

CUSTOMER ADVISORY NOTIFICATION

To users of the V5Ms transesophageal transducer

Dear Valued Customer:

First, let us thank you for being a Siemens ACUSON customer.

Due to our ongoing quality improvement efforts, we are informing you of an engineering advisory for increasing the lifetime of your V5Ms transesophageal transducer.

As a result of recent engineering investigations, the yellow tip protector shipped with the V5Ms transducer has proven to be incompatible with the material for the articulation sleeve on the transducer.

We recommend you immediately discontinue use of the yellow tip protector.

Additionally, to ensure proper use and care of the V5Ms transducer, 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.
- Siemens recommends that you use market-cleared transducer sheaths specifically designed for transesophageal applications. Follow the instructions provided by the manufacturer of the transducer sheath.
- When you store the transesophageal transducer, take extreme care that the distal tip is straight. Never move the distal tip by hand. Always use the flex controls.

These recommended steps are also provided in the user manual for your ultrasound system.

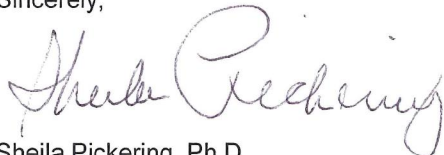
In addition to the above guidance, we are in the process of identifying a replacement for the yellow tip protector. When the replacement becomes available, your local Siemens organization will notify you.

If you should 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.

Please share this information with all applicable personnel within your organization.

If you have any questions, please do not hesitate to contact your local Siemens Customer Care Center.

Sincerely,



Sheila Pickering, Ph.D.
Senior Director, Quality and Regulatory Affairs
Siemens Medical Solutions USA, Inc.
Ultrasound Business Unit

English