

URGENT - Field Safety Notice

Patient support

Hardware update of Patient Support (12NC 989001087431)

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 *Patient Support*, 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:

<Philips representative contact details to be completed by the KM / country>

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

Sincerely,

<Signature, to be signed by Senior Management of the BS/BU/BL or GS&S/KM>


Michael Mizrahi
Head of Q&R DXR Hamburg

DXR

Quality Management System DXR

DXR Field Safety Notice

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FSN MA-FCO 71200185

2018-April-23

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AFFECTED PRODUCTS	Patient support (NC989001087431)
PROBLEM DESCRIPTION	<p>The footplate of the Patient support for stitching can be fixed in upper position. When the fixing clamp (hook) is not in its correct locking position, the footplate is not securely held. If it falls down, it may hurt the operator's or patient's foot or leg (e.g. when moving the stand or when the operator fails to fix it correctly upon moving the footplate up).</p> <p>Following factors are needed that the situation occurs:</p> <ul style="list-style-type: none"> • Hinges are worn differently on both sides • Hook does not hold • Operator does not check that the hook securely holds the footplate • Footplate falls unexpectedly when touched or during transport • Foot or leg in "target area" <p>Foot in "hazard area"</p>
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	All Patient support (NC989001087431) are affected

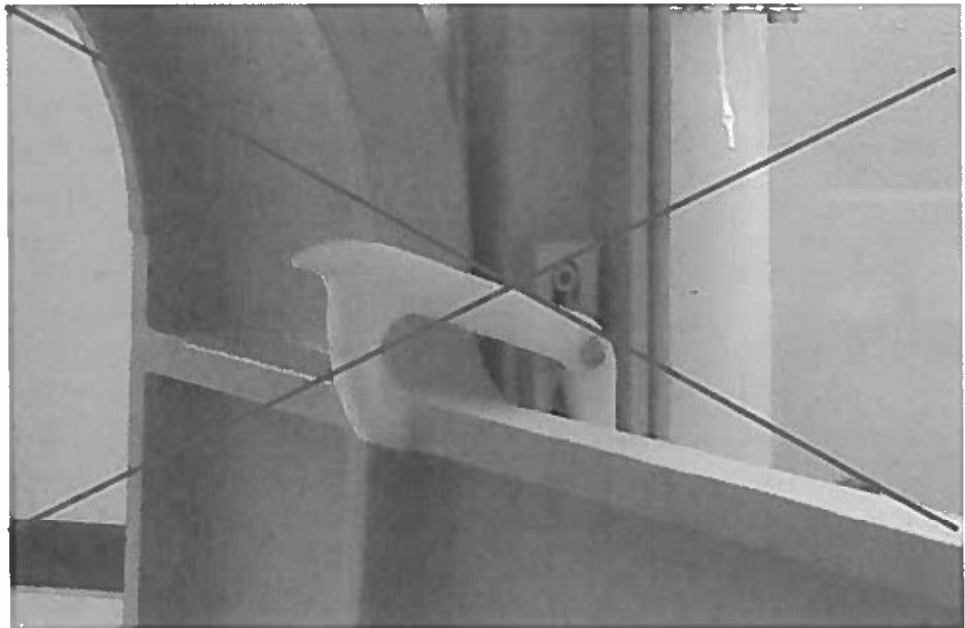
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**ACTION TO BE TAKEN
BY CUSTOMER / USER**

