Halo Medical Technologies

Transrectal Ultrasound Probe and Proctoscope System

for Use with Catalyst™ Ultrasound Systems

Instructions for Preparation and Use

CAUTIONS AND WARNINGS

READ CAREFULLY BEFORE USE!

Prescription Device Statement

CAUTION: Federal law restricts this device to sale by or on the order of a licensed physician.

Appropriate Specialists

WARNING: The Catalyst XL system should only be used on the request by and under the direction of a licensed physician specialist.

System Use

WARNING: CATALYST SOFTWARE IS SUPPLIED ON EQUIPMENT PROVIDED BY HALO MEDICAL TECHNOLOGIES ONLY. CATALYST SOFTWARE SHOULD NEVER BE INSTALLED AND USED ON OTHER COMPUTERS OR MEDICAL EQUIPMENT SUPPLIED BY OTHER VENDORS. All equipment provided by Halo Medical Technologies is labeled with name, part number, and serial number. If there is a question about the authenticity of the equipment or software, DO NOT USE IT and contact Halo Medical Technologies Customer Service at (877) 686-8149.

WARNING: Only trained technicians should operate this device. The operator should read the User Manual entirely and refer to any additional training materials before using the device.

WARNING: Before the patient exam, inspect the HALO Transrectal Ultrasound Probe for any physical damage such as leaking fluid and/or cracked and/or broken: membrane; housing; strain relief; stand-by switch; USB cable. Inspect the proctoscope system for any signs of damage. If physical damage exists, do not use for patient evaluation and call Halo Medical Technologies for servicing.

WARNING: Always use the transducer probe appropriate for the exam. Connect only one probe to the system at a time.

WARNING: Use the HALO™ Transrectal Probe and with Halo Medical Technologies Catalyst ultrasound systems ONLY.

WARNING: Catalyst software is warranted to work with MidCRYSTL and HALO probes ONLY.

WARNING: Always disconnect the probe from the system before maintenance or cleaning.

WARNING: The USB cable is an integral part of the probe assembly. DO NOT ATTEMPT to disconnect the USB cable from the probe.

WARNING: Keep the cable USB connector end dry at all times. Do not immerse the probe beyond the tip of the handle where the cable meets the handle. Make sure the USB connector is dry before connecting it to the Catalyst system.

WARNING: DO NOT ATTEMPT TO OPEN OR REPAIR the system or probes. ONLY trained Halo Medical Technologies technicians may service these devices.

WARNING: Any additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO Standard (e.g., IEC 60950 for Data Processing Equipment). All configurations shall comply with the requirements for Medical Electrical Systems. Anyone connecting supplementary equipment to Medical Electrical Equipment configures a Medical System and is therefore responsible that the system complies with the requirements for Medical Electrical Systems.

CAUTION: Portable and mobile RF communications equipment may affect the normal function of the HALO transrectal ultrasound probe.

CAUTION: Be careful when handling the USB probe. If the USB probe dropped on a solid surface it can be damaged.

CAUTION: Do not store the probe in the shipping case. It may become a source of infection.

To prevent damage to the probe, do not store in areas where it might be exposed to:

- Excessive vibration
- Excessive dust & dirt

Store the probe under the following ambient conditions:

- Temperature: -10°C to 50°C (14°F to 122°F)
- Relative Humidity: 20% to 80% (no condensation)
- Atmospheric pressure: 700 hPa to 1060 hPa

Indications for Use

"Catalyst" is a diagnostic ultrasound system designed to be used for investigating disorders of the pelvic floor. An ultrasonographic crystal within the probe records images of the organ, muscle, and tissue structures of the pelvic region. MidCRYSTL and HALO probes allow for ultrasonography of the following: 1) on the surface of the perineum and/or abdomen, 2) endocavity, by inserting the endovaginal probe into the vagina, and 3) endocavity, by inserting the endoanal probe into the anal canal.

Contraindications

The safety of the individual being tested is the sole responsibility of the physician performing the diagnostic study. The system is contraindicated for any patient with one or more of the following conditions:

- The system is not indicated for use on a patient who is pregnant
- Uncooperative patients
- Patients with GI bleeding
- Patients who are comatose or incapable of providing informed consent for the procedure
- For endoanal/transrectal applications: It is inappropriate to insert the probe and perform an endoanal/transrectal ultrasound procedure on individuals who have a degree of anal stenosis and/or have an anal canal deemed too narrow or short for its insertion, as is typical of infants

Safety Information

ALARA Declaration

Ultrasound is considered safe at low clinical levels for short exposure, as is typical of examinations performed with Catalyst ultrasound systems. At high levels and longer exposures, however, its safety is not completely understood. For this reason, always exercise caution when exposing patient to ultrasound. Always use the lowest transit power levels and minimize the time of exposure.

