Guidance Document

Transducer Disinfection for Assessment and Insertion of Peripheral and Central Catheters for Vascular Access Teams and Clinicians

Judy Thompson, MSN, RN, VA-BC™
J. Hudson Garrett Jr., PhD, FNP-BC, IP-BC™, VA-BC™

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Introduction / Summary

Use of real-time ultrasound guidance for vascular access (USGVA) procedures is recommended by multiple organizations, associations, guidelines and standards (2,4,7,8,10,12,17,26,32,35,44,49,50). When performed by trained, competent clinicians, USGVA has been shown to decrease complications and reduce multiple attempts to gain vascular access (2,4,7-10,12,13,15,17,18,26-29,31,33,35,36,41,44,48-50,52).

Use of ultrasound for vascular access, particularly peripheral access, presents distinct challenges to existing recommendations. Healthcare professionals responsible for vascular access also have a responsibility to ensure patient safety during those procedures, therefore, they also must address inconsistent practice with respect to cleaning and disinfection practices involving USGVA.

There are conflicting published guidelines regarding the level of disinfection a transducer must undergo between patients/procedures (3,5,6,14,16,19-21,33,38,42,51). The Association for Vascular Access (AVA), in conjunction with experts in infectious disease and infection prevention, have developed this professional guidance document which serves as a basis for evidence-based decision making. Additionally, this document identifies areas of practice that require continued monitoring and clinical research.
Background / Problem

Greater than ninety percent (90%) of hospitalized patients have a Vascular Access Device (VAD) inserted, making VAD insertion the most common invasive procedure patients experience (22,23,30). Use of ultrasound in VAD insertion also has a strong and increasing presence in outpatient settings making consistent practice across the care continuum an essential yet complex goal. Use of ultrasound for vessel assessment and real-time guidance is strongly recommended by many professional clinical societies and organizations, is widely practiced, and has shown to decrease complications, reduce multiple access attempts and, as a result, has improved patient safety and satisfaction (2,4,7-10,12,15,17,18,26-29,31,32,35,36,41,44,48-50). Use of ultrasound for the placement of VADs is directly aligned with the Institute for Healthcare Improvement Triple Aim philosophy of improved population health, improved patient satisfaction with care, and cost reduction (24).

As identified previously, conflicting guidance documents have been published regarding the most appropriate level of disinfection for ultrasound transducers. As defined by the Spaulding Classification, global recommendations range from High-Level Disinfection (HLD) to Low-Level Disinfection (LLD) (3,5,6,11,14,16,19-21,25,33,34,38,42,53-55). AVA’s collaborative document will guide safe practice for the disinfection of ultrasound transducers used in access procedures providing a consistent approach to the application of the Spaulding classification scheme. Adhering to recommendations of HLD or sterilization for ultrasound transducers used during peripheral and central intravenous catheter insertion may have unacceptable repercussions resulting in adverse patient outcomes.

This guidance document examines existing practice with respect to ultrasound transducer disinfection as it is currently performed. Furthermore, this document evaluates how the current evidence supports existing best practice and meets the evidence-based criteria. Recommendations and guidelines must be able to be reasonably operationalized if we expect compliance. That is not to say that patient safety is ever negotiated, but we must address risk versus benefit. Complexities layer this issue and require insights of front line specialists with respect to practice and areas where there is a need for process and outcomes research (13).

Use of ultrasound has been demonstrated to improve clinical outcomes through the:

1. Reduction of:
   a. Multiple needle sticks
   b. Pneumothorax/Hemothorax
   c. Inadvertent arterial access

2. Assessment/identification of:
   a. non-patent vasculature to prevent inappropriate catheterization complications
   b. vessel irritation, thrombosis, and other potentially adverse events
c. nerve bundles and prevents associated complications
d. guidewire direction \(^{2,4,7-10,12,15,17,18,26-29,31,32,35,36,41,44,48,49,51}\)

