

URGENT - Field Safety Notice

Medical Device Correction

BrightView SPECT, BrightView X, BrightView XCT ***Uncommanded motion related to handcontroller***

Discontinue Use of the BrightView Handcontroller

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 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.

Sincerely,

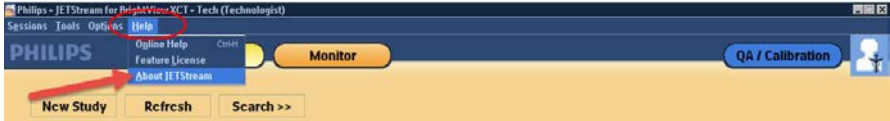
Melissa Pieplow
Head of Post Market Surveillance



URGENT - Field Safety Notice Medical Device Correction

BrightView SPECT, BrightView X, BrightView XCT *Uncommanded motion related to handcontroller*

Discontinue Use of the BrightView Handcontroller


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 has been found to result in either spontaneous uncommanded motions or continued motion after the buttons were released. Philips continues to investigate the issue.
HAZARD INVOLVED	The detector(s) may move down onto the patient or operator, 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>



URGENT - Field Safety Notice Medical Device Correction

BrightView SPECT, BrightView X, BrightView XCT
Uncommanded motion related to handcontroller

Discontinue Use of the BrightView Handcontroller

	 <p style="text-align: center;">Figure 2</p>
<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<ul style="list-style-type: none"> ➤ 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.



URGENT - Field Safety Notice Medical Device Correction

BrightView SPECT, BrightView X, BrightView XCT
Uncommanded motion related to handcontroller

Discontinue Use of the BrightView Handcontroller

Instead of the physical handcontroller, use the virtual handcontroller located on the touchscreen monitor attached to the gantry as shown in Figure 3.



Figure 3

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



URGENT - Field Safety Notice Medical Device Correction

BrightView SPECT, BrightView X, BrightView XCT
Uncommanded motion related to handcontroller

Discontinue Use of the BrightView Handcontroller

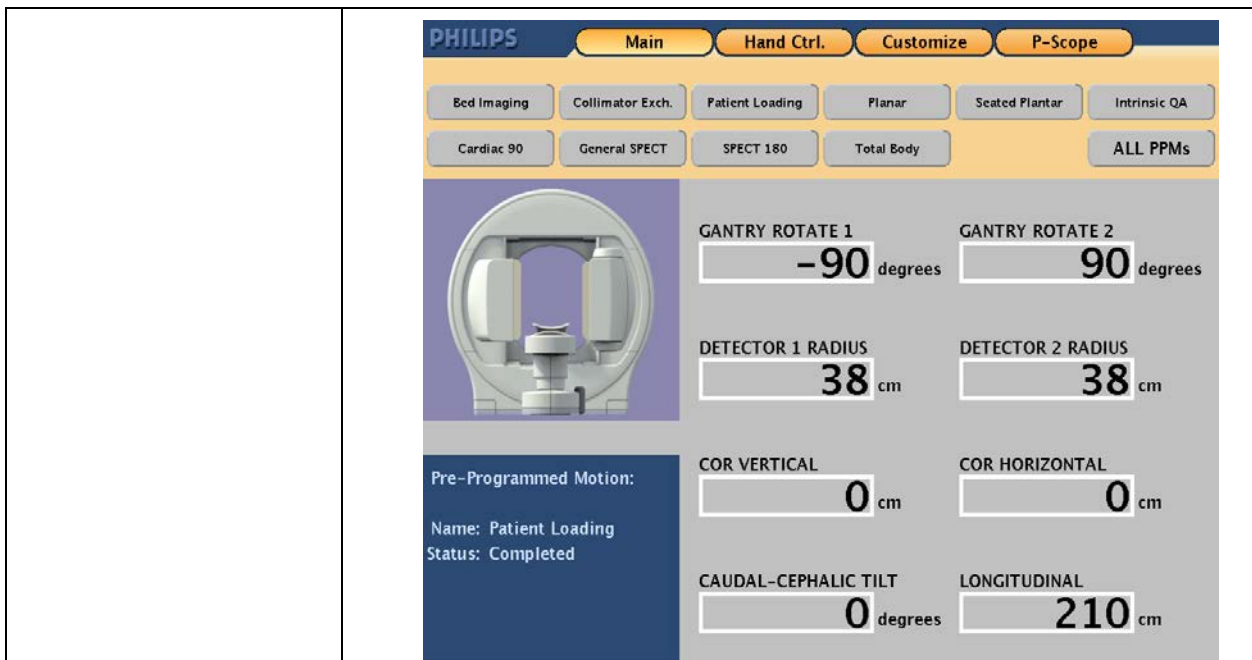


Figure 4

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

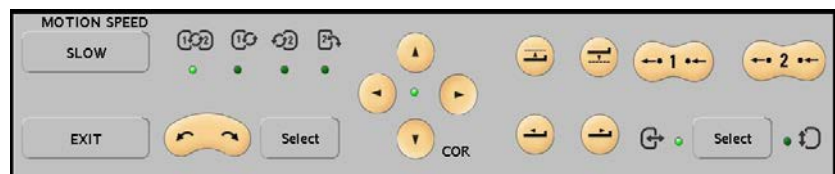


Figure 5

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.



URGENT - Field Safety Notice
Medical Device Correction

BrightView SPECT, BrightView X, BrightView XCT
Uncommanded motion related to handcontroller

Discontinue Use of the BrightView Handcontroller

**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.

