01.39 – Safe Ultrasound Practices

Purpose

To provide a process that renders Ultrasound Transducers safe for patient use.

Audience

All healthcare workers in UTMB hospitals (LCC, CLC, ADC and Galveston) and clinics.

Definitions and Spaulding Classification

External Transducers: Transducers that contact intact external body surfaces and used for non-invasive procedures are classified as a non-critical device under Spaulding Classification (e.g. linear, curvilinear, and passed array).[15, 16, 17] External transducers that routinely contact non-intact skin are classified as semi-critical under Spaulding Classification.

Internal Transducers (also known as Endocavity Transducers): Transducers that contact internal surfaces and mucous membranes during invasive procedure are classified minimally as a semi-critical device under Spaulding Classification (e.g. vaginal, gastric, rectal, and transesophageal).[15, 16, 17]

Transducers for Ultrasound-Guided (USG) Interventional Procedures: External transducers used to localize placement of percutaneous needles or catheters such as vascular access (e.g. PIV, midline, PICC, CVC, and arterial line insertion, thoracentesis, paracentesis, arthrocentesis, pericardiocentesis, lumbar puncture, ultrasound- guided regional/local anesthesia, and percutaneous biopsies.[15, 16, 17] are classified minimally as a non-critical device under Spaulding classification and the Association for Medical Ultrasound (AIUM); however, certain disinfection requirements must be met. Interventional transducers used during percutaneous biopsies routinely exposed to gross soil or contamination, internal transducers, or transducers used in sterile operation suites are minimally classified as semi-critical devices and, in some cases, critical devices based on MFG IFU recommendations

Non-critical Medical Devices: devices that come into contact with intact skin (meaning unbroken skin) but not mucous membranes.

Critical Medical Devices: critical medical devices that enter normally sterile tissue or the vascular system or through which blood flows should be sterilized before each use (refer to methods of sterilization and disinfection in this policy and MIFU for medical devices being sterilized).

Semi-Critical Medical Device: Devices that come in contact with mucous membranes or skin that is not intact should be free of all microorganisms except for bacterial spores and are called semi-critical medical devices. Respiratory and anesthesia devices, endoscopes, diaphragm fitting rings, vaginal speculums, and ultrasound probes are included in this category. Semi-critical medical devices require high-level disinfection using chemical disinfectants.

Manufacturer Instructions for Use (MIFU) are detailed, step-by-step guides provided by the manufacturer to explain how a product, especially medical devices, should be used and handled. They outline the correct procedures for use, including cleaning, disinfection, and other safety precautions. MIFUs ensure the product is used safely and effectively, while also addressing potential hazards and

ensuring compliance with legal and regulatory standards.

Policy

Ultrasound Cover and Gel Use Based on Transducer Placement/ Procedure

External Transducers

- Clean intact skin – no cover, bacteriostatic gel
- Contaminated intact skin – single use cover, bacteriostatic gel
- Non intact skin – single use cover, sterile gel

Internal Transducer Procedures (vaginal and rectal):

- Single use cover, sterility determined by use, sterile or bacteriostatic gel depending on use

Intra-operative and Transesophageal:

- Single use cover, (sterility of cover determined by procedure sterility), sterile gel

Gel Bottle Requirements

Non-Refillable Ultrasound Gel

- Ultrasound gel bottles used for multiple patients may not be refilled.
- Non-refillable bottles of ultrasound gel must have a discard date written on them when they are first opened. The discard date is 30-days from when the bottle was opened or by the manufacturer's expiration date, whichever comes first.
- Dispensing nozzles must not come into direct contact with patients, staff, instrumentation or the environment. In the event the nozzle becomes soiled or contacts the patient, staff, instruments, or environment, wipe the dispensing nozzle with an alcohol pad.

Ultrasound Gel Warming Requirements

- Dry heat should be the only method used to warm gel. [16]
- Bottles should be removed from the warmer as soon as possible and dried immediately. Do not store the ultrasound gel bottles in the warmer overnight.
- Gel warmers should be cleaned and disinfected regularly, minimally weekly, according to the manufacturers' instruction for use using a low-level hospital grade disinfectant. [16]

Ultrasound Gel Storage

- Ultrasound gel should be stored in an area that is dry and protected from potential sources of contamination such as dust, moisture, insects, and rodents.
- If evidence of potential contamination is present, or if the package integrity has been breached, the ultrasound gel must be discarded

immediately. [11-14]

Transducer Cleaning and Disinfection Requirements

Cleaning: Transducers will be cleaned and disinfected between each use using the manufacturer recommended processes and products. Cleaning begins at point of use and requires that all blood and body fluid are removed with the approved wipe. Disinfection, based on use, may require the use of a low-level disinfectant (LLD) wipe or high-level disinfection (HLD) / sterilization process as required by the manufacturer and this policy. Components that do not come into direct contact with the patient should also undergo LLD/HLD according to the manufacturer's IFU for each device.

Refer to the algorithm and outline below based on transducer use.

