SONOGRAPHER BEST PRACTICES FOR INFECTION PREVENTION AND CONTROL:

Reprocessing the Ultrasound Transducer

SOCIETY OF DIAGNOSTIC MEDICAL SONOGRAPHY

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This document replaces the Guides for Infection Prevention and Control in Sonography: Reprocessing the Ultrasound Transducer, published in 2020. Sonographers should consult with their facility's infection control and risk management personnel to determine and document their facility-specific infection control and disinfection policies and procedures.

Comments/Suggestions: The SDMS is committed to providing informational resources like these best practices to its members. If you have comments or suggestions for these best practices or other informational white papers, please contact the SDMS at: executivestaff@sdms.org

Discussions: SDMS Members are encouraged to utilize the *SDMS Collaborate* Community, https://collaborate.sdms.org, to discuss the issues addressed in these best practices and other SDMS white papers.

Reporting: If you suspect a problem with a reusable medical device or reprocessing procedures for a reusable medical device, we encourage you to file a report with the FDA.

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EXECUTIVE SUMMARY

The diagnostic medical sonography profession is comprised of sonographers working in abdominal, breast, cardiac, obstetrics, gynecology, musculoskeletal, pediatric, phlebology, vascular, and other emerging specialty/clinical areas. Sonographers use ultrasound as the primary technology in their daily work.

Risks of infection leave patients and sonographers unprotected.

Risks of infection from contaminated ultrasound transducers, transducer covers, or coupling agents (gel) can leave patients and sonographers unprotected. Situational risks also include sonographers (or managers) being unfamiliar with best practices for transducer reprocessing – that is, the proper use, handling, cleaning, sterilization or disinfection, transport, and storage of transducers (hereinafter referred to as "reprocessing") used in diagnostic medical sonography. Additionally, there may be a temptation to truncate known infection control, disinfection, and safety processes to cope with the compressed scheduling of sonography procedures or healthcare staffing shortages.

To reinforce safety, the Society of Diagnostic Medical Sonography (SDMS) has updated its infection prevention and control guidance, originally published in 2018 and revised in 2020, with the *Sonographer Best Practices for Infection Prevention and Control: Reprocessing the Ultrasound Transducer.*

While these best practices focus on the reprocessing of the transducer, the importance of infection prevention and control principles applies equally to the ultrasound machine and any ancillary equipment used during the procedure (e.g., cables, keyboards, beds, chairs, IV poles, oxygen systems, cords). Cross-contamination of the ultrasound machine, ancillary equipment, and other surfaces (e.g., gel bottles, light switches, doorknobs/handles) presents significant infection prevention and control risks and challenges.

Transducer safety and infection prevention: Whose responsibility?

Sonographers are on the front line of defense in protecting their patients and themselves from infection due to contaminated transducers, as well as the ultrasound machine and ancillary equipment. However, protection is a shared responsibility among manufacturers, suppliers, healthcare facilities, and, of course, the sonographers themselves.

Manufacturers and suppliers should be intimately familiar with equipment functioning, contamination risks, and best practices for mitigating risks and then consistent and reliable in providing clear and concise Instructions For Use (IFU) to mitigate risk. Manufacturers' IFU and other guidance for infection prevention and control should be easily accessible on their website. Manufacturers and suppliers that refurbish transducers should take the steps necessary to prevent contamination during or after the manufacturing or refurbishment process.

Healthcare facilities should establish policies, standard operating procedures, sonographer training programs and refresher courses, and provide workflows that offer sonographers the time and resources to follow best practice infection control, disinfection, and safety procedures.

Sonographers should stay current on manufacturers' IFU and other guidance for infection prevention and control and follow established infection control, disinfection, and safety procedures in all instances to ensure the facility has the capability and capacity to adequately clean and reprocess the transducer.

Approach to best practices for transducer reprocessing

In outlining best practices for transducer reprocessing to protect sonographers and their patients, the SDMS relied on authoritative, evidence-based sources of information, including the Centers for Disease Control and Prevention (CDC) *Guideline for Disinfection and Sterilization in Healthcare Facilities*. The ***Sonographer Best Practices for Infection Prevention and Control: Reprocessing the Ultrasound Transducer*** applies the industry-accepted Spaulding Classification (related to sterilization and disinfection of medical equipment) to transducers.

Transducer risk is assigned as critical, semi-critical, or non-critical, based on whether the transducer will or did come in contact with sterile tissue of the body, mucous membranes or non-intact skin, or only intact skin respectively. The classification can be interpreted and/or change pre-procedure, during the procedure, or post-procedure. Based on the classification in each case, a transducer should be cleaned and given either sterilization, high-level disinfection (HLD), or low-level disinfection (LLD).

This paper outlines the steps that the sonographer should take before, during, and after the procedure. These steps include identifying the level of sterilization/disinfection, method of disinfection, rinsing and drying procedure, documentation needed, storage type, and workflow processes. This paper also outlines numerous factors that potentially affect the efficacy of transducer reprocessing.

Finally, appendices and an educational worksheet are provided to assist sonographers, managers, healthcare facilities, and infection control professionals in determining the proper transducer reprocessing steps based on the Spaulding Classification at each stage of the sonographic procedure.

Keeping up with change and ultrasound equipment innovation

Transducer's materials and electronics can react differently to some reprocessing techniques, so gaps may exist in the ability to perform the desired method of reprocessing for the transducer. New technologies (e.g., transducers connected to smartphones or tablets) also represent possible new risks and challenges that manufacturers, facilities, and sonographers must consider and address in the future. Therefore, while this paper addresses current best practices, users need to be vigilant in monitoring how technological advances, new research, and new methods of disinfection or classifications continue to evolve best practices for infection prevention over time.

SCOPE AND LIMITATIONS: The best practices described:

- Do not represent a legal requirement under state or federal law. Consult your facility's infection control department for additional guidance.
- Do not address an "intermediate-level disinfection" (ILD) that has been proposed by some medical organizations, but which has not yet received Food and Drug Administration (FDA) or CDC-acceptance as a recognized standard for ultrasound equipment.[1]
- Do not address ultrasound transducers used for endoscopic, intracardiac, intravascular, or laparoscopic purposes.
- Are only intended for transducers used on people and not those used on animals.

