Guidelines for Infection Prevention and Control in Sonography:

Reprocessing the Ultrasound Transducer

Endorsing Organizations

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Supporting Organizations*

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* *Some organizations have internal policies that do not permit endorsement of external documents. "Supporting organization" denotes a more limited level of review and approval than endorsement and means the organization considers the clinical document to be of educational value, although it may not agree with every recommendation or statement in the document.*

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Scope

The diagnostic medical sonography profession is comprised of specialities in abdominal, breast, cardiac, obstetrics, gynecology, pediatric, phlebology, vascular, and other emerging clinical areas. These diverse areas of sonography all use ultrasound as the primary technology in their daily work.

Sonographers have a responsibility to ensure that the ultrasound transducer ("transducer") and other equipment used are properly reprocessed. These guidelines specifically address reprocessing (e.g., cleaning, disinfection or sterilization, transport, and storage) of transducers used in diagnostic medical sonography, but not those used for endoscopic, intracardiac, intravascular, or laparoscopic purposes.

Because of the sensitivity of the transducer's materials and electronics to some sterilization techniques, gaps may exist in the ability to perform the desired method of sterilization for the transducer. Therefore, while these guidelines address current best practices, users of these guidelines should recognize that best practices will evolve over time based on technological advances and new research.

To ensure the facility has the capability and capacity to adequately clean and reprocess the transducer, sonographers should obtain and review the manufacturer's Instructions for Use (IFU) or other guidance on use, handling, cleaning, disinfection or sterilization, transport, and storage of the manufacturer's equipment before purchasing. Manufacturers and suppliers should ensure guidance on use, handling, cleaning, disinfection or sterilization, transport, and storage specific to each machine, transducer, or other equipment is easily accessible on their website. Manufacturers and companies that refurbish transducers should take the steps necessary to prevent contamination during or after the manufacturing or refurbishment process. However, regardless of the source, a newly acquired, non-sterile transducer should be processed as if it was used previously.

While these guidelines focus on the reprocessing of the transducer, the importance of infection prevention and control principles apply equally to the ultrasound machine and any ancillary equipment used during the procedure (e.g., cables, keyboards, gel bottle, beds, chairs, IV poles, oxygen systems, light switches, door knobs/handles). Cross-contamination of the ultrasound machine and any ancillary equipment presents significant infection prevention and control risks and challenges. Where applicable, refer to the manufacturer's IFU or the facility's policies for the proper cleaning, disinfection or sterilization, transport, and storage (as applicable) for ultrasound machines, transducers, and any ancillary equipment. New technologies (e.g., transducers connected to smartphones or tablets) will add new risks and challenges that the manufacturer, facilities, and sonographers must address in the future.

NOTE: These guidelines apply only to transducers used to scan humans and not those used to scan animals. A sonographer should never use a transducer on a human that has been used on an animal, regardless of the subsequent cleaning, disinfection, or sterilization level.

Development Process

At the end of 2017, the Society of Diagnostic Medical Sonography's (SDMS) Sonography Disinfection & Infection Control Task Force developed draft guidelines consistent with existing regulations, standards, and current best practices. In early 2018, the Task Force shared the draft with sonography and infection prevention and control-related organizations and manufacturers for input. The Task Force met to finalize the second draft in early 2019 and shared the second draft with sonography and infection control-related organizations and manufacturers for input. The Task Force will distribute the final guidelines for organizational endorsement or support.

> **Note:** *Some organizations have internal policies that do not permit endorsement of external documents. Therefore, notation as a "supporting organization" will denote a more limited level of review and approval than endorsement and means the organization considers the clinical document to be of educational value, although it may not agree with every recommendation or statement.*

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1. Introduction

Sonography is a safe and effective imaging modality widely used across various inpatient and outpatient settings for the perfomance of a variety of procedures and diagnostic imaging. 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 Centers for Disease Control and Prevention (CDC) *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 Food and Drug Administration (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, including from the following organizations: 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 recommendations that any sonographer can use to answer disinfection and transducer reprocessing questions or to implement the recommendations.

2. Infection Prevention and Control Risks and Challenges

Proper infection prevention and control practices are necessary to protect patients and sonographers. Contaminated transducers and 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 with 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 (e.g., proper transducer cleaning and disinfection, appropriate transducer cover, sterile gel). 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]

Several studies suggest that bacteria and other pathogens that may be resistant to some disinfectants including glutaraldehyde and ortho-phthalaldehyde (OPA) can contaminate the transducer.[9,23] Use of a properly disinfected transducer, transducer cover, and sterile gel can reduce the risk of transmitting bacteria and other pathogens during sonographic procedures and promote patient safety.

