

URGENT - Field Safety Notice ***DigitalDiagnost***

Replace footplate hook of patient carriage

Dear Customer,

As part of Philips' continuous focus on reliability and safety we continuously monitor the performance of our products. During recent evaluations of the Philips DigitalDiagnost, we have identified a potential issue that may affect the performance of the equipment under certain conditions. This letter is intended to provide you with information regarding:

- what the issue is, and under what circumstances it may occur
- the actions you can take to avoid or minimize the occurrence of the issue
- the actions planned by Philips to correct the issue

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, please contact your local Philips representative: Technical Support Line: 1-800-722-9377.

We apologize for any inconvenience this may cause and trust that this information is adequately addressing any concerns you may have.

Sincerely,



Sr. Manager of Radiation Health and Product Safety

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AFFECTED PRODUCTS	DigitalDiagnost patient carriage with serial number range from 00 000 00 to 09 000 543.
PROBLEM DESCRIPTION	The footplate of the patient carriage can be fixed in a vertical position with a hook. The hook may fail when moving the carriage, or when the operator does not secure it correctly upon moving the plate up, and the footplate can fall down.
HAZARD INVOLVED	The hook does not securely hold the footplate in vertical position. Therefore the footplate can fall or swing down and may hurt the operator or patient.
HOW TO IDENTIFY AFFECTED PRODUCTS	The serial number of affected patient carriage ranges from 00 000 00 to 09 000 543. The serial number label can be located at the rear side of the patient carriage.
ACTION TO BE TAKEN BY CUSTOMER / USER	Please follow the Instruction for Use. Additionally, when the footplate is locked in the vertical position and the patient carriage is being moved, no person should remain in the area next to the footplate.
ACTIONS PLANNED BY PHILIPS	Philips plans to replace the old hook with one that has a new design. A Philips Service Engineer will contact you as soon as the Field Action Kit is ready to be implemented. Should you need to communicate with Philips in regards to this program, please reference FCO-71200080.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative. 1-800-722-9377.