



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

January 12, 2007
FMI: 15049; 15050

To: Director Surgery/Urology
Director/Manager of Radiology

Subject: Product Safety Issues

Affected Products: OEC® UroView 2800 and OEC® UroView 2800 with Dual Monitor Option

Our records indicate that your facility has one or more **OEC® UroView 2800 and/or OEC® UroView 2800 with Dual Monitor Option**

GE Healthcare has identified two (2) potential safety issues that may occur with the **OEC® UroView 2800** product based upon feedback from some customers. The details of these issues, as well as the associated interim solutions, are outlined below.

1. Dual Monitor Safety Risk:

Affected Products: OEC® UroView 2800 Dual Monitor Configuration

There have been instances in which the dual monitor on a Uroview 2800 became disconnected from the assembly arm. **The dual monitor assembly arm on the Uroview 2800 could pose a safety risk to patients, users, or other personnel should the monitors become disconnected.**

A small hardware component on your Uroview 2800 needs to be inspected and possibly modified to correct this potential safety risk. Your GEHC-OEC Field Service Engineer will be contacting your

facility to inspect your Uroview 2800 to see if it is impacted by this potential risk. If your system is affected, your GEHC-OEC Field Service Engineer will be able to make the needed modification to your Uroview 2800 at that time.

Interim Solution:

Until a GE OEC Field Service Engineer has inspected your Uroview 2800 with the Dual Monitor Option, please **cease using your Uroview 2800 for procedures where the use of the dual monitors is required. In addition to reduce the potential of the monitors falling and causing injury:**

- **Follow the instructions below for the positioning of the monitors and placement of the enclosed warning tag**
- **Do not move the monitors from this position until your Uroview 2800 has been inspected and/or repaired.**

INSTRUCTIONS FOR MONITOR PLACEMENT

- Position the dual monitors so that they rest on top of the tower as shown in Figure #1 (Please be advised that this should be done carefully or you could scratch the surface of the generator housing.)
- Attach the WARNING Tag (Example of Tag in Figure #2) to the left or right dual monitor handles as shown in Figure #3 with the supplied Cable Tie. (Please note that the tag should be placed in such a manner that the WARNING Tag is clearly visible to any user)