3. Understanding How the Spaulding Classification Affects Transducer Reprocessing

The Spaulding Classification determines the disinfection and sterilization requirements for medical devices based on the level of infection risk associated with their use.[5] Medical device reprocessing standards, regulations, and guidelines widely use this classification system.[1,2,24-26] For example, the CDC guidelines categorize medical devices reprocessing requirements based on risk using the Spaulding Classification (Table 1).

The intended use of the transducer in the procedure determines its classification into one of three groups:

Critical – Transducer contacts sterile tissues or a device (e.g., needle, catheter) inserted into sterile tissue during the procedure. Sterile tissue includes body sites, cavities, or tissues that are endogenously free from all living organisms. This would include the vascular system, joints and joint spaces, other internal body fluids such as blood or synovial fluid, the vasculature, internal body organs, peritoneum, and retroperitoneum.

Semi-critical – Transducer contacts mucous membranes or non-intact skin or a device that contacts 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 only contacts intact skin, or a device used during the procedure that contacts intact skin (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.

It is the nature of the procedure itself that determines the transducer's status as critical, semi-critical, or non-critical and the sonographer may classify the same transducer differently when it is used in another procedure. Each Spaulding Classification has different disinfection and sterilization requirements (Table 1).

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] Any ancillary equipment used in conjunction with the transducer should also be disinfected based on the type of equipment, manufacturer's IFU, and other available guidance.

Table 1. How the Spaulding Classification Affects Transducer Reprocessing (adapted from the CDC guidelines[1])

Risk Associated with Intended Use	Spaulding Classification	Disinfection/ Sterilization Level Required[#]
Transducer contacts sterile tissues or a device (e.g., needle, catheter) inserted into sterile tissue during the procedure.	Critical	Cleaning followed by sterilization. If sterilization is not possible, then use high-level disinfection (HLD) and a sterile transducer cover.[1]
Transducer contacts mucous membranes or non-intact skin or a device that contacts mucous membranes or non-intact skin during the procedure (i.e., no risk of contact with sterile tissues).	Semi-critical	Cleaning followed by HLD
Transducer only contacts intact skin, or a device used during the procedure that contacts intact skin (i.e., no risk of contact with sterile tissues, mucous membranes, or non-intact skin).	Non-critical	Cleaning followed by low-level disinfection (LLD)

HLD = high-level disinfection, LLD = low-level disinfection.

[#]See section 5.2 for definitions of sterilization, high-level disinfection, and low-level disinfection.

3.1. Assigning the Spaulding Classification Based on Intended Use

Make the Spaulding Classification determination before the procedure commences. It is sometimes difficult to anticipate what tissues or devices the transducer might contact (e.g., catheter, sterile tissue, mucous membranes, intact, or non-intact skin).

Where some risk of contact exists, apply the higher classification. For example, a procedure to guide a tissue biopsy is as a critical procedure due to the increased risk that the transducer might contact the needle inserted into the sterile tissue.

4. Sonographic Procedure

Refer to the steps below to prevent infection transmission in conjunction with 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 the Spaulding Classification guidance regarding the procedure. If the patient's circumstances unexpectedly change before or during the procedure, ensure that the selected transducer is still appropriate based on the reassessment of the procedure and its alignment with the Spaulding Classification.

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 transducer cover is optional with a sterilized transducer, but a sterile transducer cover should be used with a high-level disinfected transducer.[1] At the minimum, use a non-sterile transducer cover 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.

If during the procedure the transducer cover is damaged (e.g., tear, puncture), immediately discard the damaged transducer cover and replace the contaminated transducer with an appropriately disinfected transducer and new transducer cover. After the procedure, inspect the contaminated transducer for possible damage.

Table 2. Transducer Cover Selection Based on the Spaulding Classification

Spaulding Classification	Transducer Cover
Critical	Sterilized transducer (preferred) or a sterile cover with an HLD transducer
Semi-critical	Sterile cover (preferred) or non-sterile cover
Non-critical	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 is the least preferred option for non-critical procedures due to the potential for patient cross-contamination and gel contamination.

Table 3. Ultrasound Gel Selection Based on the Spaulding Classification

Spaulding 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 come in contact with 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.

