

Field Safety Notice

Computed Tomography

FSN 72800751 Revision: A

MAY 2021

**URGENT - Field Safety Notice
Medical Device Correction**

Continuous CT Fluoroscopy DVI Ceiling Mount – CCT Arm DVI Option - Monitor Bracket Assembly
Significant Wear of CCT Fluoroscopy Monitor Bracket Mounted into the Suspension Arm

Dear Customer,

A problem has been detected in the Philips Monitor Bracket Assembly mounted into the Continuous CT Fluoroscopy Digital Visual Interface (DVI) Ceiling Mount, 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 Healthcare CT/AMI 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.

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 Agencies.

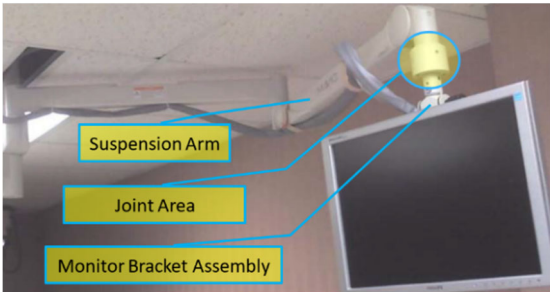
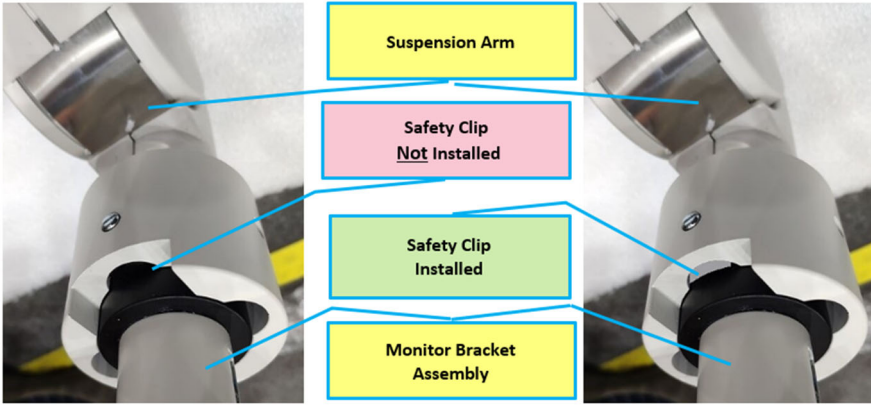
Sincerely,

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AFFECTED PRODUCTS	Philips Monitor Bracket Assemblies mounted into the Continuous CT (CCT) Digital Visual Interface (DVI) Ceiling Mount Arm Option for select CT products.
PROBLEM DESCRIPTION	Significant wear of the Monitor Bracket Assembly shaft that goes unrecognized could potentially lead to the Monitor Bracket Assembly detaching from the Suspension Arm.
HAZARD INVOLVED	If the Monitor Bracket Assembly were to detach from the Suspension Arm, there is a potential hazard for the monitor to fall while remaining attached to the cables. There is potential that a patient, operator, bystander, or service person located in the path of a falling part could sustain injury or may lead, in rare and specific circumstances, to serious injury or even death. There have been no reports of death or serious injury.
HOW TO IDENTIFY AFFECTED PRODUCTS	Philips has identified that your device may be affected by this issue.
ACTION TO BE TAKEN BY CUSTOMER / USER	<ul style="list-style-type: none"> Be aware of this hazard when the safety clip is missing from the joint assembly between the Monitor Bracket Assembly and the Ceiling Suspension Arm. Inspect the joint area of your CCT DVI Ceiling Mount Arm (the circled area in picture at the right) and observe that the safety clip is installed (as depicted in pictures below). When this hazard occurs, the monitor may become difficult to rotate relative to the Suspension Arm.   <p>(continued on next page)</p>

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ACTION TO BE TAKEN BY CUSTOMER / USER	<p><i>(continued from previous page)</i></p> <p>When these symptoms are recognized, in order to avoid the occurrence of a hazardous situation, take the following actions:</p> <ul style="list-style-type: none">▪ stop using the suspension monitor clinically▪ move the monitor arm away from any person▪ call Philips Service for repairs. <p>Please acknowledge the receipt of this notice by completing, signing, and returning the form attached at the end of this communication to the indicated email address.</p>
ACTIONS PLANNED BY PHILIPS	Philips will inspect systems via Field Change Order FCO 72800751. Systems failing the inspection will be corrected via Field Change Order FCO 72800752.
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this issue, please contact your local Philips representative:</p> <p>0800 80 3000</p>

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Customer Response Form

Please email completed form to: customercare.ch@philips.com

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