USGVA is transforming practice into the accepted standard of care across the entire healthcare continuum. Ultrasound technology is now being used in Emergency Departments, Intensive Care Units, preoperative units, acute care units, long term care facilities and clinics for peripheral and central access. AVA expects this trend to continue and overall usage of these evidence-based technologies to expand in the coming years. Recent literature from global publications recommend HLD for reprocessing non-invasive ultrasound transducers used for the insertion of VADs. \(^{6,14,16,19,20,21,33,38,42}\)

Use of HLD for these procedures make reprocessing of these transducers impracticable and problematic for multiple reasons:

1. Reduce throughput by creating delays in transducer availability due to HLD cycle time.
2. Increase cost of additional ultrasound probes
3. Increased cost related to HLD products (special facilities, equipment and associated disinfection chemicals)
4. Non-Compliance with HLD policy and procedure
5. Additional HLD training and competency requirements
6. Reduced ultrasound guidance for VAD insertion

Through this guidance document, AVA provides a pragmatic approach to disinfection of the USGVA transducers which promote patient safety, reduce risk for healthcare-associated infections, creates uniformity and consistency to healthcare facilities across the continuum of care and enhances the opportunity to improve patient satisfaction which is so critical to evidence-based care.

**Using the Spaulding Classification to Assess Patient Risk and Influence Decision-making**

The authors of this guidance document conducted an extensive literature review of relevant published manuscripts to provide background and context on this important clinical issue. In addition, the authors reviewed relevant clinical guidelines and guidance statements from clinical societies and the United Stated Food and Drug Administration and Centers for Disease Control and Prevention. Each guideline cites the Spaulding Classification Scheme \(^{38,46,47,51}\). Interpretation of the Spaulding Classification is very specific in some areas and left to interpretation in others. According to the CDC, the Spaulding classification is strategy for determining reprocessing methods for contaminated medical devices based upon the use of that device \(^{37}\). The system classifies a medical device as critical, semicritical, or noncritical on the basis of risk to patient safety from contamination of a device. The system also recommends three levels of disinfection activity (Sterilization, HLD, and LLD) for use according to the classification of medical devices (critical, semicritical, and noncritical). By necessity, the Classification must recognize the prior use of the device as well as the intended use in determining the level of disinfection or sterilization. For example, an ultrasound used during a procedure where contamination with purulent tissue or material is present must be cleaned and disinfected using a process that can reliably remove and inactivate the organisms involved. In addition, the user must consider the intended subsequent use of the device, so it is
disinfected to meet that purpose. This demonstrates the complexity involved in disinfection of an ultrasound transducer that healthcare personnel may share and use as equipment for more than vascular assessment or VAD insertion.

The intended use of an ultrasound transducer for the purposes of placing peripheral or central vascular access devices is to assess vasculature under intact skin and not come in contact with mucous membranes. However, during insertion, the device comes into contact with the blood of the patient, and de facto the bloodstream of the patient. Therefore, cleaning and disinfection practices used within a given facility must assess the risks involved in the ultrasound transducer use and the ability to perform the necessary level of cleaning and disinfection in a manner that is consistent, reliable and reproducible.

The Association for Vascular Access (AVA) recommendations:
Vascular Access Device Low-Level Disinfection

Practice Recommendations
Given the variability of facilities, personnel, organizational capabilities, and practices, AVA recommends the following steps regarding cleaning, disinfection of an ultrasound transducer used for vascular access:

1. Healthcare Facilities should conduct a thorough infection prevention and control risk assessment in collaboration with Vascular Access, Infection Prevention and Control, Environmental Services, and other relevant facility stakeholders to evaluate risks with ultrasound transducers used for vascular access to evaluate risks of healthcare associated infection transmission.
2. Prior to the first episode of ultrasound transducer use, and at least annually, all clinicians involved in USGVA will undergo comprehensive training on proper disinfection of US transducers/probes.
3. Training to include, at a minimum, cleaning and disinfection of all ultrasound transducers used as part of job responsibilities, application and use of sheaths (sterile and unsterile), application and use of gel (single use sterile), process monitoring, and performance improvement.
4. Training should be competency-based with validation.
5. All transducers/probes used for peripheral VAD insertion will undergo, at a minimum, low level disinfection using an EPA-registered, hospital-grade germicide with broad spectrum efficacy claims against clinically relevant microorganisms (including enveloped and non-enveloped viruses such as Hepatitis B Virus and HIV, multidrug resistant bacteria, pathogenic fungi, and mycobacterium). Collaboration with the facility infection prevention and control personnel and review of the device manufacturer’s instructions for use should be part of this decision-making process.
6. Clean the ultrasound transducer prior to disinfection following the device manufacturer’s instructions for use.
7. Germicide use must conform with the manufacturer’s instructions for use with respect to product selection, application process, and product overall contact/dwell time. Vascular access clinicians should follow the level of disinfection (i.e. Low Level Disinfection, Intermediate Level Disinfection, High Level Disinfection, or Sterilization) as dictated by the manufacturer’s instructions for use.

8. During assessment, consider using a single use condom or commercially manufactured transducer sheath (excluded: transparent dressing, gloves) during all use where there is the possibility of contact with blood/body fluids or non-intact skin \(^{(2,6,18,45)}\).

9. Perform ALL ultrasound guided vascular access device insertions (PIV, Midline, PICC, CVC, Arterial line) with the use of a sterile sheath and single-use sterile gel \(^{(1,3,43)}\).

10. Following the conclusion of the procedure, the used sheath should be immediately inspected for any tears or punctures. The sheath should then be discarded in accordance with institutional waste policies.

11. Inspect the transducer for potential compromise such as puncture evidence. If damaged, remove the device from service and consult the facility’s infection prevention and control team and the device manufacturer to determine the most appropriate cleaning, reprocessing, and repair methods.

12. Once the probe has been inspected, the devices should be thoroughly cleaned of any visible bioburden, and then disinfected using an EPA-registered, hospital-grade disinfectant according to the manufacturer’s instructions for use with particular attention to the product’s overall contact time. The disinfectant must be at least capable of proving LLD and preferably be effective against *Mycobacterium spp*, and therefore meet the criteria as an intermediate level disinfectant.

13. The institution performing these procedures should document and retain the verification and validation of steps 1-12 above.

14. In the event ongoing process monitoring identifies cleaning and disinfectant failure(s), adverse patient outcomes that may be attributable to transducer reprocessing methods, or user techniques that demonstrate risk to the use of Low Level Disinfection (e.g., needlestick injuries, damage to transducer/probes, punctures of sheaths during procedures) existing approaches should be re-evaluated with consideration of operational and organizational changes including centralization of cleaning and disinfection, use HLD, or other changes that serve to protect the safety of the patient.

**Product Evaluation Checklist for the safe practice of ultrasound transducer disinfection for vascular access procedures:**

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<tbody>
<tr>
<td>1</td>
<td>Is the ultrasound technology cleared by the US Food and Drug Administration?</td>
<td>Yes/No</td>
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<tr>
<td>2</td>
<td>Is the ultrasound technology capable of being cleaned and disinfected?</td>
<td>Yes/No</td>
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<tr>
<td></td>
<td>Question</td>
<td>Answer</td>
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<td>3</td>
<td>Does the manufacturer provide validated instructions for use for cleaning and disinfection using an EPA registered, hospital-grade disinfectant with an efficacy claim against broad spectrum, clinically relevant microorganisms (including enveloped and non-enveloped viruses such as Hepatitis B Virus and HIV, multidrug resistant bacteria, pathogenic fungi, and mycobacterium)?</td>
<td>Yes/No</td>
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<tr>
<td>4</td>
<td>Does facility have a policy and procedure for ultrasound transducer (used for vascular access) disinfection?</td>
<td>Yes/No</td>
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<td>5</td>
<td>Does clinician demonstrate competence (annual and on-going) in the fundamentals of cleaning and disinfection of transducers used for vascular access.</td>
<td>Yes/No</td>
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<td>6</td>
<td>Does clinician have documented competency in the appropriate disinfection of the transducer according to the manufacturer’s instructions for use?</td>
<td>Yes/No</td>
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<td>7</td>
<td>Has the facility conducted an infection control risk assessment based on current use of ultrasound technologies and current clinical practice for reprocessing these portable devices?</td>
<td>Yes/No</td>
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<tr>
<td>8</td>
<td>Does the facility have a comprehensive cleaning and disinfection process that has been, and is regularly validated (at least annually) for medical devices and relevant users?</td>
<td>Yes/No</td>
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**Summary:**