The use of a refilled gel bottle as well as heating of gel is discouraged, as this can lead to microorganism growth, pathogen transmission, cross-contamination, and possible outbreaks.[27]

4.2. During the Procedure

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

4.3. After the Procedure

After the procedure, remove the transducer cover (if used) from the transducer and discard in a designated, approved receptacle. Immediately clean the transducer (e.g., remove any remaining gel, visible soil, or bioburden), place it in a transport container (e.g., container with lid, impermeable bag), label 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 (bevels, crevices, lumens, etc). Additionally, temperature and pH of the process and relative humidity may affect the sterilization process.[1]

Reprocess the transducer and any ancillary equipment used between each patient use. Reprocessing refers to the procedure undertaken to prepare an instrument for reuse. The reprocessing phases include cleaning, disinfection or sterilization, transport, and storage. Additional considerations such as traceability are also important. See details below.

5.1. Cleaning

Effective disinfection or sterilization 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. Selection of a cleaning process should factor in cleaning efficacy, cost, time, complexity, safety, designated location for reprocessing, and the transducer manufacturer's IFU.

5.2. Disinfection and Sterilization

Disinfection or sterilization refers to the destruction or inactivation of microorganisms, which in turn minimizes infection transmission risk. Choice of disinfection or sterilization level depends on the Spaulding Classification of the transducer or other ancillary equipment, which is based on use in the prior completed procedure and the intended use in the next procedure. Use of a transducer cover does not change the Spaulding Classification since transducer covers have been shown to leak or tear.[1] Transducer manufacturer's IFUs should be consulted for the recommended disinfection or sterilization methods. Other factors to consider include disinfection or sterilization efficacy, cost, cycle time, complexity, safety, designated location, simultaneous transducer reprocessing capability, and the transducer manufacturer's IFU. See below for further detail on sterilization, high-level disinfection, and low-level disinfection.

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 (e.g., per the manufacturer's IFU), HLD is

acceptable if the transducer is used in conjunction 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)

HLD is the removal of all microorganisms except bacterial endospores, of which small numbers are permitted to remain.[1,6-8,12] HLD is required for a semi-critical transducer that contacts mucous membranes or non-intact skin and any device used during the procedure that contacts mucous membranes, non-intact skin, or the transducer. HLD is also suitable for a critical transducer in the event they cannot be sterilized, as long as the transducer is used with a sterile transducer cover.[1,12]

According to the CDC *Guidelines for Disinfection and Sterilization in Healthcare Facilities*, unlike sterilization, disinfection is not sporicidal. A few disinfectants, known as chemical sterilants, will kill spores with prolonged exposure times (3–12 hours). At similar concentrations but with shorter exposure periods (e.g., 20 minutes for 2% glutaraldehyde), these same disinfectants are called high-level disinfectants and 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 due to the reduced 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 high-level disinfects the transducer (head and handle) in conjunction with low level disinfection of cables and connectors is preferred, as these components can harbor clinically relevant pathogens.[23,30] Refer to the manufacturer's IFU to ensure that the HLD process selected is compatible with the transducer and for other suitable HLD options. Refer to the FDA's website (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm437347.htm) for a list of liquid HLD disinfectant chemistries.

5.2.3. Low-Level Disinfection (LLD)

LLD is the inactivation of vegetative bacteria, enveloped viruses, some non-enveloped viruses, and most fungi in a practical period of time (≤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. 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 disinfection or sterilization if required by the manufacturer's IFU. This step may be necessary to ensure that no chemical residues remain on the transducer after reprocessing. Some automated processes may not require a rinsing step. Follow the disinfectant manufacturer's IFU for rinse requirements, rinse water quality and sterility, the number of rinses, and drying method. Following HLD, perform the rinses in a separate clean container using critical water (treated water). [4] Sterile water is required for immunocompromised patients.[1,2,4,31]

5.4. Documentation and Traceability

The facility should develop a written policy outlining the process for 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 and serial number, reprocessing personnel identification (ID), cycle number, validation result (e.g. chemical indicator/test strip, temperature, soaking time), date/time, and patient identification. [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., log books, stickers) or automated processes (e.g., electronic health record (EHR), RFID tracking systems). In the event of a reprocessing failure or an outbreak, complete documentation for each transducer reprocessing cycle will aid in traceability for patient trace-back.

5.5. Storage

Store the reprocessed transducer properly to prevent re-contamination of the transducer before use. Suitable options for transducer storage include storage covers, boxes, or cabinets (e.g., HEPA-filtered, ventilated or non-ventilated). Proper storage reduces the risk of re-contamination of the transducer from environmental contaminants or accidental contamination during storage. Follow the manufacturer's IFU or other guidance for proper storage. Clearly label the container holding the transducer with disinfection level and date during storage to facilitate easy identification. Maintain distinct separation of clean and dirty transducers (e.g., dirty transducer not placed in the same cabinet as clean transducers). Conduct a risk assessment to determine the maximum storage duration for the transducer. Refer to the manufacturer's IFU regarding the maximum storage duration, if applicable, and any reprocessing requirements.

