European guidelines agree – HLD is required for interventional procedures using ultrasound probes

International guidelines classify ultrasound probes that contact sterile tissues as critical medical devices. Contact with sterile tissue can occur during procedures that penetrate the skin such as biopsies, drainages and vascular access as well as during intraoperative procedures. These devices require sterilisation or a minimum of HLD in addition to use of a sterile sheath before use on patients.[1,2,5,6,8]

Europe – ESR 2017[1]

"High-level disinfection is mandatory for... all interventions."[1]

"The general consensus is that these procedures [all US guided interventional procedures including injections, tissue sampling, use in theatre] require HLD of US transducers including the handle."[1]

"The use of transducer covers does not replace thorough decontamination."[1]

Europe – ECMUS 2017[2]

"All internal transducers (e.g. vaginal, rectal, transoesophageal transducers) and intra-operative transducers, require a high-level of disinfection before they can be used in a new patient."

United Kingdom – SCoR/BMUS 2017[8]

"All critical probes (probes contacting sterile tissues or blood) should be preferably sterilised, but if sterilisation is not possible, they should be minimally high-level disinfected and used with a sterile sheath."

Netherlands – WIP 2017[9]

"Critical medical devices contact sterile tissue regardless of whether via non-intact skin or mucous membranes and should be sterile. Thermolabile reusable medical devices (e.g. ultrasound probes) cannot be heat sterilised and therefore must undergo chemical bactericidal, mycobactericidal, fungicidal, virucidal and sporicidal disinfection."

Germany – KRINKO/BfArM 2012[10]

"Critical ultrasound probes contact blood and sterile tissue and should be sterilised."

Scotland – HPS/HFS 2017[5]
Ireland – HSE 2017[6]

"The advancement of ultrasound scanning means they are increasingly used for scanning the skin which can be broken through the insertion of vascular devices or for the assessment of complex wounds. This increases the risk of contamination of the probe with the blood which requires a high-level disinfection process."[5,6]

"Use of a sheath/condom does not negate the need for probes to undergo manual cleaning and HLD as there is limited evidence on their effectiveness as a barrier to reducing the risk of HAI."[5,6]

High-Level Disinfection (HLD) = bactericidal, mycobactericidal, fungicidal and virucidal disinfection

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Procedures where HLD is required

Spaulding Classification	Procedures		Recommended disinfection
Critical	**Intraoperative procedures** **Ultrasound guided procedures where the probe may contact sterile tissue*** • Drainages • Injections • Tissue sampling • Biopsies **Surface ultrasound with open wound** • Surgical wound • Skin avulsion • 2nd-3rd degree burn		Sterilisation or minimum of HLD*
Semi-critical	**Endocavitary** • Transvaginal scans • Transrectal scans **Surface ultrasound with broken skin** • Scan across rash • Scan across dermatitis • Scan across 1st degree burn		Minimum of HLD
Non-critical	**Surface ultrasound with intact skin**		Minimum LLD or further protection with HLD

*According to many European guidelines, critical probes must be sterilised, however if sterilisation is not possible, HLD with use of a sterile sheath is permitted.[1-4] Semi-critical devices require bactericidal, mycobactericidal, fungicidal and virucidal (HLD) disinfection in addition to use of a sheath between patients.[1-12]

High-Level Disinfection (HLD) = bactericidal, mycobactericidal, fungicidal and virucidal disinfection

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