A Complete Users Reprocessing Guide for Ultrasound Probes:

Manual, Semi-Automated, and Fully-Automated Cleaning and High-Level Disinfection of Transvaginal or Transrectal Probes

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Executive Summary

Reprocessing medical devices is crucial to patient safety and the prevention of hospital associated infections (HAIs). A study by The Joint Commission in 2016 found that 74 percent of all immediate threat to life declarations were associated with the improper equipment sterilization or high-level disinfection.[1] Similarly, performance of intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies (IC.02.02.01, EP 2) was recorded as an area with the highest non-compliance amongst facilities surveyed in 2022.[2] Similarly, a survey of infection preventionists in the US found that 20% of respondents were aware of a time that a probe used in a procedure was incorrectly processed.[3] This response rate likely represents an underestimate because deviations from the reprocessing procedure may go unnoticed. Together, these findings suggest that many facilities continue to struggle with proper medical device reprocessing.

Proper medical device reprocessing requires a balance between the time and resources required to complete the procedure and the risk of HAIs and probe damage. Most professional and regulatory agencies recommend that facilities use the Spaulding classification to determine how to reprocess medical devices. This classification system divides medical devices into three categories: non-critical, semi-critical, and critical devices (Table 1). Using this classification system, non-critical devices should be low or intermediate level disinfected, semi-critical devices should be high-level disinfected, and critical devices should be sterilized.[4-8] According to the Spaulding classification, transvaginal and transrectal ultrasound probes are considered semi-critical devices and must be cleaned and high-level disinfected prior to use.[4-8] Importantly, the use of a procedure cover does not change the Spaulding classification of a medical device.[4,5] High-level disinfection (HLD) is a process that eliminates all microorganisms from a device, except for small numbers of bacterial spores. HLD of transvaginal and transrectal ultrasound probes, as well as other medical devices, is no small feat. However, innovations in the last two decades have improved the available transvaginal and transrectal probe reprocessing methods from manual and semi-automated (manual cleaning and automated disinfection) to completely automated procedures.

Table 1. Spaulding classification of medical devices.

Classification	Definition	Recommended reprocessing
Non-critical	Devices used on intact skin	Cleaning and low- or intermediate- level disinfection
Semi-critical	Devices that come in contact with mucous membranes or non-intact skin	Cleaning and high-level disinfection
Critical	Devices that come in contact with sterile body sites	Cleaning and sterilization

Traditional reprocessing has utilized manual cleaning and HLD procedures. In these methods, the transvaginal or transrectal probe is processed at the point-of-use then cleaned and high-level disinfected by submersion in a compatible cleaner and high-level disinfectant, respectively. While these methods do not require specialized equipment, they can be tedious. Each probe must be inspected and reprocessed individually and correctly using a detailed, multi-step procedure that may vary between probe models; potentially resulting in confusion and an increase in human errors. Human error is a significant drawback for any manual procedure. Missteps during the reprocessing procedure can result in ineffective reprocessing putting patients at increased risk of infection and increasing the likelihood of ultrasound probe damage.

In addition to being tedious, manual reprocessing procedures are more time-consuming than their semi-automated (hybrid) or automated counterparts. Using the procedures outlined in this guide, it is estimated that the total reprocessing time, or the time required to reprocess a probe from point-of-use to storage and hand washing is approximately 48-88 minutes. This timeline is heavily dependent upon the contact time required for the high-level disinfectant. Longer reprocessing times can result in fewer probes available for procedures or require the facilities to purchase additional probes to compensate for longer reprocessing times (Table 2). The manual nature of these methods requires that staff must dedicate the entirety of the lengthy reprocessing time to cleaning and disinfecting a single probe, with little time to complete other clinical duties. Together, these factors may result in pressure on technicians to skip steps to decrease reprocessing times.[9]

Table 2. Estimated maximum number of probes reprocessed in an 8-hour workday per current standards and guidelines

Method	Manual	Semi-Automated**	Automated
Number of probes	10	12	17

**Calculated from fastest estimated total reprocessing time assuming 100% efficiency*
***Manual cleaning and automated disinfection*

Long and tedious manual reprocessing procedures have led to the development of automated disinfectors, which are FDA cleared devices that high-level disinfect ultrasound probes using automated methods. Automated disinfectors can decrease the total reprocessing time as much as 61 minutes. As well as the total operator hands-on time or the time that technicians or clinical staff must spend actively engaged in the reprocessing procedure (estimated 27-35 minutes). However, these procedures still require manual cleaning methods and may depend upon manual testing of the disinfectant concentration. Manual cleaning procedures require dedicated time from the operator to complete and are subject to human error. Further, it can be difficult to clean cracks and crevices using manual cleaning methods; resulting in an improperly cleaned device and suboptimal conditions for high-level disinfection.[5,10,12]

The potential for human error associated with manual methods has resulted in recommendations to use automated methods over manual procedures.[1] Greater than 90% of infection preventionists prefer automated ultrasound reprocessing procedures over manual processes.[3] Similarly, a survey found that staff feel that automated reprocessing procedures are safer than their manual counterparts.[9] However, until recently, there were no options for fully automated reprocessing systems for transvaginal and transrectal ultrasound probes. FDA clearance of the CS Medical Ethos Automated Cleaner Disinfector in 2023 provided the field with the first automated device to clean and disinfect transvaginal and transrectal ultrasound probes in a single cycle. With a total cycle time of 18 minutes, technicians and clinical staff can clean and disinfect probes quickly so they are ready for the next procedure. The automated

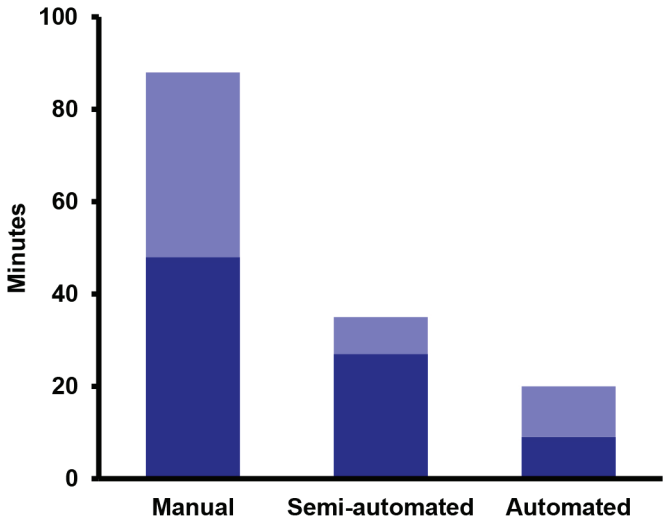


Figure 1. Operator hands on time required to reprocess one transvaginal probe. Operator hands-on times: Manual, 48-88 min.; Hybrid (Semi-Automated), 27-35 min.; Automated, 9-20 min. Light blue shows difference between minimum and maximum estimated hands-on time.

nature can reduce human errors and the operator hands-on time required for reprocessing to an estimated 9-20 minutes (Figure 1). This leaves at least 18 minutes of each reprocessing cycle available for other clinical responsibilities to maximize staff and technician time. A fully automated reprocessor provides a reliable and repeatable outcome each time and ultimately gives time back to the healthcare professional to perform other critical tasks, like patient care.

