

**URGENT - Field Safety Notice
Medical Device Correction
Philips Allura Xper X-ray Systems**

***Potential system damage due to leakage of coolant liquid
from the detector cooling system***

Dear Customer,

A problem has been detected in a limited number of Philips Allura Xper, Allura CV20 and UNIQ X-ray Systems 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.

Philips has discovered through customer complaints a problem with the detector cooling system.

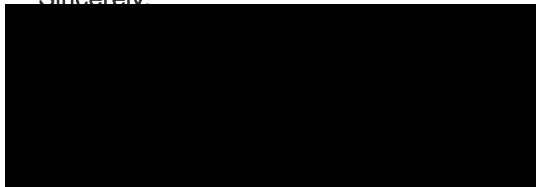
Due to a leak in the detector cooling system, cooling liquid may leak outside the drip tray of the chiller. If this occurs the liquid may drip onto electrical components, which could lead to damage to the system and potentially cause thermal events such as a burning odor, smoke or fire.

If you need any further information or support concerning this issue, please contact your local Philips representative.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,



Hugo Weusten
Head of Quality & Regulatory
Image Guided Therapy Systems

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AFFECTED PRODUCTS	<ul style="list-style-type: none"> • Allura Xper and Allura CV20 Releases 3 to 8.1 with an installed Laird chiller • Allura Xper Release 8.2 and UNIQ: only configurations FD10, FD10/10, FD20/10, FD20/20 have a Laird chiller and are therefore affected.
PROBLEM DESCRIPTION	<p>Philips has discovered through customer complaints a problem with the detector cooling system.</p> <p>Due to a leak in the detector cooling system, cooling liquid may leak outside the drip tray of the chiller. If this occurs the liquid may drip onto electrical components in the R-cabinet located in the technical room, which could lead to damage to the system and potentially cause thermal events such as a burning odor, smoke or fire.</p>
HAZARD INVOLVED	<p>If coolant liquid comes into contact with electrical components it may potentially exhibit thermal events such as a burning odor, smoke or fire.</p> <p>To date, Philips is not aware of any injuries that may have occurred as result of this situation.</p>

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HOW TO IDENTIFY AFFECTED PRODUCTS	The affected systems will be clearly identified by the local Philips Organization.	
	Product name:	Product code:
	Allura Xper Release 8.2 (Laird chiller is always installed)	
	Allura Xper FD10	722026
	Allura Xper FD10/10	722027
	Allura Xper FD20/10 biplane	722029
	Allura Xper FD10 OR Table	722033
	Allura Xper FD10/10 OR Table	722034
	Allura Xper FD20/10 OR Table	722036
	Allura Xper FD20/20	722038
	Allura Xper FD20/20 biplane OR Table	722039
	UNIQ	
	UNIQ FD10	722026
	UNIQ FD10/10	722027
	UNIQ FD20/10 biplane	722029
	UNIQ FD10 OR Table	722033
	UNIQ FD10/10 OR Table	722034
	UNIQ FD20/10 OR Table	722036
	UNIQ FD20/20	722038
	UNIQ FD20/20 biplane OR Table	722039
	The following systems are <u>only affected</u> if a Laird chiller is installed (11NC: 98960021599):	
	- Allura Xper Releases 3 to 8.1:	
	Product name:	Product code:
	Allura	
	Allura Xper FD10 (C+F).	722003
Allura Xper FD10/10	722005	
Allura Xper FD20	722006	
Allura Xper FD20/10 and FD20/20	722008	
Allura Xper FD10	722010	
Allura Xper FD10/10	722011	
Allura Xper FD20	722012	
Allura Xper FD20 biplane	722013	
Allura Xper FD10 OR Table	722014	
Allura Xper FD20 OR Table	722015	
Allura Xper FD10/10 OR Table	722019	
Allura Xper FD20 Biplane OR Table	722020	
Allura Xper FD10 OR Table	722022	
Allura Xper FD20 OR Table	722023	
Allura Xper FD10/10 OR Table	722024	
Allura Xper FD20 Biplane OR Table	722025	
Allura CV20	722031	

IGT Systems

FSN for 2016-IGTBST-002

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<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<p>Inform your staff of the potential hazard. No additional measures other than pre-established institutional procedures for managing potential fire hazards are considered necessary.</p> <p>If a burning odor, smoke or fire is detected coming from the technical room, the main switch should be turned off and system taken out of service immediately. The institution's emergency procedures for such events should be followed. Once any hazardous situation has been abated, the local Philips representative should be informed.</p>
<p>ACTIONS PLANNED BY PHILIPS</p>	<p>Philips will start inspecting affected systems for leaks and repair as required. In addition as from April 2017 Philips will install an extended drip tray to prevent damage from any future leaks. This service will be provided free of charge for affected systems. A Philips service representative will contact customers with affected devices to arrange for the service.</p>
<p>FURTHER INFORMATION AND SUPPORT</p>	<p>If you need any further information or support concerning this issue, please contact your local Philips representative: <i><Philips representative contact details to be completed by the Market></i></p>