

A rational approach to the disinfection of the ultrasound probe body, handle and cable

Critical Summary

- Different ultrasound probe areas present varying degrees of infection risk.
- The microbiological bioburden associated with each of these areas on the ultrasound probes may present different levels of risk to patients.
- The Spaulding Classification may be applied to determine decontamination requirements.



Ultrasound probes are reusable medical devices that must undergo reprocessing between patients to minimise infection transmission risk. A typical ultrasound probe can be divided into different areas such as the cable, handle and head.

This Medical Bulletin will discuss how best to evaluate the disinfection or sterilisation requirements of these components based on the internationally adopted Spaulding Classification.

Typical ultrasound probe components

Ultrasound probes generally have three basic components; the head which houses the transducer and transmits the ultrasound signal, the handle which is the portion the user grasps to position the probe and the cable which connects to the console.

The typical ultrasound probes discussed here include those used in endocavitary procedures such as transvaginal and transrectal scans, as well as surface probes used in procedures including abdominal or pelvic scans. Transoesophageal probes have a more complex form factor and will not be discussed here.

Probe head

The probe head is generally in direct contact with the patient. Endocavitary probe heads are likely to contact mucous membranes and can also potentially contact sterile tissue or blood during invasive procedures. Surface probe heads can potentially contact sterile tissue, blood, broken skin, mucous membranes or intact skin depending on the procedure.

Probe handle

The handle is directly adjacent to the head and being in such proximity means it could pose a cross-contamination risk. While the handle itself is not intended for patient contact, direct or indirect contact could occur. For instance, the gloved hands of the ultrasound user could be soiled by any contamination on the handle as the probe is manipulated and these could be transferred to the patient.

Cable

The cable does not ordinarily come into contact with the patient. On occasion it may contact the intact skin of the patient as the probe is positioned. There may be exceptional circumstances such as in emergency care settings where the cable could come into contact with sterile tissue if it was inadvertently draped across an open wound.

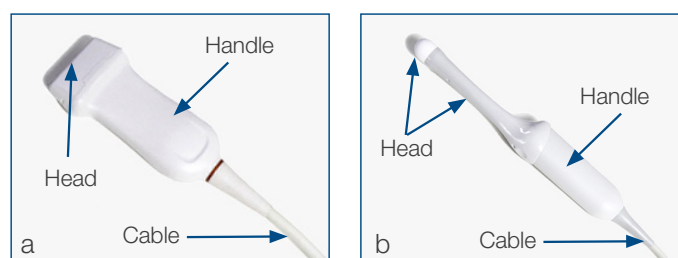


Figure 1. The different ultrasound probe components on (a) surface and (b) endocavitary ultrasound probes.

Spaulding Classification

The Spaulding Classification is a risk based framework setting out the decontamination requirements for medical devices.¹

Critical devices are those that contact sterile tissue or blood and these should generally be cleaned and sterilised.¹ Where sterilisation is not possible, high level disinfection (HLD) is acceptable with the use of a sterile cover for critical ultrasound probes.²⁻⁶

Semi-critical devices contact intact mucous membranes and do not ordinarily penetrate sterile tissue. These devices should minimally receive cleaning and high level disinfection.¹⁻⁸

Non-critical devices only contact intact skin. Surfaces that are not intended for patient contact in a healthcare setting can also be considered to be non-critical. These devices or surfaces should be cleaned and/or low level disinfected.¹⁻⁶ Low level disinfection is defined as the elimination of most bacteria, some fungi and some viruses.³⁻⁶

A summary of the Spaulding Classification rationale is provided below (Table 1).

Table 1: Summary of the Spaulding Classification

SPAULDING CLASSIFICATION	CONTACTS	STERILISATION OR DISINFECTION LEVEL
Critical	Sterile tissue or blood	Sterilisation or high level disinfection*
Semi-critical	Mucous membranes or non-intact skin	High level disinfection
Non-critical	Intact skin	Low level disinfection

* Critical ultrasound probes can be high level disinfected and used with a sterile sheath if sterilisation is not possible.²⁻⁶

Applying the Spaulding Classification to ultrasound probes

The Spaulding Classification can be applied logically to each area of the ultrasound probe to determine the decontamination requirements.

The head of the ultrasound probe should be classed as critical, semi-critical or non-critical depending on the type of contact associated with its use. Due to the proximity of the probe handle to the probe head and patient contact site, it would be logical to apply the same Spaulding Classification to the probe handle.⁹

Under this approach, the ultrasound probe (i.e. head and handle) should be decontaminated based on the level of risk associated with the patient contact site. Studies have demonstrated the importance of appropriate handle disinfection as this part of the probe can be heavily contaminated with ≥80% handles harbouring residual contamination where they were not disinfected.^{10,11}

As the probe cable is not intended for patient contact, it could be considered to be part of the general clinical environment alongside the ultrasound console, any work surfaces or other items close to the patient. If contact with the cable were to occur, it would most likely be with intact skin only suggesting that cleaning or low level disinfection would be an appropriate level of reprocessing.

When ultrasound probes are used in settings where the cable could contact sterile tissue, mucous membranes or broken skin, additional decontamination of the cable may be warranted. Disinfect the ultrasound cable in accordance with the ultrasound manufacturer's instructions. Sterile sheaths which extend to the probe cable could also be considered in these settings.

Contact us today for your specific needs on point-of-care reprocessing, understanding when to HLD or for an educational session at your facility.



References 1. Spaulding EH (1968). Chemical disinfection of medical and surgical materials. Disinfection, sterilization, and preservation. Lawrence C, Block SS. Philadelphia (PA), Lea & Febiger: 517-531. 2. Society and College of Radiographers (SCoR), and British Medical Ultrasound Society (BMUS) 2019. Guidelines for Professional Ultrasound Practice. 3. Nyhsen CM, Brady A, D'Onofrio M, Sidhu P, Humphreys H, Nicolau C, et al. Infection prevention and control in ultrasound - best practice recommendations from the European Society of Radiology Ultrasound Working Group. Insights Imaging. 2017;8(6):523-35. 4. US CDC 2008. Guideline for Disinfection and Sterilization in Healthcare Facilities. Updated May 2019. 5. Canadian National Standards. CSA Z314-18. Canadian Medical Device Reprocessing. 6. Australian & New Zealand Standards. AS/NZS 4187:2014. Reprocessing of reusable medical devices in health service organisations. 7. Ministère des Solidarités et de la Santé. Proposition technique du groupe de travail national. Prévention du risque infectieux associé aux actes d'échographie endocavitaire. 2019. 8. Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO), and Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM). Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten. Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz 2012; p. 66. 9. Alfa MJ. Infect Control Hosp Epidemiol. 2015;36(5):585-6. 10. Buescher DL, et al. Ultrasound Obstet Gynecol. 2016;47(5):646-51. 11. Ngu A, et al. Infect Control Hosp Epidemiol. 2015;36(5):1-4.

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