

IGT Systems

FSN for 2016-IGTBST-002

2017 Mar 09

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,

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	<p>The affected systems will be clearly identified by the local Philips Organization.</p> <p>Product name: Product code:</p> <p>Allura Xper Release 8.2 (Laird chiller is always installed)</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td>Allura Xper FD10</td><td style="text-align: right;">722026</td></tr> <tr><td>Allura Xper FD10/10</td><td style="text-align: right;">722027</td></tr> <tr><td>Allura Xper FD20/10 biplane</td><td style="text-align: right;">722029</td></tr> <tr><td>Allura Xper FD10 OR Table</td><td style="text-align: right;">722033</td></tr> <tr><td>Allura Xper FD10/10 OR Table</td><td style="text-align: right;">722034</td></tr> <tr><td>Allura Xper FD20/10 OR Table</td><td style="text-align: right;">722036</td></tr> <tr><td>Allura Xper FD20/20</td><td style="text-align: right;">722038</td></tr> <tr><td>Allura Xper FD20/20 biplane OR Table</td><td style="text-align: right;">722039</td></tr> </table> <p>UNIQ</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td>UNIQ FD10</td><td style="text-align: right;">722026</td></tr> <tr><td>UNIQ FD10/10</td><td style="text-align: right;">722027</td></tr> <tr><td>UNIQ FD20/10 biplane</td><td style="text-align: right;">722029</td></tr> <tr><td>UNIQ FD10 OR Table</td><td style="text-align: right;">722033</td></tr> <tr><td>UNIQ FD10/10 OR Table</td><td style="text-align: right;">722034</td></tr> <tr><td>UNIQ FD20/10 OR Table</td><td style="text-align: right;">722036</td></tr> <tr><td>UNIQ FD20/20</td><td style="text-align: right;">722038</td></tr> <tr><td>UNIQ FD20/20 biplane OR Table</td><td style="text-align: right;">722039</td></tr> </table> <p>The following systems are <u>only affected</u> if a Laird chiller is installed (11NC: 98960021599): - Allura Xper Releases 3 to 8.1:</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Product name:</th> <th style="text-align: right;">Product code:</th> </tr> </thead> <tbody> <tr><td>Allura</td><td></td></tr> <tr><td>Allura Xper FD10 (C+F).</td><td style="text-align: right;">722003</td></tr> <tr><td>Allura Xper FD10/10</td><td style="text-align: right;">722005</td></tr> <tr><td>Allura Xper FD20</td><td style="text-align: right;">722006</td></tr> <tr><td>Allura Xper FD20/10 and FD20/20</td><td style="text-align: right;">722008</td></tr> <tr><td>Allura Xper FD10</td><td style="text-align: right;">722010</td></tr> <tr><td>Allura Xper FD10/10</td><td style="text-align: right;">722011</td></tr> <tr><td>Allura Xper FD20</td><td style="text-align: right;">722012</td></tr> <tr><td>Allura Xper FD20 biplane</td><td style="text-align: right;">722013</td></tr> <tr><td>Allura Xper FD10 OR Table</td><td style="text-align: right;">722014</td></tr> <tr><td>Allura Xper FD20 OR Table</td><td style="text-align: right;">722015</td></tr> <tr><td>Allura Xper FD10/10 OR Table</td><td style="text-align: right;">722019</td></tr> <tr><td>Allura Xper FD20 Biplane OR Table</td><td style="text-align: right;">722020</td></tr> <tr><td>Allura Xper FD10 OR Table</td><td style="text-align: right;">722022</td></tr> <tr><td>Allura Xper FD20 OR Table</td><td style="text-align: right;">722023</td></tr> <tr><td>Allura Xper FD10/10 OR Table</td><td style="text-align: right;">722024</td></tr> <tr><td>Allura Xper FD20 Biplane OR Table</td><td style="text-align: right;">722025</td></tr> <tr><td>Allura CV20</td><td style="text-align: right;">722031</td></tr> </tbody> </table>	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 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	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
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ACTION TO BE TAKEN BY CUSTOMER / USER	<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>
ACTIONS PLANNED BY PHILIPS	<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>
FURTHER INFORMATION AND SUPPORT	<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>