The potential benefits and risks of each examination should be considered. The *as low as reasonably achievable* (ALARA) principle should be observed when adjusting controls that affect the acoustic output and by considering transducer dwell times.

Further details on ALARA may be found in the AIUM publication "Medical Ultrasound Safety, Third Edition." (Publication available through online store at http://www.aium.org/)

Probe Cover Latex Warning

WARNING: To prevent infection and cross contamination between patients, always use a probe cover (sheath) during endocavity examinations. Use a non-latex probe cover (as supplied in the Rectal Scanning Kit, part number HMT-RSK) or equivalent to avoid common and potentially dangerous, allergic reactions to latex.

Other probe covers may contain latex, natural rubber and talc, which may cause allergic reactions. For more information, see the Food and Drug Administration, “Allergic Reactions to Latex Containing Medical Devices,” *FDA Medical Alert,* Pub. No. MDA91-1 (March 29, 1991).

Transrectal Probe Infection Control

WARNING: Follow all infection control policies/procedures established within the clinical institution to prevent any cross-contamination. Users must provide the highest level of infection control for patients,
for co-workers, and for themselves at all times.

WARNING: Probes must be cleaned and disinfected after each use.

WARNING: The type of tissue contacted by the probe during use dictates the level of disinfection required for a device. Ensure that the solution strength and duration of contact are appropriate for disinfection. Be sure to follow the manufacturer's instructions.

WARNING: Using a non-recommended disinfection solution, incorrect solution strength, or immersing a probe deeper or for a period longer than recommended can damage or discolor the probe and will void the probe warranty.

WARNING: Do not immerse probes in any solution longer than prescribed duration. Probes may be damaged by longer immersion times. Do not use heat or radiation to sterilize. This will permanently damage the probe and void the warranty.

WARNING: Disinfect probes using only liquid solutions. Using autoclave, gas (EtO), or other non-HALO approved methods will damage the probe and void the warranty.

WARNING: Do not use a brush when cleaning probes; even the use of soft "brushes" can damage the probe.

Proctoscope System Infection Control

WARNING: Follow all infection control policies/procedures established within the clinical institution to prevent any cross-contamination. Users must provide the highest level of infection control for patients,
for co-workers, and for themselves at all times.

WARNING: All instruments should be cleaned and disinfected immediately after use. Disassemble where applicable. Remove any residual blood, protein material and contamination from instruments with a cloth or sponge. Do not allow blood or tissue to dry on instruments. Never use abrasives to clean instruments. Use only neutral pH solutions for cleaning. Flush instruments and ports (where applicable) well with distilled water after disinfecting.

WARNING: After cleaning, inspect instruments for signs of damage. Worn or damaged instruments should be removed for repair or replacement.

WARNING: The type of tissue contacted by the probe during use dictates the level of disinfection required for a device. For disinfection, ensure that the solution strength and duration of contact are appropriate. Be sure to follow the manufacturer's instructions.

WARNING: Using a non-recommended disinfection solution, incorrect solution strength, or immersing instruments deeper or for a period longer than recommended can damage or discolor the probe and will void the probe warranty. Do not mix instruments made of different metals such as chrome, aluminum, and stainless steel during the cleaning process as this can cause rusting and should be avoided.

WARNING: Do not leave instruments in disinfecting solutions overnight, as this may damage the instruments. Never soak instruments in bleach.

Steam Sterilization (Autoclave) Parameters

WARNING: The approved sterilization parameters provided in this document are only valid with sterilization equipment that is properly maintained and calibrated. The sterilizer manufacturer's written instructions should be followed. Any deviation from the recommended parameters for sterilization should be validated by the user.

Cyber-Security

The Catalyst XL system has been designed with a closed architecture structure as a stand-alone device. If the system is connected to a network, the end user is responsible for all Cybersecurity aspects for information security, including but not limited to: confidentiality, integrity, availability, and accountability.