1. INTRODUCTION

Evidence-based and reproducible infection prevention and control practices are essential to ensure that sonography procedures are safe for patients and sonographers. Infection prevention and control guidelines and standards covering sonography have been in place for many years in the United States, but pre-date the rapid expansion of the use of sonography in many medical specialties and procedures.

In particular, those guidelines and standards incorporate the CDC's *Guidelines for Disinfection and Sterilization in Healthcare Facilities* (published in 2008, reviewed in 2017), the Association for the Advancement of Medical Instrumentation (AAMI) Standard *ST58:2013: Chemical Sterilization and High-Level Disinfection in Healthcare Facilities*, the FDA, and the AAMI Standard *ST34:2014: Water for the Reprocessing of Medical Devices, and the Spaulding Classification*.[1-5] Other transducer reprocessing guidelines have also been released, both in the United States and internationally, by various organizations, including the American Institute for Ultrasound in Medicine, World Federation for Ultrasound in Medicine and Biology, European Society of Radiology, European Committee for Medical Ultrasound Safety, Australasian Society for Ultrasound in Medicine/Australasian College for Infection Prevention and Control, Health Service Executive Ireland and Health Facilities Scotland.[6-12]

This document builds upon earlier guidelines and provides a comprehensive set of recommended sonographer best practices related to disinfection and transducer reprocessing. Sonographers should consult the manufacturer's IFU for use of appropriate cleaners, disinfectants, and sterilants that have undergone both material compatibility and reprocessing validation and efficacy testing.

2. INFECTION PREVENTION AND CONTROL RISKS AND CHALLENGES

Proper infection prevention and control practices are necessary to protect patients and sonographers. Contaminated transducers and ultrasound gel or coupling agent (hereinafter referred to as "gel") have been associated with infection outbreaks, including those in the bloodstream, urinary tract, respiratory tract, biopsy sites, and wounds. There are also documented cases of hepatitis B and C, some resulting in patient death.[13-19] These infections were attributable to a failure to follow evidence-based and reproducible infection prevention and control practices. As a result, regulatory, accrediting, and public health agencies, including the FDA, The Joint Commission, and the CDC have issued several alerts regarding transducer use and reprocessing.[20-22] In addition, infections from inadequately reprocessed devices are not often recognized or reported to the FDA.[23]

A study of 15 pathogens linked to healthcare acquired infections reported pathogen survival rates on dry, inanimate surfaces ranging from a few hours to as much as 16 months. The potential health threat posed by pathogen exposure is compounded by the emergence of a relatively unknown or new disease agent, such as the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) for which a global pandemic was declared in 2020. Use of a properly reprocessed transducer with an appropriate transducer cover and gel can reduce the risk of transmitting pathogens during sonographic procedures and promote patient safety.

3. UNDERSTANDING HOW THE SPAULDING CLASSIFICATION AFFECTS TRANSDUCER REPROCESSING

The CDC Guidelines use the Spaulding Classification ("classification") to determine the sterilization and disinfection requirements for medical devices based on the level of infection risk associated with their use.[5] Sterilization is defined as the destruction or inactivation of microorganisms to minimize infection transmission risk. Some healthcare professionals and literature refer to "disinfection" as "sterilization." Medical device reprocessing standards, regulations, and guidelines widely use this classification system.[1,2,26-28]

Assessment of risk of transducer contact with sterile tissue of the body, mucous membranes or non-intact skin, or only intact skin determines its classification into one of three groups:

Critical – Transducer will or did contact sterile tissues during the procedure. Sterile tissue includes body sites, cavities, or tissues that are endogenously free from all living organisms. This includes, but is not limited to, the vascular system, joints and joint spaces, other internal body fluids (e.g., blood, synovial fluid), vasculature, internal body organs, peritoneum, and retroperitoneum.

Semi-critical – Transducer will or did contact mucous membranes or non-intact skin during the procedure (i.e., no risk of contact with sterile tissues). Mucous membranes produce mucus and line cavities or surfaces of the body that open to the external environment, such as the digestive tract, the respiratory passages, and the genitourinary tract. Non-intact skin includes cuts, punctures, abrasions, dermatitis, etc.

Non-critical – Transducer will or did only contact intact skin during the procedure (i.e., no risk of contact with sterile tissues, mucous membranes, or non-intact skin). Intact skin is completely healthy and does not have open cuts, punctures, abrasions, dermatitis, etc.

NOTE: Use of a transducer cover does not change the Spaulding Classification or disinfection process as transducer covers have been shown to have micro-perforations and they can break, open, or tear.[1,26]

The expected classification could change during or after the procedure if the transducer comes in contact with mucous membranes or sterile tissues. The sonographer may classify the same transducer differently when it is used in another procedure. Sonographers should work closely with their facility's infection control and risk management personnel to determine and document their infection control and disinfection policies and procedures. Any deviations from these policies and procedures (e.g., due to a transducer manufacturer's IFU limiting the type of approved disinfectant) should be documented and reviewed in accordance with the facility's policies and procedures.

4. SONOGRAPHIC PROCEDURE

The sonographer determines the classification before commencing the procedure. It is sometimes difficult to anticipate what tissues or devices the transducer might contact (e.g., needle/catheter, sterile tissue, mucous membranes, intact, or non-intact skin). Where a significant risk of contact exists, it may be prudent to apply the higher classification.

The sonographer should ensure proper hand washing and use of gloves before and after the procedure. Refer to the steps below to further prevent infection transmission before, during, and after performing the procedure.

4.1. Before the Procedure

Ensure the procedure area is clean and surfaces have been appropriately disinfected, the transducer has been appropriately reprocessed, and any necessary ancillary equipment is clean for the upcoming procedure.

4.1.1. Select the Correct Transducer

Determine the correct transducer for the procedure, visually inspect the transducer (e.g., damage, visible soil, bioburden), and prepare the transducer based on classification for the procedure. If the transducer's classification status changes before or during the procedure, the needed transducer reprocessing may change.

