

## CUSTOMER SAFETY ADVISORY NOTIFICATION

To users of the Siemens Z6Ms transesophageal transducer with a serial number listed below,

Dear Valued Customer:

This letter is to notify you of an issue with the Siemens Z6Ms transesophageal transducer.

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

We have received reports about "acquisition errors" and the deterioration of material covering the articulating section of the Z6Ms transesophageal transducer.

To date, no patient injury has been reported, and we believe the risk of injury to be remote. However, "acquisition errors" can cause a delay in the study for patients who are consciously sedated and possibly expose the patient to a second intubation.

Also, a compromise or fault in the transducer's material, combined with a failure to use a transducer sheath as directed in the user manual, may cause esophageal cuts, bleeding, and perforation to the patient, and severe trauma, electrical burns, and serious electrical hazards to the patient.

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

#### **Continue Use**

You can continue to use the Z6Ms transesophageal transducer if the transducer passes the required leakage current test and if you connect and activate the transducer prior to preparing the patient for a transesophageal procedure.

#### **Acquisition Error**

"Acquisition error" messages commonly present themselves upon connection and selection of the transducer, therefore, always connect and activate the transducer prior to patient preparation.

#### **Articulation Material**

Leakage current tests indicate cracks, cuts, tears, perforations, and protrusions in the articulation material.

To help avoid the potential risk associated with these issues, the following steps are required:

- Perform the leakage current test for a transesophageal transducer prior to each use. Follow the manufacturer's instructions included with the tester.
- Use only Siemens approved cleaning and disinfecting solutions. Carefully follow the manufacturer's instructions.
- Use transducer sheaths specifically designed for TEE applications. Follow the instructions provided by the manufacturer of the transducer sheath.

These required steps and other recommended steps are provided in the existing user manual for your ultrasound system.

## Discontinue Use

If you notice any damage or wear on your transducer, or if the transducer fails to pass the leakage current test, immediately discontinue use of the transducer and contact your local Customer Service Engineer.

### How will this issue be resolved?

New Z6Ms transducers are shipping from manufacturing with corrections for both the articulation sleeve material and root cause of the "acquisition errors."

Siemens will initiate a product replacement of the Z6Ms transducers with a serial number on the following list:

63029009	63029015	63029016	63229003	63229007	63229008	63229011
63229012	63230002	63230003	63230009	63260584	63260585	63319012
63322007	63325007	63328003	63328007	63329017	63329018	63332002
63332004	63360611	63360612	63430519	63430524	63432007	63432010
63432015	63432017	63530515	63530516	63530518		

### If you have any questions, please contact your local service support person for information.

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

As always, patient safety issues are a high priority, and we alert customers of product concerns which may occur under various conditions.

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

Sincerely,



Robert Gifford  
Head of Supply Chain Management and Quality  
Siemens Medical Solutions USA, Inc.  
Ultrasound Business Area

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