External Transducers: External transducers classified as non-critical used on intact skin will be cleaned and disinfected using a MFG approved low-level disinfectant wipe at bedside immediately after use.

External transducers classified as semi-critical used routinely on non-intact skin (ex., Burns Unit) will be cleaned at bedside and then high-level disinfected within 1 hour.

Ultrasound-Guided Interventional Procedure Transducers: Transducers used for needle or catheter placement classified as non-critical will be cleaned and disinfected with a low-level disinfectant wipe per MFG IFU immediately after use at bedside.

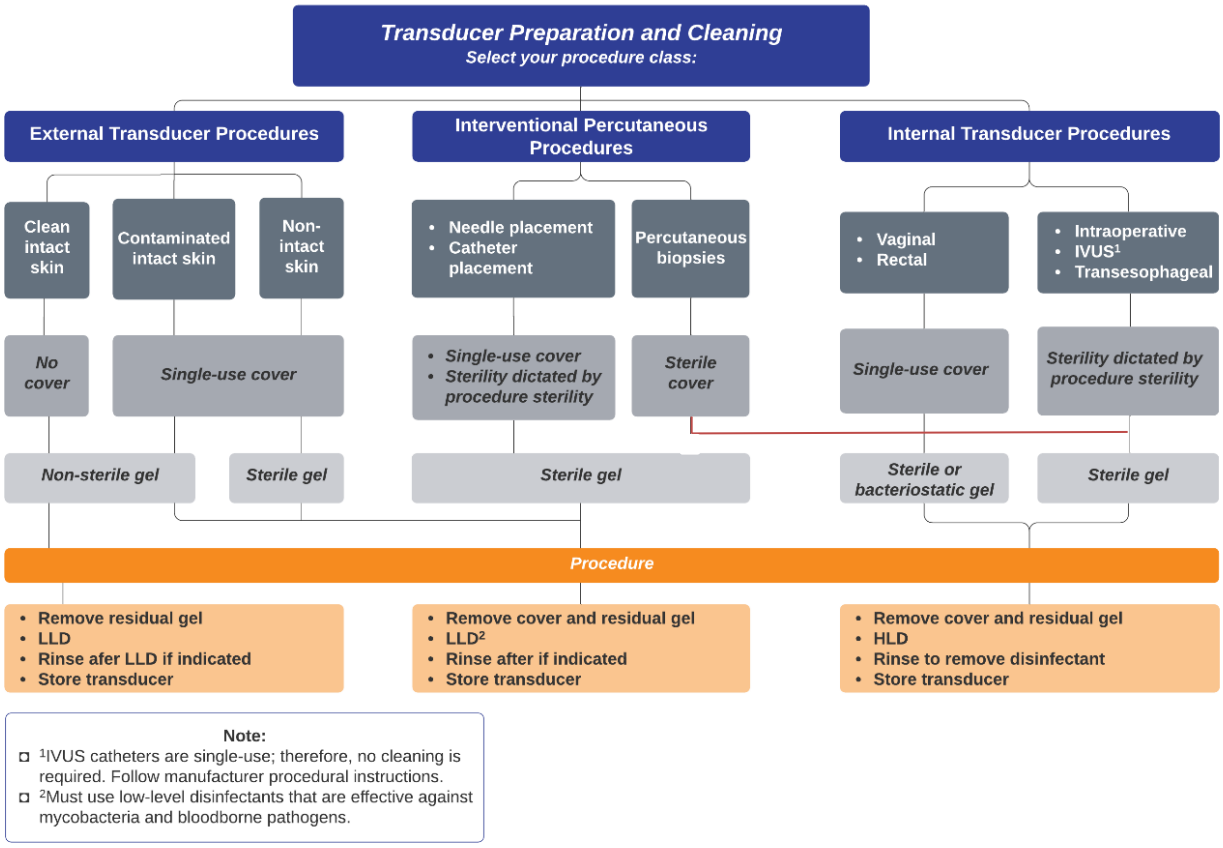
Internal Transducers (also known as Endocavity Transducers): Transducers used on mucus membranes classified as semi-critical will be cleaned at bedside immediately after use and minimally high level disinfected with manufacturer approved process within 1 hour.

Intra-operative and Transesophageal: Transducers used for percutaneous biopsy or intra-operatively including those performed in semi-critical procedural areas (e.g., Echo and Cath Lab) will be cleaned immediately after use and must minimally be high level disinfected with MFG approved high level disinfection or sterilization method within 4 hours.

Storage

- Non-critical probes may be stored in an upright position on a designated rack or machine. Storage of low-level disinfected probes should allow for adequate space for circulation.
- Semi-critical probes may be stored in a closed or covered cabinet. Open shelving may be used but requires special attention to traffic control, air ventilation, and environmental services. All semi-critical probes should be covered with a clean storage cover.
- Transesophageal probes may be stored in a HEPA filtered enclosed cabinet in a secure, clean location.
- Sterilized transducers should be stored within an approved sterilization container and wrap. The use of a dust cover is required if stacking. Transducers should be stored at least 8" from floor and 18" from ceiling.