Table 1. Transducer Selection (adapted from the CDC Guidelines[1])

CLASSIFICATION	REPROCESSED TRANSDUCER
Critical	Cleaned followed by sterilization. *If not compatible with sterilization process, then HLD may be used*
Semi-critical	Cleaned followed by HLD. *If not compatible with HLD process, disinfect to the highest level possible.*
Non-critical	Cleaned followed by LLD

4.1.2. Select the Correct Transducer Cover

The choice of transducer cover will depend on the procedure to be performed. For critical procedures, a sterile transducer cover should be used.[1] At the minimum, a non-sterile transducer cover should be used for all semi-critical procedures (e.g., endocavitary); however, a sterile cover is preferred. Transducer covers are optional for non-critical procedures. Do not reuse transducer covers.

Table 2. Transducer Cover Selection

CLASSIFICATION	TRANSDUCER COVER
Critical	Sterile Cover
Semi-critical	Sterile cover (preferred) or non-sterile cover.
Non-critical	Non-sterile cover (optional)

4.1.3. Select the Correct Ultrasound Gel

A single-use, sterile gel packet is recommended for all critical procedures and is preferable for semi-critical procedures.[6,12] A single-use, non-sterile gel packet is recommended for all semi-critical procedures and is preferred for non-critical procedures. Do not use a multi-use gel bottle for critical and semi-critical procedures. A multi-use gel bottle may be used for non-critical procedures but is the least preferred option due to the potential for patient cross-contamination and gel contamination.

Table 3. Ultrasound Gel Selection

CLASSIFICATION	ULTRASOUND GEL
Critical	Single-use, sterile gel only
Semi-critical	Single-use, sterile gel (preferred) or single-use, non-sterile gel
Non-critical	Single-use, non-sterile gel (preferred) or multi-use non-sterile gel (i.e., bottle)

Discard unused portions of a single-use gel packet; do not use on other patients. If using a multi-use gel bottle, ensure the tip of a multi-use gel bottle does not contact the patient, transducer, and any ancillary equipment. If the multi-use gel bottle tip comes in contact, discard the multi-use gel bottle. If a multi-use gel bottle is used with an isolation patient or in an isolation precaution setting, discard the multi-use gel bottle after use.

The use of a refilled gel bottle, as well as the heating of gel bottles, is discouraged as this can lead to micro-organism growth, pathogen transmission, cross-contamination, and possible outbreaks.[29]

4.2. During the Procedure

During the procedure, use caution to prevent the transfer of pathogens from potentially contaminated surfaces (e.g., clothing, non-sterile gloves, other equipment, and environment) to the reprocessed transducer, transducer cover, or gel.

If the transducer cover is damaged during the procedure (e.g., tear, puncture), immediately discard it and replace the damaged transducer cover with a new transducer cover. In such a case, the transducer's assessed classification may need to be altered if the transducer contacts sterile tissue or mucous membrane due to the damaged cover and may require different reprocessing procedures. If feasible, replace the contaminated transducer with an appropriately reprocessed transducer before continuing the procedure.

4.3. After the Procedure

After the procedure, inspect and remove the transducer cover (if used) and discard it in a designated, approved receptacle. Inspect the transducer for possible damage. Immediately clean (e.g., remove any remaining gel, visible soil, or bioburden) and disinfect the transducer if classified as non-critical based on the procedure performed. If the transducer is classified as critical or semi-critical, place it in a transport container (e.g., container with lid, impermeable bag), label the container as dirty with a biohazard symbol, and deliver it to the reprocessing area.

Clean and disinfect all high-touch surfaces in the procedure area including, but not limited to bed railings and the ultrasound machine's console and controls (see the manufacturer's IFU or other guidance). Discard waste (e.g., used gloves, wipes, drapes) in a designated, approved receptacle.

5. TRANSDUCER REPROCESSING

According to the CDC *Guidelines for Disinfection and Sterilization in Healthcare Facilities*, there are various factors that affect the efficacy of reprocessing including prior cleaning, removal of bioburden, the organic and inorganic load that is present, type and degree of microbial contamination, concentration and exposure time of the germicide, and the physical features of the transducer or equipment (e.g., bevels, crevices, lumens). Additionally, the temperature and pH of the process and relative humidity may affect the sterilization process.[1]

Reprocess the transducer and disinfect any ancillary equipment used. Reprocessing includes cleaning, sterilization or disinfection, transport, and storage based on the transducer's contact with sterile tissue of the body, mucous membranes or non-intact skin, or only intact skin. Additional considerations such as traceability are also important. See details below.

5.1. Cleaning

Effective sterilization or disinfection requires adequate cleaning. Cleaning should remove all visible gel, soil, and bioburden on all surfaces of the transducer or any ancillary equipment including any indentations or complex surfaces. Potential cleaning agents for the transducer include neutral pH cleaner, approved wipes, soap and running water, and enzyme soaks. The selection of a cleaning process should factor in the manufacturer's IFU, cleaning efficacy, cost, time, complexity, safety, and designated location for reprocessing.

5.2. Sterilization and Disinfection

Sterilization or disinfection refers to the destruction or inactivation of microorganisms, which in turn minimizes infection transmission risk. Choice of sterilization or disinfection level depends on the classification of the transducer, which is based on use in the prior completed procedure and the intended use in the next procedure. The transducer manufacturer's IFU should be consulted for the recommended sterilization or disinfection methods. Other factors to consider include, but are not limited to, sterilization or disinfection efficacy, cost, cycle time, complexity, safety, designated location, and simultaneous transducer reprocessing capability. See below for further detail on sterilization, HLD, and LLD.

