



GE Healthcare

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Certified Mail Return Receipt Requested

URGENT RECALL NOTICE

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

November 8, 2006
FMI: 15046; 15057; 15087

To: Hospital Administrator
Director/Manager of Radiology

Subject: Product Safety Issues

Affected Products: OEC® 9900 Elite, OEC®, 9900 Elite^{MD} Motorized C-arm System, OEC® 9900 Elite^{NAV}

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

- OEC® 9900 Elite
- OEC® 9900 Elite^{MD} Motorized C-arm System
- OEC® 9900 Elite^{NAV}

GE Healthcare has identified several intermittent potential safety issues that may occur with these products based upon feedback from some customers. The details and symptoms of these issues, as well as the associated interim or permanent solutions, are outlined below.

1. Navigation Tracking Inaccuracy:

Affected Products: OEC 9900 Elite ^{NAV}

An issue has been discovered with the **OEC 9900 Elite ^{NAV}** that could result in an incorrect position of instrumentation versus the displayed reference image. **This issue could result in an injury to the patient due to incorrect anatomical location of an instrument during a procedure.**

Permanent Solution:

The GE OEC service team will be contacting you to upgrade your system's software to 6.15.3.

Users are advised to stop using the system WITH NAVIGATION until the software upgrade has been successfully completed. Your 9900 system may be used as a standard C-Arm providing you review the other issues as listed below.

2. System Lock Up:

Affected Products: OEC® 9900 Elite, OEC®, 9900 Elite^{MD} Motorized C-arm System, OEC® 9900 Elite^{NAV}

GEHC OEC has become aware of a potential problem with the above-indicated products where the C-arm may lock-up. Specifically, during system usage, the system may fail to function (produce live x-rays), and the collimators may close. In addition, the system display may indicate that the system is active (such as sound and/or light displays) when, in fact, the system is not producing live x-rays. The left monitor of the system will not update (no live fluoroscopy). There will be no radiation emission occurring despite the audible and visual indicators. If it is suspected that the system has emitted an uncommanded radiation exposure the user should contact GEHC to have the exposure logs reviewed to confirm if an exposure was made.

In critical clinical scenarios in which the C-arm is being used to make real-time therapeutic decisions or guide real-time interventions, a system lock-up may cause a procedural delay. Users should always be certain that the images shown on the Left Monitor are refreshing and are in fact live x-ray images (one indicator of this status is that the word "live" displayed on the screen).

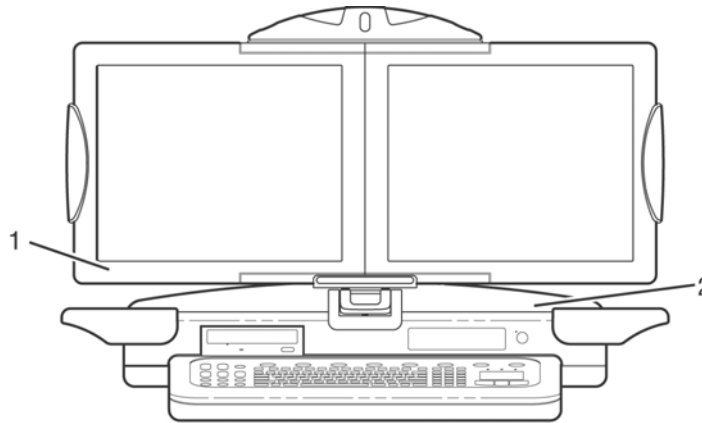
Interim Solution:

Should your OEC System experience a Lock-up, restarting (rebooting) the system should restore system functionality. The restarting (rebooting) sequence for the 9900 Elite System takes approximately 3 minutes to restore functionality. **Images saved prior to the system locking up will be restored and are retrievable. Images not saved prior to the system failure will not be restored.**

Enclosed is a sheet of supplemental stickers, including instructions for attachment, that demonstrates the restart steps. These stickers should be promptly attached to your system(s) as indicated below (suggest placement in location #2). These instructions are also located in the Operators Guide.

⚠ CAUTION	POWER OFF 1. Wait 1 minute after performing any system function. 2. Press the power switch. 3. Wait for the system to power off. RESTART 1. Wait 10 seconds. 2. Press power switch to restart.
DATA LOSS	

SUGGESTED PLACEMENT OF STICKER ON SYSTEM



3. Incorrect Image Display:

Affected Products: OEC® 9900 Elite, OEC®, 9900 EliteMD Motorized C-arm System, OEC® 9900 EliteNAV

When the image directory is accessed and thumbnail images are used to recall patient images, incorrect images may be displayed or there may be an inability to locate images on the system. The actual images, however, are labeled with the correct patient information, and may be located within another patient’s file.

