URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
9900 Innovation Drive
Mailstop: RP2138
Wauwatosa, WI 53226,
USA

May 11, 2009

To: Hospital Administrator / Risk Manager
Managers of Radiology/Cardiology
Radiologists/Cardiologists

RE: **Coolix 4000 failure on Innova® single plane 2100IQ, 3100/3100IQ, and 4100/4100IQ and Innova® biplane 2121IQ / 3131IQ cardiovascular X-ray imaging systems.**

Dear Healthcare Professional:

GE Healthcare has become aware of a potential pump failure associated with the Coolix 4000 chiller of your Innova ® single plane and biplane systems that may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

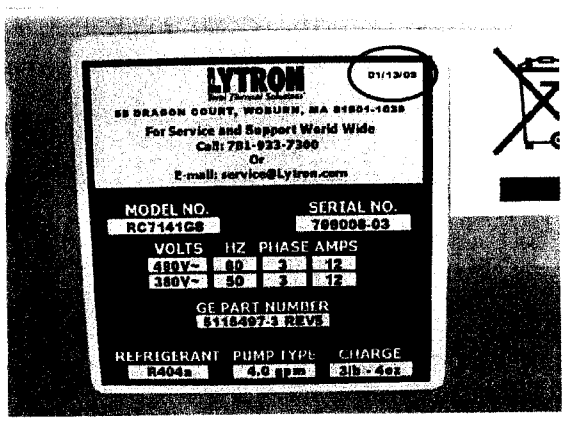
A potential pump malfunction associated with the Coolix 4000 chiller could cause the chiller to stop working. If a chiller failure occurs, the user will be informed with a message on the in-room monitor stating that three minutes are left before the X-ray is inhibited.

The potential harm associated with this issue is a delay in treatment and possible additional X-ray exposures and contrast media when examination is resumed on other equipment. To date, no harm has been reported related to this issue.

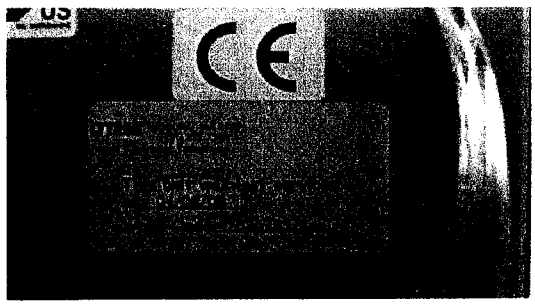
Affected Product Details

All Innova single plane 2100IQ, 3100/3100IQ, and 4100/4100IQ and Innova biplane 2121 IQ /3131 IQ cardiovascular X-ray imaging systems with tube chiller manufactured since August 2008.

The manufacturing date of the chiller is shown on the label below, affixed on the rear of the cabinet. Your product may potentially have this issue if the date is between 08/01/08 (1st of August 2008) and 04/01/09 (1st of April 2009).



If the chiller has been serviced between 08/01/08 (1st of August 2008) and 04/01/09 (1st of April 2009), it may also be impacted. The date of service is written on the label shown below, affixed on the rear of the cabinet:



Safety Instructions	If a chiller failure occurs, a warning message will be displayed on the in-room monitor instructing the user to secure the patient and safely stop the procedure within three minutes before X-ray is inhibited. The following messages will be repeated at two minutes and then at one minute intervals before X-ray is inhibited: "! 3 min (2 min, 1 min) before X-ray inhibit. Tube cooling failure. Secure patient" and then "Cooling Failure; Shut System down and call Service". As stated in the Innova Operator's Manual, the users of the equipment should have in place an emergency procedure to ensure patient safety in the event of loss of fluoroscopy during a patient exam.
Product Correction	GE Healthcare will correct all affected systems in the field by replacing the relevant part. Your system will be corrected at no cost to you. A GEHC service representative will contact you to arrange for this correction.
Contact Information	If you have any questions or concerns regarding this issue, please contact GE Healthcare immediately. In the United States, contact the Call Center at 1-800-437-1171, Option 4. In the other countries, please contact your local GE Healthcare Field Service representative. This information has been communicated to the appropriate National Competent Authorities.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately.

Thank you,

[redacted]

[redacted]
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[redacted]