6. Infection Prevention and Control Considerations for Transducer Reprocessing Workflow

There are many things to consider when establishing an infection prevention and control workflow for transducer reprocessing. Perform reprocessing with a dirty-to-clean workflow. See below for some considerations to assist in streamlining this process.

6.1. Types of Procedures

Consider the type of procedure, location, and disinfection or sterilization 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 disinfected transducers available in storage or to reprocess transducers as needed.

6.2. Reprocessing Time

Consider the length of each patient procedure and the reprocessing time. If the reprocessing time is more than the amount of time available between scans, 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

After the procedure, immediately remove the transducer cover, 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 then return the transducer in a designated, approved clean or sterile transport container, as appropriate. Handle and transport the transport containers in a manner to prevent contamination of the transducer, other equipment, and the facility. Disinfect transport containers and any transport carts. 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 the transducer. Consult the manufacturer's IFU or other guidance on use, handling, cleaning, disinfection or sterilization, transport, and storage 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. Cost, Complexity, and Safety

Before adopting a reprocessing workflow, consider the total cost of reprocessing including equipment, consumables, personnel, time, personal protective equipment, and turnover 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.

6.6. Establishing Policies and Standard Operating Procedures (SOPs)

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 disinfection or sterilization requirements. Align the policies and SOPs with current regulations, guidelines, standards, and transducer manufacturer's IFUs. Conduct ongoing risk assessments and review of policies and SOPs and update accordingly.

6.7. 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]

6.8. Evaluation and Quality Improvement

A process that monitors infection prevention and control practices related to ultrasound use and reprocessing workflow should be in place for each clinical setting. The process should reflect an assessment of risks with the procedure to both patients and sonographers. 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. If equipment damage is identified, such as a transducer with a crack, abrasion, or tear, there should be processes in place to promptly identify the damage, remove the equipment from use, and document the damage and repair. Damaged equipment may harbor pathogens, tear transducer covers, or impact the ability of the sonographer to safely and accurately perform the procedure.

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8. Glossary of Terms and Abbreviations/Acronyms

AAMI: Association for the Advancement of Medical Instrumentation.

Ancillary Equipment: Equipment used during the procedure (e.g., cables, keyboards, beds, chairs, IV poles, oxygen systems, light switches, door knobs/handles).

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

CDC: Centers for Disease Control 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: See *Gel*.

Critical Water: Treated water, which has microorganisms and inorganic/organic material removed, 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 Health Record; 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 Drug Administration; 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: An acoustic coupling agent used between the transducer and the patient's skin to facilitate ultrasound transmission and reception.

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.

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 in conjunction with or blended with other chemicals such as peracetic acid.

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, disinfection or sterilization, 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.

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 and any ancillary equipment (e.g., keyboards, beds, chairs, IV poles, oxygen systems, light switches, door knobs/handles) for reuse, including: cleaning, disinfection or sterilization, transport, and storage.

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

RFID: Radio Frequency Identification; uses electromagnetic fields to automatically identify and track tags attached to medical devices, etc.

SOP: Standard Operating Procedures; step-by-step instructions to assist in carrying out complex processes, such as reprocessing the transducer.

Spaulding Classification: A classification system that determines the disinfection and sterilization 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.

Sterility Assurance Level (SAL): 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).