Interim Solution:

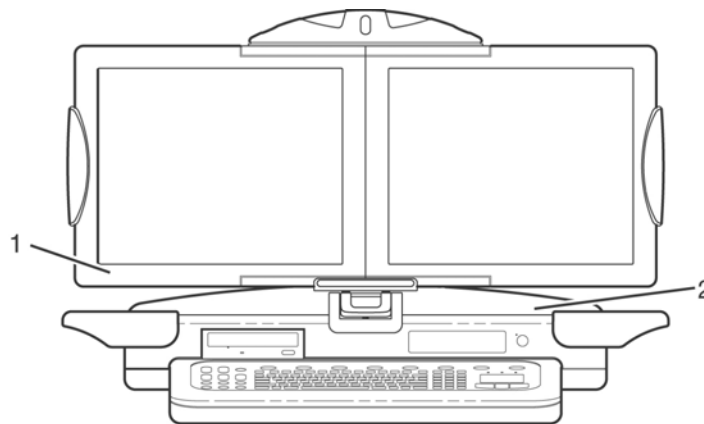
To reduce the occurrence of this issue The GEHC OEC service team will be contacting you to upgrade your 9900 system’s software to 6.15.3. Additional solutions to eliminate this issue are under investigation by GEHC OEC. To reduce the occurrence of this issue users should follow the correct power down procedure. The power down procedure is described in the Operators Guide and on the supplemental stickers enclosed with this notification.

Users are advised to exercise caution in using the system by verifying that the image displayed is consistent with current examination being reviewed and contains the correct patient demographic information on the image itself until a comprehensive and permanent solution has been developed.

The supplemental stickers should be installed on your system(s) promptly following the enclosed instructions and as indicated below (suggest placement in location #2).

⚠ CAUTION	POWER OFF 1. Wait 1 minute after performing any system function. 2. Press the power switch. 3. Wait for the system to power off. RESTART 1. Wait 10 seconds. 2. Press power switch to restart.
DATA LOSS	

SUGGESTED PLACEMENT OF STICKER ON SYSTEM



4. Annotation Selections:

Affected Products: OEC® 9900 Elite, OEC®, 9900 EliteMD Motorized C-arm System, OEC® 9900 EliteNAV

When a user annotates a cine run and selects annotations for one image the annotations may persist from frame to frame.

Permanent Solution:

This functionality is expected and is part of the product design. Annotations persist on the images in the cine run until the user manually deletes the text from the image annotation screen or exits the current cine run. As always, the saved images will have the annotations saved with them.

5. Subtracted Image Display:

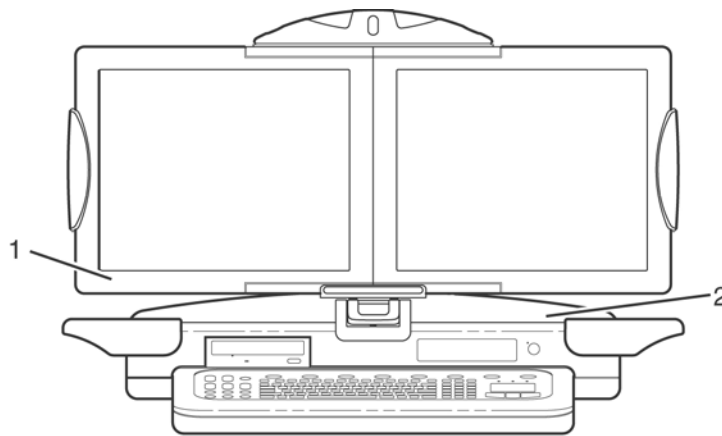
Affected Products: OEC® 9900 Elite, OEC®, 9900 EliteMD Motorized C-arm System, OEC® 9900 EliteNAV

During subtraction a different static image may appear under the real time image.

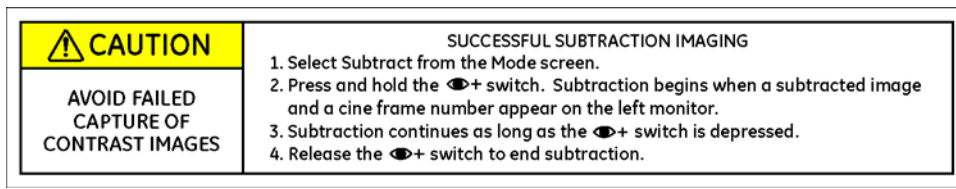
Interim Solution:

When acquiring the pre-injection image at the beginning of a subtraction run, the user must allow the system to enter subtraction mode before ending the exposure. A user can confirm that they have entered subtraction mode by the appearance of a subtracted image and the cine frame number on the display screen on the left monitor. If the user does not see the frame number and the subtracted image on the screen the image should be re-acquired prior to continuing with the study. Currently, the only available option, should this situation occur, is to reacquire the image if it serves the best interest of the patient.

Supportive labels containing the above information have been included with this notification. These labels should be placed on your systems following the instructions included with the labels and as indicated below (suggest placement in location #1).