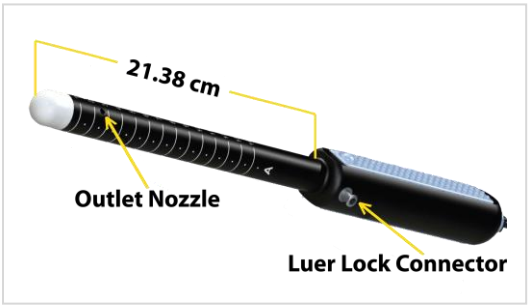
Catalyst Software Instructions

Please refer to separate "CatalystXL™ Ultrasound System User Manual" Document.

TABLE OF CONTENTS

PROCEDURE EQUIPMENT AND ACCESSORIES

- Catalyst™ Ultrasound System from Halo Medical Technologies
- HALO Transrectal Probe (part no. HMT-TRP) with infusion channel
- Proctoscope with obturator and viewing window (part no. HMT-PRBS)
- Rectal Scanning Kit (part no. HMT-RSK), containing non-sterile, latex-free transducer probe cover (1), stopcock (1), O-rings (3), and bands (2)
- Ultrasound gel
- Lubrication
- 30CC or larger syringe
- Sterile water
- Portable light source (optional)
- Manual insufflator (optional)



HALO Transrectal Probe
with built-in infusion channel

Proctoscope System
with obturator, light post and viewing window

Rectal Scanning Kit

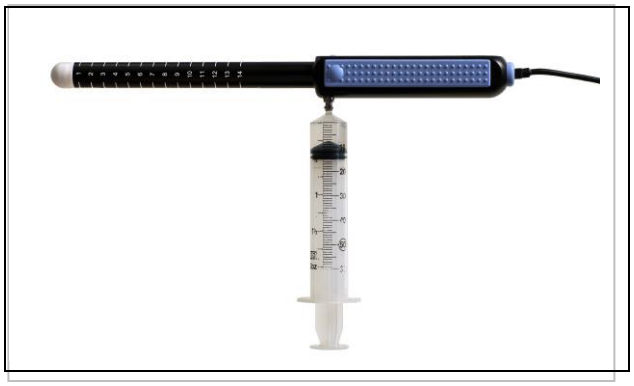
TRANSRECTAL PROBE PREPARATION FOR USE

⚠ **WARNING:** Before the patient exam, inspect transrectal probe for any physical damage such as leaking fluid and/or cracked and/or broken: membrane; housing; strain relief; stand-by switch; USB cable. Inspect the proctoscope for any signs of damage. If physical damage exists, do not use for patient evaluation and call Halo Medical Technologies for servicing.

⚠ **WARNING:** Always maintain the cleanliness of the probe cover.

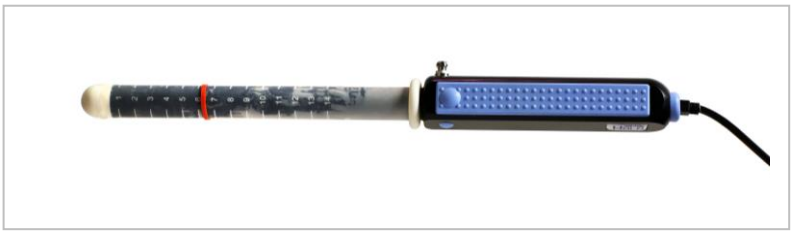
1) Attach a two-way stopcock to probe
   (NOT PICTURED BUT ESSENTIAL)

2) Instill 20cc water to syringe to prime the water pathway of the HALO transrectal probe. Close stopcock. Remove syringe.



3) Open Rectal Scanning Kit. Unroll balloon (latex-free probe cover) over HALO transrectal probe.

4) Put orange bands over the balloon on the transducer probe, placing it anywhere below the 4/5cm line. This will secure the probe cover against leaking water during the procedure. *Note: If using the probe without the proctoscope, two bands must be used to ensure water seal.*

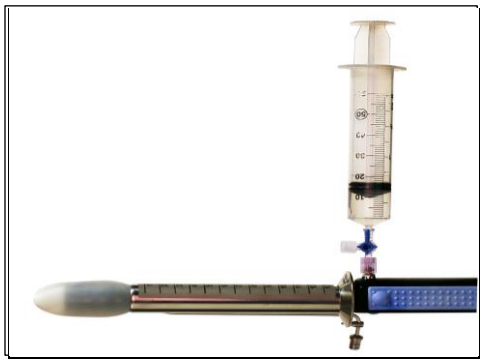


5) Instill up to 60 cc water into syringe, and attach it to the two-way stopcock.

