relative 180 SPECT is to be ceased until implementation of FCO.**

Relative 180 SPECT – CEASE USE IMMEDIATELY	
Justification	**Relative 180 SPECT procedures require the detector heads to remain in the Relative 180 detector configuration.** • Relative 90 detector configuration does not allow for a 360 degree orbit thus cannot be used as an alternative for Relative 180 SPECT acquisitions.
Factory Protocols	• **CIRCULAR ECT** • **NON-CIRCULAR ECT** • **SH SPECT** • **COINCIDENCE** • **MCD AC**
Studies Affected	Including but not limited to the following: • Gallium SPECT • Indium SPECT • MIBG SPECT • I-131 SPECT • 180 degree Single head acquisitions • Brain SPECT • 180 Circular SPECT- 180 Non-Circular SPECT • Bone SPECT
Instruction	**Per this FSN 88200481 Relative 180 SPECT is to be ceased until implementation of FCO.**

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Field Safety Notice

PHILIPS

Philips Healthcare

Advanced Molecular Imaging -7/13- FSN 88200481 March 10, 2014

URGENT – Field Safety Notice

ADAC Vertex Classic, Vertex Plus, Solus and Vertex V60 Systems

Detector head may drift, resulting in potential patient injury or death

ACTION: CEASE USE of Relative 180 SPECT scans and procedures using the Pinhole Collimator
LIMITED SYSTEM USE described in Addendum

NOTE: The ADAC Cardio System is NOT affected by this Field Safety Notice

Total Body Planar	
Justification	Total Body Planar (TB) procedure may continue to be performed with modification of the scanning protocol and eliminating learn-mode from the acquisition.
Factory Protocols	**TB PLANAR**
Studies Affected	Including but not limited to the following: • TB Bone • TB Gallium • TB Indium • TB I-131
Instruction	1. From the acquisition protocol set up page, the Body Contour option should be set to "NOT INSTALLED". 2. Using the Total Body Pre-Programmed Motion (PPM) establish the orientation of the detectors in the 0 - 180 degree configuration prior to placing the patient on the table. 3. Decrease the Anterior/Superior detector height to its lowest possible position. Keep the detector at this height for the duration of the scan. (Detector 1 Radius at +11.2cm as shown in the Picture 1 below) 4. Lower the table as far as possible without encountering the gantry support rings or creating interference with the arm support board. (Approximate Table Height Z -32.0cm as shown in Picture(s) 1, 2 and 3)  **Picture 1: Display Panel**

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Field Safety Notice

PHILIPS

Philips Healthcare

Advanced Molecular Imaging -8/13- FSN 88200481 March 10, 2014

URGENT – Field Safety Notice

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Detector head may drift, resulting in potential patient injury or death

ACTION: CEASE USE of Relative 180 SPECT scans and procedures using the Pinhole Collimator
LIMITED SYSTEM USE described in Addendum

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Picture 2: Lateral view of the Superior/Inferior Detector heads

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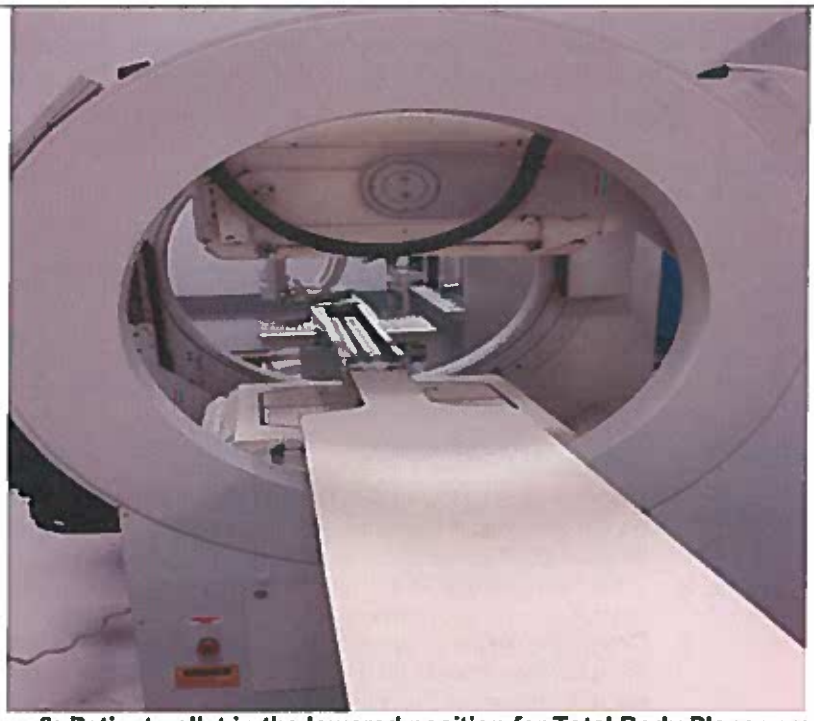
LIMITED SYSTEM USE described in Addendum

