

URGENT Field Safety Notice

Philips Allura Xper, UNIQ and Allura CV20 Systems

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

9-Dec-2021

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.

Dear Customer,

A problem has been detected in a limited number of Philips Allura Xper, UNIQ and Allura CV20 Systems that could pose a risk for patients or users. This Urgent Field Safety Notice is intended to inform you about:

1. What the problem is and under what circumstances it can occur

Philips has discovered a problem with the flat detector cooling system. Due to a leak in the flat detector cooling system, cooling liquid may leak outside the drip tray of the Laird chiller. If this occurs, the liquid may drip into electrical components in the R-cabinet located in the technical room which could cause damage to the system.

To date, Philips has not received any report of patient harm due to this issue.

2. Describe the hazard/harm associated with the issue

If coolant liquid comes into contact with electrical components it may potentially cause thermal events such as a burning odor, smoke, or fire. If this occurs, there will be a delay in procedure and potentially an interruption of the procedure.

3. Affected products and how to identify them

The following products that have a Laird chiller without an extended drip tray are affected:

| | |
|---------------------------------|------------|
| Allura Xper systems | 6NC |
| 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 FD20 | 722012 |
| Allura Xper FD20 OR Table | 722015 |
| Allura Xper FD10 | 722026 |
| Allura Xper FD10/10 | 722027 |
| Allura Xper FD20 | 722028 |
| Allura Xper FD20/10 biplane | 722029 |
| Allura CV20 | 722031 |
| | |
| UNIQ Systems | 6NC |
| UNIQ FD10 | 722003 |
| UNIQ FD20 | 722006 |
| UNIQ FD20 | 722012 |
| UNIQ FD10 | 722026 |

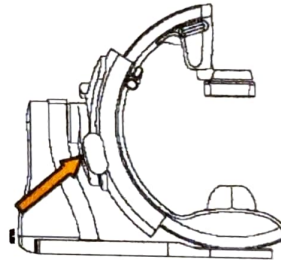


Figure 1: System identification

The system product number and model number can be found in the System Identification Label located on the system stand as shown in Figure 1.

Philips is sending this Field Safety Notice to all customers with affected systems.

4. Describe the actions that should be taken by the customer / user in order to prevent risks for patients or users

- If a burning odor, smoke or fire is detected coming from the technical room, turn off the main switch of the system, stop using the system and contact Philips. In case of smoke or fire, follow your institution's emergency procedures.
- Place this Urgent Field Safety Notice letter with the documentation of the system until Philips has corrected your system.
- Circulate this notice to all users so they are aware of the product issue.
- Return the attached reply form to Philips to confirm that the users of the system have reviewed and understood this Urgent Field Safety Notice letter.

5. Describe the actions planned by Philips to correct the problem

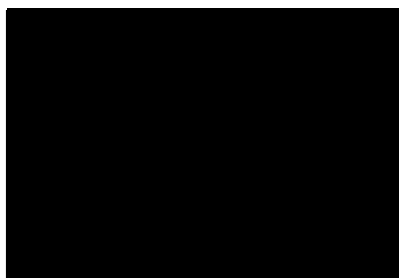
Philips will inspect the affected systems for leaks and repair as required. In addition, Philips will install an extended drip tray to prevent damage from any future leaks. This service will be provided free of charge for affected systems.

A Philips service representative will contact customers with affected devices to arrange for the service. If you need any further information or support concerning this issue, please contact your local Philips representative (FCO72200484).

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this problem.

Sincerely,



Philips' proprietary information. Unauthorized use is prohibited.

URGENT FIELD SAFETY NOTICE RESPONSE FORM

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

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- If a burning odor, smoke or fire is detected coming from the technical room, turn off the main switch of the system, stop using the system and contact Philips. In case of smoke or fire, follow your institution's emergency procedures for such events.
- Place this Urgent Field Safety Notice letter with the documentation of the system until Philips has corrected your system.
- Circulate this notice to all users so they are aware of the product issue.
- Return the attached reply form to Philips to confirm that the users of the system have reviewed and understood this Urgent Field Safety Notice letter.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice Letter and confirm that the information from this Letter has been properly distributed to all users that handle the Philips Allura Xper and/or Allura CV20 System(s).

Name of person completing this response form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date
(DD/MM/YYYY): _____

<provide instructions here for the customer regarding returning the form to Philips, e.g. fax #, email address. For example, "Please fax this completed form to Philips at (xxx)xxx-xxxx">