Over the last two decades, innovation and technological advances have led transvaginal and transrectal ultrasound probe reprocessing methods from manual to semi-automated, and now completely automated procedures. These changes in methods have also driven changes in regulations and guidance. The processes described in this guide were written to follow current recommended guidelines and best practices for reprocessing a transvaginal or transrectal ultrasound probe using manual, semi-automated, and automated methods. Each section provides a short summary of the method, a list of recommended equipment, definitions and abbreviations, a high-level procedure with estimated times to completion, as well as a discussion of each method. This guide is meant to be used as a reference to help develop and compare transvaginal and transrectal probe reprocessing methods and should not be used in place of facility standard operating procedures, manufacturer's instructions, regulatory documents etc. While there are more options for transvaginal probe reprocessing than ever before, fully automated methods offer numerous advantages. A quick, simple, and efficient workflow can help facilities promote patient safety and prevent HAIs from incorrectly reprocessed ultrasound probes.

Section I:
Manual reprocessing procedure for a transvaginal or transrectal probe

Summary

This section describes a manual immersion process for both transvaginal and transrectal probe cleaning and high-level disinfection (HLD). Manual cleaning and disinfection were the first methods available for reprocessing transvaginal or transrectal ultrasound probes. The dirty probes are processed at the point-of-use and then transported to a central reprocessing department. Following transport, the probe is manually cleaned by submersion in a compatible cleaner, rinsed, and dried. Once it is confirmed that cleaning was successful and there is no visual soil remaining on the probe, the probe is then submerged in high-level disinfectant within a basin or sink for the appropriate contact time. The probe is then rinsed again, dried, and stored. Reprocessing technicians should ensure that the details of the entire procedure are correctly documented before starting reprocessing of the next probe. The procedure in this guide is discussed in general terms to account for potential differences between cleaners and disinfectants. Methods for specific cleaners/disinfectants may vary.

Definitions and abbreviations

Cleaning – the process of removing soil, debris, and foreign materials from medical devices

Critical water – a category of water defined by specific parameters for conductivity, bioburden, mineral content, etc. in ANSI/AAMI standard ST108:2023 that can be used for rinsing medical devices after high-level disinfection. In general, the requirements for critical water are more stringent than that of utility water.

High-level disinfectant – a chemical (usually in liquid, foam, or gaseous form) that kills all microorganisms on a device or instrument, except for a small number of bacterial spores when used according to the manufacturer's instructions for contact time, temperature, etc.

High-level disinfection (HLD) – most commonly defined as the elimination of all microorganisms on a device or instrument, except for small numbers of bacterial spores

Low-level disinfectant - a chemical (usually in liquid or gaseous form) that eliminates all vegetative bacteria on a device or instrument, (except tubercle bacilli) and most viruses from a device or instrument when used according to the manufacturer's instructions for contact time, temperature, etc.

Low-level disinfection – a disinfection process that eliminates all vegetative bacteria (except tubercle bacilli) and most viruses from a device or instrument. Low-level disinfection does not eliminate bacterial spores.

Minimum recommended concentration (MRC) – the lowest concentration of a chemical or active ingredient at which the disinfectant has been demonstrated to be effective.

Personal protective equipment (PPE) – equipment that is worn by an individual to minimize their exposure to workplace hazards such as hazardous chemicals/disinfectants and microorganisms.

Point-of-use cleaning – a cleaning process performed immediately after use to remove large amounts of gross soil and debris. This process is also sometimes referred to as pre-cleaning.

Probe storage cover – a sleeve designed to shield high-level disinfected probes during storage to protect them from environmental contamination. These sleeves are not designed to be used during ultrasound or medical procedures.

Probe transport vessel – a vessel (ex. bag) that is used to transport soiled probes from the point of care to the appropriate reprocessing area. These vessels should be marked as biohazardous.

Standard operating procedure (SOP) – clear step-by-step instructions for carrying out a specific routine process in a facility or organization. SOPs are important for consistency and quality across multiple operators or departments.

Test strip – or a chemical indicator is a device that contains material on part or its entirety that reacts with a chemical or compound. Often, this reaction will produce a visible color change that provides the user some information about the solution tested (i.e. concentration of an active ingredient, pH, etc.).

Total estimated reprocessing time – time required to reprocess a probe from point-of-use processing to the final hand hygiene step following probe storage and documentation.

Total operator hands-on time - time that reprocessing technicians or clinical staff must spend actively engaged in the reprocessing procedure.

Transducer procedure cover – a cover, sheath, or condom that is used during ultrasound procedures to provide a physical barrier between the transducer and the tissue to help reduce probe contamination. Transducer procedure covers can fail (tear or be punctured) and should not be used as the only line of defense against cross-contamination. Use of a procedure cover does not change the Spaulding classification of a device.

Utility water – a category of water defined by specific parameters for conductivity, bioburden, mineral content, etc. in ANSI/AAMI standard ST108:2023 that can be used for rinsing medical devices after cleaning.

Recommended equipment list

	Basin(s) or sink(s) for manual cleaning
	Basin(s) or sink(s) for manual disinfection
	Calibrated thermometer
	Calibrated timer
	Clean, low-lint drying cloth (following cleaning)
	Clean, low-lint (Gamma-irradiated) drying cloth after disinfection
	Cleaning agent
	Cleaning tools (brushes, sponges, cloths, swabs etc.)
	Critical water
	Disinfectant for sinks/basins
	Hand soap
	Hand washing sink

	High-level Disinfectant
	Log book or electronic reprocessing record system
	Low-level disinfectant wipes for cleaning cords and connectors that cannot be submerged
	Personal protective equipment (PPE) (gown/ apron, shoe covers, eye protection, face shield, bonnet, gloves, etc.)
	Probe storage bag
	Stickers to label high-level disinfected probes for storage (optional)
	Storage cabinet with high efficiency particulate (HEPA)-filtered air (optional)
	Test strip
	Transport vessel/bag with biohazard label(s)
	Utility water
	Wipe/sponge/cloth for point-of-use cleaning

Procedure

1. Point-of-Use Processing (Estimated time: 3 minutes): Don the proper personal protective equipment (PPE) including gloves and eye protection to protect from exposure to pathogens on the contaminated probe.[5,6] Disconnect the probe from the console and inspect and remove the transducer procedure cover taking care to avoid further contaminating the transducer with blood or bodily fluids.[4,6,7] Once removed, the transducer cover should be discarded as biohazardous waste. Immediately, perform point-of-use cleaning with a compatible wipe, sponge, or detergent to remove gross soil and gel. Completion of point-of use cleaning prevents drying of the soil or gel, which makes it more difficult to remove in subsequent steps.[8]

2. Transport (Estimated time: 5 minutes): Manual soaking cleaning and disinfection methods are generally not conducive to completion within patient rooms due to space, equipment availability, and the potential for chemical exposures. Therefore, probes should be transported to an appropriate reprocessing area. Place the point-of-use processed probe in a designated, clean transport vessel (ex. bag), label the transport vessel as biohazardous materials, and deliver to the reprocessing area.[4,13] Personnel should remove and discard their gloves in the biohazardous waste and wash their hands after handling the probe to prevent the spread of potentially pathogenic microorganisms from the contaminated probe.[7]

3. Cleaning Setup (Estimated time: 7 minutes): Once the probe has been transported to the cleaning area, don the appropriate PPE (ex. gown/apron, shoe covers, bonnet, safety glasses, face shield, gloves) as dictated by facility standard operating procedures (SOPs). Proper PPE can protect from splashes associated with manual cleaning and disinfection methods.[5,6,14] Setup as many necessary components and materials for manual cleaning and disinfection as possible to minimize delays between steps and prevent microbial growth.[8] Keep in mind that the cleaning and reprocessing area setup should promote a clear dirty to clean workflow.[13] In addition to gathering any brushes, sponges, cloths, swabs etc., be sure to check the expiration date for the chosen cleaning agent and double check its compatibility with the soiled probe.[4-6] Lastly, fill the basin or sink with cleaning solution prepared at the temperature and concentration specified by the manufacturer's instructions for use (IFU).