5.2.1. Sterilization

The FDA defines sterilization as the complete removal of all viable microorganisms, including bacterial endospores, to the extent of achieving a sterility assurance level (SAL) of at least 10^{-6}.[3] Ideally, all critical transducers and devices that are to be inserted into sterile tissue (e.g., needles, catheters) would be sterilized. However, if the transducer cannot be sterilized (see manufacturer's IFU), HLD is acceptable if the transducer is used with a sterile transducer cover and sterile gel.[1,12] Common sterilization options for the transducer include ethylene oxide gas, hydrogen peroxide gas plasma, and liquid chemicals with extended contact times (e.g., glutaraldehyde, ortho-phthalaldehyde).[2] It is critical to ensure that any sterilization process is compatible with the transducer and will not cause damage (see manufacturer's IFU).

5.2.2. High-Level Disinfection

HLD is the removal of all microorganisms except bacterial endospores, of which small numbers are permitted to remain.[1,6-8,12] HLD is suitable for a transducer that contacts sterile tissue if the transducer cannot be sterilized (and if used with a sterile transducer cover).[1,12] HLD is recommended for a transducer that contacts mucous membranes or non-intact skin unless the transducer is not compatible with HLD and, therefore, should be disinfected to the highest level possible and used with a sterile transducer cover and sterile gel.

According to the CDC *Guidelines for Disinfection and Sterilization in Healthcare Facilities*, unlike sterilization, disinfection does not generally kill spores. Only a few disinfectants, known as chemical sterilants, are effective in killing spores over prolonged exposure times (3–12 hours). When similar concentrations are used, but for shorter exposure periods (e.g., 20 minutes for 2% glutaraldehyde), these same disinfectants (so-called high-level disinfectants) will kill all microorganisms *except large numbers of bacterial spores.*[1]

Automated HLD methods include hydrogen peroxide mist devices and liquid soak devices using approved liquid chemicals such as glutaraldehyde, ortho-phthalaldehyde, and accelerated hydrogen peroxide. Manual HLD can safely occur using HLD vapor-control soaking stations with approved liquid chemicals such as glutaraldehyde, ortho-phthalaldehyde, peracetic acid, hydrogen peroxide, and accelerated hydrogen peroxide. Automated processes are preferable because they reduce the risk of operator error.[7,12,28,29]

Select HLD methods that are efficient, effective, reliable, reproducible, and safe for the transducer, sonographer, and environment. A process that provides HLD to the transducer (head and handle) with LLD of cables and connectors is preferred, as these components can harbor clinically relevant pathogens.[25,32] Refer to the manufacturer's IFU to ensure that the HLD process selected is compatible with the transducer and for other suitable HLD options. The FDA website provides a list of FDA-cleared sterilants and HLD disinfectant chemistries.[34]

5.2.3. Low-Level Disinfection

LLD is the inactivation of vegetative bacteria, enveloped viruses, some non-enveloped viruses, and most fungi in a practical timeframe (i.e., ≤10 minutes).[1] LLD is used for a non-critical transducer that only contacts intact skin.[1] Common low-level disinfecting agents include quaternary ammonium compounds, alcohols, and phenols available as sprays and disinfectant wipes. Refer to the manufacturer's IFU to ensure that the chosen LLD disinfection method is compatible with the transducer. Alcohols are often contraindicated due to material incompatibility.

5.3. Rinsing and Drying

Perform rinsing and drying after sterilization or disinfection, if required based on the reprocessing method and requirements of the manufacturer's IFU. Thoroughly dry the transducer before storing. These steps can help ensure that no chemical residues remain on the transducer after reprocessing.

Follow the disinfectant manufacturer's IFU for rinse requirements, rinse water quality and sterility, the number of rinses, and drying method. Following HLD, perform any required rinses in a separate, clean container using critical water (treated water).[4] Sterile water is typically required for immunocompromised patients.[1,2,4,33]

5.4. Documentation and Traceability

The facility should develop a written policy outlining the requirements for transducer reprocessing documentation and traceability. Documentation and traceability measures are needed for critical and semi-critical transducers requiring sterilization and HLD but may not be necessary for non-critical transducers requiring LLD.[2]

Document all reprocessing details including, but not limited to, the transducer model, serial number, or other unique identifier, reprocessing personnel identifier, validation result (e.g., chemical indicator/test strip, temperature, soaking time), date/time, and patient identifier.[2]

To ensure traceability, reprocessing records must be linked to the patient on whom the transducer is used. Traceability is ensured through manual (e.g., logbooks, stickers) or automated processes (e.g., electronic health records, tracking systems). In the event of a reprocessing failure or an outbreak, thorough documentation for each transducer reprocessing cycle will aid in traceability to a patient.

5.5. Storage

Proper storage reduces the risk of re-contamination of the transducer from environmental contaminants or accidental contamination. Storage practices, including maximum storage duration, should be consistent with the transducer's intended use, manufacturer's IFU, and facility's policies. Suitable options for transducer storage include storage covers, boxes, or cabinets (e.g., HEPA-filtered, ventilated or non-ventilated). Clearly label the container housing the transducer with disinfection level, storage date, and maximum storage duration. Maintain distinct separation of clean (based on disinfection level) and dirty transducers. Dirty transducers should not be placed in the same cabinet as clean transducers.

6. INFECTION PREVENTION AND CONTROL CONSIDERATIONS FOR TRANSDUCER REPROCESSING WORKFLOW

There are many important considerations inherent in the infection prevention and control workflow for transducer reprocessing. Perform reprocessing by using a dirty-to-clean workflow. Assistance for streamlining the workflow is described next.

6.1. Types of Procedures

Consider the type of procedure, location, and reprocessing requirements. In some clinical settings, the transducer may be used for the same type of procedure throughout the day or may be used for a variety of procedures. Therefore, the sonographer should select the transducer based on the intended use. The facility's policies should address whether to have appropriately processed transducers available in storage or to reprocess transducers as they are needed.

6.2. Reprocessing Time

Consider the length of each patient procedure and the reprocessing time needed. If the reprocessing time is more than the amount of time available between procedures, the facility may need additional transducer inventory. It may be helpful to map out the patient-to-patient workflow, including reprocessing, to identify potential efficiency gains. For example, it may be possible to conduct reprocessing in parallel to the patient change-over process.

