

[REDACTED]
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[REDACTED]

18th April 2018

TO: WHOM IT MAY CONCERN

CC: Chairman Medical Board and relevant Head of Department

Attached is a Field Safety Notice/Field Corrective Order pertaining to Philips equipment due to FCO 72200422 . Please note that the serial number of the units affected are stated below:

[REDACTED]

If you need any further information or support concerning this issue, please contact your local Philips Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).

This is a mandatory requirement based on 21CFR Part 820 by USA FDA, thus we seek your cooperation to acknowledge that you are thus notified of the above within 5 working days from the issuance of this letter.

Acknowledged By:

Customer Name/Signature:

Company Name/Stamp:

Date:

URGENT - Field Safety Notice

Medical Device: Allura Xper with FlexVision large screen monitor.

FlexVision Freeze

Dear Customer,

Philips has been reported instances in which the FlexVision large screen monitor froze for about 15 seconds, after a continuous operation (in the instances reported after one day and a half), after which the system restored itself and was fully operational again.

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 until the system is corrected by Philips.

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,

R. Kathuria
Head Q&R IGT systems

BU IGT Systems

FSN: 2018-IGTBST-003
DocID: DHF312084

2018, March 13

URGENT - Field Safety Notice**Medical Device: Allura Xper with FlexVision large screen monitor.****FlexVision Freeze**

AFFECTED PRODUCTS	<p>Allura Xper and UNIQ systems with a FlexVision large screen monitor.</p> <p>System names:</p> <table><tr><td>Allura 8.1.25.0</td></tr><tr><td>Allura 8.1.25.1</td></tr><tr><td>Allura 8.1.25.5</td></tr><tr><td>Allura 8.2.25.0</td></tr><tr><td>Allura 8.2.25.5</td></tr><tr><td>Allura 8.2.27</td></tr><tr><td>UNIQ 1.0.10</td></tr><tr><td>UNIQ 1.0.10.5</td></tr></table>	Allura 8.1.25.0	Allura 8.1.25.1	Allura 8.1.25.5	Allura 8.2.25.0	Allura 8.2.25.5	Allura 8.2.27	UNIQ 1.0.10	UNIQ 1.0.10.5
Allura 8.1.25.0									
Allura 8.1.25.1									
Allura 8.1.25.5									
Allura 8.2.25.0									
Allura 8.2.25.5									
Allura 8.2.27									
UNIQ 1.0.10									
UNIQ 1.0.10.5									
PROBLEM DESCRIPTION	<p>Philips has been reported instances where after a continuous operation of more than one and a half day, the image on the FlexVision large screen monitor froze, for about 15 seconds. Thereafter, the system restored itself and was fully operational again.</p> <p>Note: This is only applicable to Allura Systems and UNIQ systems with a FlexVision large screen monitor. All other monitors to the system are not affected.</p>								
HAZARD INVOLVED	<p>When the system is not switched on/off every day (cold restart) the FlexVision large screen monitor might freeze for about 15 seconds.</p> <p>When the FlexVision freezes there is a potential loss of key image functionality or a live image may not be identified by the user. This could pose a risk to the patient.</p> <p>Note: To date Philips is not aware of any injuries that may have occurred due to this issue.</p>								
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>All systems with the specific release as identified and with FlexVision large screen monitor in the section “Affected Products” are affected.</p>								
ACTION TO BE TAKEN BY CUSTOMER / USER	<p>To prevent occurrence of the issue customers shall restart the system at least once a day.</p> <p>Customer shall ensure that all staff with access to the affected systems are informed of the contents of this Field Safety Notice.</p> <p>A copy of this Field Safety Notice shall be placed together with the documentation of the system until the system has been corrected by Philips.</p>								

URGENT - Field Safety Notice**Medical Device: Allura Xper with FlexVision large screen monitor.****FlexVision Freeze**

ACTIONS PLANNED BY PHILIPS	<p>The problem will be resolved by a software update, which is expected to be available by the second half of 2018.</p> <p>You will be notified by your local Philips representative when the software update is available for installation.</p>
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this issue, please contact your local Philips representative.</p>