

GE Healthcare

Surgery

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URGENT FIELD SAFETY NOTICE

2012-02-20

Ref: 15117

To:

Hospital Administrator

Director/Manager of Radiology

Subject:

Product Safety Issue related to interconnect PO Cable failure; Series 7600/7700 Mobile C-Arm,

Compact 7600/7700 Mobile C-Arm, Compact 7700 Plus Mobile C-Arm

Affected Products:

Interconnect PO Cable (P/N: 00-452118-01; 00-453118-01)

Our records indicate that your facility has one or more of the above mentioned products.

GE Healthcare has identified a potential safety issue related to the interconnect PO Cable that connects the C-arm to the monitor cart. The details and symptoms of this issue, as well as the associated interim or permanent solutions, are outlined below. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issue

The interconnect PO Cable that connects the C-arm to the monitor cart may fail, resulting

in loss of video signal transmission to the monitors.

Affected Product Details

Series 7600/7700 Mobile C-Arm, Compact 7600/7700 Mobile C-Arm, Compact 7700 Plus Mobile C-Arm using interconnect PO Cable part number 00-452118-01 or 00-453118-01 in

the serial number range 2457-2632.

Safety Instructions

Avoid making sharp or low angle bends with the PO interconnect cable.

Product Correction

In the near future, your GE Healthcare Surgery field service representative will be contacting you to arrange for replacement of the interconnect cable at no charge.

Contact Information

If you have any questions regarding this Field Safety Notice or the identification of affected items please contact your local Sales/Service representative.

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,

Joe Shrawder President and CEO GE Healthcare, Surgery

Dan Eagar Executive, Quality Assurance and Regulatory Affairs

GE Healthcare, Surgery