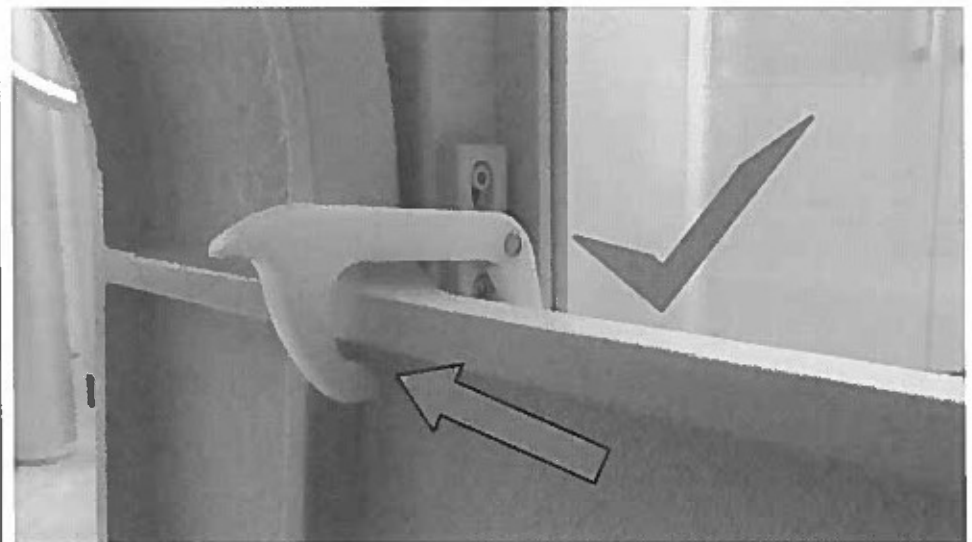
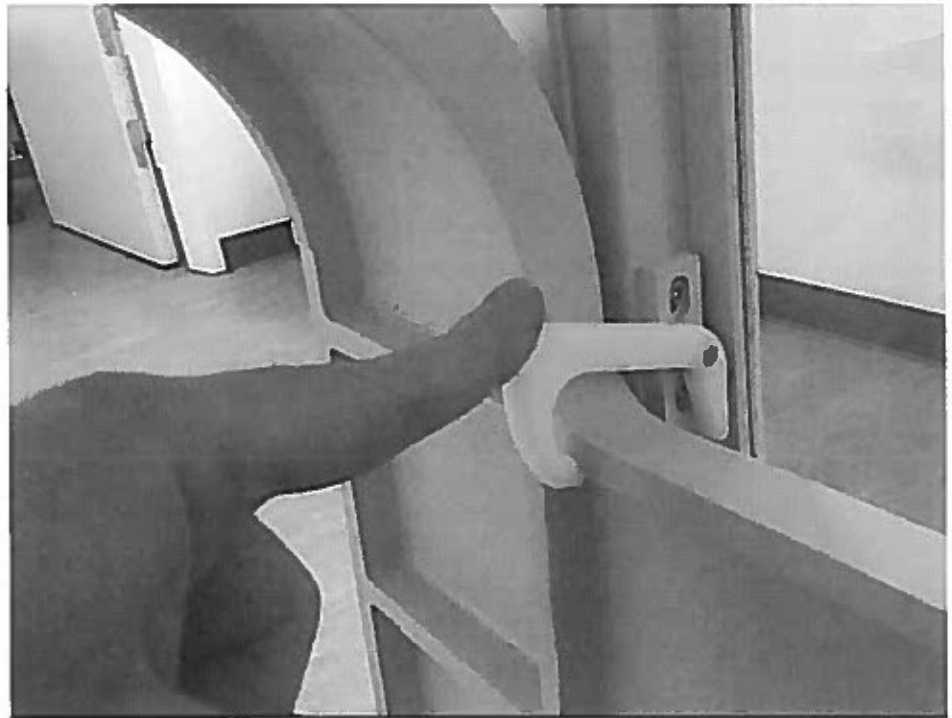
The customer / user should always check the right position of the hook and that the hook is locked according to IfU. (Press hook down until it is locked) Make sure that the hook is in position as shown in the picture with the green arrow



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ACTIONS PLANNED BY PHILIPS	Philips plans to redesign the: <ul style="list-style-type: none">• sturdier replacement hinges for floor plate• install modified hook for floor plate (adapted to new hinges)• brake cylinder below floor plate to minimize kinetic energy <p>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-71200185.</p>
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative.