

URGENT - Field Safety Notice

Medical Device Correction

Vereos PET/CT Vereos Cover Alignment Issues

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:

0800 80 3000

This notice has been reported to the appropriate Regulatory Agency.



Sincerely,

Melissa Pieplow
Head of Post Market Surveillance
Quality & Regulatory

URGENT - Field Safety Notice

Medical Device Correction

Vereos PET/CT Vereos Cover Alignment Issues

| | |
|--|---|
| 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>Below pictures illustrates examples of potential gaps in the Front and Rear Cover.</p> <div style="display: flex; justify-content: space-around;">   </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. |

URGENT - Field Safety Notice

Medical Device Correction

Vereos PET/CT Vereos Cover Alignment Issues

| | |
|--|--|
| 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: 0800 80 3000 |