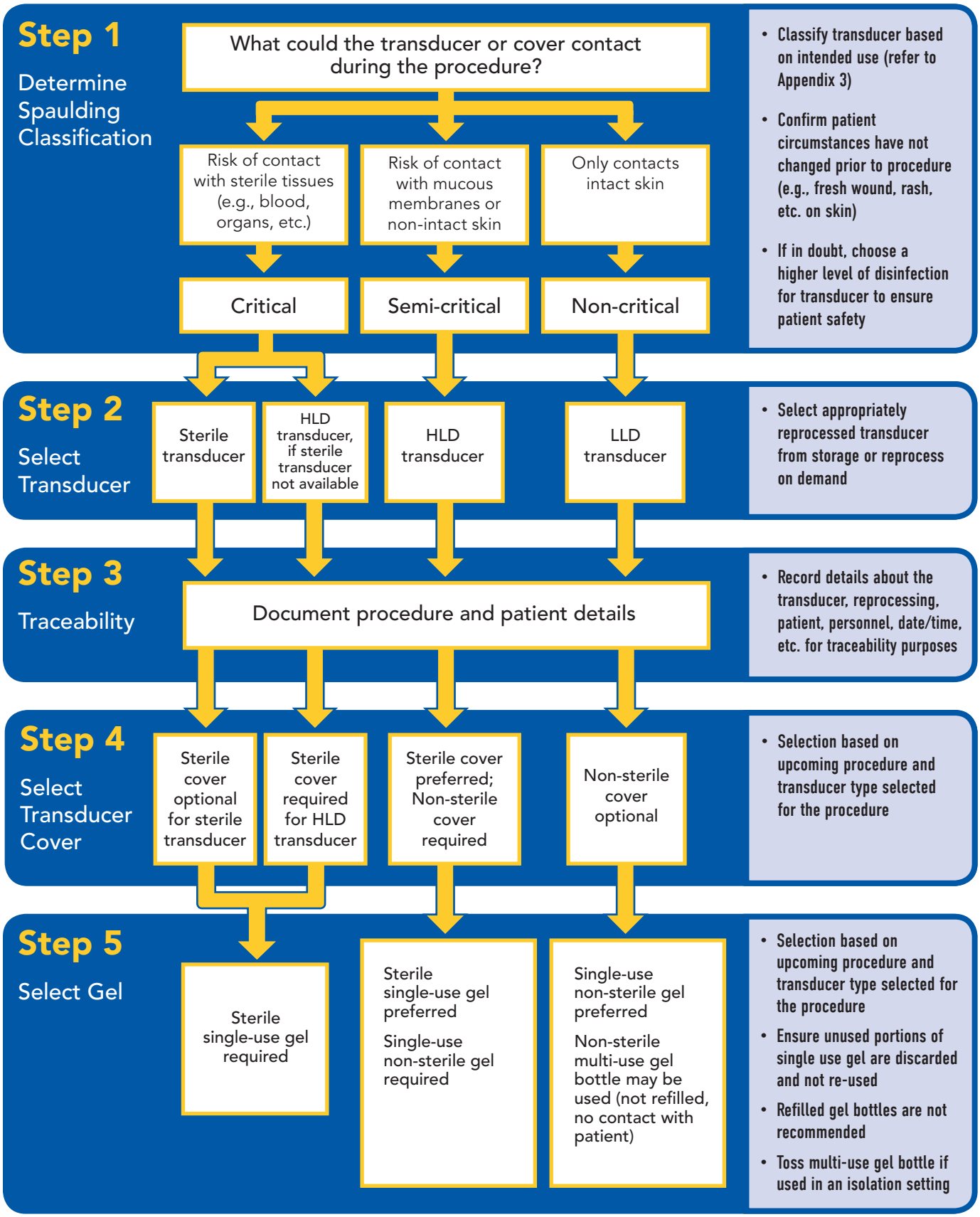
Sterilization: The destruction or inactivation of microorganisms, which minimizes infection transmission risk; choice of disinfection/sterilization level depends on the Spaulding Classification of the transducer and ancillary equipment, which is based on the intended use in the next procedure; some healthcare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