6.3. Reprocessing Location and Transportation

After the procedure, immediately remove the transducer cover (if applicable), excess gel, and other contaminated items (e.g., gowns, sheets) and dispose of them in a designated approved receptacle. The transducer can potentially be reprocessed in the exam room if the cleaning and disinfection processes are suitable for use in that environment and a dirty-to-clean workflow is established.[12]

If the transducer cannot be safely reprocessed in the exam room, transport the transducer in a designated, approved container to a separate room for reprocessing and, once complete, return the transducer in a designated, approved clean or sterile transport container, as appropriate. Handle the transport containers in a manner to prevent contamination of the transducer, other equipment, and the facility. Containers used to transport contaminated items by hand should be maintained in a position parallel to the floor.[2] Transport containers and any transport carts should be disinfected. Clearly mark designated, approved containers as clean or dirty with a biohazard symbol.

6.4. Compatibility

The facility must have the capability and capacity to adequately clean and reprocess transducers. Consult the manufacturer's IFU or other guidance on use, handling, and reprocessing of the manufacturer's equipment before purchasing. If an entity other than the manufacturer has repaired the transducer, ensure the manufacturer's IFU for cleaning and reprocessing is still valid.

6.5. Establishing Policies and Standard Operating Procedures (SOPs)

Before adopting a reprocessing workflow, consider the total cost of reprocessing including equipment, consumables, personnel, time, personal protective equipment, and turnaround time. It is also important to look at how safe, reliable, and reproducible the process is for the patient, sonographer, and transducer.[1,2] Additionally, consider how reprocessing time might impact patient throughput.

The facility should have written reprocessing policies and standard operating procedures (SOPs) that are specific to the types of procedures, transducers, ancillary equipment, clinical settings, and reprocessing requirements. Align the policies and SOPs with the current manufacturer's IFU, regulations, guidelines, and standards. Conduct ongoing risk assessments and review of policies and SOPs and update accordingly.

6.6. Personnel

Personnel assigned to perform transducer reprocessing (typically the sonographer) should undergo documented competency-based training and assessment on transducer reprocessing at least annually. Policies should define the roles and responsibilities of the personnel assigned to manage and ensure compliance with procedures and reprocessing requirements.[1,2]

6.7. Evaluation and Quality Improvement

A process that monitors infection prevention and control practices related to ultrasound equipment use and reprocessing workflow should be in place for each clinical setting. The process should reflect an assessment of risks to patients and sonographers for each type of procedure. The process should include methods for observation, performance measurement, intervention, feedback, and documentation to identify practice gaps. Report process results as part of a continuous quality and performance improvement approach.

Maintenance of the transducer and ancillary equipment should follow the same process of risk assessment, performance measurement, intervention, feedback, and documentation. Damaged equipment may harbor pathogens, tear transducer covers, or impact the ability of the sonographer to perform the procedure safely and accurately. If equipment damage is identified, such as a transducer with a crack, abrasion, or tear, there should be processes in place to promptly remove the equipment from use, document the damage, and ensure repair or replacement.

7. PROCESS OVERVIEW: IDENTIFICATION OF FACTORS IMPACTING TRANSDUCER CLASSIFICATION

Step 1. Factors known before the procedure:

- ❑ Determine the prior disinfection level of transducer used.
- ❑ Determine if there are any factors that can or will affect the transducer, cover, or gel needed and the procedure to be performed (e.g., open wound, unsanitary location, a high-risk immunocompromised patient).
- ❑ Determine the expected classification and post-procedure disinfection requirements (based collectively on the known factors).

Step 2. Factors identified during the performance of the procedure:

- ❑ Determine if any additional factors are identified during the procedure (e.g., transducer contacts a mucous membrane, transducer cover tear) that may affect the actual classification and post-procedure disinfection requirements.

Step 3. Factors identified after the procedure:

- ❑ Determine if there are any additional factors identified after the procedure (e.g., transducer contacts mucous membranes or sterile tissues, transducer cover tear) that may affect the actual classification and post-procedure disinfection requirements.

Step 4. Actual classification:

- ❑ Determine the actual classification and post-procedure disinfection requirements (based collectively on the factors identified in Steps 1, 2, and 3 above).

8. SONOGRAPHY PROCEDURES: TRANSDUCER DISINFECTION AND INFECTION CONTROL WORKSHEET

The *Sonography Procedures: Transducer Disinfection and Infection Control Worksheet* is an educational worksheet that can be used to educate students and sonographers about the analytical process needed before, during, and after a sonographic procedure to determine the applicable classification, proper transducer cover and gel to use (if applicable), and proper transducer reprocessing. The worksheet can also be used by facilities to evaluate their policies and procedures and document variances from best practice (e.g., due to transducer manufacturer's IFU limits).[35]

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10. ADDITIONAL READING

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11. GLOSSARY OF TERMS AND ABBREVIATIONS/ACRONYMS

AAMI: **A**ssociation for the **A**dvancement of **M**edical **I**nstrumentation.

Ancillary Equipment: Equipment used during the procedure (e.g., cables, keyboards, beds, chairs, IV poles, oxygen systems).

Bioburden: The number of bacteria living on an unsterilized transducer or other surface.

CDC: Centers for **D**isease **C**ontrol and Prevention; a federal agency of the United States Department of Health and Human Services, which is responsible for developing and applying disease prevention and control to improve the health of the people and reduce the burden of infectious diseases.

Chemical Indicator: A device for monitoring the sterilization process.

Cleaning: The removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and is normally accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before HLD and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes.

Coupling Agent: A medium used to facilitate transmission and reception of ultrasound energy by eliminating air between the transducer and the patient's skin (See *Gel*).

Critical Water: Treated water, which has microorganisms and inorganic/organic material removed, typically used for the final rinse.

Disinfection: Thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).

Disinfectant: Normally a chemical agent (but sometimes a physical agent) that destroys disease-causing pathogens or other harmful microorganisms. The EPA groups disinfectants by product label claims of "limited," "general," or "hospital" disinfection.

EHR: Electronic **H**ealth **R**ecord; an electronic record of patient health information generated from one or more encounters in any healthcare delivery setting.

