

Updated URGENT - Field Safety Notice

Medical Device Correction

BrightView SPECT, BrightView X, BrightView XCT
Un-commanded motion related to handcontroller

Discontinue Use of the BrightView Handcontroller

<Hospital/Clinic Name>

cc: Chairman Medical Board and relevant Head of Departments

Dear Customer,

A problem has been detected in the Philips BrightView family of gamma cameras (BrightView, BrightView X, and BrightView XCT), that, if it were to re-occur, 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 update includes additional information about the problem description, hazardous situation and recommended actions.

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: For North America and Canada, contact the Customer Care Solutions Center (1-800-722-9377).

Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,

Holly Wright Lee

Sr. Manager, Quality & Regulatory




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AFFECTED PRODUCTS	BrightView SPECT BrightView X and BrightView XCT
PROBLEM DESCRIPTION	An issue has been found with the handcontroller for the BrightView Family of cameras that results in either spontaneous uncommanded (not initiated by the operator) motions or continued motion after the buttons were released. Philips continues to investigate the issue.
HAZARD INVOLVED	The detector(s) may unexpectedly move until and collide with the patient, operator, or equipment, such as a patient bed. It is possible for a portion of the detector that is not equipped with collision detection to come into contact with any of the above mentioned objects, potentially resulting in entrapment and/or serious injury.
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>This issue applies to all versions of BrightView, BrightView X, and BrightView XCT.</p> <p>The product can be determined by selecting Help > About JETStream as shown in Figure 1.</p>  <p style="text-align: center;">Figure 1</p> <p>The About JETStream window appears as shown in Figure 2.</p>



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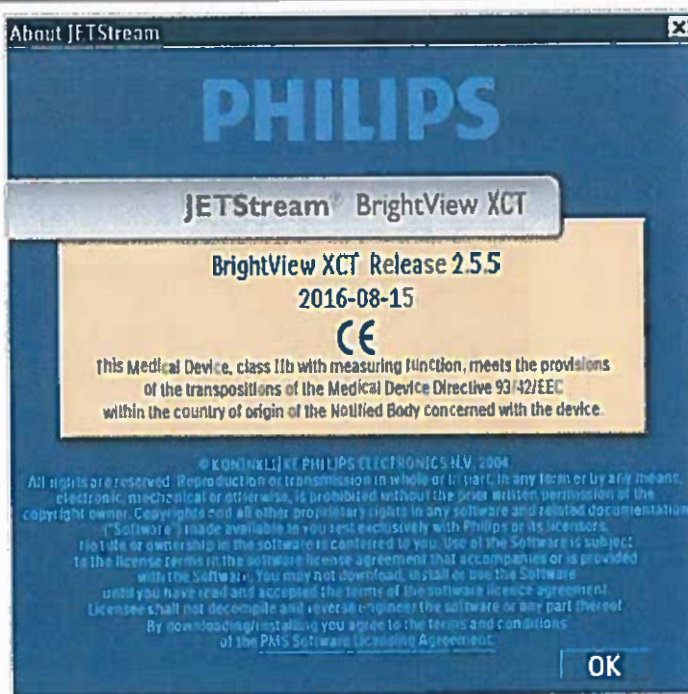


Figure 2

ACTION TO BE TAKEN BY CUSTOMER / USER

- **Discontinue use of the BrightView/BrightView X/BrightView XCT handcontroller until further notice.**
- **Remove the handcontroller from the charging station and store in a secure location inaccessible by technicians, at least 20 meters (65 feet) away from the system and outside of the imaging room. If 20 meters (65 feet) is not possible, then store the handcontroller in an area that is shielded, such as a hot lab.**
- **Do not dispose of the hand controller, as it will be needed once a solution is identified.**



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Instead of the physical handcontroller, use the virtual handcontroller located on the touchscreen monitor attached to the gantry as shown in Figure 3. In some cases, use of the virtual handcontroller may require the system operator to be closer to the patient than they would be when using the physical handcontroller. Therefore, the use of radiation protection accessories to protect the operator may be considered as appropriate



Figure 3

The virtual handcontroller can be accessed from the top menu (Hand Ctrl.) as shown in Figure 4.



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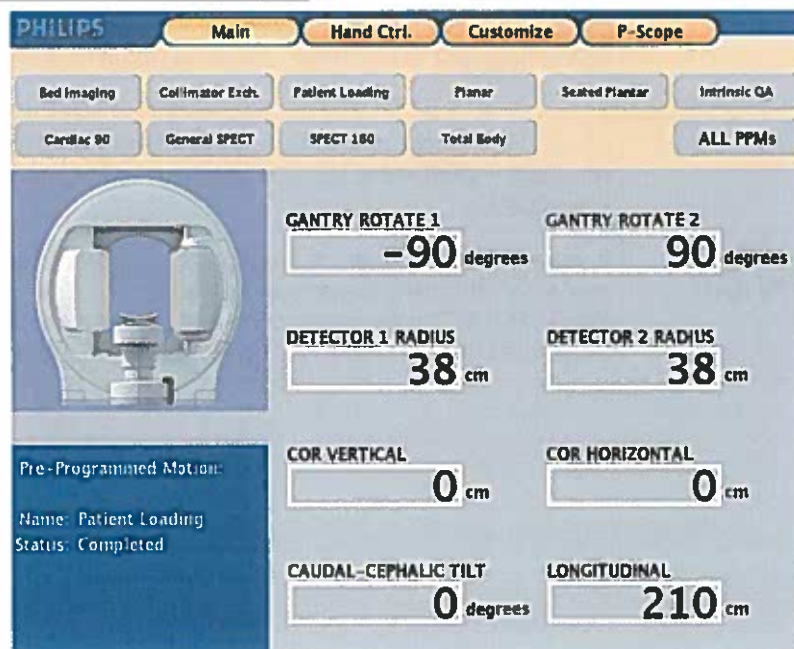


Figure 4

All Gantry/table motions on the physical handcontroller can be used. Below in Figure 5 is an example from a BrightView system.



Figure 5

When using the controls on the virtual handcontroller, only one motion can be executed at a time and the motions will be slower than when using the



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	physical handcontroller. This may increase the time needed for patient positioning and study setup, and may result in reduced patient throughput.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare is distributing this FSN to all affected customers/users and will deploy a technical solution addressing the issue upon completion of the investigation.
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)



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