4. Cleaning (Estimated time: 3 minutes): To clean the probe, remove the probe from the transport vessel and submerge in the cleaning solution. Use caution to only submerge the portions of the probe that are submersible according to the probe manufacturer's IFU. If indicated by the probe manufacturer, scrub the probe using a sponge, cloth, or soft bristle brush to remove all visible gel, soil, and bioburden from transducer.[4-7] The types of tools that can be used to clean transvaginal probes, such as soft brushes or sponges varies significantly between probe manufacturers and models. Therefore, it is important to check the manufacturer's instructions for cleaning for each probe. Any scrubbing should be completed while the probe is submerged to avoid creating aerosolized droplets of potentially hazardous or infectious material. Pay special attention to indentations and needle guide areas, as they may require extra cleaning to remove all visible soils.

5. Rinsing and Drying (Estimated time: 3 minutes): Remove and replace gloves to avoid contaminating the clean probe with dirty gloves. Discard dirty gloves appropriately.

a. Rinsing: Rinse the cleaned probe with utility water (or better), as defined by ANSI/AAMI ST108:2023[15] to remove residual cleaning agent that could interfere with subsequent disinfection.[5] Complete the number of rinses specified by the cleaning agent manufacturer (ex. three rinses lasting at least one minute each). If not specified, rinse the probe well enough to remove all visible residue/cleaner. If you need to drain and refill the sink/basin for each rinse, the time for rinsing can drastically increase.

b. Drying: Thoroughly dry the device using a single-use, soft, low-lint cloth. Drying is a crucial step to prevent dilution of the disinfectant in subsequent HLD processes and to prevent the growth of microorganisms, especially if there is a delay between probe cleaning and disinfection.[6,8] Following cleaning, inspect the probe for residual soil and damage.[8] Probes containing residual soil should be cleaned again, while scratched or damaged probes should be separated to be repaired or discarded. Probes needing repair may need to undergo special disinfection and rinsing steps before being sent out for repair.

c. Clean-up: Following cleaning, the sinks or basins used for soaking and rinsing should be drained, cleaned, and disinfected according to facility SOPs prior to re-use. This will prevent the build-up of soil within the sink/basin that could increase the soil and bioburden during cleaning of subsequent probes. Separate sinks/basins should be used for cleaning and subsequent HLD steps in order to facilitate a dirty to clean workflow.[13] Brushes or other tools used for cleaning should be single-use and disposable. Reusable brushes/cleaning tools must be cleaned and disinfected and/or sterilized after each use.[5,13]

d. Transport: If cleaning and disinfection are in separate areas, the probe will again need to be transported to the disinfection area, again adding additional time to the process.

6. High-level Disinfection (HLD) Setup (Estimated time: 7 minutes): Manual soaking methods require a cleaned probe to be submerged in a disinfectant bath for a specified contact time under specific conditions.

a. Vapor Control: Many high-level disinfectants are known to irritate the skin and respiratory tract. Over time, repeated exposures can lead to increased sensitization and occupational asthma. Therefore, exposure to most high-level disinfectants should be avoided. Direct skin and eye contact can be prevented using gloves and proper eye protection. However, disinfectant vapors can also irritate the respiratory tract. Ventilation in reprocessing and disinfection areas should be designed in a way to reduce staff exposure to hazardous disinfectants and keep vapor levels below the Occupational Safety and Health Administration (OSHA) permissive exposure limits (PELs) or the American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit values (TLVs) for each disinfectant.[13] Staff could wear an appropriate form of respiratory protection and/or only utilize disinfectants within a vapor controlling workstation or equivalent.

b. Disinfectant: Choose a high-level disinfectant that is compatible with the transvaginal or transrectal probe to be disinfected and facility disinfection SOPs. A list of selected FDA cleared high-level disinfectants is provided in Table 3. Disinfectants used for manual procedures may be single-use or labeled for re-use for a designated number of uses or over a specified time period (i.e. 14 days from preparation). When opening a new multi-use bottle of disinfectant, label the opened bottle with the open date and new expiration date, if applicable. Prepare the disinfectant at the temperature and concentration specified by the manufacturer's IFU, preferably within a container, sink or basin located within an HLD vapor-control soaking station to reduce exposure to disinfectant vapors.[5] Prepared disinfectants cleared for reuse should be labeled with the date of preparation and the date the preparation's reuse life ends. Measure the initial disinfectant temperature using a calibrated thermometer. High-level disinfectant prepared outside of the manufacturer's specified temperatures cannot be used.

Table 3. Selected FDA cleared high-level disinfectants.

High-level disinfectant	Active ingredient	Contact time for high-level disinfection	Maximum re-use period
Cidex OPA Solution High-Level Disinfectant	0.55% ortho-phthalaldehyde	12 min at 20°C	14 days
Metricide	2.6% glutaraldehyde	45 min at 25°C	14 days
Wavicide – 01	2.5% glutaraldehyde	45 min at 22°C	30 days
Rapicide OPA-28 High-Level Disinfectant	0.575% ortho-phthalaldehyde	10 min at 20°C	28 days
Sporox Sterilizing & Disinfection Solution	7.5% hydrogen peroxide	30 min at 20°C	21 days

**FDA list can be found here: https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and*[16]

c. Test Strips: If required, test the concentration of the disinfectant using test strips (or other method) specified by the disinfectant manufacturer. Prior to use, check that the test strips have not expired. Each time a new container or pack of test strips is opened, record the date. Note that the shelf life of open containers of some test strips may decrease when compared to the shelf life of an unopened container. If this is the case, record the new expiration date of the opened container as well. The test strip will determine if the disinfectant is at least at the minimum recommended concentration or MRC. Once disinfectant testing is completed, store the test strips according to the manufacturer's instructions (ex. at room temperature, away from light, in a closed container provided by the manufacturer, etc.). If it is unclear whether the test strips have been stored properly (ex. container was left open since last use) the test strips should not be used as this could lead to erroneous results. Disinfectant that does not reach the correct concentration as determined by a passing test strip result cannot be used for disinfection. The disinfectant must be discarded, and new disinfectant prepared, even if it is a re-usable disinfectant within its re-use date.

7. High-level Disinfection (HLD) (Estimated time: 10-45 minutes): Once the disinfectant has been prepared, submerge the transducer in disinfectant. Take care to only submerge the portions of the probe that are considered submersible by the probe manufacturer's IFU. Keep the transducer submerged for the contact time specified by the disinfectant manufacturer (usually between 5-45 minutes). Ensure there are no air bubbles on the device, any area where an air bubble is present is a potential spot where the device will not be properly disinfected. Disinfectant temperature is a critical parameter to ensuring adequate microbial killing. Each FDA cleared disinfectant has been shown to provide HLD (as defined by the FDA[17]) within a specified temperature range. The disinfectant may or may not achieve HLD of medical devices outside of this range. Therefore, the temperature should be monitored using a calibrated thermometer throughout the disinfectant contact time. If the temperature falls outside of the range specified by the disinfectant manufacturer at any point during the time of contact with the probe, the probe has not been properly disinfected. Follow facility SOPs and/or the disinfectant manufacturer's instructions to repeat the disinfection process. The probe must be considered "not disinfected" until it has been soaked in high-level disinfectant under the proper conditions (contact time, temperature, and concentration). Disinfect non-submersible cables/cords using a compatible low-level disinfectant.[4] The cables can be disinfected while the probe is soaking as long as the process does not remove any portion of the probe from the high-level disinfectant.