NOTE: The ADAC Cardio System is NOT affected by this Field Safety Notice



Picture 3: Patient pallet in the lowered position for Total Body Planar procedure

5. Position the patient on the patient pallet, using aids and pillows as necessary.

   Warning: Maintain a minimum 5cm distance between the patient and the collimator face of the Anterior/Superior detector.

6. To ensure image quality, maintain patient to detector proximity by using the hand controller to raise the patient pallet height and the Posterior/Inferior detector head during gantry travel of the requested scan length.

Field Safety Notice

PHILIPS

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Advanced Molecular Imaging -10/13- FSN 88200481 March 10, 2014

URGENT – Field Safety Notice

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ACTION: CEASE USE of Relative 180 SPECT scans and procedures using the Pinhole Collimator
LIMITED SYSTEM USE described in Addendum

NOTE: The ADAC Cardio System is NOT affected by this Field Safety Notice

Planar Static & Dynamic	
Justification	**Planar Static & Dynamic imaging may continue to be performed with modification of the scanning protocol and using the camera detectors in the 90 degree configuration only.**
Factory Protocols	• **GATED BLOOD POOL** • **FIRST PASS** • **RENAL FLOW-PERF** • **GFR SINGLE DETECTOR** • **STATICS, DUAL DET.**
Studies Affected	Including but not limited to the following exams using a factory default protocols listed above or user modified acquisition parameters. • Renal Perfusion & Flow • Lung Perfusion & Ventilation (V/Q) • MUGA – Planar Gated Blood Pool • First Pass • 3 Phase Bone Flow & Statics • Planar Thyroid allowed with parallel hole collimator only.
Instruction	1. All Planar Static & Dynamic scans should use the detector head configuration of Relative 90/Cardiac 90. 2. Utilize the Relative 90 or Cardiac 90 Pre-Programmed Motion (PPM) prior to placing the patient on the imaging pallet. 3. Depending on the required image output of Anterior, Posterior, Oblique, Lateral, etc. the user may have to modify the number of detectors used on the acquisition setup page, as shown in Pictures 4, 5 and 6. 4. Check the Detector field to make sure the proper detector is selected. (Examples of these steps are in the "Acquiring Studies" section of the Cardio, Solus, Vertex, and Vertex PLUS User's Manual) 5. Verify the appropriate View ID is present prior to starting the study acquisition. **CAUTION:** Careful attention must be paid regarding the VIEW ID with the altered detector head configuration. Modifications may be required to maintain accurate image labeling.

