



Urgent Medical Device Correction

February 22, 2008

Attention: Hospital Administrators
Hospital Risk Management Department
Managers of Radiology/Cardiology
Radiologists/Cardiologists

Dear Healthcare Professional:

Subject : Risk of sudden table drop on Omega IV and Omega V tables on Advantx-E® as well as on Innova® 2000, 2100^{IQ}, 3100/3100^{IQ}, and 4100/4100^{IQ} cardiovascular X-ray systems

Affected Products: All Advantx-E® as well as all Innova® 2000, 2100^{IQ}, 3100/3100^{IQ}, and 4100/4100^{IQ} cardiovascular X-ray systems that have an Omega IV or Omega V table manufactured between July 2003 and January 2007.

Innova® 2121IQ and Innova® 3131 IQ biplane cardiovascular x-ray systems ARE NOT affected by this issue.

Safety Issue:

GE Healthcare has become aware that some Omega IV and Omega V tables may experience a sudden and unexpected quick downward drop to its lowest position.

This event is most likely to occur during table vertical motion.

Immediately following such an event, the table's vertical motion capability locks up.

To date, no injuries have been reported related to this issue. Thus far, only eight sites have been affected out of over 1000 global installations since July 2003. Statistically the potential to experience this issue is low as only eight malfunctions and zero injuries have been reported out of approximately more than 2 million exams.

Should such an event occur, the system remains operational with the exception of the table vertical motion capability; therefore, a procedure can be finished in this degraded mode.

Below are some examples of procedures that could present a risk for the patient in case of sudden table drop:

- Procedures that use cerebral stereotactic frames or involve needle punctures.
- Procedures involving the introduction and the manipulation of a catheter into an artery.
- Procedures involving balloon inflation, stent or coil deployment.
- Procedures where the patient is in a prone position on the table with arms underneath the tabletop.



- Procedures where accessories are placed on the tabletop.

Short Term Recommendations: If you experience sudden tabletop drop and the loss of vertical motion on your Omega table, please contact your local GEHC Field Engineer who will install a fix on your system.

In the meantime, GE Healthcare recommends:

- Avoid procedures that could severely hurt the patient in case of a sudden tabletop drop (e.g. procedures that use cerebral stereotactic frames, needle punctures, etc.)
- Be sure to keep extra slack in any cables that are connected to the patient
- Do not position the patient's arms or any other materials underneath or on the side of the tabletop
- Do not leave materials on the tabletop that could be damaged in case of a sudden table drop

Long Term Solution: GE Healthcare has developed a technical fix to avoid such unwanted table movement. This hardware fix will require approximately one hour to install. This fix will be installed at your site at no cost to you and will be scheduled around your clinical workload.

Contact Information: **If you have any questions/concerns regarding this issue, please contact us immediately:**
United States Call Center telephone number: 800 437 1171, Option 4.
For all other countries, please contact your local GE Healthcare field service representative.

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

Thank you,



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