8. Rinsing and Drying (Estimated time: 3-4 minutes): Remove and replace gloves to avoid contaminating the disinfected probe with dirty gloves. Discard dirty gloves appropriately. The probe should be handled using aseptic technique for the remainder of the reprocessing procedure to avoid contamination.[13]

a. Rinsing: Following HLD, rinse the probe in a separate, clean container using critical water (as defined by ANSI/AAMI ST108:2023[15]) for the number of rinses and duration of rinse time as specified by the disinfectant manufacturer.[4] As in rinsing after cleaning, time can drastically change based on number of rinse and time, as well as the potential of having to drain/refill the basin/sinks, etc.

b. Drying: Thoroughly dry the probe using a sterile or gamma-irradiated, single-use low-lint cloth. The probe should be completely dry to help prevent microbial growth on the probe during storage. Place the dried probe in a clean probe storage cover.

c. Disinfection Clean Up: Following HLD, discard the prepared single-use disinfectant according to the manufacturer's instructions, facility SOPs, and local waste disposal regulations. Some disinfectants may require neutralization prior to disposal. Adding even more time to the overall process (neutralization time, verification, if necessary, etc.) Disinfectant preparations labeled for re-use that are still within their reuse life should be stored appropriately until the next use or the end of the reuse life (whichever comes first). Once the disinfectant has been discarded, the sink or basin used for soaking should be rinsed thoroughly according to facility SOPs to remove any disinfectant residues prior to re-use.

9. Storage (Estimated time: 1-5 minutes): Probes should be clearly labeled with the storage date, level of disinfection (e.g. HLD), and maximum storage duration according to institutional policies.[4] Storage information should be attached to the probe in a way that does not damage the probe, compromise the integrity of the probe storage cover, or result in contamination of the high-level disinfected probe. In some facilities, probes may need to be transported to another storage location. Covered probes should be handled and transported to the storage area in a manner that prevents contamination.[4] Store probes in probe storage covers and/or cabinets with high efficiency particulate air (HEPA) filtration to reduce the risk of re-contamination from the environment. Many manufacturers recommend that probes be stored vertically to prevent damage to the lens. Do not place dirty and clean/disinfected transducers in the same cabinet or probe storage cover.[4] Unless otherwise specified by the manufacturer, only one probe should be stored in each probe storage cover.

10. Documentation and Traceability (Estimated time: 4 minutes): Document all details including (but not limited to) model, serial number, reprocessing personnel, high-level disinfectant identity, lot number and expiration date, validation result (e.g. chemical indicator, temperature, soaking time), date/time, and patient identifier according to institutional policies.[4] Documentation can be completed using manual or electronic processes.[4] Enough details should be documented that the completion of all cleaning and HLD can be confirmed by an independent audit. Documentation should also facilitate traceability in the event of an adverse event investigation.

11. Hand Hygiene (Estimated time: 2 minutes): Remove PPE and discard appropriately. Wash hands before proceeding to next task.[6]

Total estimated reprocessing time: 48 - 88 minutes

Total operator hands-on time: 48 - 88 minutes

Discussion

Despite the development of newer technologies, manual processes are still used in some facilities today. While manual procedures do not require any type of specialized reprocessing equipment, many factors must be taken into consideration when using these methods.

The first is safety. Immersion methods require the use of large basins of cleaner, rinse water, and disinfectant. Moving in and out of these basins and scrubbing the probes may increase the risk of cross-contamination, environmental contamination, and staff exposure by creating droplets and splashes that have been shown to travel up to 6 ft from the sink/basin.[14] The use of basins can also increase the amount of high-level disinfectant fumes released into the environment. Most high-level disinfectants in use today are considered hazardous chemicals and multiple studies demonstrate adverse effects associated with disinfectant exposure.[18-21] Therefore, manual procedures require that staff consistently don sufficient PPE to prevent contact exposures. Reprocessing areas used for HLD must also have adequate ventilation to prevent inhalation of disinfectant fumes. In many facilities, HLD must be completed within a fume hood or similar enclosure designed to contain chemical fumes. Adequate ventilation systems can be costly and fume hoods/enclosures require thoughtfully planned space within the reprocessing area. Further, multiple hoods or enclosures may be needed to allow for the simultaneous disinfection of many probes to meet time constraints.

In addition to safety considerations for staff, facilities considering manual methods must also think about the safety of their patients. Manual methods tend to be quite tedious and time-consuming, when compared to semi-automated and automated methods. Combining detailed, multi-step procedures with completely manual processes makes these methods highly susceptible to human error.

Potential procedure deviations during manual processes could include, preparing cleaners and disinfectants at the incorrect concentration and/or temperature, the disinfectant temperature falling outside the use range, or incorrect storage of cleaners, disinfectants, or test strips. Further, expiration and re-use periods must be manually tracked, which could lead to accidental use of expired supplies. If there are any known deviations from the manual processing procedure, a portion or the entirety of the process must be repeated. This adds extra time and steps to an already lengthy procedure. Of more concern are deviations that go unnoticed, which result in improperly reprocessed probes being used in medical procedures. Therefore, while manual methods offer a “low tech” option for reprocessing transvaginal or transrectal ultrasound probes, they carry the substantial risk of human error.

Section II:
Semi-Automated reprocessing procedure for a transvaginal or transrectal probe

Summary

A semi-automated reprocessing method using manual cleaning followed by automated high-level disinfection (HLD) using an automated disinfector is outlined in this section. The point-of-use processed probe is transported to a central reprocessing area where it is manually cleaned using immersion in a prepared cleaner. The probe is then rinsed and dried. Once clean, the probe is high-level disinfected using an automated disinfector. Following a successful cycle, the probe is dried and stored to avoid contamination from the environment. All procedure details are documented using manual or electronic systems prior to reprocessing the next probe. This section was written in general terms to provide the most broadly applicable procedure. Always consult the manufacturer's instructions to determine the specific procedures that must be followed for a particular probe/cleaner/disinfectant/disinfector.

Definitions and abbreviations

Automated disinfector – an FDA–cleared medical device that has been cleared for use to disinfect medical devices using an automated process. For the purposes of this document, automated disinfector refers to FDA-cleared medical devices that are cleared for the high-level disinfection of semi-critical transvaginal ultrasound probes.

Cleaning – the process of removing soil, debris, and foreign materials from medical devices

High-level disinfectant – a chemical (usually in liquid, foam, or gaseous form) that kills all microorganisms on a device or instrument, except for a small number of bacterial spores when used according to the manufacturer's instructions for contact time, temperature, etc.

High-level disinfection (HLD) – most commonly defined as the elimination of all microorganisms on a device or instrument, except for small numbers of bacterial spores

Low-level disinfectant - a chemical (usually in liquid, foam, or gaseous form) that eliminates all vegetative bacteria on a device or instrument, (except tubercle bacilli) and most viruses from a device or instrument when used according to the manufacturer's instructions for contact time, temperature, etc.

Low-level disinfection – a disinfection process that eliminates all vegetative bacteria (except tubercle bacilli) and most viruses from a device or instrument. Low-level disinfection does not eliminate bacterial spores

Minimum recommended concentration (MRC) – the lowest concentration of a chemical or active ingredient at which the disinfectant has been demonstrated to be effective.

Personal protective equipment (PPE) – equipment that is worn by an individual to minimize their exposure to workplace hazards such as hazardous chemicals/disinfectants and microorganisms.

Point-of-use cleaning – a cleaning process performed immediately after use to remove large amounts of gross soil and debris. This process is also sometimes referred to as pre-cleaning.

Probe storage cover – a sleeve designed to shield high-level disinfected probes during storage to protect them from environmental contamination. These sleeves are not designed to be used during ultrasound or medical procedures.

Probe transport vessel – a vessel (ex. bag) that is used to transport soiled probes from the point of care to the appropriate reprocessing area. These vessels should be marked as biohazardous.

