Transrectal, Endoanal, Endovaginal and Surface Probes

INSTRUCTIONS FOR PREPARATION AND USE

For Use with Catalyst™ Ultrasound Systems

v2 (08/2026)

MD

REF

HMT-TRP
HMT-TRP 3D
HMT-MCP
HMT-MCP 3D
HMT-EVG
HMT-EVG 3D
HMT-SURM

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SYMBOLS GLOSSARY

	Medical Device
	Medical Device Manufacturer
	Contraindications
	Part Number/Item Number
	Caution
	Consult/Instructions for Use
	For Prescriptive Use Only
	Latex Free

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℞ Only Prescription Device Statement

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

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

CAUTION

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.

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.

Before the patient exam, inspect ultrasound probe(s) for any physical damage such as leaking fluid and/or cracked and/or broken: membrane; housing; strain relief and cable. If physical damage exists, do not use for patient evaluation and call Halo Medical Technologies for servicing.

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

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

Keep the cable USB connector end dry at all times. Do not submerge the probe handle/cable junction. Do not submerge the USB connection.

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

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.

Never carry the probe by the cable. The cable could disconnect from the probe handle allowing it to drop and possibly damage the probe.

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

Be careful when handling the ultrasound probe. If the probe is dropped on a hard surface, it can be damaged.

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.

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

Do not immerse probes longer than one hour. 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.

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

Do not use a surgeon’s brush when cleaning probes; even the use of soft brushes can damage the probe.

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

- Excessive vibration
- Excessive dust and 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

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 patients 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/)

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.

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 applications: It is inappropriate to insert the probe and perform an endoanal 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.

Probe Cover Latex Warning

To prevent infection and cross contamination between patients, Halo recommends the use of Halo IMPERA Impermeable barrier during endocavity (endovaginal or endoanal/ transrectal) examinations which is latex free.

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).

Catalyst Software Instructions

Please refer to Catalyst Ultrasound System User Manual. Download

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PREPARATION FOR EXAMS

Ultrasound Gel

Ultrasound gel is required for successful ultrasound imaging.

Transducer Covers

Endocavity (endoanal, transrectal, endovaginal) transducers should be covered during ultrasound exams.

Transducer covers for surface (translabial/transabdominal) are optional.

Commercially available covers can be sterile or non-sterile.

Latex-free versions are strongly recommended.

In the United States, it is recommended that only FDA-approved covers are used.

Halo ultrasound probes are compatible with most of the commercially available FDA-approved probe covers on the market.

General guidelines for the use of transducer covers with Halo ultrasound transducers:

1A Endocavity	For all endocavity exams, please introduce a generous amount of ultrasound gel into the tip of the probe cover prior to placing transducer cover over the probe
1B Surface	Covers are optional. Introduce a generous amount of ultrasound gel either inside cover or on patient contact surface.
2	After the exam is complete, the probe cover should be removed and discarded into biohazard waste container.
3	Wipe off any remaining ultrasound gel. Care should be taken not to contaminate the probe with secretions from the patient.

IMPERA Impermeable barrier

In place of transducer covers for endocavity exams, eliminates the need for High-Level Disinfection

Halo Medical offers an alternative to traditional endocavity probe covers. The IMPERA barrier for ultrasound transducers (REF 590810) is an FDA-approved, specifically-designed protective barrier for use with medical endocavity ultrasound transducers.

By providing a protective and impermeable barrier that covers the patient and clinician contact area, including the probe, handle and cable, the IMPERA barrier replaces High-Level Disinfection with Intermediate-Level Disinfection.

Please refer to the Halo IMPERA Barrier Instructions for Use for complete information and steps for the use of this product. Download

Not available for sale/pending FDA approval.

REPROCESSING STEPS

Anyone involved with reprocessing medical devices should be thoroughly trained in the healthcare facilities policies and procedures. Users have an obligation to provide infection control to themselves, their patients and co-workers. Follow all established infection control policies and procedures.

Decontamination

Applies to all Halo transducers

Decontamination (cleaning) is the physical removal of soil and contaminants from an item and is normally accomplished with neutral or near neutral pH detergents or enzymatic products.

