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URGENT SAFETY ADVISORY NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

October 10, 2008
Auto Injector Cable

**To: Hospital Administrator
Director/Manager of Radiology**

**Subject: Product Safety Issues:
Auto-Injection Cable for GE OEC 9800 and GE OEC 9900 Elite C-arms for
Connection to the MEDRAD® Mark V ProVis® Angiographic Injection System**

Affected Products: OEC® 9900 Elite, OEC® 9800

Our records indicate that your facility has one or more of the following GEHC OEC products:

- OEC® 9900 Elite
- OEC® 9800

GE Healthcare has found that the GE OEC 9800 and GE OEC 9900 Elite C-arms, when connected with the Auto-Injection Cable provided by GE Healthcare and connected to a MEDRAD Mark V ProVis injector can provide a signal to trigger the injector in modes other than the Digital Subtraction Mode. If the Auto-Injection Cable is connected to the contrast injector, and the injector is armed for contrast injection, the GE OEC 9800 and GE OEC 9900 will send a signal to trigger a contrast injection in the Digital Subtraction Mode and in the Digital Cine Pulse Mode. Additionally, GE OEC 9800 Cardiac and GE OEC 9900 Elite Cardiac systems equipped with the Cardiac Foot Switch, when set in the Cardiac Mode, will send a signal to trigger a contrast injection when the Digital Cine Pulse Foot Pedal is depressed. It was additionally discovered that the proper validation of the Auto-Injection Cable (interface) was not properly performed or documented for use on the GE OEC 9800 and GE OEC 9900 Elite Vascular and Cardiac Systems.

Interim Solution:

Because the proper validation procedures for the Auto-Injection cable were not properly performed or documented, it is recommended that the Auto-Injection Cable not be used until the proper validation procedures are performed and the appropriate instructions for use are updated.

GEHC OEC is actively working on a solution that will permanently resolve this issue. When a solution becomes available GEHC OEC will contact you and at no cost resolve this issue.

If you have any questions or concerns regarding this issue, please do not hesitate to contact the service team for further information at 800-874-7378 option #8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,



Pete McCabe
President and CEO



Maria Frame
Vice President Quality and Regulatory Affairs