

URGENT - Field Safety Notice**BrightView Gamma Camera**

If the Radius Drive Assembly on the BrightView detector is compromised, the detector may slide under the influence of gravity

AFFECTED PRODUCTS	All BrightView Gamma Cameras are potentially affected by this issue.
PROBLEM DESCRIPTION	Philips has recently determined that in the unlikely event the radius drive assembly on the detectors of the BrightView Gamma Camera is severely compromised during assembly, the detector may slide, under the influence of gravity, to its hardware limit.
HAZARD INVOLVED	If the radius drive assembly has been severely compromised, the detector may slide down, under the influence of gravity, to its hardware limit and make contact with the patient.
HOW TO IDENTIFY AFFECTED PRODUCTS	All BrightView Gamma Camera systems are potentially affected by this issue. You are receiving this notice because your BrightView system may potentially be affected.
ACTION TO BE TAKEN BY CUSTOMER / USER	Customers should cease using the system and contact Philips Field Service if they experience radius drive errors or notice "motion incomplete" messages on the system during pre-programmed motions. Any grinding noises during detector radius motions should also be immediately reported to the Philips service representative.
ACTIONS PLANNED BY PHILIPS	A Philips Healthcare Field Service Engineer will contact you and schedule a time to implement a safety plate which will prevent the detector from sliding towards its hardware limit if the radius drive assembly fails. The correction will be released to the field in July of 2009.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: Customer Care Center (1-800-722-9377, option 5: Diagnostic Imaging, option 5: Radiation Therapy, option 3: Oncology) or your local Philips Healthcare office.



URGENT - Field Safety Notice

BrightView Gamma Camera

If the Radius Drive Assembly on the BrightView detector is compromised, the detector may slide under the influence of gravity

Dear Customer,

A problem has been identified with the radius drive assembly on the BrightView Gamma Camera that if it were to happen, may pose a risk for patients. You are receiving this Notice because your BrightView Gamma Camera has been identified as one of those potentially affected. 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.
- 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:

Customer Care Solution Center: dial 1-800-722-9377. Select option 5 for "All Imaging Systems". (Next, at this point, if you do not have a Site ID # for your BrightView, simply pause for a moment.) Then, select option 5 for "Nuclear Medicine"; and finally, select option 1 for SPECT support. This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,



Senior Director, Quality, Regulatory, & Sustainability
Philips Healthcare - Nuclear Medicine