Standard operating procedure (SOP) – clear step-by-step instructions for carrying out a specific routine process in a facility or organization. SOPs are important for consistency and quality across multiple operators or departments.

Test strip or a chemical indicator is a device that contains material on part or its entirety that reacts with a chemical or compound. Often, this reaction will produce a visible color change that provides the user some information about the solution tested (i.e. concentration of an active ingredient, pH, etc.).

Total estimated reprocessing time – time required to reprocess a probe from point-of-use processing to the final hand hygiene step following probe storage and documentation.

Total operator hands-on time - time that reprocessing technicians or clinical staff must spend actively engaged in the reprocessing procedure.

Transducer procedure cover – a cover, sheath, or condom that is used during ultrasound procedures to provide a physical barrier between the transducer and the tissue to help reduce probe contamination. Transducer procedure covers can fail (tear or be punctured) and should not be used as the only line of defense against cross-contamination. Use of a procedure cover does not change the Spaulding classification of a device.

Utility water – a category of water defined by specific parameters for conductivity, bioburden, mineral content, etc. in ANSI/AAMI standard ST108:2023 that can be used for rinsing medical devices after cleaning.

Recommended equipment list

	Automated High-Level Disinfector
	Basin(s) or sink(s) for manual cleaning
	Calibrated thermometer
	Calibrated timer
	Clean, low-lint drying cloth (following cleaning)
	Clean, low-lint (Gamma-irradiated) drying cloth (following disinfection)
	Cleaning agent
	Cleaning tools (brushes, sponges, cloths, swabs etc.)
	Critical water
	Hand soap
	Hand washing sink
	High-level Disinfectant for use in disinfector

	Log book or electronic reprocessing record system
	Low-level disinfectant wipes for cleaning cords and connectors that cannot be subjected to automated disinfection
	Personal protective equipment (PPE) (gown/apron, shoe covers, eye protection, face shield, bonnet, gloves, etc.)
	Probe storage bag
	Stickers to label high-level disinfected probes for storage (optional)
	Storage cabinet with high efficiency particulate (HEPA)-filtered air (optional)
	Test strip
	Transport vessel/bag with biohazard label(s)
	Utility water
	Wipe/sponge/cloth for point-of-use cleaning

Procedure

1. Point-of-Use Processing (Estimated time: 3 minutes): Don the proper personal protective equipment (PPE) including gloves and eye protection to protect from exposure to pathogens on the contaminated probe.[5,6] Disconnect the probe from the console and inspect and remove the transducer procedure cover taking care to avoid further contaminating the transducer with blood or bodily fluids.[4,6,7] Once removed, the transducer cover should be discarded as biohazardous waste. Immediately, perform point-of-use cleaning with a compatible wipe, sponge, or detergent/water to remove gross soil and gel. Completion of point-of use cleaning prevents drying of the soil or gel, which makes it more difficult to remove in subsequent steps.[8]

2. Transport (Estimated time: 5 minutes): Manual soaking cleaning and disinfection methods are generally not conducive to completion within patient rooms due to space, equipment availability, and the potential for chemical exposures. Therefore, probes should be transported to an appropriate reprocessing area. Place the point-of-use processed probe in a designated, clean transport vessel (ex. bag), label the transport vessel as biohazardous materials, and deliver to the reprocessing area.[4,13] Personnel should remove and discard their gloves in the biohazardous waste and wash their hands after handling the probe to prevent the spread of potentially pathogenic microorganisms from the contaminated probe.[7]

3. Cleaning Setup (Estimated time: 7 minutes): Once the probe has been transported to the cleaning area, don the appropriate PPE (ex. gown/apron, shoe covers, bonnet, safety glasses, face shield, gloves) as dictated by facility standard operating procedures (SOPs). Proper PPE can protect from splashes associated with manual cleaning and disinfection methods.[5,6,14] Setup as many necessary components and materials for manual cleaning and disinfection as possible to minimize delays between steps and prevent microbial growth.[8] Keep in mind that the cleaning and reprocessing area setup should promote a clear dirty to clean workflow.[13] In addition to gathering any brushes, sponges, cloths, swabs etc., be sure to check the expiration date for the chosen cleaning agent and double check its compatibility with the soiled probe.[4-6] Lastly, fill the basin or sink with cleaning solution prepared at the temperature and concentration specified by the manufacturer's instructions for use (IFU).

4. Cleaning (Estimated time: 3 minutes): To clean the probe, remove the probe from the transport vessel and submerge in the cleaning solution. Use caution to only submerge the portions of the probe that are submersible according to the probe manufacturer's IFU. If indicated by the probe manufacturer, scrub the probe using a sponge, cloth, or soft bristle brush to remove all visible gel, soil, and bioburden from transducer.[4-7] The types of tools that can be used to clean transvaginal probes, such as soft brushes or sponges varies significantly between probe manufacturers and models. Therefore, it is important to check the manufacturer's instructions for cleaning for each probe prior to cleaning. Any scrubbing should be completed while the probe is submerged to avoid creating aerosolized droplets of potentially hazardous or infectious material. Pay special attention to indentations and needle guide areas, as they may require extra cleaning to remove all visible soils.

5. Rinsing and Drying (Estimated time: 3 minutes): Remove and replace gloves to avoid contaminating the clean probe with dirty gloves. Discard dirty gloves appropriately.

a. Rinsing: Rinse the cleaned probe with utility water (or better), as defined by ANSI/AAMI ST108:2023[15] to remove residual cleaning agent that could interfere with subsequent disinfection.[5] Complete the number of rinses specified by the cleaning agent manufacturer (ex. three rinses lasting at least one minute each). If not specified, rinse the probe well enough to remove all visible residue/cleaner. If you need to drain and refill the sink/basin for each rinse, the time for rinsing can drastically increase.

b. Drying: Thoroughly dry the device using a single-use, soft, low-lint cloth. Drying is a crucial step to prevent dilution of the disinfectant in subsequent HLD processes and to prevent the growth of microorganisms, especially if there is a delay between probe cleaning and disinfection.[6,8] Following cleaning, inspect the probe for residual soil and damage.[8] Probes containing residual soil should be cleaned again, while scratched or damaged probes should be separated to be repaired or discarded. Probes needing repair may need to undergo special disinfection and rinsing steps before being sent out for repair.

c. Clean-up: Following cleaning, the sinks or basins used for soaking and rinsing should be drained, cleaned, and disinfected according to facility SOPs prior to re-use. This will prevent the build-up of soil within the sink/basin that could increase the soil and bioburden during cleaning of subsequent probes. Separate sinks/basins should be used for cleaning and subsequent HLD steps in order to facilitate a dirty to clean workflow.[13] Brushes or other tools used for cleaning should be single-use and disposable. Reusable brushes/cleaning tools must be cleaned and disinfected or sterilized after each use.[5,13]

d. Transport: If cleaning and disinfection are in separate areas, the probe will again need to be transported to the disinfection area, again adding additional time to the process.