Field Safety Notice

PHILIPS

Philips Healthcare

Advanced Molecular Imaging -11/13- FSN 88200481 March 10, 2014

URGENT – Field Safety Notice

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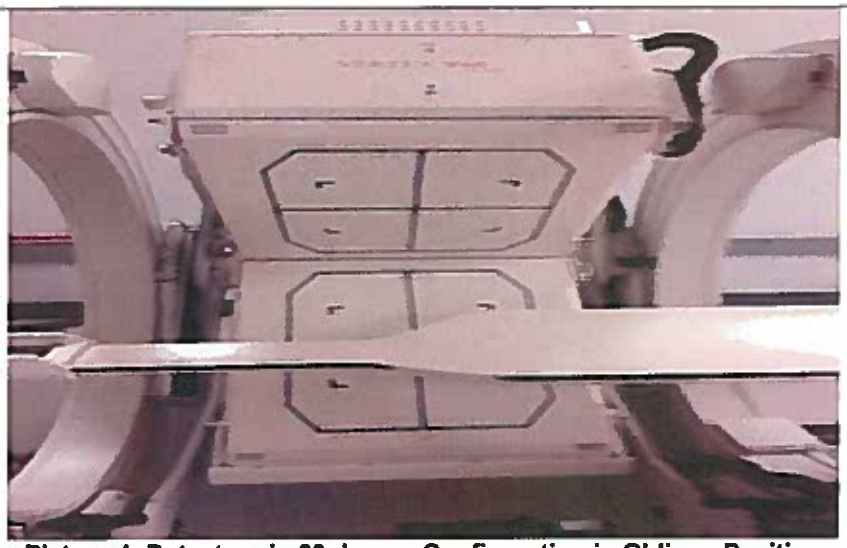
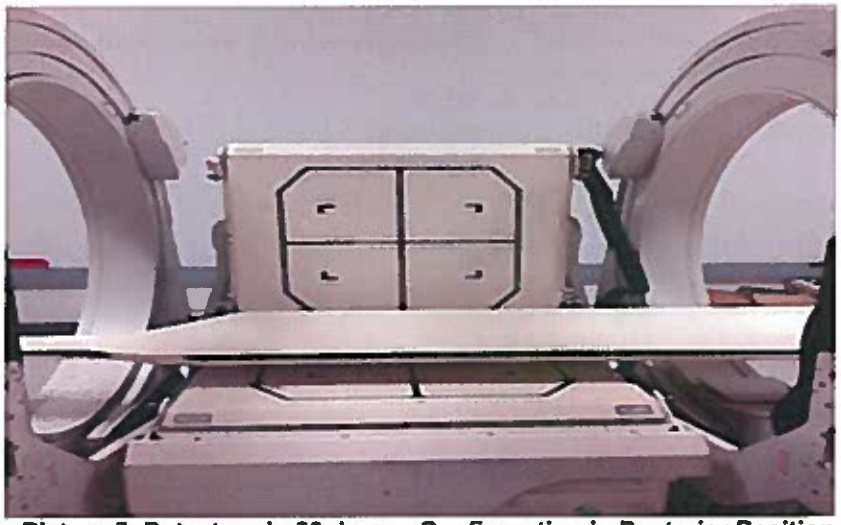
ACTION: CEASE USE of Relative 180 SPECT scans and procedures using the Pinhole Collimator
LIMITED SYSTEM USE described in Addendum

NOTE: The ADAC Cardio System is NOT affected by this Field Safety Notice



Picture 4: Detectors in 90 degree Configuration in Oblique Position



Picture 5: Detectors in 90 degree Configuration in Posterior Position

Field Safety Notice

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Advanced Molecular Imaging -12/13- FSN 88200481 March 10, 2014

URGENT – Field Safety Notice

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LIMITED SYSTEM USE described in Addendum

NOTE: The ADAC Cardio System is NOT affected by this Field Safety Notice

Picture 6: Detectors in 90 degree Configuration in Anterior Position

Cardiac & Relative 90 SPECT – NOT AFFECTED	
Justification	**Cardiac SPECT imaging requires the detector heads to remain in the Relative 90 configuration.**
Factory Protocols	• CIRCULAR G SPECT • GATED NONCIRCULAR • CARDIOLITE LOW DOSE • TC-VANTAGE • TL-VANTAGE • TC-REFERENCE • TL-REFERENCE • GATED VANTAGE • THALLIUM ECT • GATED SPECT SINGLE
Studies Affected	**NONE** Affected.
Instruction	Continue normal use.

Field Safety Notice

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URGENT – Field Safety Notice

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FIELD SAFETY NOTICE 88200481 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_____

- I have received, read and understand the content within the Field Safety Notice (FSN) 88200481 and Addendum, "Instructions to Continue Use with Limited Studies"
- I acknowledge Philips Healthcare's information and instructions in the Addendum, "Instructions to Continue Use with Limited Studies" for the continued use of the system until a Philips Healthcare Representative conducts the appropriate field correction.

NAME:_____
PRINT

TITLE:_____
PRINT

SIGNATURE:_____

DATE:_____

** **IMPORTANT: Please complete this "Field Safety Notice 88200481 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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