SUGGESTED PLACEMENT OF STICKER ON SYSTEM



6. Incorrect Dose Area Product/Calculated Air Kerma in “Film Mode ” and “Digital Spot Mode”:

Affected Products: Affected Products: OEC® 9900 Elite, OEC®, 9900 EliteMD Motorized C-arm System, OEC® 9900 EliteNAV.

An issue has been reported that results in incorrect calculation, display and recording of patient dose while in film or digital spot mode. During a procedure, both the calculated Cumulative Air Kerma and the Air Kerma Rate can be observed on the live imaging monitor. This shows the

AKR (air kerma rate) during fluoro exposures, and CAK (cumulative air kerma) after & between fluoro acquisitions. Either during the procedure, or more typically, after the procedure, Cumulative Air Kerma and/or Dose Area Product (DAP is optional, depending on system configuration) can be viewed in a Dose Summary Screen, which can be invoked and displayed on the left monitor. This summary shows the total procedure CAK and DAP with a breakdown on what exposure modes were used, and what fractions of the total dose each mode was responsible for. In GE OEC systems, AKR is calculated from technique factors (kVp, mA, and if pulsing, the duty factor.) CAK is calculated from the same, but accumulated over the duration of the procedure. DAP is calculated from the same parameters and also the collimator opening area. The total dose listed on this screen will be incorrect only if the Film or Digital Spot are used during the relevant procedure. All other fluoroscopic modes correctly display the dose within current specifications (i.e. Fluoro, High Level Fluoro, Pulsed, Cine Record). This mis calculation could lead the clinicians to erroneously document the radiation exposure received by the patient

Permanent Solution:

An upgrade of the OEC 9900 Elite, OEC 9900 Elite ^{NAV} to version 6.15.3 by the GEHC OEC Field Service Engineer will correct this issue. Users are advised to refrain from basing clinical assessments/treatment on these calculated values until the system has been upgraded if a film or digital spot were used during a procedure. In clinical scenarios in which an accurate record of the radiation exposure to the patient is required prior to the system receiving an upgrade, users should contact their GEHC OEC service provider for assistance in determining the actual radiation exposure.

7. System does not boot:

Affected Products: OEC® 9900 Elite, OEC®, 9900 EliteMD Motorized C-arm System, OEC® 9900 EliteNAV,

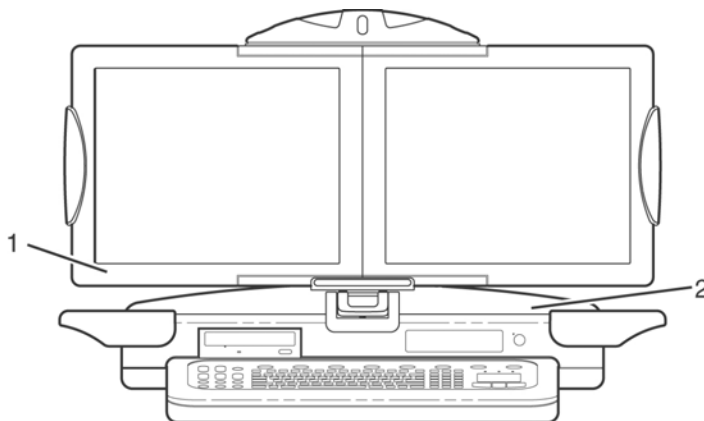
OEC 9900 Elite, OEC 9900 Elite ^{NAV} may stall during its boot cycle causing a delay in usage. The most common symptom of an incomplete boot cycle is when the workstation progress bars stall at $\frac{3}{4}$ of completion. The vacuum fluorescent display on the C-arm will stop on 5 arrows. If this condition persists for longer than a minute, the system is stalled.

Interim Solution:

Rebooting the system should clear the issue and restore system functionality. When rebooting the system for this issue, before reapplying power, it is important to place the power switch in the OFF position and wait **10 seconds**. Should the system fail to reboot a second attempt at rebooting may be required. These instructions are also located in the Operators Guide.

⚠ CAUTION	POWER OFF 1. Wait 1 minute after performing any system function. 2. Press the power switch. 3. Wait for the system to power off.
DATA LOSS	RESTART 1. Wait 10 seconds. 2. Press power switch to restart.

SUGGESTED PLACEMENT OF STICKER ON SYSTEM



Enclosed is a sheet of supplemental stickers, including instructions for attachment, that demonstrates the restart steps. These stickers should be promptly attached to your system(s) as indicated above (suggest placement in location #2).

GEHC OEC is actively working on solutions that will permanently resolve each of these issues. When solutions become available for those issues that currently do not have a permanent solution, GEHC OEC will contact you and without charge, remedy these issues. For those issues that currently have a permanent fix identified, the GEHC OEC service team will be contacting you to install the correction shortly.

If you have any questions or concerns regarding these issues, 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,

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