

URGENT - Field Safety Notice Juno DRF

Exceeded value of 10 Roentgen without audible signal

Dear Customer,

As part of Philips' continuous focus on reliability and safety we continuously monitor the performance of our products. During recent evaluations of the Philips Juno DRF, we have identified a potential issue that may affect the performance of the equipment under certain conditions. This letter is intended to provide you with information regarding:

- what the issue is, and under what circumstances it may occur
- the actions you can take to avoid or minimize the occurrence of the issue
- the actions planned by Philips to correct the issue

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, please contact your local Philips representative:

If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

We apologize for any inconvenience this may cause and trust that this information is adequately addressing any concerns you may have.

Sincerely,

Stephanie Berger
Director Q&R DXR Hamburg (Print Name)

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AFFECTED PRODUCTS	Juno DRF
PROBLEM DESCRIPTION	It has been discovered that the system - in certain rare but possible combinations of user behavior (in zoom modes 30x30 and 15x15 only, but not in other zoom modes, and only in cases with manual override outside the operator's working location) - does not provide the appropriate audible signal, permanent activation, and manual override, although the system is in high-level control functionality.
HAZARD INVOLVED	Failure in providing the appropriate audible signal, permanent activation, and manual override doesn't directly create a hazard for the patient or the operator. The hazard is that the patient might be exposed to elevated radiation without the operator being constantly reminded of the high-level radiation. This does not necessarily mean excessive radiation even in situations where the performance standard is violated.
HOW TO IDENTIFY AFFECTED PRODUCTS	If you receive this letter your Juno DRF is affected by this FCO.
ACTION TO BE TAKEN BY CUSTOMER / USER	Pending the correction, the system can be operated setting the technical factors, when in manual mode, from the Juno DRF console.
ACTIONS PLANNED BY PHILIPS	This field action will instruct the Field Service Engineer to install a new main controller and a new generator software, which correct the problem. You will be contacted by Philips to schedule the installation. Should you need to communicate with Philips with regard to this program, please reference FCO70900026.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.