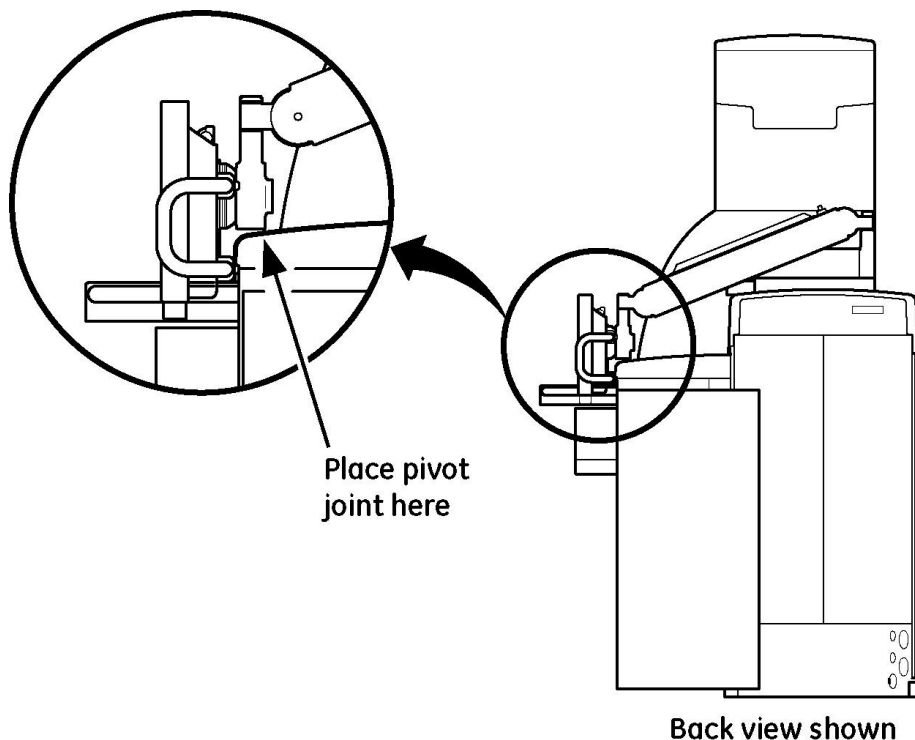


Figure #1 – Mount Monitors as shown in Back View of System

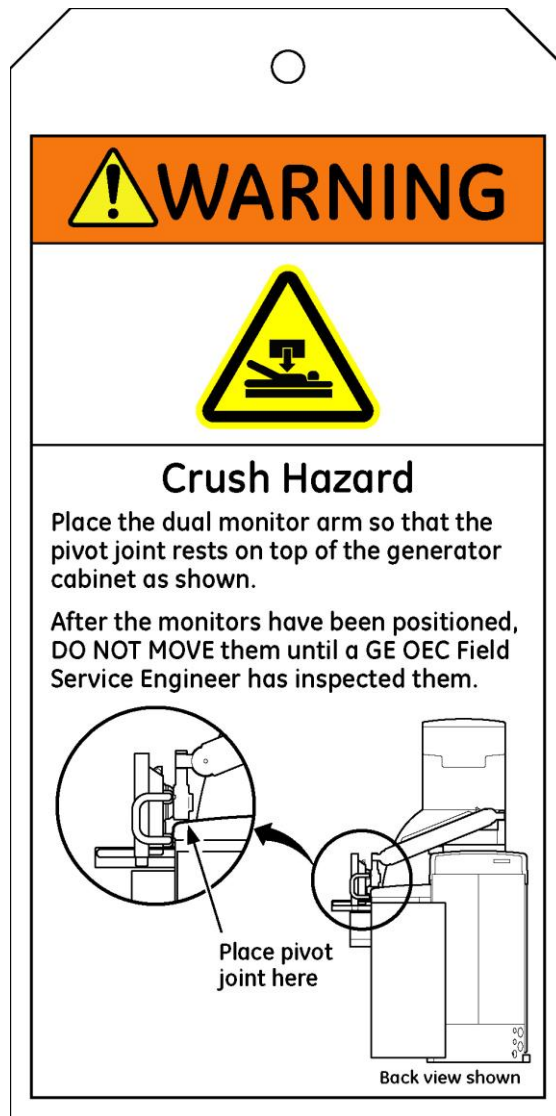


Figure #2 – Example of WARNING Tag – Apply to 2800 Dual Monitor Handle

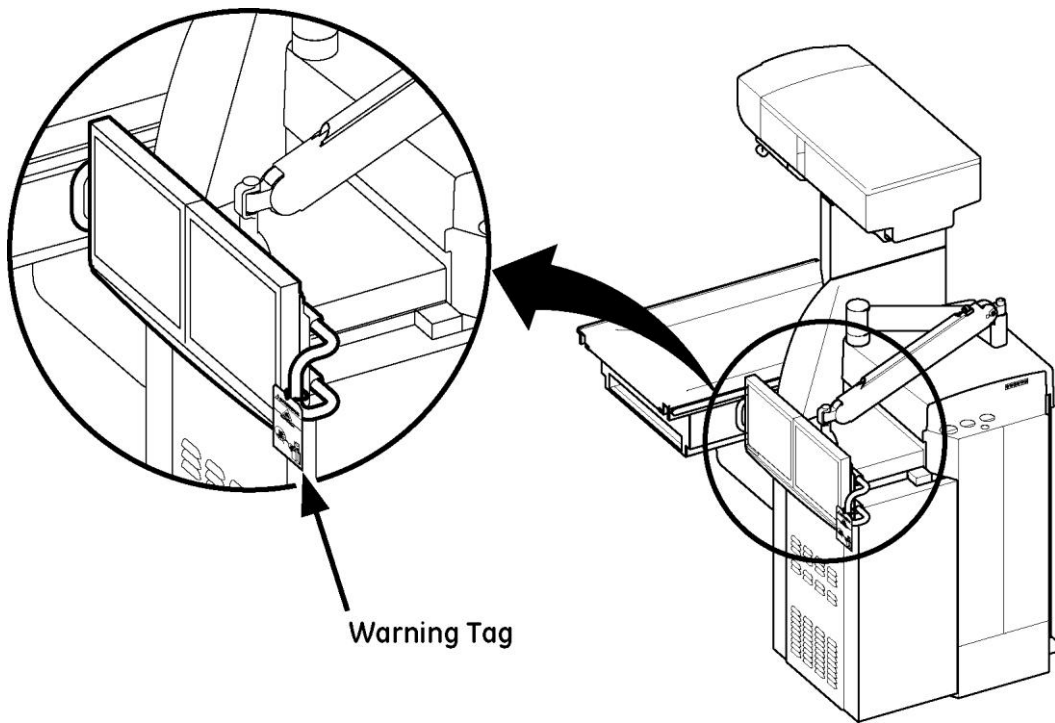


Figure #3 – WARNING Tag Position on 2800 System

2. 2800 3 Phase Power Distribution Box Shock Hazard:

Affected Products: OEC® UroView 2800

The 2800 3 Phase Power Box has been found to be not in compliance with the specifications. The following issues have been identified that can present a potential electrical safety hazard:

- Interlock mechanism on some boxes prevents the user from energizing the panel without first disengaging the mechanism. The effected locking mechanism is located inside the door and should allow the user to engage the power to the Power Box with the door closed, this does not always function as designed and results in the user having to push on the door to be able to engage the power.
- External latch and interlock mechanism on some box doors have been found to be inadequate and could allow the door to open with power energized.
- User can engage power with the box door slightly open.

The box door should always be closed completely and the external latch engaged before energizing the unit.



2800 3 Phase Power Box

Interim Solution:

Until a solution has been identified and installed at your facility, users are cautioned to **ensure that the access door to the 3 Phase Power Box is completely closed when the unit is powered on.**

Failure to do so can present a shock hazard to the user.

GEHC OEC is actively working on solutions that will permanently resolve both of these issues. When solutions become available, GEHC OEC will contact you and without charge, remedy these issues.

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 a day, 7 days a week.

Thank you,

A handwritten signature in cursive script that reads "Pete McCabe".

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