6. Automated High-level Disinfection (HLD) (Estimated time: 8 – 15 minutes): Automated HLD processes are preferred over manual procedures because automation reduces the likelihood of operator error.[4]

a. Disinfector Set Up: Check that the automated disinfector is ready for use. If not, power on the device and follow any setup or device prompts according to the manufacturer's instructions. Startup times may vary considerably for automated disinfectors. If the disinfector uses a multi-use disinfectant bottle/vessel, verify that the correct disinfectant is loaded into the device and the disinfectant is compatible with the probe to be disinfected. Replace the disinfectant if needed or prompted by the disinfector's automated use and expiration tracking system. Disinfectant replacement may take over an hour to complete under some circumstances, so plan accordingly.

b. Starting a Cycle: Once the automated disinfector and disinfectant are ready for use, place the cleaned probe into the disinfector. Care must be taken to place probes in the disinfector properly to avoid potential damage to non-submersible parts, contact with heated elements, and to prevent incomplete disinfection of the probe. Note that differences in the length and size of transvaginal probes means that the placement of the probe in the automated disinfector (i.e. the location on the cord from which the probe is suspended) may be unique to each probe. Follow the manufacturer's instructions and/or device prompts to input relevant run information and start the HLD cycle.

c. Test Strips: Some automated disinfectors may require a test strip to be placed in the device prior to starting each cycle. This test strip will be used to test if active ingredient in the high-level disinfectant reaches the minimum recommended concentration during the disinfection run. Be sure this test strip is properly placed within the device and double check that the test strips have not expired nor display any visual abnormalities prior to inserting into the device. If the automated disinfector does not use a pre-loaded test strip, the operator may need to stay in the vicinity of the disinfector while it is running to test that the disinfectant reached the appropriate concentration using a test strip or other manufacturer specified method, when prompted. Make sure that the proper test strip information is recorded in the system for each run to ensure that reminders about test strip expiration and the number remaining in each bottle are accurate. Regardless of the specific test strip procedure, the date opened should be recorded each time a new bottle or pack of test strips is opened. Store test strips according to the manufacturer's instructions (ex. at room temperature, away from light, in a closed container provided by the manufacturer). If it is unclear whether the test strips have been stored properly (ex. container was left

open following prior use) the test strips should not be used as this could lead to erroneous results.

d. Disinfection: When a disinfectant cleared for use in the machine is utilized, the automated disinfector will complete the disinfection cycle with the disinfectant at FDA cleared concentration, temperature, and exposure time.[5] Disinfect cables/cords using a compatible low-level disinfectant.[4] The cables can be disinfected while the automated disinfector is running, as long as the process does not disturb or hamper the HLD process in any way and there is no safety risk to the operator. Remove gloves and wash hands after handling the contaminated probe.[7] Discard dirty gloves appropriately.

7. Cycle Completion and Drying (Estimated time: 1-3 minutes): Don new clean gloves to avoid contaminating the disinfected probe with dirty gloves. Check that the HLD cycle is complete, and the automated disinfector encountered no system errors. If using a pre-loaded indicator system, confirm that the test strip indicator displays a passing result.

a. Passed and Complete Cycle: Following a successful cycle (i.e. the test strip provided passing result and cycle was completed without errors) remove the probe from the automated disinfector being careful not to contaminate or damage the probe. Probes that are disinfected using automated systems that remain heated after cycle completion should be removed promptly to avoid heat damage to fragile or sensitive areas of the probes (i.e. lens).

b. Failed or Incomplete Cycle: If the indicator test strip does not show a passing result for the cycle, the indicator was not used (ex. forgot to test/ put indicator in disinfector), or there was a system error that prevented cycle completion, the probe cannot be considered to be high-level disinfected. The probe may require rinsing and drying to remove residual disinfectant, but should be handled as not disinfected. HLD of the probe must be repeated until the probe completes an HLD cycle with a passing result. Follow facility SOPs and manufacturer's instructions for repeating HLD. Some disinfection systems may also require the disinfectant bottle be changed prior to initiating a repeat cycle. Consult the manufacturer's instructions for troubleshooting and contact information.

c. Drying: Dry the probe thoroughly using a sterile or gamma-irradiated, single-use low-lint cloth; starting at the lens and working toward the handle and cord. Do not use any drying cloth with compromised packaging or that is visibly soiled. For drying cloths that are not individually packaged, make sure that cloths were properly stored (ex. in a closed, sealed container) to avoid environmental contamination. Drying cloths that were improperly stored (ex. open to the environment) should not be used. Place the dried probe in a clean probe storage cover.

8. Storage (Estimated time: 1-5 minutes): Probes should be clearly labeled with the storage date, level of disinfection (e.g. HLD), and maximum storage duration according to institutional policies.[4] Storage information should be attached to the probe in such a way that does not damage the probe, compromise the integrity of the probe storage cover, or result in contamination of the high-level disinfected probe. In some facilities, probes may need to be transported to another storage location. Covered probes should be handled and transported to the storage area in a manner that prevents contamination.[4] Store probes in probe storage covers and/or cabinets with high efficiency particulate air (HEPA) filtration to reduce the risk of re-contamination from the environment. Do not place dirty and clean/disinfected transducers in the same cabinet or probe storage cover.[4] Unless otherwise specified by the manufacturer, only one probe should be stored in each probe storage cover.

9. Documentation and Traceability (Estimated time: 4 minutes): Document all details including (but not limited to) model, serial number, reprocessing personnel, high-level disinfectant identity, lot number and expiration date, validation result (e.g. chemical indicator, temperature, soaking time), date/time, and patient identifier according to institutional policies.[4] Documentation can be completed using manual

or automated processes.[4] Some automated disinfectors store cycle details that can be printed and stored or can be uploaded electronically to a tracking database supplied by the manufacturer or facility. Enough details should be documented that the completion of all cleaning and HLD can be confirmed by independent audit. Documentation should also facilitate traceability in the event of an adverse event investigation.

10. Hand Hygiene (Estimated time: 2 minutes): Remove PPE and discard appropriately. Wash hands before proceeding to next task.[6]

Total estimated reprocessing time: 37 - 50 minutes

Total operator hands-on time: 29 - 35 minutes

Discussion

Semi-automated methods using automated disinfectors can decrease the total reprocessing time and the total operator hands-on time to allow for a few minutes to complete other documentation or clinical duties. Further, semi-automated workflows may help reduce human error associated with HLD. However, these procedures do not address any issues or errors associated with manual cleaning methods. Proper cleaning is essential for effective HLD.[4,5,22-24]

Ultrasound probes, including transvaginal and transrectal probes contain crevices and divots that allow for the attachment of accessories during procedures. It can be difficult to reach and remove all of the soil from these areas using manual cleaning methods. This remaining soil on ultrasound probes could inactivate the high-level disinfectant[10,12] or protect microorganisms from disinfectant killing.[5,11] Therefore, improper manual cleaning as a result of human errors or improper training can decrease the efficacy of the entire workflow, regardless of the HLD method chosen.

Section III:
Automated reprocessing procedure for a transvaginal or transrectal probe in Ethos® Automated Ultrasound Probe Cleaner Disinfector

Summary

This section details the procedure for automated cleaning and disinfection of a transvaginal or transrectal probe using CS Medical's Ethos Automated Cleaner Disinfector with AquaCide cleaner disinfectant. Following use, probes are processed at the point-of-use and cleaned and disinfected using the Ethos Automated Ultrasound Probe Cleaner Disinfector (hereafter, Ethos). Once the cycle is complete, the probe is dried and stored to avoid probe contamination. Relevant procedure details are recorded and stored by the Ethos to facilitate documentation using paper or electronic records systems.

Definitions and abbreviations

Automated cleaner disinfector – an FDA-cleared medical device that has been cleared for use to clean and disinfect medical devices using an automated process. For the purposes of this document, automated cleaner disinfector refers to an FDA-cleared medical device cleared for the cleaning and high-level disinfection of semi-critical transvaginal ultrasound probes.

Chemical indicator – a substance that undergoes an observable change (usually color) when exposed to a threshold concentration of a chemical or active ingredient to determine if minimum recommended concentration is achieved.

Cleaning – the process of removing soil, debris, and foreign materials from medical devices

High-level disinfection (HLD) – most commonly defined as the elimination of all microorganisms on a device or instrument, except for small numbers of bacterial spores

High-level disinfectant – a chemical (usually in liquid, foam, or gaseous form) that kills all microorganisms on a device or instrument, except for a small number of bacterial spores when used according to the manufacturer's instructions for contact time, temperature, etc.

