



GE Healthcare

GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116

CUSTOMER PRODUCT UPDATE

November 17, 2009
FMI 15083

To: Director/Manager of Radiology
Subject: OEC 8800 Operator's Manual Update

Affected Products: OEC® 8800

A design specification to the OEC 8800 has been updated and at the request of the FDA, this information is being provided to you, to update the Operator's Manual of the OEC 8800.

This specification change does not affect your system, or the operation of the OEC 8800. This is a technical update to the Operator's Manual only.

The linearity specification, as originally noted in the OEC 8800 Operator's Manual specified a linearity of ≤ 0.08 . This specification has changed to align with the 21CFR 1020.31 (c) regulation, which allows up to 0.10 non-linearity.

The enclosed pages are being provided to update the OEC 8800 Operator's Manual for this specification change.

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

Thank You,

Pete McCabe
President
GE Healthcare Surgery

Doug Uelmen
Vice President Quality and Regulatory Assurance
GE Healthcare Surgery