

URGENT - Field Safety Notice
Allura Xper Systems and Allura Integris Systems with Velara Generator

System restart required caused by Generator exceptions

Dear Customer,

At Philips Healthcare, safety has the highest priority. Medical equipment is sophisticated, complex technology. Even with all the safety measures and tests performed during the design phase, the risk for occasional and exceptional unwanted situations can not be eliminated completely. From the installed base we received reports of failing Velara Generators that causes the need for a warm or cold restart.

We are working on a solution for the installed base. In the mean while we want to inform you via this Field Safety Notice 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 if applicable.
- 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.

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

<Philips representative contact details to be completed by the KM / country>

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

<Signature, to be signed by Senior Management of the BS/BU/BL or GS&S/KM>


QR&S Manager X-Ray CV



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AFFECTED PRODUCTS	Allura Xper Systems and Allura Integris Systems with Velara Generator.
PROBLEM DESCRIPTION	Due to intermittent shortcuts inside the Velara Generator, a System lock-up might occur that can only be resolved by a warm or cold System restart. In exceptional cases the Generator is damaged and the System cannot be restarted.
HAZARD INVOLVED	When a System locks-up during a critical interventional case this might impose a serious injury to patients. A warm restart takes about 90 seconds while a cold restart takes about 4 minutes. During the restart the System cannot be used.
HOW TO IDENTIFY AFFECTED PRODUCTS	Allura Integris and Xper Systems with Velara Generator. The affected Systems will be clearly identified by the local Philips Organization.
ACTION TO BE TAKEN BY CUSTOMER / USER	As this is an intermittent failure no work around is available and no actions can be done by the user to prevent the failure from happening. If the problem occurs the System must be warm or cold restarted. (see Instructions for use) If this does not work local Service should be contacted.
ACTIONS PLANNED BY PHILIPS	A mandatory FCO will be issued to solve this problem. Depending on the System type the FCO numbers will be: 72200167 Allura Integris and Xper Monoplane Systems with Velara Generator 72200168 Allura Integris and Xper Biplane Systems with Velara Generator The FCO will contain Software and Hardware modifications The expected issue date of these FCO's will be February 2010 You will be contacted by Philips for implementation of the corrective action
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>