Low-level disinfection – a disinfection process that eliminates all vegetative bacteria (except tubercle bacilli) and most viruses from a device or instrument. Low-level disinfection does not eliminate bacterial spores

Low-level disinfectant - a chemical (usually in liquid, foam, or gaseous form) that eliminates all vegetative bacteria on a device or instrument, (except tubercle bacilli) and most viruses from a device or instrument when used according to the manufacturer's instructions for contact time, temperature, etc.

Minimum recommended concentration (MRC) – the lowest concentration of a chemical or active ingredient at which the disinfectant has been demonstrated to be effective.

Personal protective equipment (PPE) – equipment that is worn by an individual to minimize their exposure to workplace hazards such as hazardous chemicals/disinfectants and microorganisms.

Point-of-use cleaning – a cleaning process performed immediately after use to remove large amounts of gross soil and debris. This process is also sometimes referred to as pre-cleaning.

Probe storage cover – a sleeve designed to cover high-level disinfected probes during storage to protect them from environmental contamination. These sleeves are not designed to be used during ultrasound or medical procedures.

Probe transport vessel – a vessel (ex. bag) that is used to transport soiled probes from the point of care to the appropriate reprocessing area. These vessels should be marked as biohazardous when being used for soiled probes.

Standard operating procedure (SOP) – clear step-by-step instructions for carrying out a specific routine process in a facility or organization. SOPs are important for consistency and quality across multiple operators or departments.

Total estimated reprocessing time – time required to reprocess a probe from point-of-use processing to the final hand hygiene step following probe storage and documentation.

Total operator hands-on time - time that reprocessing technicians or clinical staff must spend actively engaged in the reprocessing procedure.

Transducer procedure cover – a cover, sheath, or condom that is used during ultrasound procedures to provide a physical barrier between the transducer and the tissue to help reduce probe contamination. Transducer procedure covers can fail (tear or be punctured) and should not be used as the only line of defense against cross-contamination. Use of a procedure cover does not change the Spaulding classification of a device.

Recommended equipment list

	AquaCide® Cleaner High-level Disinfectant
	Clean, low-lint (Gamma-irradiated) drying cloth (following disinfection)
	Ethos® Automated Ultrasound Probe Cleaner Disinfector
	Hand soap
	Hand washing sink
	Log book or electronic reprocessing record system
	Low-level disinfectant wipes for cleaning cords and connectors that cannot be subjected to automated disinfection
	Personal protective equipment (PPE) (eye protection, gloves)
	Probe storage bag
	Stickers to label high-level disinfected probes for storage (optional)
	Storage cabinet with high efficiency particulate (HEPA)-filtered air (optional)
	Transport vessel/bag with biohazard label(s)
	QwikCheck chemical indicator solution
	Wipe/sponge/cloth for point-of-use cleaning

Procedure

1. Point-of-Use Processing (Estimated time: 3 minutes): Don the proper personal protective equipment (PPE) including gloves and eye protection to protect from exposure to pathogens on the contaminated probe.[5,6] Disconnect the probe from the console and inspect and remove the transducer cover taking care to avoid further contaminating the transducer with blood or bodily fluids.[4,6,7] Once removed, the transducer cover should be discarded as biohazardous waste. Wipe the probe with a low-level disinfectant wipe or simple wipe to complete point-of-use cleaning. Minimize delays between use and reprocessing to prevent microbial growth.[2] Reprocessing should begin within one hour of point-of-use cleaning.

2. Transport (Estimated time: 0-5 minutes): The Centers for Disease Control and Prevention (CDC) recommends reprocessing be completed in a central reprocessing location.[5] However, probes may be reprocessed with the Ethos at the point of care because it is a closed automated system that minimizes the release of fumes from the disinfectant/cleaner. If transport to a designated reprocessing area is needed, place the point-of-use processed probe in a designated, clean transport vessel (ex. bag) labeled as biohazardous materials and deliver to the reprocessing area.[4,12] Personnel should remove and discard their gloves in the biohazardous waste and wash their hands after handling the probe to prevent the spread of potentially pathogenic microorganisms from the contaminated probe.[7]

3. Cleaning and High-level Disinfection (HLD) Setup (Estimated time: 1 minute): Check that the Ethos is ready for use. If the Ethos is off, flip the power switch to "on" and wait for the system to startup. Remove the probe from the transport vessel and examine the probe for obvious signs of damage that may prohibit reprocessing (cracks, missing pieces, etc.). Confirm the soiled probe is compatible with reprocessing in the Ethos.[4-6] Obtain a single-use bottle of AquaCide and check that the disinfectant has not expired and the bottle's integrity is intact.

4. Automated Cleaning and High-level Disinfection (HLD) (Estimated time: 18 minutes): The Ethos uses automated cleaning and HLD to minimize operator hands-on time and human errors.

a. Starting a Cycle: Follow the prompts on the Ethos display to insert the probe and record run information. Insert the AquaCide bottle into the Ethos, shut the door, and the cleaning and disinfection cycle will begin.

b. Cleaning and Disinfection: Ethos automatically cleans, high-level disinfects, and rinses the transvaginal probe using the FDA cleared concentration and exposure time for AquaCide. Disinfect cables/cords using a compatible low-level disinfectant.[4] The cables can be disinfected while the automated disinfector is running. Once the cord has been disinfected, the operator can walk away until the cycle is complete. Remove gloves and wash hands after handling the contaminated probe.[7] Discard gloves as biohazardous waste.

c. Automated Chemical Indicator System: During the cycle, the cleaner/disinfectant is automatically tested using the QwikCheck chemical indicator to determine if the active ingredient concentration is above the minimum recommended concentration (MRC). The multi-use QwikCheck chemical indicator bottle can be stored at room temperature, and is attached inside Ethos on its built-in shelf. The Ethos also automatically tracks chemical indicator liquid levels and expiration dates to prevent usage of expired indicator or insufficient indicator volume.

5. Cycle Completion and Drying (Estimated time: 1-3 minutes): Don appropriate PPE (e.g. clean gloves and eye protection). Check that the cycle is complete, and the Ethos encountered no system errors, as evidenced by a printed ticket stating that the run "Passed."

a. Passed and Complete Cycle: Following a successful cycle, remove the probe from the automated disinfector being careful not to contaminate or damage the probe.

b. Failed or Aborted Cycle: In the rare event that the system detects a run abnormality, the run will abort and automatically rinse the probe using fresh water. A "failed" report ticket will be automatically printed and should not be discarded. The probe is not considered disinfected and should be handled accordingly.

c. Drying: Once removed from the Ethos, dry the probe thoroughly using a gamma-irradiated, single-use low-lint cloth; starting at the lens and working toward the handle and cord. Do not use any drying cloth with compromised packaging or that is visibly soiled. For drying cloths that are not individually packaged, make sure that cloths were properly stored (i.e. in a closed, sealed container) to avoid environmental contamination. Drying cloths that were improperly stored (i.e. open to the environment for an extended time) should not be used. While drying, inspect the probe for any residual soil or damage. Place the dried probe in a clean probe storage cover.

6. Storage (Estimated time: 1-5 minutes): Probes should be clearly labeled with the storage date, level of disinfection (e.g. HLD), and maximum storage duration according to institutional policies.[4] In some facilities, probes may need to be transported to another storage location. Covered probes should be handled and transported in a manner that prevents contamination.[4] Store probes in probe storage covers or cabinets with high efficiency particulate air (HEPA) filtration to reduce the risk of re-contamination from the environment. Do not place dirty and clean/disinfected transducers in the same cabinet or probe storage cover.[4] Unless otherwise specified by the manufacturer, only one probe should be stored in each probe storage cover.