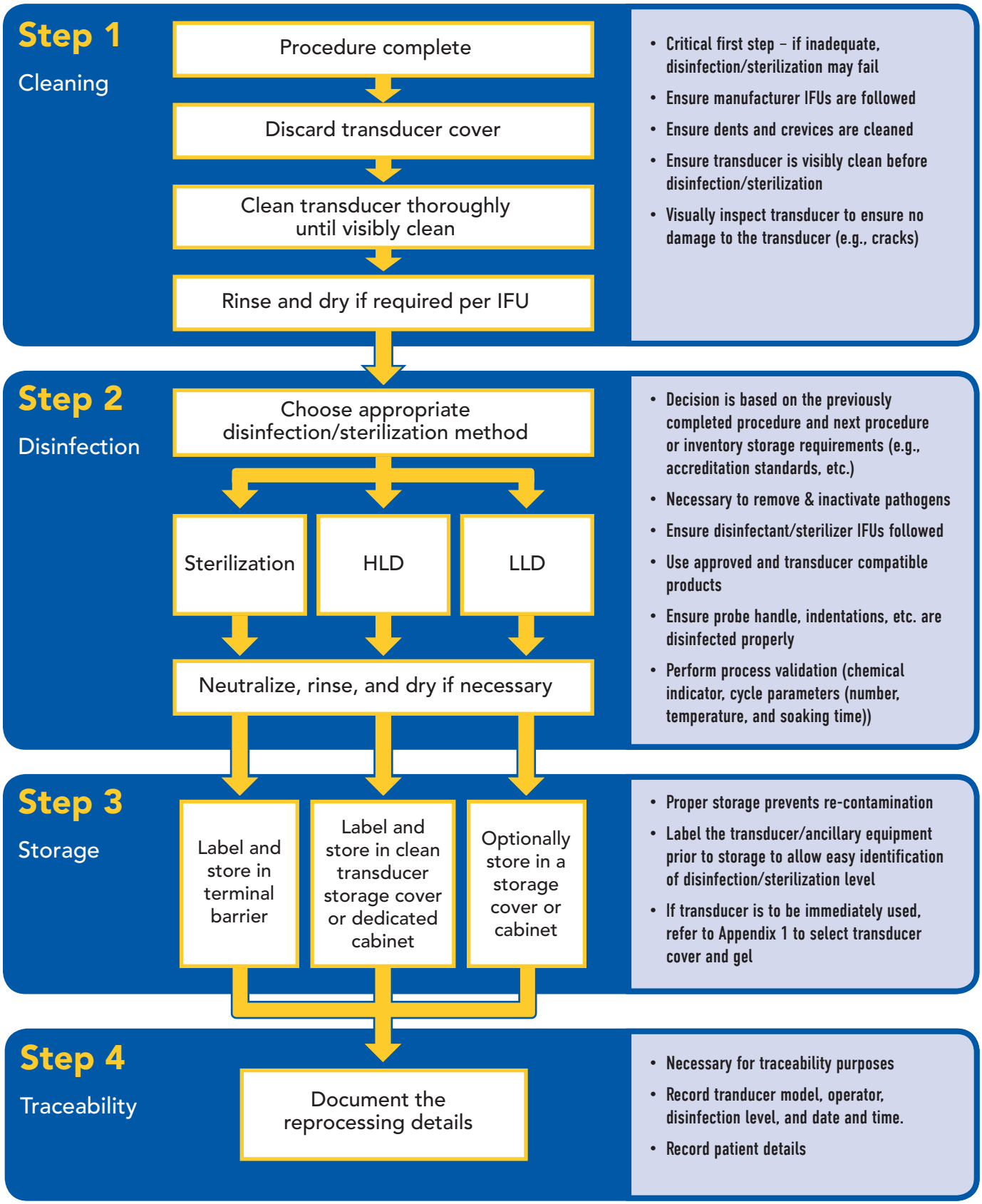
Transducer Cover: An FDA cleared barrier that covers the transducer to prevent contamination and transmission of infection or disease.

Appendix 1: Preparing for the Next 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

Note that the expected Spaulding Classification for a sonography procedure could change upon patient condition (e.g., has open wound or infection in the scan area) or during the procedure (e.g., blood is present).

SONOGRAPHY PROCEDURES	EXPECTED: BEFORE PROCEDURE			KEY: ✓* = Allowed/Preferred; ✓ = Allowed; ⊘ = Not Allowed							
PROCEDURE DESCRIPTION	ASSESS RISK THAT THE TRANSDUCER (with or without a transducer cover) WILL COME IN CONTACT WITH:			SPAULDING 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 (Echoencephalography)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Ophthalmic (A-scan)		X		Semi-Critical	optional	✓*	⊘	✓*	✓	✓*	✓
Ophthalmic (A-scan/B-scan)		X		Semi-Critical	optional	✓*	⊘	✓*	✓	✓*	✓
Ophthalmic (B-scan)		X		Semi-Critical	optional	✓*	⊘	✓*	✓	✓*	✓
Ophthalmic Anterior Segment (immersion B-scan)		X		Semi-Critical	optional	✓*	⊘	✓*	✓	✓*	✓
Ophthalmic Biometry (A-scan w/ intraocular lens power calc)		X		Semi-Critical	optional	✓*	⊘	✓*	✓	✓*	✓
Ophthalmic Biometry (A-scan w/ lens power calc)		X		Semi-Critical	optional	✓*	⊘	✓*	✓	✓*	✓
Ophthalmic Biometry (A-scan)		X		Semi-Critical	optional	✓*	⊘	✓*	✓	✓*	✓
Ophthalmic Corneal Pachymetry		X		Semi-Critical	optional	✓*	⊘	✓*	✓	✓*	✓
Ophthalmic Foreign Body		X		Semi-Critical	optional	✓*	⊘	✓*	✓	✓*	✓
Spinal Canal & Contents	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
CHEST/BREAST											
Breast w/ axilla (unilateral, complete)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Breast w/ axilla (unilateral, limited)	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 (dynamic, physician manipulation)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Infant Hips (limited, static)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Non-Vascular Extremity (complete)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Non-Vascular Extremity (limited)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
ABDOMEN											
Abdomen (complete)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Abdomen (limited)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Abdomen Elastography	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Aorta (limited, AAA screening)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Renal Retroperitoneal (complete)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*

