



Urgent Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226,
USA

GE Healthcare Ref: FMI 12164

2011-07-13

To: Hospital Administrators / Risk Managers
Radiology Managers
Mammography Managers

RE: **Seno Advantage 2.1 and 2.2 Workstations with RIS CCOW integration: Patient Mismatch**

GE Healthcare has become aware that patient mismatch could occur on some Seno Advantage workstations. This issue may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue When Seno Advantage workstation is synchronized with RIS using CCOW (an HL7 standard protocol designed to enable disparate applications to synchronize in real-time), the following issues could occur:

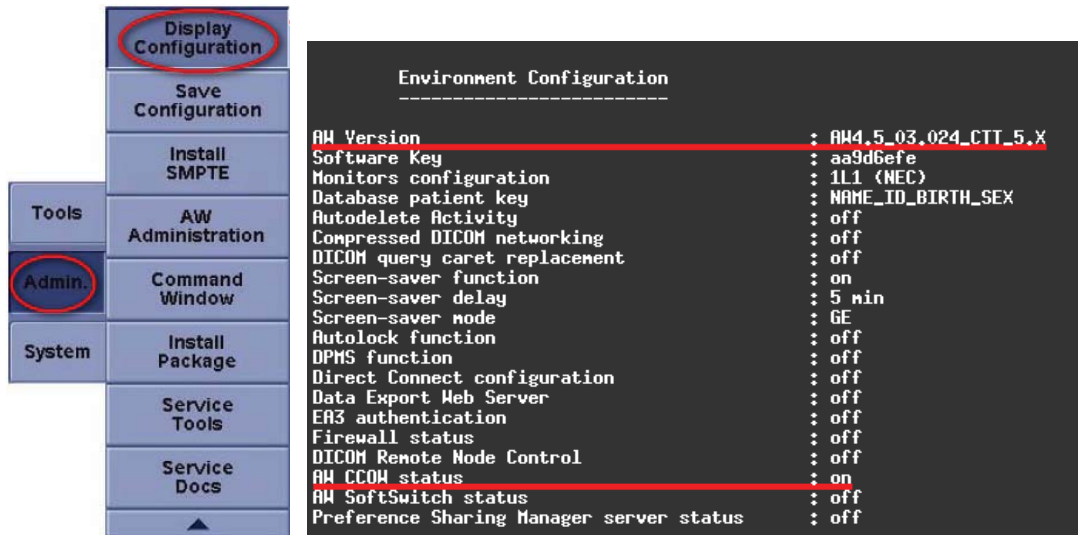
1. Two different patient images may be displayed at the same time. The Seno Advantage workstation may display one patient's multi-modality images on the 1 megapixel (landscape) color monitor and another patient's Mammography images on the 5 megapixel (portrait) high-resolution black and white monitors. The Patient name annotation is correct whenever it is displayed on any monitor.
2. The patient images displayed on the Seno Advantage high-resolution black and white monitors may not show images of the patient selected on RIS and on the Seno Advantage color monitor. The Patient name annotation is correct whenever it is displayed on any monitor.

Please refer to the Appendix for more details.

Safety Instructions Visually verify the patient images and selection displayed on the RIS monitor, color monitor and the high-resolution black and white monitors are the same patient. Make sure that the patient name is displayed on all monitors to identify that the patient selection and images belong to the same patient.

Affected Product Details Seno Advantage workstations version 2.1 and 2.2 using CCOW synchronization with specific AW versions are affected. To know if your workstation is affected, click on the Admin button on the color monitor, select Display Configuration from the List and check the following two lines, both should match:

- AW Version: AW4.4_04 up to and including AW4.4_09, AW4.5_02, or AW4.5_03
- AW CCOW status: on



Product Correction GE Healthcare will upgrade all affected workstations at no cost. A GE Healthcare service representative will contact you to arrange for this correction.

Contact Information If you have any questions regarding this Field Safety Notice or the identification of affected items please contact your local Sales/Service representative.

GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately.

Sincerely,



[Redacted]
Vice President QARA
GE Healthcare Systems

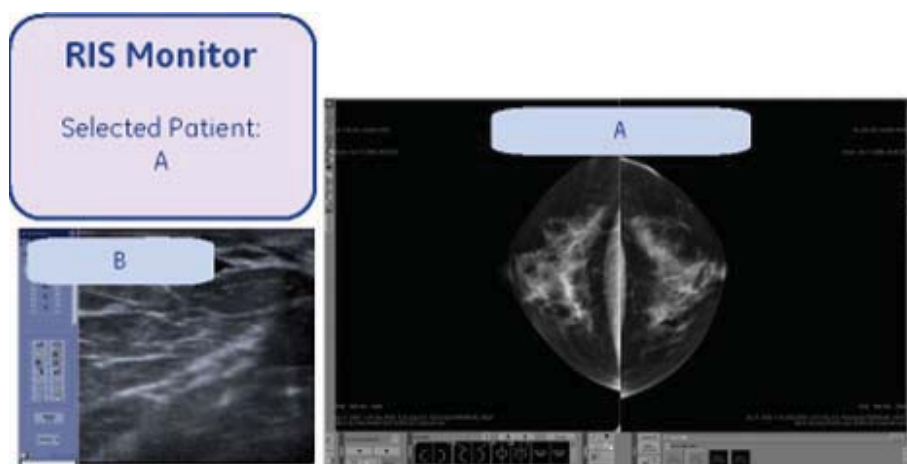


[Redacted] M.D., FRCA
Chief Medical Officer
GE Healthcare

Safety Issue

1. When Seno Advantage workstation is synchronized with RIS using CCOW, two different patient images may be displayed at the same time. The Seno Advantage workstation may display one patient's multi-modality images on the color monitor and another patient's Mammography images on the high-resolution black and white monitors. The Patient name annotation is correct whenever it is displayed on any monitor.

Mismatched Display: Patient A on RIS monitor, Patient B on Seno Advantage color monitor and Patient A on Seno Advantage high-resolution black and white monitors.



2. When Seno Advantage workstation is synchronized with RIS using CCOW in a way that if you select the next patient on Seno Advantage Patient List the RIS selection is automatically updated, the patient images displayed on Seno Advantage high-resolution black and white monitors may not show images of the patient selected on RIS and on Seno Advantage color monitor. The Patient name annotation is correct whenever it is displayed on any monitor.

Mismatched Display: Patient B on RIS monitor and on Seno Advantage color monitor and Patient A on Seno Advantage high-resolution black and white monitors.