7. Documentation and Traceability (Estimated time: 1 minute): At the end of each run, a ticket containing the relevant run information, such as model, serial number, reprocessing personnel, validation result (e.g. chemical indicator information, temperature, disinfection time), lot numbers, and date/time is printed. Documentation can be completed using manual or automated processes.[4] Printed tickets can easily be maintained using the Ethos Log book. Run information is also stored on a USB drive for uploading to electronic systems.

8. Hand Hygiene (Estimated time: 2 minutes): Remove PPE and discard appropriately. Wash hands before proceeding to next task.[6]

Total estimated reprocessing time: 27 – 38 minutes

Total Operator Hands-on time: 9 – 20 minutes

Discussion

Ethos is the first FDA-cleared automated system for cleaning and high-level disinfecting transvaginal or transrectal ultrasound probes. The fully automated workflow eliminates many of the potential issues associated with manual and semi-automated reprocessing methods. Ethos is an enclosed system, which helps contain disinfectant fumes to protect staff and eliminates the need for bulky and costly fume hoods and enclosures. The Ethos workflow also requires the least amount of operator hands-on time, when compared to the manual and semi-automated methods detailed in previous sections. This combined with the automated sampling and reading of the chemical indicator provides a completely hands-free process from the cycle start to end. Clinical staff and reprocessing technicians can then be available to focus on completing other tasks. Further, the automated workflow also addresses the issue of human error associated with both the manual cleaning and HLD procedures, while eliminating potential variability between operators. With a single automated workflow for multiple probe models and manufacturers, the Ethos represents the next advancement in transvaginal and transrectal ultrasound probe reprocessing procedures.

Section IV: Conclusion

Proper cleaning and disinfection of transvaginal and transrectal probes is essential to providing a safe patient environment and preventing healthcare associated infections. Developing and following procedures in accordance with current best practices and guidelines can help reprocessing staff work safely and efficiently without compromising patient safety. As described in this guide, reprocessing procedures for transvaginal or transrectal probes may utilize manual, semi-automated, or automated methods. However, completely automated cleaning and disinfection of transvaginal and transrectal probes in CS Medical's Ethos automated ultrasound probe cleaner disinfector provides some distinct advantages. Automated workflows are safer for staff by preventing chemical exposures and for patients by reducing the likelihood of human error to provide a reproducibly, and reliably clean and disinfected probe each time. Further, the ability to use a single reprocessing workflow for compatible probes from different manufacturers can reduce confusion and time spent checking reference materials for each individual probe. Clinical staff and reprocessing technicians have more hands-off time during the automated reprocessing procedure to complete other clinical tasks to maximize their time. The result is a single, efficient, and reproducible workflow that promotes patient safety and infection prevention in healthcare settings.

References

1. The Joint Commission, Quick Safety Issue 33: Improperly sterilized or HLD equipment - a growing problem. 2017.

2. The Joint Commission, Top 5 Most Challenging Requirements for 2022. 2023, The Joint Commission Online.

3. Carrico, R.M., S. Furmanek, and C. English, Ultrasound probe use and reprocessing: Results from a national survey among U.S. infection preventionists. American Journal of Infection Control, 2018. 46(8): p. 913-920.

4. Society of Diagnostic Medical Sonography, Sonographer Best Practices for Infection Prevention and Control: Reprocessing the Ultrasound Transducer. 2022: Plano, TX.

5. Rutala, W.A., D.J. Weber, and Healthcare Infection Control Practices Advisory Committee, Guideline for Disinfection and Sterilization in Healthcare Facilities, , Centers for Disease Control and Prevention Editor. 2008. p. 14-21. Medicine.

6. American Institute of Ultrasound in Medicine, AIUM Official Statement: Guidelines for Cleaning and Preparing External- and Internal-Use Ultrasound Transducers and Equipment Between Patients as Well as Safe Handling and Use of Ultrasound Coupling Gel. J Ultrasound Med, 2023. 42(7): p. E13-E22.

7. American College of Emergency Physicians, Guideline for Ultrasound Transducer Cleaning and Disinfection. 2021.

8. Food and Drug Administration, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Center for Diagnostic and Radiological Health. 2017.

9. Johnson, S., et al., Evaluation of a hydrogen peroxide-based system for high-level disinfection of vaginal ultrasound probes. J Ultrasound Med, 2013. 32(10): p. 1799-804.

10. Lambert, R.J. and Johnston, M.D., The effect of interfering substances on the disinfection process: a mathematical model. J Appl Microbiol, 2001. 91(3): p. 548-55.

11. Lewis, D.L. and Arens, M., Resistance of microorganisms to disinfection in dental and medical devices. Nat Med, 1995. 1(9): p. 956-8.

12. Rutala, W.A. and Weber, D.J., Uses of inorganic hypochlorite (bleach) in health-care facilities. Clin Microbiol Rev, 1997. 10(4): p. 597-610.

13. AAMI Chemical Sterilants Hospital Practices Working Group, ANSI/AAMI ST58:2013 (R2018) Chemical Sterilization And High-Level Disinfection In Health Care Facilities. 2018, Association for the Advancement of Medical Instrumentation: Arlington, VA.

14. Ofstead, C.L., et al., Splash generation and droplet dispersal in a well-designed, centralized high-level disinfection unit. Am J Infect Control, 2022. 50(11): p. 1200-1207.

15. Association for the Advancement of Medical Instrumentation, ANSI/AAMI ST108: Water for the Processing of Medical Devices. 2023.

16. Food and Drug Administration, FDA-Cleared Sterilants and High-Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices. 2023. [Accessed February 6, 2024]; Available from: https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and.

17. Food and Drug Administration, Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/ High-Level Disinfectants. Center for Diagnostic and Radiological Health. 2000.

18. Ackerman, S.B., et al., Toxicity testing for human in vitro fertilization programs. J In Vitro Fert Embryo Transf, 1985. 2(3): p. 132-7.

19. Fujita, H., M. Ogawa, and Y. Endo, A case of occupational bronchial asthma and contact dermatitis caused by ortho-phthalaldehyde exposure in a medical worker. J Occup Health, 2006. 48(6): p. 413-6.

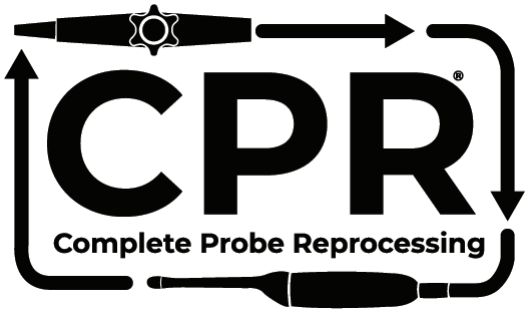
20. Lawson, C.C., et al., Occupational exposures among nurses and risk of spontaneous abortion. Am J Obstet Gynecol, 2012. 206(4): p. 327.e1-8.

21. Sokol, W.N., Nine episodes of anaphylaxis following cystoscopy caused by Cidex OPA (ortho-phthalaldehyde) high-level disinfectant in 4 patients after cytoscopy. J Allergy Clin Immunol, 2004. 114(2): p. 392-7.

22. CS Medical, Manual vs. Automation. [Accessed February 5, 2024]; Available from: https://www.csmedicalllc.com/manual-vs-automation.

23. CS Medical, Cleaning Makes All the Difference. [Accessed February 5, 2024]; Available from: https://www.csmedicalllc.com/cleaning-makes-all-the-difference.

24. CS Medical, The Role of Automation in Cleaning. [Accessed February 5, 2024]; Available from: https://www.csmedicalllc.com/the-role-of-automation-in-cleaning.



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