There is an associated risk for transmission of healthcare-associated pathogens and infection anytime a medical device is used between patients. This problem is not unique to the use of portable ultrasound devices in the specialty of vascular access, but rather a systems-related issue that must be addressed using the multi-faceted approach of People, Processes, and Products.

First, the user of these devices, the vascular access clinician must grasp the principles of cleaning and disinfection and have a comprehensive understanding of the product (transducer and disinfectant) instructions for use prepared by the manufacturer.

Second, healthcare facilities must develop, implement and constantly evaluate highly-reliable infection prevention and control processes for cleaning, disinfecting and storing portable ultrasound equipment used for the insertion of VADs. Facilities must validate and document each process, assess individual competencies for the user population at the time of hire, when the device’s instructions for use change and at least annually to document on-going competence.
Third, facilities should continuously evaluate practice, identify situations where actual practice does not meet the standard of practice, and implement a performance improvement and/or research strategy to improve process and outcomes.

Fourth, healthcare facilities, clinicians, regulators, and manufacturers must be called upon to collaborate in order to deliver to the market new clinical product innovations that not only provide access to improved diagnostic and therapeutic products, but also incorporate infection prevention and control and patient safety as a key element of the product’s design, approval and clinical utilization.

Finally, we must address the need for further research in the area of transducer disinfection used for vascular access. By focusing on each element of the multi-faceted approach, healthcare facilities can reduce risk, improve outcomes and remove unnecessary costs from the healthcare delivery system.

**Conclusion:**

Low level disinfection or preferably Intermediate level disinfection with an EPA-registered, hospital-grade disinfectant is appropriate for the general reprocessing of an ultrasound transducer used externally for the placement of VADs when a sterile probe cover is utilized. Additionally, further research is needed to address this critical topic and better understand current clinical practices related to disinfection competencies of vascular access clinicians and methods to create high-reliability clinical practices to ensure ultrasound transducers do not serve as vectors for cross transmission.

**About the authors:**

**Judy Thompson, MSN, RN, VA-BC™**

Ms. Thompson is the Director of Clinical Education at the Association for Vascular Access. She is a vascular access clinician with expertise in the assessment and insertion of ultrasound guided peripheral and central vascular devices. She has no relevant financial relationships to disclose.

**J. Hudson Garrett Jr., PhD, MSN, MPH, MBA, FNP-BC, PLNC, IP-BC™, VA-BC™, FAAPM**

Assistant Professor of Medicine
Division of Infectious Diseases
University of Louisville School of Medicine
President, Board of Directors
Vascular Access Certification Corporation
Co-Founder
Infection Prevention Institute
Dr. Garrett is an international expert in the field of infectious diseases and infection prevention and control. He currently serves as an Assistant Professor of Medicine in the Division of Infectious Diseases at the University of Louisville School of Medicine as part of the division’s gratis faculty. He is an expert in healthcare associated infections and frequently collaborates with the Centers for Disease Control and Prevention to educate healthcare providers on evidence-based practices to reduce vascular access related infections. Dr. Garrett has no financial relevant relationships to disclose.

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**Approved by:**
Association for Vascular Access Board of Directors June 12, 2018.
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Disclaimer: This document is meant to serve as a basis for evidence-based decision making. Nothing contained within this guidance document should take the place of following a medical...
device’s approved instructions for use provided by the manufacturer. This document should also be used in conjunction with a facility-specific infection control risk assessment to create institutional procedures for the proper use and cleaning/disinfection of these ultrasound devices.