Facility: For purposes of these guidelines, a facility is a clinical setting where transducers are used to generate medical images, including but not limited to: hospital, clinic, physician's office, dedicated imaging lab, ambulance, etc.

FDA: Federal **D**rug **A**dministration; a federal agency of the United States Department of Health and Human Services, which is responsible for protecting and promoting public health; among other areas of responsibility, the FDA is responsible for the control and supervision of medical devices including the transducer and ancillary equipment.

Gel: A type of coupling agent commonly used with ultrasound transducers (See *Coupling Agent*).

Glutaraldehyde: A disinfectant used for sterilization of heat-sensitive equipment and instruments; it is a broad-spectrum microbicide effective against vegetative bacteria, fungi, and viruses, is sporicidal, and used as a liquid sterilant with an extended exposure time; its use requires safety precautions, specialized equipment, and proper ventilation to avoid respiratory injury or skin reactions; use on transducers should comply with the manufacturer's IFU.

HLD: High-**L**evel **D**isinfection; removal of all microorganisms, except bacterial endospores (a small number may remain).

Hydrogen Peroxide: A chemical used against a wide range of microorganisms, including bacteria, yeasts, fungi, viruses, and spores; used with or blended with other chemicals such as peracetic acid; its use requires safety precautions, specialized equipment, and proper ventilation to avoid respiratory injury or skin reactions; use on transducers should comply with the manufacturer's IFU.

Intact Skin: Skin that is completely unbroken (e.g., no skin cut, abrasion, dermatitis, needle puncture).

IFU: Instructions **F**or **U**se; typically provided in print or online by the manufacturer or supplier, and may include guidance for the proper use, cleaning, sterilization or disinfection, transport, storage, and repair.

LLD: Low-**L**evel **D**isinfection; the inactivation of all vegetative bacteria, enveloped viruses, some non-enveloped viruses, and most fungi.

Mucous Membranes: Membranes which produce mucus and line cavities or surfaces of the body that open to the external environment, such as the digestive tract, respiratory passages, and genitourinary tract.

Non-Intact Skin: Unhealthy (e.g., dermatitis, rash, psoriasis) or broken skin (e.g., skin cut, abrasion, previous needle puncture).

OPA: Ortho-**p**hthal**a**ldehyde; a chemical approved for high-level disinfection of medical equipment; its use requires safety precautions, specialized equipment, and proper ventilation to avoid respiratory injury or skin reactions; use on transducers should comply with the manufacturer's IFU.

Peracetic Acid: A highly biocidal oxidizer disinfectant that oxidizes the outer cell membranes of microorganisms used to deactivate a large variety of pathogenic microorganisms, viruses, and spores; its use requires safety precautions, specialized equipment, and proper ventilation to avoid respiratory injury or skin reactions; use on transducers should comply with the manufacturer's IFU.

Probe: An informal term sometimes used to refer to the transducer (see *Transducer*).

Procedure: A sonography procedure or examination (also known as sonogram, sonographic examination, ultrasound procedure, ultrasound examination, etc.) that can help diagnose a variety of medical conditions, assess illnesses in tissues and organs, or evaluate injury; the procedure may be performed in a variety of clinical settings, including but not limited to a hospital, at the patient's bed-side, clinic, dedicated specialty imaging lab (e.g., cardiac, vascular), or by mobile service (e.g., performed at a home, a nursing home); sonography-guidance may also be used with invasive procedures such as biopsies, etc.

Reprocessing: Procedure to prepare the transducer for reuse, including cleaning, sterilization or disinfection, transport, and storage.

Reprocessing Area: Area of a healthcare facility designated for collection, retention, and cleaning of soiled and/or contaminated items.

SOP: Standard **O**perating **P**rocedures; step-by-step instructions to assist in carrying out complex processes, such as reprocessing the transducer.

Spaulding Classification: A classification system that determines the sterilization and disinfection requirements for medical devices based on the level of infection risk associated with use.

Sterile Tissues: Body sites, cavities, or tissues that are endogenously free from all living organisms. Sterile tissues include the vascular system, joints and joint spaces, other internal body fluids such as blood or synovial fluid, the vasculature and internal body organs, peritoneum, and retroperitoneum.

SAL: Sterility **A**ssurance **L**evel; The probability that a single item (e.g., transducer) subjected to sterilization, nevertheless remains nonsterile; A SAL of 10–6 is the generally accepted level for sterilization procedures, (i.e., a probability of not more than one viable microorganism in one million sterilized items).