SONOGRAPHY PROCEDURES	EXPECTED: BEFORE PROCEDURE			KEY: ✓* = Allowed/Preferred; ✓ = Allowed; ⊘ = Not Allowed							
PROCEDURE DESCRIPTION	ASSESS RISK THAT THE TRANSDUCER (with or without a transducer cover) WILL COME IN CONTACT WITH:			SPAULDING 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
ABDOMEN (continued)											
Renal Retroperitoneal (limited)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Retroperitoneal - Transplanted Kidney (w/ Duplex Doppler)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Scrotum & Testicles	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Transrectal		X		Semi-critical	optional	✓*	⊘	✓*	✓	✓*	✓
Transrectal, Prostate		X		Semi-critical	optional	✓*	⊘	✓*	✓	✓*	✓
NON-OBSTETRICAL PELVIC											
Pelvic (non-OB, transvaginal)		X		Semi-critical	optional	✓*	⊘	✓*	✓	✓*	✓
Sonohysterography w/ Doppler (non-OB, transvaginal)		X		Semi-critical	optional	✓*	⊘	✓*	✓	✓*	✓
Pelvic (non-OB, complete, transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Pelvic (non-OB, limited or follow-up, transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
OBSTETRIC											
Fetal Biophysical Profile (w/ non-stress testing)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Fetal Biophysical Profile (w/o non-stress testing)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Fetal Middle Cerebral Artery (Doppler velocimetry)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Fetal Umbilical Artery (Doppler velocimetry)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Pregnant < 14 weeks (single/first, transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Pregnant < 14 weeks (additional gestation, transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Pregnant > 14 weeks (single/first, transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Pregnant > 14 weeks (additional gestation, transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Pregnant (Follow-up transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Pregnant (limited, transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Pregnant (limited, transvaginal)		X		Semi-critical	optional	✓*	⊘	✓*	✓	✓*	✓
Pregnant (transvaginal)		X		Semi-critical	optional	✓*	⊘	✓*	✓	✓*	✓
Pregnant w/ Detailed Fetal Anatomic Exam (single/first gestation, transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Pregnant w/ Detailed Fetal Anatomic Exam (additional gestation, transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Pregnant w/ First Trim Fetal Nuchal Translucency (single/first gestation, transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Pregnant w/ First Trim Fetal Nuchal Translucency (additional gestation, transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Pregnant w/ First Trim Fetal Nuchal Translucency (single/first gestation, transvaginal)		X		Semi-critical	optional	✓*	⊘	✓*	✓	✓*	✓

SONOGRAPHY PROCEDURES	EXPECTED: BEFORE PROCEDURE			KEY: ✓* = Allowed/Preferred; ✓ = Allowed; ⊘ = Not Allowed							
PROCEDURE DESCRIPTION	ASSESS RISK THAT THE TRANSDUCER (with or without a transducer cover) WILL COME IN CONTACT WITH:			SPAULDING 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 w/ First Trim Fetal Nuchal Translucency (additional gestation, transvaginal)		X		Semi-critical	optional	✓*	⊘	✓*	✓	✓*	✓
ECHOCARDIOGRAPHY (FETAL)											
Fetal Doppler Echocardiography (complete)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Fetal Doppler Echocardiography (follow-up or repeat)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Fetal Echocardiography (2D)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Fetal Echocardiography (follow-up or repeat)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
ECHOCARDIOGRAPHY (PEDIATRIC/ADULT)											
Doppler Echocardiography (velocity mapping)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Doppler Echocardiography (complete)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Doppler Echocardiography (limited or follow-up)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Echocardiography (complete)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Echocardiography (limited)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Echocardiography (w/o Doppler/color flow)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Echocardiography (congenital, complete)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Echocardiography (congenital, follow-up or limited)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Stress Echocardiography	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Stress Echocardiography w/ ECG	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
VASCULAR											
Abdominal Duplex Arterial/Venous (complete, transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Abdominal Duplex Arterial/Venous (complete, transvaginal)		X		Semi-critical	optional	✓*	⊘	✓*	✓	✓*	✓
Abdominal Duplex Vascular (limited, transabdominal)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Abdominal Duplex Vascular (limited, transvaginal)		X		Semi-critical	optional	✓*	⊘	✓*	✓	✓*	✓
Carotid Intima-Media Thickness (complete, bilateral)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Carotid Doppler (limited, unilateral)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Carotid Duplex (complete, bilateral)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Duplex Aorta, IVC, iliac, or bypass grafts (complete, bilateral)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Duplex Aorta, IVC, iliac, or bypass grafts (limited, unilateral)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Duplex Arterial/Venous Penile (complete)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Duplex Arterial/Venous Penile (follow-up or limited)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*

