



## URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

Healthcare Systems  
9900 Innovation Drive  
Wauwatosa, WI 53226,  
USA

December 21, 2009

GE Ref: 12137

To: Hospital Administrators / Risk Managers  
Managers of Radiology/Cardiology  
Radiologists/Cardiologists


RE: **Omega IV and Omega V tables on Advantx-E® and on Innova® 2000, 2100<sup>IQ</sup>, 3100, 3100<sup>IQ</sup>, 4100, 4100<sup>IQ</sup>, 2121<sup>IQ</sup> and 3131<sup>IQ</sup> cardiovascular X-ray imaging systems: Unintended Table Rotation**

GE Healthcare has become aware of a potential table rotation issue on Omega IV and Omega V tables affecting Advantx-E and Innova systems that may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

- Safety Issue** Due to potential weakness of some table rotational brakes, an unintended table rotation may occur while the table is locked. This issue could potentially lead to a patient fall if the unintended motion occurs during patient transfer.
- Affected Product Details** Omega IV and Omega V tables on Advantx-E and on Innova 2000, 2100<sup>IQ</sup>, 3100, 3100<sup>IQ</sup>, 4100, 4100<sup>IQ</sup>, 2121<sup>IQ</sup> and 3131<sup>IQ</sup> cardiovascular X-ray imaging systems may be affected.
- Safety Instructions** When loading or unloading patients onto or off the table, lower the table to the lowest height, and fully retract the table top towards the foot end side. Take extra precautions and support the patient securely during loading or unloading procedure in order to minimize the risk of patient fall.
- Product Correction** GE Healthcare will correct all affected systems by replacing the table rotational brakes. A GE Healthcare service representative will contact you to arrange for this correction. This activity will be performed at no cost to you.
- Contact Information** Call Center phone numbers:  
United States: 800 437 1171, option 4  
Japan: 0120 - 055 - 919  
For other countries, please contact your local GE Healthcare Service Representative if you have any questions or concerns regarding this notification.

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.

Sincerely,



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