

A21266 - High Priority Medical Device Alert

Medical Device Ongoing Action

Updated: November 22, 2013

UMDNS Terms:

- Radiographic Systems, Digital [18430]
- Radiographic Systems, Film [17174]
- Mounts, Monitor [15311]

Suggested Distribution:

- Clinical/Biomedical Engineering
- Diagnostic Imaging

Geographic Regions:

- Australia
- Canada
- China
- Egypt
- Europe
- Japan
- Korea
- Saudi Arabia
- Turkey
- United Arab Emirates
- U.S.

GE—Video Monitor Suspensions Used with Various X-Ray Imaging Systems: May Be Missing Screws

Product Identifier:

Video Monitor Suspensions used with the following X-Ray Imaging Systems: (1) Legacy, (2) Monitrol, (3) Precision 500D, (4) Prestige SI, (5) Prestige SII, (6) Prestige VH, (7) Prestilix, (8) RFX, (9) SFX, (10) Tilt-C [Capital Equipment]

All CRT monitor suspensions installed beginning January 1993

Manufacturer:

- GE Healthcare USA9900 Innovation Dr, Wauwatosa, WI 53226, United States

Summary: On November 22, 2013, the manufacturer confirmed the information in the source material and provided the geographic regions of distribution bolded above.

Problem: In a November 7, 2013, Urgent Medical Device Correction letter submitted by ECRI Institute member hospitals, GE states that the above x-ray systems may be missing the 4 outer screws that hold the overhead video monitor suspension to the carriage, potentially increasing the risk of the monitor suspension falling. GE also states that it has received no reports of the suspension falling and no reports of patient injury related to this problem.

Action Needed: Identify any affected product in your inventory. If you have affected product, verify that you have received the November 7, 2013, Urgent Medical Device Correction letter from GE. Refer to the picture in the [letter](#), and visually check that the 4 screws (A1, A2, A3, A4) are present on affected systems. If the screws are missing, immediately contact your GE local representative to arrange for a product correction. A GE representative will contact your facility to arrange for inspection and correction at no cost.

For Further Information:

GE
U.S.
Tel.: (800) 437-1171
Japan
Tel.: (0120) 055919
Website: [Click here](#)

Comment:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our [HDA Format Guide](#).

Source(s):

- 2013 Nov 14. Member Hospital. GE letter submitted by ECRI Institute member hospitals. GE reference no. 10887
- 2013 Nov 22. Manufacturer. Manufacturer confirmed information