



GE Medical Systems
OEC

GE OEC Medical Systems Product Safety Alert

August 4, 2003

FMI 15014

Reference: System Serial Number «MailMerge1»

Dear Clinical/Biomedical Engineering Manager:

GE OEC Medical Systems' records indicate that an OEC UROVIEW 2000, UROVIEW 2500, or UROVIEW 2600 Imaging System has been installed at your healthcare facility. Please be advised that a potential safety concern associated with these models of the OEC UROVIEW system has been identified. Specifically, GE OEC has determined that uncontrolled table motion may occur if the Uroview hand control device has been exposed to liquids and those liquids have penetrated the hand control assembly. Further, the hand control holster is currently positioned such that table cleaning may result in liquid dripping onto this assembly. **UROVIEW 2800 systems are not affected.**

Because it is possible that the hand control circuitry may be damaged or contaminated even after it has dried, **GE OEC strongly recommends that all hand controls on UROVIEW 2000, 2500 and 2600 systems be removed from service.** Please disconnect the hand control using the connector on the underside of the urology table and store it in a safe place (see figure 1).

GE OEC is now in the process of redesigning the hand control to correct this condition. A new hand control assembly will be provided at no cost to you, starting in approximately 45 days.

Removal of the hand control will eliminate the table position memory function, tomography capability, and manual film cassette ejection from the system. The cassette will still automatically eject following a film shot or upon system re-boot.

Please also be advised of the following:

- Should uncontrolled table motion ever occur on your UROVIEW system, use the red "Fast Off" button located on the side of the table support to turn off system power (see figure 2).
- When cleaning the system, do not pour, squirt, or drip liquids onto the system, footswitches, or control panels. This can cause electronic failure in the system. Clean covers and panels using only a damp cloth and mild detergent.
- Always make sure all electronic assemblies are draped or bagged. Protect the footswitch from liquids and other foreign matters with a plastic footswitch cover.
- GE OEC urges you to review your operator's guide regarding the procedures for safe operation and proper care and cleaning of your system.

Please convey this information to all users of UROVIEW 2000, 2500, and 2600 systems, as well as other concerned parties within your facility. GE OEC appreciates your cooperation in proactively addressing this safety concern. For questions, safety information, or concerns about continued utilization of your system, please contact GE OEC Medical Systems Field Service at (800) 874-7378 and select option number 1.

Sincerely,

Jackie Magno
Vice President, Regulatory and Six Sigma
GE OEC Medical Systems



Figure 1

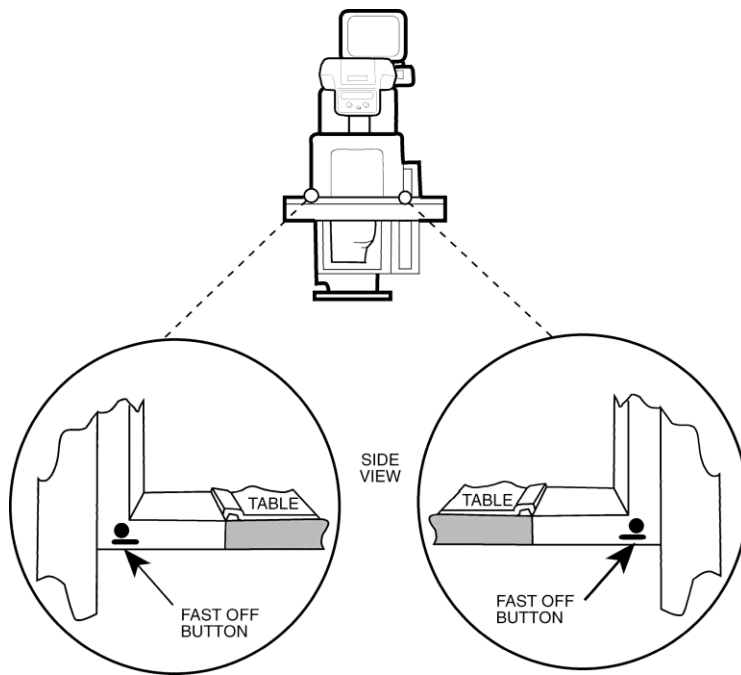


Figure 2