SONOGRAPHY PROCEDURES	EXPECTED: BEFORE PROCEDURE			KEY: ✓* = Allowed/Preferred; ✓ = Allowed; ⊘ = Not Allowed								
PROCEDURE DESCRIPTION	ASSESS RISK THAT THE TRANSDUCER (with or without a transducer cover) WILL COME IN CONTACT WITH:			SPAULDING 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
VASCULAR (continued)											
Duplex Lower Extremity Veins (complete, bilateral)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Duplex Upper Extremity Veins (complete, bilateral)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Duplex Lower Extremity Veins (limited, unilateral)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Duplex Upper Extremity Veins (limited, unilateral)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Duplex Hemodialysis Access	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Duplex Lower Extremity Arterial (complete, unilateral)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Duplex Lower Extremity Arterial (limited, unilateral)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Duplex Upper Extremity Arterial (complete, bilateral)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Duplex Upper Extremity Arterial (limited, unilateral)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Transcranial Doppler Intracranial Artery (vasoreactivity)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Transcranial Doppler Intracranial Artery (complete)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Transcranial Doppler Intracranial Artery (limited)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Transcranial Doppler Intracranial Artery (emboli detection w/ contrast)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Transcranial Doppler Intracranial Artery (emboli detection w/o contrast)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
GUIDANCE											
Abdominal Paracentesis			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Amniocentesis			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Arterial Pseudoaneurysms or Arteriovenous Fistulae			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Arthrocentesis (intermediate joint or bursa)			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Arthrocentesis (major joint or bursa)			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Arthrocentesis (major joint or bursa)			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Breast Biopsy, Localization Device (first lesion)			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Breast Biopsy, Localization Device (additional lesion)			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Breast, Localization Device (first lesion)			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Breast, Localization Device (additional lesion)			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Chorionic Villus Sampling			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Endomyocardial Biopsy			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Endovenous Ablation w/ laser (first vein)			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Endovenous Ablation w/ laser (additional vein)			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘

SONOGRAPHY PROCEDURES	EXPECTED: BEFORE PROCEDURE			KEY: ✓* = Allowed/Preferred; ✓ = Allowed; ⊘ = Not Allowed							
PROCEDURE DESCRIPTION	ASSESS RISK THAT THE TRANSDUCER (with or without a transducer cover) WILL COME IN CONTACT WITH:			SPAULDING 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
GUIDANCE (continued)											
Endovenous Ablation w/ Radiofrequency (first vein)			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Endovenous Ablation w/ Radiofrequency (additional vein)			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Fine Needle Aspiration Biopsy (first lesion)			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Fine Needle Aspiration Biopsy (additional lesion)			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Intraoperative			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Intrauterine Fetal Transfusion or Cordocentesis			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Needle Placement (e.g., biopsy, aspiration, injection, localization device)			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Ova Aspiration (transvaginal)			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Penile Injection with Vasoactive Agent			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Pericardiocentesis			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Peritoneal Lavage			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Pleural Drainage			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Radiation Therapy Placement			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Thoracentesis			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Tissue Ablation			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Vascular Access			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
OTHER											
Contrast (non-cardiac, initial lesion)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Contrast (non-cardiac, additional lesion)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Elastography (first lesion)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Elastography (additional lesion)	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Assessment of Subclinical Atherosclerosis	X			Non-Critical	optional	optional	✓*	optional	optional	optional	✓*
Cervical or Thoracic injection (single level)			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Cervical or Thoracic Transforaminal Epidural Injection (single level)			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘
Lumbar or Sacral Transforaminal Epidural Injection (single level)			X	Critical	✓*	✓	⊘	✓*	⊘	✓*	⊘