- Maintain cleaning and maintenance requirements for all storage devices.



References:

1. Centers for Disease Control and Prevention. Safety Communication: Bacteria Found in Other – Sonic Generic Ultrasound Transmission Gel Poses Risk of Infection. http://emergency.cdc.gov/coca/reminders/2012/2012apr20.asp. Accessed on 7/28/13.
2. Keizur JJ, Lavin B, Leidich RB. Iatrogenic urinary tract infection with Pseudomonas cepacia after transrectal ultrasound guided needle biopsy of the prostate. J Urol 1993;149: 523-526.
3. Organ M, Grantmyre J, Hutchinson J. *Burkholderia cepacia* infection of the prostate caused by inoculation of contaminated ultrasound gel during transrectal biopsy of the prostate. Can Urol Assoc J 2010; 4:E58-E60.
4. Olshtain-Pops K, Block C, Temper V, Hidalgo-Grass C, Gross I, Moses AE, Gofrit ON, Benenson S. An outbreak of Achromobacter xylosoxidans associated with ultrasound gel used during transrectal ultrasound guided prostate biopsy. J Urol 2011;185:144-147.
5. Hutchinson J, Runge W, Mulvey M, Norris G, Yetman M, Valkova N, Villemur R, Lepine F. *Burkholderia cepacia* infections associated with intrinsically contaminated ultrasound gel: the role of microbial degradation of parabens. Infect Control Hosp Epidemiol 2004;25:291-296.
6. Kanemitsu K, Endo S, Oda K, Saito, K Kunishima H, Hatta M, Inden K, Kaku M. An increased incidence of *Enterobacter cloacae* in a cardiovascular ward. J Hosp Infect 2007;66:130-134.
7. Chittick P, Russo V, Sims M, Robinson-Dunn B, Oleszkowicz S, Sawarynski K, Powell K, Makin J, Darnell E, Boura JA, Boyanton B, Band J. An outbreak of *Pseudomonas aeruginosa* respiratory tract infections associated with intrinsically contaminated ultrasound transmission gel. Infect Control Hosp Epidemiol 2013;34:850-853.
8. Gaillot O, Maruéjouls C, Abachin É, Lecuru F, Arlet G, Simonet M, Berche P. Nosocomial outbreak of *Klebsiella pneumoniae* producing SHV-5 extended- spectrum B-lactamase, originating from contaminated ultrasonography coupling gel. J Clin Microbiol 1998;36:1357-1360.
9. Weist K, Wendt C, Petersen LR, Versmold H, Rüden H. An outbreak of pyodermas among neonates caused by ultrasound gel contaminated with methicillin-susceptible *Staphylococcus aureus*. Infect Control Hosp Epidemiol 2000;21:761-764.
10. Jacobson M, Wray R, Kovach D, Henry D, Speert D, Matlow A. Sustained endemicity of *Bulkholderia cepacia* complex in a pediatric institution, associated with contaminated ultrasound gel. Infect Control Hosp Epidemiol 2006;27:362- 366.
11. Medical gels and the risk of serious infection. Health Canada. Notice to hospitals: important safety information on ultrasound and medical gels. 2004 October 20. Available: www.hc-sc.gc.ca/hpfb- dgpsa/tdp/ultrasoundgel_e.html(accessed2004Oct27).
12. Oleszkowicz SC, Chittick P, Russo V, Keller P, Sims M, Band J. Infections associated with use of ultrasound transmission gel: proposed guidelines to minimize risk. Infect Control Hosp Epidemiol 2012;33:1235-1237.
13. CHICA-Canada Position Statement. Medical gels. Original: November 2003. Last

revision: March 2005.

14. Creighton Medical Association. Policy 1-20. Ultrasound gel use, handling and storage. 5/20/12.
15. Guidance Document. Transducer Disinfection for Assessment and Insertion of Peripheral and Central Catheters for Vascular Access Teams and Clinicians. Association for Vascular Access, June, 2018
16. American Institute of Ultrasound in Medicine. Guidelines for Cleaning and Preparing External-and Internal use Ultrasound Probes Between Patients, Safe Handling, and Use of Ultrasound Coupling Gel, 2022. https://www.aium.org/resources/official-statements/view/guidelines-for-cleaning-and-preparing-external--and-internal-use-ultrasound-transducers-and-equipment-between-patients-as-well-as-safe-handling-and-use-of-ultrasound-coupling-gel
17. Guidelines for Infection Prevention and Control in Sonography: Reprocessing the Ultrasound Transducer. Society of Diagnostic Medical Sonography. Revised May 20, 2020. Journal of Diagnostic Medical Sonography 2020, Vol 36(4) 381-403.
18. AAMI TIR99: 2024 Processing of dilators, transesophageal and ultrasound probes in health care facilities, April 2024
19. Non-IHOP Healthcare Epidemiology 01.05.04 High Level Disinfection of Semi critical Medical Devices.