



Urgent Field Safety Notice

GE Healthcare
384 Wright Brothers Dr.
Salt Lake City, UT 84116
USA

October 7, 2010

GE Ref: FMI 15088

To: Hospital Administrator
Radiology Administrator

RE: High Voltage Bridge Driver (Snubber Board) Design Change

GE Healthcare has become aware of a change in the design of a component associated with the snubber board of your OEC 9800 C-Arm and 9900 C-Arm that may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification.**

Safety Issue The High Voltage Bridge Driver did not conform to the IEC 60601-1/ EN 60601-1 safety standard for clearance and creepage of voltage isolation. This can lead to a blown fuse during the generation of an x-ray, which would result in the loss of C-Arm imaging functionality since x-rays could not be produced.

Affected Product Details The affected product is the GE OEC 9800 C-arm and 9900 C-Arm.

Safety Instructions No additional safety instructions are required for this FMI.

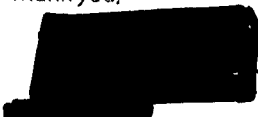
Product Correction GE OEC will be replacing this driver on these C-Arms. Your GE OEC service representative will be contacting you in the near future to arrange for an inspection to replace the driver board at no charge to you.


Contact Information Please contact your local sales or service representative if you need additional information regarding this notification.

GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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,


President and CEO
GE Healthcare Surgery


Vice President, Quality Assurance and Regulatory Affairs
GE Healthcare Surgery