1) Apply lubricant to outside of proctoscope and obturator. Insert proctoscope with obturator into patient.

2) Remove obturator and attach viewing window to confirm location of lesion. Light and air can be attached, if desired.

3) Remove viewing window. Apply ultrasound gel liberally on the tip of the prepared transrectal probe. Insert through the proctoscope to the appropriate depth for best visualization of lesion.



4) Slowly instill **small** amount of fluid into probe to achieve the best visualization.

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Note:
it is important to instill only a small amount of fluid into the balloon, as excess fluid will cause image distortion.

CAUTION: Do not instill water until the probe is inserted into the patient to the appropriate depth. This image is for instructive purposes only.

5) Perform exam. Note: Probe orientation is indicated on the TRUS probe, with "P" for posterior, and "A" for anterior. Orient the probe with "P" facing the patient's spine.

⚠ **WARNING:** Balloon must be deflated before removing transrectal probe from patient by retracting water with a syringe.

6) To end exam, first deflate balloon by retracting fluid back into syringe after procedure. Then, remove transrectal probe. Finally, remove proctoscope.

⚠ **WARNING:** Always disconnect the probe cable from the computer before performing maintenance or cleaning.

☣ **WARNING:** Discard used probe covers into proper biohazard waste container. Disposal of all regulated waste must be in accordance with applicable state regulations.

⚠ **WARNING:** Probes must be cleaned and disinfected after each use. DO NOT immerse the entire handle in fluids. The cord, INCLUDING THE HUB WHERE CORD MEETS PROBE HANDLE MUST BE DRY AT ALL TIMES.

⚠ **WARNING:** Do not use a brush when cleaning probes; even the use of soft brushes can damage the probe. Use only soft sponges or cloths.

⚠ **WARNING:** Always use protective eyewear and gloves when cleaning and disinfecting any equipment.

After use, the balloon (probe cover) should be removed and discarded into biohazard waste container. Care should be taken not to contaminate the probe with secretions from the patient. Cleaning is an essential step in the process and must be done prior to high level disinfection. **All probes supplied by HALO Medical Technologies can be submerged up to, but NOT INCLUDING, the END OF HANDLE/CORD CONNECTION.** The End of Handle/Cord Connection can be disinfected using commercially available wipes including but not limited those containing bleach, hydrogen peroxide, glutaraldehyde, and other germicidal disinfectants.

Using commercially-available neutral or near neutral pH detergent or enzymatic cleaner, wash the exterior of the probe and handle. Please follow manufacturer's instructions closely as it pertains to duration and/or dilution. Connect a syringe to the luer lock channel on the probe and flush with enzymatic cleaner. Upon completion of cleaning, rinse the surface of the probe. Attach a syringe to the luer lock channel and flush with water. Next, using a syringe, flush the luer lock channel with air. Finally, dry the exterior of the probe with a soft towel. At the completion of the procedure, hands should be thoroughly washed with soap and water. Next follow "High Level Disinfection" Procedures.

TRANSRECTAL PROBE HIGH LEVEL DISINFECTION INSTRUCTIONS

⚠ **WARNING:** Disinfect probes using only liquid solutions. Using autoclave, gas (EtO), or other non-Interson-approved methods will damage the probe and void the warranty.

Because endocavity ultrasound probes are considered "semi-critical" medical devices, they require high-level disinfection. Recommended high level disinfectants include the following:

- 2.4-3.2% glutaraldehyde products:
  - Cidex® Fast-Acting High Level Disinfectant, from ASP (Ethicon US,LLC)
  - MetriCide® High Level Disinfectant, from Metrex (Sybron Dental Specialties, Inc.)
  - Procide-D® High Level Disinfectant, from Metrex (Sybron Dental Specialties, Inc.)

- Non-glutaraldehyde agents:
  - Cidex OPA® High Level Disinfectant (o-Phthalaldehyde), from ASP (Ethicon US,LLC)
  - Nu-Cidex® High Level Disinfectant (Peracetic Acid), from ASP (Ethicon US,LLC)

- 7.5% Hydrogen Peroxide solution
  - Revital-Ox™ Resert® High Level Disinfection (Steris Corporation)

Each solution has individual guidelines for disinfection times and procedures. Please refer to manufacturer's instructions for specific instructions and disinfection guidelines to ensure that high-level disinfection is met.