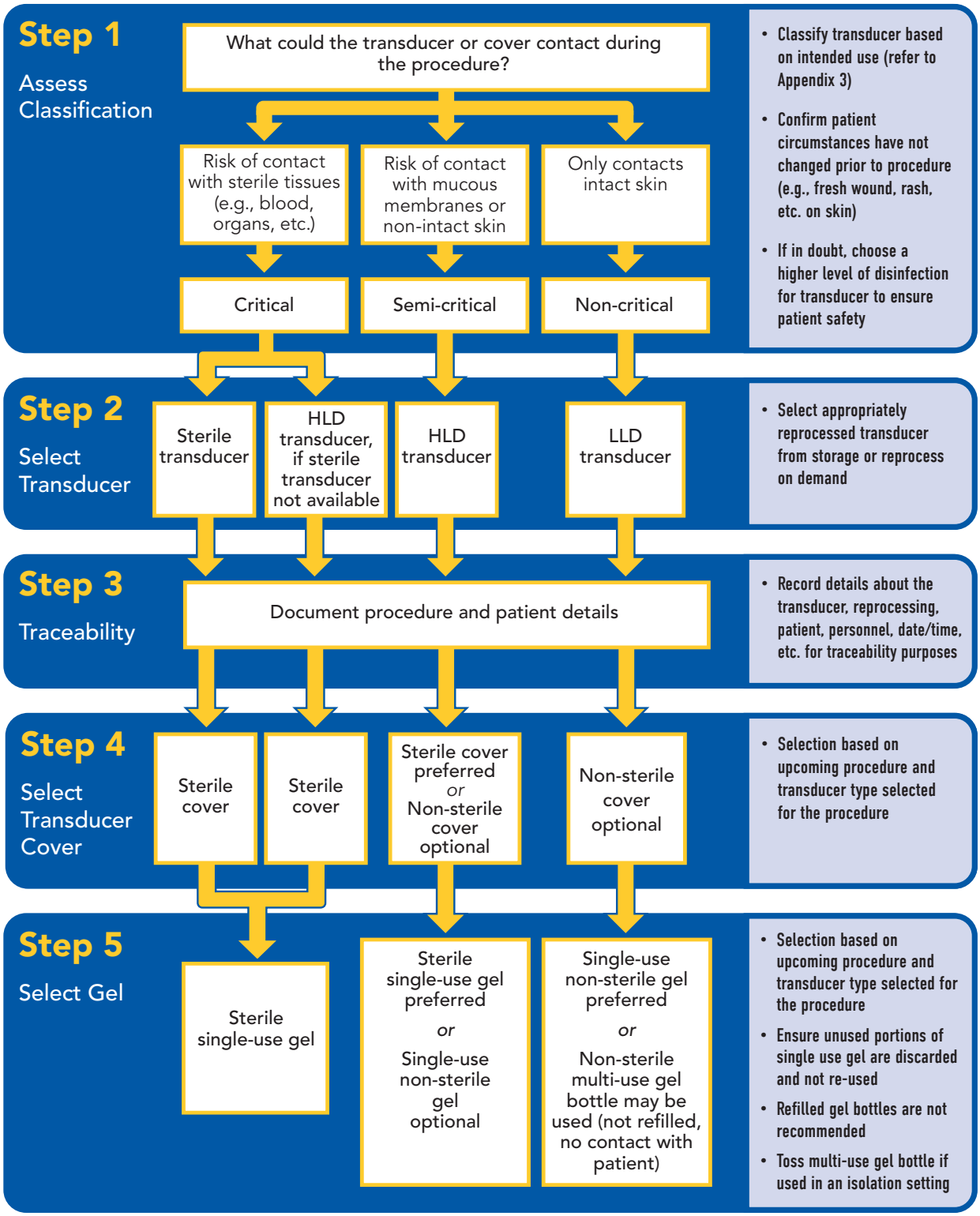
Sterilization: The destruction or inactivation of microorganisms, which minimizes infection transmission risk; choice of disinfection/sterilization level depends on the Spaulding Classification of the transducer and ancillary equipment, which is based on the intended use in the next procedure; some healthcare professionals and literature refer to "disinfection" as "sterilization".

Storage: An area or cabinet designed to protect transducers, and any ancillary equipment from damage or contamination; storage should be consistent with the manufacturer's recommendations and other requirements.

Transducer: A medical device that sends sound waves into a body and receives the returning echoes from tissues, structures, or spaces, which are analyzed by a computer to generate a medical image.

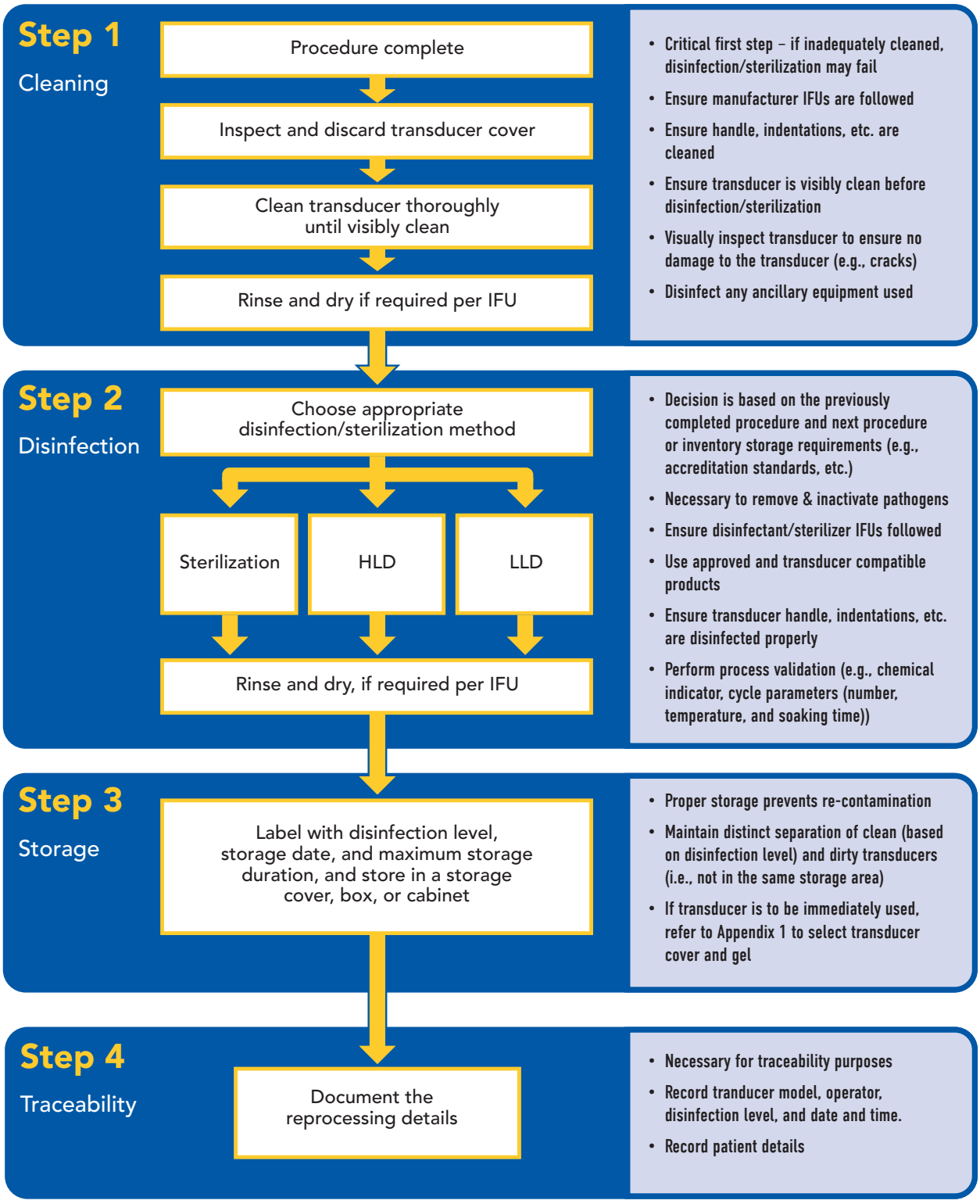
Transducer Cover: An FDA cleared barrier that covers the transducer to prevent contamination and transmission of infection or disease.

