



## Urgent Medical Device Correction

May, 2008

Attention:                   Managers of Radiology/Cardiology  
                                  Radiologists/Cardiologists  
                                  Biomedical / Clinical Engineering

### Dear Healthcare Professional:

GE Healthcare (GEHC) has recently become aware of two potential conditions associated with installation of some Mavig LCD suspensions used with some of our vascular systems that may impact patient safety.

Statistically, the probability to experience either of the two conditions is unlikely. Out of a global Installed Base of 1300+ systems only three installations have reported an incident caused by incorrect installation on site. To date, no injuries have been reported related to either of the two conditions.

**Condition 1:** Due to insufficient securing of the connecting elements, the LCD vertical monitor support may disengage from its arm and fall on the table or in the table vicinity.

Out of a global installed base of 1300+ systems, only one installation has reported this condition.

**Condition 2:** Only Service personnel working inside the suspension may potentially experience this condition: Incorrect cable routing on site, inside the LCD monitor suspension arm, may cause the ECG monitor power cable to be damaged, potentially resulting in a short circuit that could cause sparks. The potential risk of an electrical shock affects only Service personnel working inside the Mavig suspension without first turning off both power supplies of the X-ray equipment and of the ECG monitor.

No electrical shock to patients or staff can occur in this situation because the suspension is sufficiently grounded.

Out of a global installed base of 1300+ systems, only two installations reported damaged cable.

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

Affected Products:   All Advantx-E®, Innova® 2000, 2100<sup>Q</sup>, 3100/3100<sup>Q</sup>, 4100/4100<sup>Q</sup> and 2121<sup>Q</sup> /3131<sup>Q</sup> cardiovascular X-ray systems that have Mavig LCD monitor suspensions.



Short Term User

Recommendations:

**Condition 1:**

As much as possible, avoid positioning the Mavig LCD monitor suspension directly above patients, operators or other staff members, until the correct installation of your Mavig system is confirmed by GE Healthcare. **Do not attempt to secure the suspension yourself. GE Healthcare will inspect and correct, when necessary, the suspension at your site.**

**Condition 2:**

In case local Service intervention, by your facilities or other servicing personnel, is needed on the Mavig LCD monitor suspension prior to the GE Healthcare corrective actions, please ensure that Service personnel follows all of the steps listed below before servicing the monitor suspension.

1. Shut down the entire Advantx-E or Innova x-ray system from the control room console;
2. Turn off the power distribution box located in the exam room or in the technical room;
3. Unplug the ECG monitor power cord from its power outlet.

Contact your GE Service representative immediately if you notice any issue with your Mavig LCD monitor suspension.

**NOTE: Pay extra attention disconnecting the ECG monitor power supply cord if it is powered by an external power outlet independent of the X-ray equipment power distribution box.**

**NOTE: DO NOT attempt to re-route cables inside the Mavig suspension yourself. GE Healthcare will inspect and, when necessary, modify the cable routing inside your suspension arm at your site.**

GE Healthcare  
Resolution plan:

GE Healthcare will launch a corrective action to inspect all potentially affected systems. The Mavig LCD suspension will be inspected, and if necessary, the mechanical connection will be corrected. Internal cabling will be re-routed when needed.

As part of the corrective action, GE Healthcare will apply a warning label inside the suspension cover. This label will inform your local Service personnel about the potential voltage that remains on the ECG monitor cable after the power supply is turned off on the X-ray system power distribution box. Voltage remains on the cable if the power of the ECG monitor is not completely disconnected from its power source.

This inspection and potential corrections will require approximately three hours to complete, at no cost to you. A GEHC service representative will contact you to arrange for this upgrade.



Contact  
Information:

If you have any questions/concerns regarding those issues, please contact GE Healthcare immediately. In the United States, contact the Call Center at 1-800-437-1171, Option 4. For other countries, please contact your local GE Healthcare Field Service representative.

Please be assured that we are constantly making every effort to maintain a high level of safety and quality in our systems.

Sincerely,

[Redacted signature]

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