The endocavity portion of the probe must be High Level Disinfected. It is ok to immerse beyond the endocavity portion of the probe up to, BUT not including the junction of the handle/cable. The cable, INCLUDING THE HUB WHERE CORD MEETS PROBE HANDLE MUST BE DRY AT ALL TIMES.

The luer lock channel, while isolated, should also be High Level Disinfected. This is accomplished by connecting a luer lock syringe filled with the HLD and flushing the channel.

For rinsing, please follow HLD manufacturer's instructions and guidelines. Ensure that the probe surface and water channel are free of disinfectant prior to use.

⚠ **WARNING:** Using a non-recommended disinfection solution, incorrect solution strength, or immersing a probe deeper or for a period longer than recommended can damage or discolor the probe and will void the probe warranty.

⚠ **WARNING:** Do not immerse probes longer than prescribed duration. Probes may be damaged by longer immersion times. Do not use heat or radiation to sterilize. This will permanently damage the probe and void the warranty.

PROCTOSCOPE SYSTEM CLEANING AND DECONTAMINATION INSTRUCTIONS

⚠ **WARNING:** All instruments must be cleaned and disinfected after each use. Remove any residual blood, protein material and contamination from instruments with a soft cloth or sponge. Do not allow blood or tissue to dry on instruments. Never use abrasives to clean instruments. Use only neutral pH solutions for cleaning.

⚠ **WARNING:** Do not mix instruments made of different metals such as chrome, aluminum, and stainless steel during the cleaning process as this can cause rusting and should be avoided.

⚠ **WARNING:** After cleaning, inspect instruments for signs of damage. Worn or damaged instruments should be removed for repair or replacement.

⚠ **WARNING:** Most chemical or cold sterilization solutions render instruments sterile only after 10-hours immersion. This prolonged chemical action can be more detrimental than the usual autoclave cycle. If instruments need to be disinfected only, a cold sterilization soak is acceptable as disinfection will take approximately 10-20 minutes, depending on the specific solution. Follow manufacturer's specifications.

⚠ **WARNING:** For chemical or cold sterilization solutions, follow all manufacturer's instructions with regards to concentration of solution and duration of soaking. Do not leave instruments in disinfecting solutions overnight, as this may damage the instruments. Never soak instruments in bleach.

⚠ **WARNING:** Flush instruments well with distilled water after disinfecting.

Clean and disinfect instruments immediately after use. Disassemble instruments where applicable.

Using a commercially-available, neutral pH cleaning solution, wash the instruments thoroughly. Use a nylon brush or soft cloth to remove any contamination. Never use abrasives. Cleaning is an essential step in the process and must be done prior to high level disinfection. At the completion of the procedure, hands should be thoroughly washed with soap and water. Next follow Sterilization Instructions below.

PROCTOSCOPE SYSTEM STEAM STERILIZATION or HIGH LEVEL DISINFECTANT INSTRUCTIONS

Use proper technique to render instruments in the required condition for use. Remember that "Sterile" is an absolute term – no living organisms survive. "Disinfected" means that some organisms may survive.

⚠ **WARNING:** The approved sterilization parameters are only valid with sterilization equipment that is properly maintained and calibrated. The sterilizer manufacturer's written instructions should be followed. Any deviation from the recommended parameters for sterilization should be validated by the user.

⚠ **WARNING:** Sterilization temperatures should not exceed 280ºF (137ºC). Other temperatures should be validated by the autoclave manufacturer.

Proctoscopes are considered "semi critical" devices thus require a minimum of "High Level Disinfection". Recommended high level disinfectants include the following:

- 2.4-3.2% glutaraldehyde products:
  - Cidex® Fast-Acting High Level Disinfectant, from ASP (Ethicon US,LLC)
  - MetriCide® High Level Disinfectant, from Metrex (Sybron Dental Specialties, Inc.)
  - Procide-D® High Level Disinfectant, from Metrex (Sybron Dental Specialties, Inc.)

- Non-glutaraldehyde agents:
  - Cidex OPA® High Level Disinfectant (o-Phthalaldehyde), from ASP (Ethicon US,LLC)
  - Nu-Cidex® High Level Disinfectant (Peracetic Acid), from ASP (Ethicon US,LLC)

- 7.5% Hydrogen Peroxide solution
  - Revital-Ox™ Resert® High Level Disinfection (Steris Corporation)

Each solution has individual guidelines for disinfection times and procedures. Please refer to manufacturer's instructions for specific instructions and disinfection guidelines to ensure that high-level disinfection is met.

