Halo Medical Technologies Ultrasound Probes

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 USB Ultrasound Probe System for any physical damage such as leaking fluid and/or cracked and/or broken: membrane; housing; strain relief; stand-by switch; USB cable. 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 MidCRYSTL™ and HALO™ Probes with the Halo Medical Technologies Catalyst system 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). Any and 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 MidCRYSTL and HALO ultrasound probes.

CAUTION: Be careful when handling the USB probe. If the USB probe dropped on a hard 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 pelvis, 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 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.

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 (endovaginal or endoanal/transrectal) examinations. Use a HALO Medical Technologies non-latex probe cover (part number HMT-PC) 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).

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 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.

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.

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

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.

GENERAL GUIDANCE AND DEFINITIONS

There are three recognized categories for medical devices. They are critical, semi-critical and non-critical. Endo-cavity ultrasound probes are considered "semi-critical". The definition of a "semi-critical" medical device is one that touches mucous membranes. Surface probes are considered "non-critical". The definition of "non-critical" items is those that come in contact with intact skin but not mucous membranes.

There are four generally recognized categories of disinfection and sterilization. They are Sterilization, High-Level Disinfection, Mid-Level Disinfection, and Low-Level Disinfection.

Endo-cavity ultrasound probes are considered "semi-critical," and so require "high-level disinfection". High-level disinfection by definition is the destruction/removal of all microorganisms except bacterial spores.

Surface probes are considered "non- critical," so require "low-level disinfection." Low level disinfection by definition is the use of a liquid chemical germicide that is registered by the EPA as a hospital disinfectant. It destroys most vegetative bacteria, some fungi, and some viruses.

For the protection of the patient and the health care worker, all surface and endocavity examinations should be performed with the operator properly gloved throughout the procedure.

To prevent infection and cross contamination between patients, always use a probe cover (sheath) during endocavity (vaginal or endoanal) examinations. **Use a HALO Medical Technologies non-latex probe cover** or equivalent to avoid common and potentially dangerous, allergic reactions to latex.

WARNING: Some probe covers contain natural rubber latex and talc, which can cause allergic reactions in some individuals. 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). Probe covers are disposable and must not be reused. If an installed probe cover is cut or contaminated before use, the probe should be cleaned and disinfected and covered with a new probe cover.

PREPARATION FOR USE

W**ARNING:** Before the patient exam, inspect the USB Ultrasound Probe System for any physical damage such as leaking fluid and/or cracked and/or broken: membrane; housing; strain relief; stand-by switch; USB cable. 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.

MidCRYSTL **Endoanal Probe**

1) Open one, HALO Medical Technologies non-latex probe cover (part number HMT-PC) or equivalent.

2) Insert your finger into *either side* of the bi-directional probe cover. Using your finger, unroll enough of the distal portion of the probe cover such that the unrolled length is equal to the entire distal tip of the probe including the white band.

3) Holding the unrolled portion of the probe cover open, squeeze a generous amount of HALO Medical Technologies ultrasound gel (part number HMT-USGB) or equivalent into the center of the probe cover. Fill the entire "well."

4) Grasp the flared end of the probe cover with your thumb, index and middle finger, and insert the MidCRYSTL probe into the gel-filled portion of the probe cover. In one gentle motion, unroll the probe cover to fully cover the transducer.

5) **Ensure that there is enough gel trapped between the MidCRYSTL probe and the cover, especially at the location of the ultrasound crystal transducer (white band)**. Press firmly to remove any air trapped in between probe and cover.

6) Before inserting the sheathed probe into the patient, add surgical lubricant such as E-Z Lubricating Jelly from Chester Labs, Inc. or equivalent to the outside. Press firmly to ensure that all air is removed between probe cover and probe.

***HALO* Ultrasound Probes**

Open one, HALO non-latex probe cover or equivalent. Apply a liberal amount of Halo Medical Technologies ultrasound gel or equivalent into the center of the probe cover. Grasping the ends of the probe cover, pull the cover over the entire length of the *HALO* Ultrasound Probe, trapping the gel between the probe cover and the probe.

For endocavity probes, add surgical lubricant to the outside before inserting the sheathed probe into the patient. Press firmly to ensure that all air is removed between probe cover and probe.

For surface probes, apply a liberal amount of ultrasound gel to the sheathed surface of the ultrasound probe before use.

DECONTAMINATION

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.

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

After use, the probe cover should be removed and discarded into biohazard waste container. Wipe off any remaining ultrasound gel. 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 the 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 dulition. At the completion of the procedure, hands should be thoroughly washed with soap and water. Next follow Disinfection Procedures below.

HIGH LEVEL DISINFECTION
For MidCRYSTL and HALO Endocavity Probes

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

Because endoanal and endovaginal ultrasound probes are considered "semi-critical" medical devices, they require high-level disinfection. Recommended high level disinfectants include, but are not limited to 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.

⚠ **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 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.

LOW LEVEL DISINFECTION

For HALO Surface Probes

Wipe or immerse the transducer with one of the following solutions, following manufacturer's recommendation for low-level disinfection:

- A glutaraldehyde-based disinfectant
- A 10% bleach solution
- Isopropyl alcohol (70%)

TRANSPORTATION AND STORAGE

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 MidCRYSTL and HALO ultrasound probe is NOT required.

The probe should be cleaned and disinfected after every use. 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

ER 12.0 MHz/ES 12.0 MHz MidCRYSTL™ /Transrectal Endoanal Probe (60601-2-37TUV 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

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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.

Centers 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