PHILIPS

URGENT - Field Safety Notice

Medical Device Correction

Forte, Forte JETStream, Forte JETStream AZ, Forte JETStream AZ upgrade, Forte JETStream upgrade, Diamond Select Forte, Diamond Select Forte JETStream

Forte Detector Unimpeded Motion

Discontinue system use until further notice

Dear Customer,

A problem has been detected in the Philips Forte product line 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:

0800 80 3000

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,

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AFFECTED PRODUCTS	882020 Forte, 882290 Forte JETStream, 882291 Forte JETStream upgrade, 882320 Forte JETStream AZ, 882321 Forte JETStream AZ upgrade, 889456 Diamond Select Forte, 889471 Diamond Select Forte JETStream
PROBLEM DESCRIPTION	As a result of a customer reported problem during detector radius movement, Philips identified an issue affecting the Forte family of gamma cameras that could result in either detector 1 or detector 2 falling unimpeded vertically to the end stops of its travel limit.
HAZARD INVOLVED	There is a possibility that a detector may fall unimpeded vertically to the end stops of its travel limit, due to a mechanical failure, possibly making contact with a patient that could result in entrapment, serious injury, or death.
HOW TO IDENTIFY AFFECTED PRODUCTS	This issue applies to all Forte gamma cameras: Forte, Forte JETStream, Forte JETStream upgrade, Forte JETStream AZ, Forte JETStream AZ upgrade, Diamond Select Forte, Diamond Select Forte JETStream The product type can be determined by finding the name of the system of the product label. Refer to the representative photos below.

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ACTION TO BE TAKEN BY CUSTOMER / USER	➢ **Discontinue use of the system until further notice.** ➢ Inform those who need to be aware within your organization or any organization where the potentially affected devices have been transferred (If appropriate). ➢ Maintain this notice with your system Instructions for Use (IFU) until the correction is made to the system.

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ACTIONS PLANNED BY PHILIPS	Philips Healthcare is distributing this FSN to all affected customers/users and will deploy a 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: **0800 80 3000**

Customer Response Form

INSTRUCTIONS: Please complete this form with the customer upon delivery of the Field Safety Notice and return to the BIU. ***Please email completed form to*** **customercare.ch@philips.com**.

Customer Name:	System Code	System Serial No.
Address:		

Our records indicate that your firm has received affected systems. By signing this form, you acknowledge having received, read, and understood the content of this letter and have taken appropriate actions.

Signature: _____ **Date:** _____

Print Name: _____ **Email:**_____