As an alternative method, the Proctoscope may be steam sterilized. Steam sterilization has been validated as an effective process for reusable instruments. Ensure your autoclave is operating correctly for effective sterilization. Consult your autoclave manual for specific instructions, conditions, and exposed periods.

For gravity displacement steam sterilization: 250ºF (121ºC) with a 30-minute exposure time is recommended. Or, 270ºF (132ºC) with a minimum of 5-minute exposure time.

For pre-vacuum conditioned steam sterilization, 270ºF (132ºC) with a 5-minute exposure time is recommended.

Use only distilled water in the sterilizer reservoir. Tap water contains minerals that will stain instruments if left to dry on the instruments.

At the end of the autoclaving cycle, unlock the door and open only slightly. Run the dry cycle for the recommended time. Fully opening the door before the dry cycle will allow condensation to form on the instruments and water stains will appear.

TRANSPORTATION AND STORAGE OF TRANSRECTAL PROBE

CAUTION: Never carry the probe by the cable. The cable could disconnect from the probe allowing it to drop and possibly damaging the probe.

CAUTION: Never bend the USB cable in a tight radius. This could result in damage to the cable.

CAUTION: Do not store the probe in the shipping case. It may become a source of infection.

CAUTION: Be careful when handling the USB probe. If the USB probe dropped on a hard surface it can be damaged.

To prevent damage to the probe, do not store in areas where it might be exposed to:

- Excessive vibration
- Excessive dust & dirt

Store and transport the probe under the following ambient conditions:

- Temperature:-10°C to 50°C (14°F to 122°F)
- Relative Humidity: 20% to 80% (no condensation)
- Atmospheric pressure: 700 hPa to 1060 hPa

When the Probe is not being used, it should be stored in a clean, dry area.

When transporting the probe to a different field location use the disinfected carrying case or enclosure that the probe was originally packaged in, or pack it in such a way that the probe is protected.

MAINTENANCE, SERVICE, AND WARRANTY REPAIR

Periodic testing and maintenance of the transrectal ultrasound probe is NOT required.

The transrectal probe and proctoscope system should be cleaned and disinfected after every use. Regularly check the transducer probe housing and front face for cracks, as this may cause a loss of fluid which would impair the performance of the probe. Regularly check the cable for cuts, cracks, and kinks. This could also impair the performance of the probe. Regularly check the proctoscope system for signs of damage.

Call Halo Medical Technologies for a Return Material Authorization (RMA) number before returning a probe or proctoscope system for evaluation and possible repair. When returning for repair, there is no need to use the original package, pack in such a way that the product is protected. This will help to control the shipping costs.

ELECTROMAGNETIC COMPATABILITY

ER 12.0 MHz/ES 12.0 MHz MidCRYSTL™ Endoanal/Transrectal Probe (60601-2-37 TUV Reinland)
EC 7.5 MHz / EB 7.5 MHz, HALO™ Endovaginal Probe (60601-2-37 TUV Reinland)
GP 3.5 MHz / AB 3.5 MHz, HALO™ Surface Probe (60601-2-37 TUV Reinland)

CONTACT INFORMATION

HALO Medical Technologies
1805 Foulk Road, Suite G
Wilmington, DE 19810
Toll-Free Phone (within USA): 877.686.8149
Worldwide Phone: 302-472-2300
E-mail: info@halomedtech.com

REFERENCES

FDA Website

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM070911.pdf

Excerpt from FDA Guidelines:

Ultrasound probes that are non-critical devices only need to be cleaned and low-level disinfected between patient uses. Probes used in semi critical applications should be sterilized whenever feasible, but high level disinfection is minimally acceptable. In addition, the use of a sheath is recommended for every semi-critical use of the probe. Critical devices should be sterilized and the use of a sterile sheath is recommended.

Please note that the use of sheaths does not change the type of processing that is recommended for the transducer. After use, the single-used sheath should be removed and discarded. The probe used in semi-critical application should be cleaned and sterilized, or at least receive a high-level disinfection after use, even if a sheath was used. Probes used for critical applications should be cleaned and sterilized after use even if a sterile sheath was used. Sheaths can fail during use and the level of resulting contamination may not be easily visible.

Center For Disease Control:

https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines.pdf

AIUM (American Institute for Ultrasound Medicine) Website

http://www.aium.org/officialStatements/27