Appendix 1: Preparing for a Sonography Procedure



HLD = High Level Disinfection; LLD = Low Level Disinfection; Cover = Transducer Cover

Appendix 2: Reprocessing the Ultrasound Transducer and Ancillary Equipment



HLD = High Level Disinfection; LLD = Low Level Disinfection; Cover = Transducer Cover; IFU = Instructions for use

Appendix 3:

Sonography Procedures: Transducer Disinfection and Infection Control

The list of example sonography procedures below describes the classification and best practices. Note that the expected classification for a sonography procedure could change based on patient condition (e.g., has open wound or infection in the scan area) or during the procedure (e.g., tear, puncture). Follow the same assessment of risk and classification for sonography procedures not listed.

KEY:

✓* = **Best Practice** ✓ = **Allowed** ⃠ = **Not Recommended** *(unless transducer cannot be sterilized or HLD processed)*

EXAMPLE PROCEDURES	ASSESS RISK THAT THE TRANSDUCER WILL OR DID COME IN CONTACT WITH:			CLASSIFICATION	BEST PRACTICE						
					TRANSDUCER REPROCESSING			TRANSDUCER COVER		COUPLING AGENT/GEL	
	Intact Skin	Mucous Membrane or Non-Intact Skin	Sterile Tissue or Blood		Clean & Sterile Process	Clean & HLD Process	Clean & LLD Process	Sterile	Non-Sterile	Sterile	Non-Sterile
HEAD/NECK											
Neck, Thyroid/Parathyroid	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Neonatal Brain	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Ophthalmic		X		Semi-Critical	optional	✓*	⃠	✓*	✓	✓*	✓
Spinal Canal & Contents	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
CHEST/BREAST											
Breast w/ axilla	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Chest (includes mediastinum, chest wall, and upper back)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
EXTREMITIES											
Infant Hips	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Non-Vascular Extremity	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
ABDOMEN											
Abdomen	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Abdomen Elastography	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Aorta (AAA screening)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Renal Retroperitoneal	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Retroperitoneal - Transplanted Kidney w/ Duplex Doppler	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Scrotum and Testicles	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Transrectal and Transrectal Prostate		X		Semi-critical	optional	✓*	⃠	✓*	✓	✓*	✓
NON-OBSTETRICAL PELVIC											
Pelvic (non-OB, transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Pelvic (non-OB, transvaginal)		X		Semi-critical	optional	✓*	⃠	✓*	✓	✓*	✓
Sonohysterography w/ Doppler (non-OB, transvaginal)		X		Semi-critical	optional	✓*	⃠	✓*	✓	✓*	✓
OBSTETRIC											
Fetal Biophysical Profile	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Fetal Middle Cerebral Artery	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Fetal Umbilical Artery	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*

SONOGRAPHER BEST PRACTICES FOR INFECTION PREVENTION AND CONTROL: REPROCESSING THE ULTRASOUND TRANSDUCER

KEY:

✓* = **Best Practice** ✓ = **Allowed** ⊘ = **Not Recommended** *(unless transducer cannot be sterilized or HLD processed)*

PROCEDURE DESCRIPTION	ASSESS RISK THAT THE TRANSDUCER WILL OR DID COME IN CONTACT WITH:			CLASSIFICATION	BEST PRACTICE						
					TRANSDUCER REPROCESSING			TRANSDUCER COVER		COUPLING AGENT/GEL	
	Intact Skin	Mucous Membrane or Non-Intact Skin	Sterile Tissue or Blood		Clean & Sterile Process	Clean & HLD Process	Clean & LLD Process	Sterile	Non-Sterile	Sterile	Non-Sterile
OBSTETRIC (continued)											
Pregnant (transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Pregnant (transvaginal)		X		Semi-critical	optional	✓*	⊘	✓*	✓	✓*	✓
Pregnant < 14 weeks (transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Pregnant > 14 weeks (transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Pregnant w/ Detailed Fetal Anatomic Exam (transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Pregnant w/ First Trim Fetal Nuchal Translucency (transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Pregnant w/ First Trim Fetal Nuchal Translucency (transvaginal)		X		Semi-critical	optional	✓*	⊘	✓*	✓	✓*	✓
ECHOCARDIOGRAPHY (FETAL)											
Fetal Doppler Echocardiography	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Fetal Echocardiography (2D)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
ECHOCARDIOGRAPHY (PEDIATRIC/ADULT)											
Doppler Echocardiography	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Echocardiography (transesophageal)		X		Semi-Critical	optional	✓*	⊘	✓*	✓	✓*	✓
Echocardiography (transthoracic)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Stress Echocardiography	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
VASCULAR											
Abdominal Duplex Arterial/Venous (transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Abdominal Duplex Arterial/Venous (transvaginal)		X		Semi-critical	optional	✓*	⊘	✓*	✓	✓*	✓
Carotid Doppler	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Carotid Intima-Media Thickness	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Duplex Aorta, IVC, Iliac, or Bypass Grafts	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Duplex Arterial/Venous Penile	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Duplex Hemodialysis Access	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Duplex Lower/Upper Extremity Arterial	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Duplex Lower/Upper Extremity Veins	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Extracranial Arteries (duplex/Doppler)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Transcranial Doppler Intracranial Artery	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
OTHER											
Intraoperative			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