



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# 15135

To: Radiology Manager or Facility Administrator/Risk Manager

RE: Potential workstation power cable assembly issue on certain OEC MiniView 6800, OEC 9800, OEC 9900 systems

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issue	An issue with the workstation power cable assembly can result in a loss of imaging functionality due to intermittent power cord failures. There have been no injuries reported as a result of this issue. However, the failure could cause an interruption of a procedure that potentially could necessitate additional medical intervention.
Safety Instructions	You may continue to use your system. Prior to each use inspect the power cord plug for discoloration, carbon build up on the terminals, or melted / degraded plug housing. If any of these conditions exist, discontinue use of the system and contact your GE Healthcare Service Representative.
Affected Product Details	<ul style="list-style-type: none">• OEC 9900 systems manufactured or refurbished with NEMA 5-15 15 Amp power cords between February 5, 2016 and November 23, 2016.• OEC 9900, OEC 9800, OEC MiniView 6800 systems that had NEMA 5-15 15 Amp power cords replaced between January 28, 2016 and November 23, 2016.
Product Correction	GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.
Contact Information	If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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 per the contact information above.

Sincerely,

[Redacted Signature]
Dan Eagar
Executive QA, DGS/Surgery
GE Healthcare

[Redacted Signature]
Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

Released