GE Healthcare

GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116

Certified Mail Return Receipt Requested

URGENT PRODUCT NOTIFICATION

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

TBD, 2008
FMI 15094

To: **Hospital Administrator**
Radiology Administrator

Subject: **Product Safety Issues:**
GE OEC 9900 Elite ESP and GE OEC 9900 Elite GSP C-arms.

Affected Products: **GE OEC 9900 Elite ESP and GE OEC 9900 Elite GSP Systems**

Our records indicate that your facility has one or more of the following GEHC OEC products:

- GE OEC 9900 Elite ESP
- GE OEC 9900 Elite GSP

GE Healthcare has discovered that your system(s) may experience operational impairment under certain circumstances as described below:

1. System Files Check Process

Under normal operation, the GE OEC 9900 Elite undergoes a boot-up process, which begins when the power button is selected and ends when the Login or Patient Information screen appears on the right monitor. This process normally takes approximately 2½ minutes.

If users interrupt the boot sequence before it is complete, e.g., by unplugging the system, interrupting the power to the system, or turning the system off prior to the boot-up process being completed, the software may become corrupted. If software corruption occurs, it will be detected by the file system integrity check at the next attempt to boot-up the system.

Be advised that the file system integrity check may take up to six minutes to be executed. During this time, the system may appear to be "Frozen". Interrupting the file system integrity check may require a service intervention to restore normal functionality.

Interim Solution:

Users of the GE OEC 9900 Elite C-arms should assure that power is not turned off during the Boot-Up sequence and that the C-arm is allowed to boot fully. Allow the boot-up sequence to complete until the Login or Patient Information screen appears on the right monitor, even if you decide you do not need to use the system at that time. Once the Login or Patient Information screen is displayed, the device may be safely powered down.

Additional information on the boot-up process is available in the *OEC 9900 Elite Workstation and C-Arm Operator Manual Update* on page 8.

A caution label is included to affix (per diagram 1.1 enclosed) to your system(s) to remind all users of the importance of proper system start up procedures.

Permanent Solution:

GE Healthcare Surgery is actively working on a software update that will provide a display message to advise users of the boot-up status of the C-arm. When available, this will be installed on your system at no cost to you.

2. Power Requirements

It has been found that variations in facility electrical power, voltage spikes introduced into the power distribution by actions like air-conditioning cycling or cycling of emergency power backup systems can affect the proper start up and operation of the 9900 Elite. Power fluctuations beyond the specified limits (as defined in the 9900 Elite Operator's Manual: Section 14; Page 14-11) may cause damage to the electronics of your system. If the system is plugged into a power outlet that is outside the range of the expected voltage a voltage alarm will sound, or if the system is exposed to voltage fluctuations it may trip a circuit breaker on the Workstation.

Continued exposure to facility voltage spikes or circuitry that is improperly grounded may result in damage to the system's electronics.

Permanent Solution:

It is imperative that the power requirements specified are met to maintain proper system operation. As with all electronics, voltage spikes and power surges will damage the electronics.

If the voltage alarm on the system activates when the system is plugged in, it indicates that the power voltage is outside the original installation settings for the system. **If this issue should occur, contact GE Healthcare Surgery Technical Support at 1-800-874-7378.**

For new and currently installed 9900 Elite systems, a site power quality audit at your facility will be performed by a GE Healthcare Service Representative.

3. K2/Power CAP Relay:

It has been discovered that if the 9900 Elite C-arm receives a severe mechanical impact (see examples below) a relay may fail and cause the system not to Boot Up.

Interim Solution:

Severe impacts to the 9900 Elite should be avoided. Examples of causes of such impacts include pushing doors open with the C-arm, allowing the C-arm to ram into walls, or transporting the C-arm over significant drops (such as uneven match of an elevator car to floor where there may be a 3"-4" drop).

Permanent Solution:

A GE Service Representative will be contacting you in the near future to schedule the installation of a mechanical tie-down / clamp to eliminate the K2/Power CAP Relay failure.

4. Vertical Lift Column

There have been several reports of Vertical Lift Column issues that are related to the operation of the new Vertical Lift Column Power Supply (PS3). The new power supply operates with certain delays to protect the power supply from failure. A copy of the Vertical Lift Column User Letter (dated May 1, 2008) is enclosed that describes the expected behavior of the Vertical Lift Column with the new power supply.

Please fill out and return the FAX-Back Form to acknowledge receipt of this letter, the information provided, and installation of the Start Up Label to your system(s).

