

URGENT - Field Safety Notice

Medical Device Correction

Vereos PET/CT Vereos Cover Alignment Issues

<Hospital/Clinic Name>

cc: Chairman Medical Board and relevant Head of Departments

Dear Customer,

A problem has been detected in the Philips Vereos PET/CT system which could pose a risk for patients or users. This Field Safety Notice 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 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: Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number)

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,



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Quality & Regulatory

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AFFECTED PRODUCTS	Vereos PET/CT System - 882446
PROBLEM DESCRIPTION	<p>The Vereos system may have gaps and/or alignment issues with Gantry Front and Rear Covers. This may result in corners on the Front and/or Rear Cover which do not follow the shape of the bore covers and may protrude into the bore diameter.</p> <p>The below pictures illustrates examples of potential gaps in the Front and Rear Covers.</p> <div data-bbox="571 980 1127 1272" data-label="Image"> </div> <div data-bbox="1182 980 1448 1272" data-label="Image"> </div>
HAZARD INVOLVED	<p>Gaps created due to Front and/or Rear Cover alignment may create a potential for accessories to collide with covers, or create a trapping zone for patient anatomy and/or items connected to the patient.</p> <p>In case of collision, the scan may be interrupted by the operator and/or E-Stop, causing the need to repeat a CT or PET acquisition.</p>
HOW TO IDENTIFY AFFECTED PRODUCTS	All installed Vereos PET/CT systems.
ACTION TO BE TAKEN BY CUSTOMER / USER	<ul style="list-style-type: none"> The operator is instructed to observe the patient during motorized motion. In case of collision, the operator should use the E-Stop to abort all motions. The operator is instructed to ensure accessories do not collide with gantry covers. Additionally, ensure that sheets, blankets and/or IV lines are not loose or hanging outside the Patient Pallet. Ensure the patient's arms/hands are positioned appropriately at their side or overhead. If necessary, use the arm restraint strap as described in the IFU. Instruct the patient to not move their hands during the scan and during any table motions until the operator removes the patient from the scanner at the completion of the study.

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ACTIONS PLANNED BY PHILIPS	Philips Healthcare is notifying the affected users of the issues via this Field Safety Notice. Field Change Order (FCO) 88200520 will be deployed free of charge to address overall cover fit on the affected systems. A Philips Field Service Engineer will contact you to schedule the updates at your site.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number)



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Advanced Molecular Imaging

FSN 88200520

Revision: 01

2019-JUNE-04

Customer Response Form

*Please email completed form to: **Philips***

By signing this form, you acknowledge having received, read, and understood the content of this letter and have taken appropriate actions.

Name (please print)

Title

Signature

Date

Contact information:

Phone

Email