Commonly used solutions and those that are recommended by Halo include (but are not limited to) the following:

- Metrex MetriSponge Pre-Moistened Enzymatic Sponge
- Steris Corp Revital-Ox Enzymatic Sponge
- Revital-Ox Enzymatic Sponge
- Ruhof Healthcare Endozime The Mini Sponge
- Ruhof Endozime Sponge with Bio-Clean Technology

Please refer to individual manufacturers' instructions.

1	Ensure that the entire surface of the probe (patient contact, handle and cord — **except for the USB connection at the distal tip** has been thoroughly wiped with enzymatic cleaner.
2	Follow manufacturer's instructions for rinsing (most suggest rinsing the sponge in water and repeating process)
3A	For HMT-TRP and HMT-TRP 3D: connect a syringe and flush the isolated pathway with enzymatic cleaner followed by a flush with water. Next flush the pathway with air. 

3B	The **handle and cable junction cannot be submerged in any solutions.** If any residue persists, use a commercially available sanitation wipe. 
4	Thoroughly dry with lint free cloth

DISINFECTION OPTIONS

1. Intermediate-Level Disinfection (ILD)

Requirement for use with surface probes.

Commonly used brands are Super Sani Cloth (Alcohol), Oxifir (Hydrogen Peroxide), Cavicide (Glutaraldehyde).

2. High-Level Disinfection (HLD): Manual or Machine Method

Requirement for use with endocavity probes.

A. MANUAL

Recommended high-level disinfectants include, but are not limited to the following:

- Tristel ULT (Parker Laboratories)
- Hydrogen Peroxide
  - Revital-Ox™ Resert® High Level Disinfection (Steris Corporation)
- Peracetic Acid Solutions
  - Cidex OPA® High Level Disinfectant (ASP)
  - MetriCide OPA ®Plus (Metrex/Envista)
- Glutaraldehyde
  - MetriCide® High Level Disinfectant (Metrex/Envista)

Disinfection is most easily accomplished using an upright container designed for ultrasound probes, (or flexible endoscopes). Typical configurations are either wall mounted or countertop. Example shown can be purchased from Halo Medical Technologies Cat # HMT-610-584.

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.

For HMT-TRP and HMT-TRP 3D:
The water pathway, while isolated, should also be flushed. This is accomplished by instilling the disinfectant through the luer lock with a syringe. During the rinsing, repeat this process with the distilled/sterile water and finish with a syringe of air to dry.

B. MACHINE

The Halo endocavity probes have been validated for use in the following machine: Civco ASTRA VR Probe Reprocessor.

Please refer to Civco for specifics: https://www.civco.com/

TRANSPORTATION AND STORAGE

When the probe is not being used, it should be stored in a clean, dry area. This includes the probe holders on the ultrasound equipment, storage cabinets and shelves. Clean covers are not required but are recommended.

When transporting the probe to a different field location use a disinfected carrying case or enclosure or pack it in such a way that the probe is protected and meets guidelines for transport of medical devices in healthcare.

MAINTENANCE, SERVICE, AND WARRANTY REPAIR

Periodic testing and maintenance of the ultrasound transducers is NOT required.

Regularly check the transducer 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.

Call Halo Medical Technologies for a Return Material Authorization (RMA) number before returning a probe 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 probe is protected. This will help to control the shipping costs.

ELECTROMAGNETIC COMPATABILITY

HMT-TRP, HMT-MCP ER 12.0 MHz/ES 12.0 MHz /Transrectal Endoanal Probe (60601-2-37TUV Reinland)

HMT-EVG EC 7.5 MHz / EB 7.5 MHz, HALO™ Endovaginal Probe (60601-2-37 TUV Reinland)

HMT-SURM GP 3.5 MHz / AB 3.5 MHz, HALO™ Surface Probe (60601-2-37 TUV Reinland)

CONTACT INFORMATION

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REFERENCES

AAMI Technical Information Report 99: 2024 Processing of Dilators, transesophageal and ultrasound probes in healthcare facilities

AIUM Guidelines for cleaning and preparing external and internal use of ultrasound transducers between patients, safe handling and use of ultrasound gel

ACKNOWLEDGEMENTS