URGENT – Medical Device Correction

Manual Collimator Exchange system in use with an ADAC VERTEX Plus, CARDIO, SOLUS or VERTEX V60 imaging system

Collimator cassette may not engage, resulting in potential injury

NOTE: Automatic Collimator Exchange system is **not** affected by this Field Safety Notice

Dear Customer,

Recently, a problem was reported from the field that while the operator was performing a manual collimator exchange procedure with an ADAC VERTEX System, a collimator and collimator cassette fell off of the Collimator Exchange Carriage and onto the floor.

If the issue were to reoccur it could pose a risk of a potential serious injury for an operator or service personnel if they were in the path of the falling collimator.

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

This Field Safety Notice 88200484 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 representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Yuchol Kim,
Sr. Manager of Q&R Post-Market.

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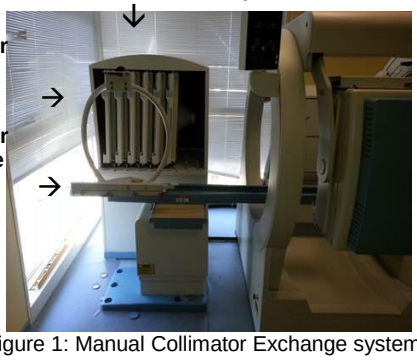
AFFECTED PRODUCTS	**Manual Collimator Exchange system in use with an** • **ADAC VERTEX Plus,** • **ADAC CARDIO,** • **ADAC SOLUS or** • **ADAC VERTEX V60 imaging system** Refer to the "HOW TO IDENTIFY AFFECTED PRODUCTS" section of this Field Safety Notice for additional information. **Please note:** • Automatic Collimator Exchange system is **not** affected by this Field Safety Notice. • The affected systems are labeled ADAC Laboratories, not Philips Healthcare.
PROBLEM DESCRIPTION	Philips Healthcare received a report from the field that during a manual collimator exchange procedure, the operator was attempting to slide the collimator cassette containing the detector 2 VERTEX High Resolution (VXHR) collimator from the Collimator Storage Cabinet onto the Collimator Exchange Carriage. As the VXHR Collimator and collimator cassette was being slid onto the carriage, the cassette did not align with the carriage top guide rollers and mechanical lock. The collimator and collimator cassette fell off of the carriage and onto the floor. This resulted in the operator receiving a minor injury. There have been no reports of serious injury as a result of this situation. The Manual Collimator Exchange system and Storage Cabinet are pictured below. Refer to Figure 1. **Stored Collimators and Collimator Cassettes (Arrow indicates the collimator cassette storing the VXHR collimator)** **Collimator Storage Cabinet** **Collimator Exchange Carriage**  **← Gantry** **←System Imaging Detector** Figure 1: Manual Collimator Exchange system

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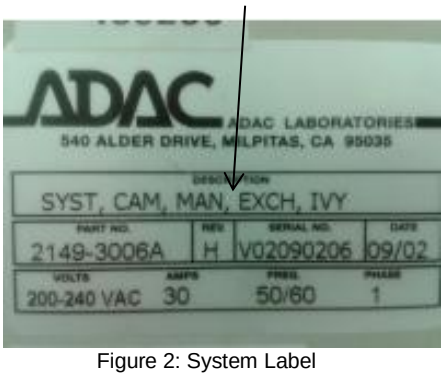
HAZARD INVOLVED	During a manual collimator exchange procedure a fall of the collimator and/or collimator cassette from the Collimator Exchange Carriage may result in serious injury to a person if it comes in direct contact with the operator and/or the service personnel.
HOW TO IDENTIFY AFFECTED PRODUCTS	Refer to the System Label affixed to the bottom right rear of the gantry cover. The "Description" box identifies a Manual Collimator Exchanger System. Refer to sample label below: "**SYST, CAM, MAN, EXCH, IVY**"  Figure 2: System Label
ACTION TO BE TAKEN BY CUSTOMER / USER	• If a misalignment on the top and/or bottom of the guide rail between the cabinet and carriage can be visually detected **do not** continue with the collimator exchange procedure. • If the misalignment is visually detected, be aware that the customer/user **cannot** remedy this issue and will require service interaction prior to the continued use of the system. • This letter should be placed in your User Documentation until otherwise notified.
ACTIONS PLANNED BY PHILIPS HEALTHCARE	Philips Healthcare is initiating this field correction consisting of: • The distribution of a Field Safety Notice 88200484 informing the operator of the issue, and • Conducting the appropriate field correction through a Field Change Order (88200484).
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.