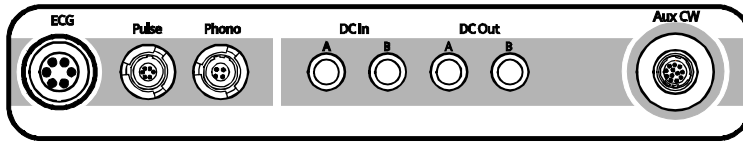
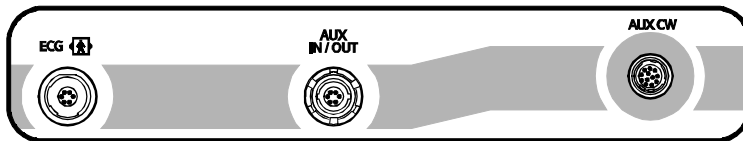


CUSTOMER SAFETY ADVISORY NOTIFICATION

To users of the ACUSON SC2000 ultrasound system with 5.0 software versions VB20A, VB20B, or VB20C and the ECG (physio) hardware and Auxiliary (AUX IN/OUT) cable



Example of ECG (physio) hardware **not impacted**.



Example of **impacted** ECG (physio) hardware on SC2000 5.0 systems manufactured prior to 14 December 2017.

Dear Valued Customer:

This letter is to notify you of a potential issue on your ACUSON SC2000 ultrasound system.

When does this issue arise and what is the potential risk?

We have become aware that in some cases the ECG signal may flatline due to electromagnetic interference during the use of electrosurgical equipment.

This issue may occur when using electrosurgical equipment and the physio module introduced in VB20 (Release 5.0) with the Auxiliary (AUX IN/OUT) cable.

The electrosurgical equipment creates electromagnetic interference (EMI) which is then transmitted to the physio module and the SC2000 system through the AUX IN/OUT cable. This interference causes the system to lose communication with the physio module.

The loss of communication with the physio module results in the loss of the ECG signal with no notification to the user.

The ECG flatlines, and delays of up to 20 seconds in system function may occur when the user attempts to clip capture or modify imaging parameters, such as depth.

Clip capture is not functional. Static frame captures are possible.

If the user does not utilize the steps outlined in this letter, allowing them to continue with the study, a potential risk in delay of the procedure may occur. In cases of a transesophageal (TEE) study, there is the potential for the user to reinsert a TEE transducer as a method to recover system functionality should the user not be aware of this issue and alternate steps. There have been no reported injuries to date and the risk for patient injury was determined to be unlikely.

11290345-691-001-01 AXSC 1/60

What steps can the user take to avoid potential risk of this issue?

If the ECG trace disappears or flatlines, perform the following steps to disable the ECG trace and exit the physio module functionality:

1. Press **F13 (Physio)** on the keyboard.
2. Press the scroll wheel to select the appropriate **ECG** or **AUX** trace option and then press the **Off** soft key.
3. To exit the Physio menu, press **F13 (Physio)** again.

After these steps are performed, the ultrasound system will use time-based captures instead of beat captures.

Also note that the system may be rebooted to reset the ECG trace. However, if the electrosurgery equipment is used again the symptom will reoccur.

How will this issue be resolved?

This issue will be resolved by a hardware update to your system. Siemens Customer Service will contact you to schedule your replacement if your system configuration is affected by the scope of this issue. If you have any further questions, please contact your Customer Care Center.

Please share this information with all personnel within your organization who need to be aware of this issue.

We sincerely regret any inconvenience this condition may cause in your daily operations.

Sincerely,

Mazi Kiani
VP, Quality and Technology
Siemens Medical Solutions USA, Inc.
Ultrasound Business Area
English