If you have any questions or concerns regarding this issue, please do not hesitate to contact the service team for further information at 800-874-7378 option #8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

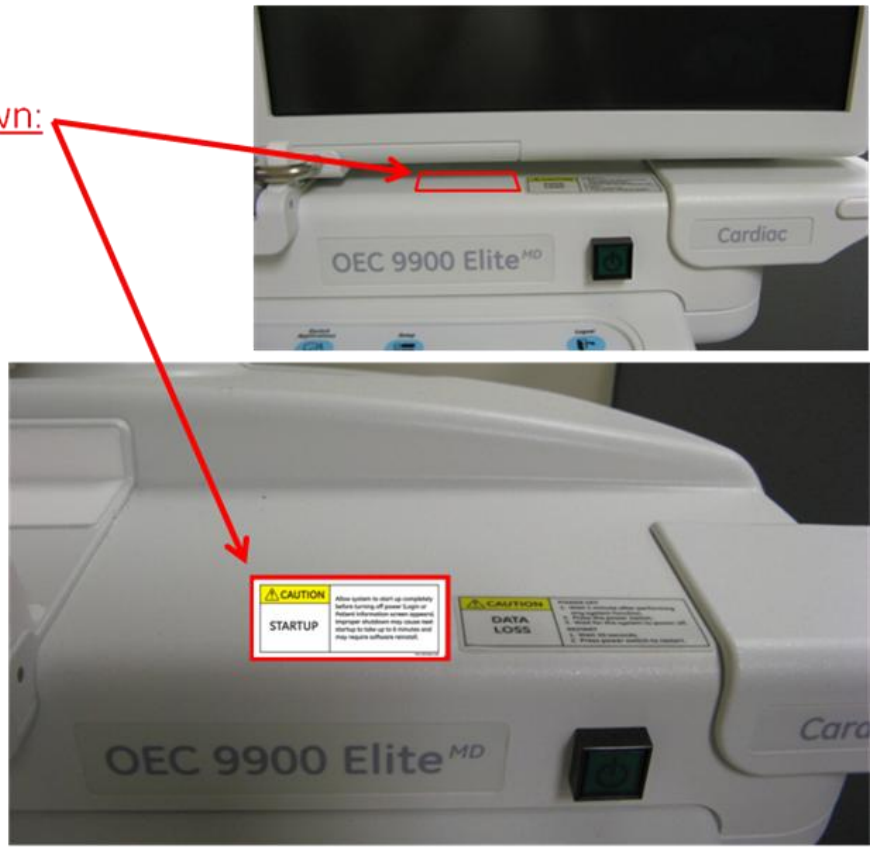
Pete McCabe
President and CEO

Maria Frame
Vice President Quality and Regulatory Affairs

Diagram 1.1:

Start Up Label Placement

Affix Start Up Label as shown:



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CUSTOMER PRODUCT IMPROVEMENT

May 1, 2008

To: **OEC Trained/Qualified Radiological Technologists**
Director/Manager of Radiology

Subject: **Vertical Lift Column Power Supply (PS3) Replacement**

Affected Products: **OEC® 8800; OEC® 9800; OEC® 9900 Elite**

The Vertical Lift Column Power Supply (PS3) has been replaced on the GE Healthcare OEC C-arm. The replacement PS3 fixes the root cause of the early life failure experienced with the previous version.

The new PS3 functions slightly different than the older version. After the C-arm is switched on the vertical up or down switch must be pressed to start the full initialization of the vertical drive functionality. This initialization takes approximately five seconds after which full vertical functionality is enabled.

The Up and Down switches for the Vertical Lift Column operates as before and in order to protect the power supply, a delay (0.4 second) was built into the Up command and Down command switch operations. If the user makes a quick change between Up and Down commands, or presses the same button quickly in succession, the respective switch will need to be released and pressed again. This delay is normal and expected, and will protect the PS3 from failure.

The overall benefit to the new Vertical Lift Column Power Supply is the elimination of a potential Vertical Lift Column failure that has been identified as a safety concern. The built in switch delay makes the integrity of the PS3 consistent with the overall life expectancy of your GE Healthcare OEC C-arm, and will eliminate the failure of the Vertical Lift Column during use.

If you have any questions or concerns regarding this issue, please do not hesitate to contact the sales or service team for further information at 800-874-7378. Information is available at this number 24 hours per day, 7 days a week.