

## The Importance of High Level Disinfection (HLD) for Ultrasound Probes

### HLD: Why, What and When

#### Why HLD?

When it comes to reprocessing (disinfecting) ultrasound probes, clinical studies have demonstrated the risks and potential serious consequences if certain standards of care are not met:

- Patients have been put at risk of infection transmission due to inadequate cleaning or disinfecting of ultrasound probes and non-compliance with recommended reprocessing procedures.<sup>1</sup>
- A meta-analysis has shown that 12.9 percent of intracavity transducers are contaminated with pathogenic bacteria following disinfection with low level disinfectant wipes or sprays.<sup>2</sup>
- Multiple studies have shown that HPV DNA persists on transducers after disinfection with low level disinfectant wipes.<sup>3-5</sup>
- Death has been associated with improperly reprocessed ultrasound probes.<sup>6</sup>
- The first population-level study of its kind revealed an increased risk of infection and antibiotic prescriptions following semi-invasive ultrasound probe procedures.<sup>7</sup>

Multiple global guidelines now recommend HLD of ultrasound probes in between patients to reduce the risk of cross contamination. HLD is mandated by the CDC as the minimum standard in ultrasound probe reprocessing for semi-critical procedures (i.e. intracavity and surface ultrasound probes that contact mucous membranes or non-intact skin).

Unfortunately, this minimum standard is not always being met.

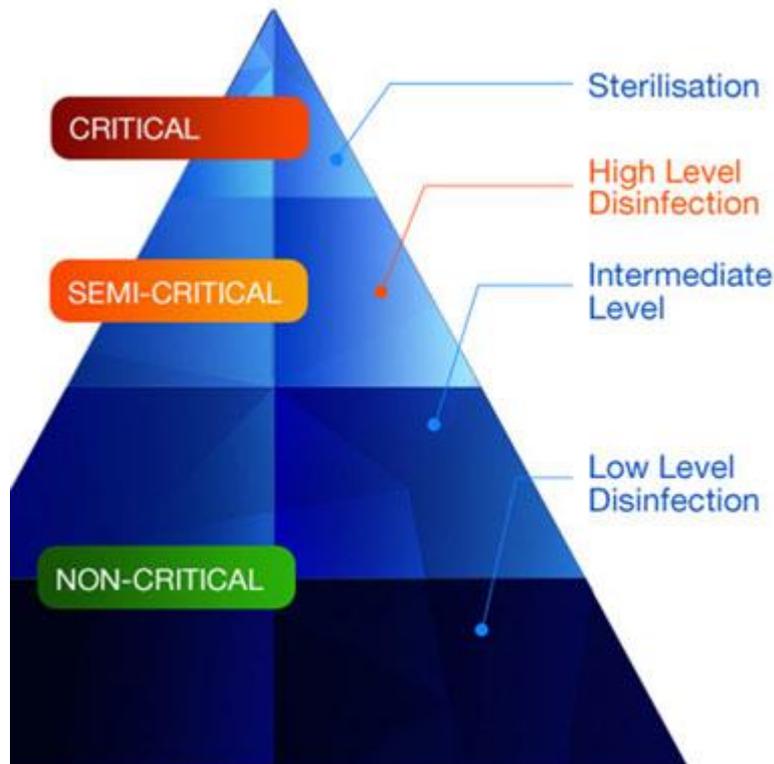
Using a protective sheath or condom on an ultrasound probe does not negate the requirement for HLD. In 2008, the Centers for Disease Control and Prevention mandated that: “Even if probe covers have been used, clean and high-level disinfect”.<sup>8</sup>

Clinical evidence confirms the risks:

- Probe sheaths have been reported to break 25 percent – 81 percent of the time.<sup>9</sup>
- Condoms used with transvaginal probes have been reported to break 0.9 percent – 5 percent of the time.<sup>10-12</sup>
- Condoms used with transrectal probes have been reported to break 9 percent of the time.<sup>13</sup>
- A study published in *The Infection Control of Hospital Epidemiology Journal*, states that probe covers “are inefficient at preventing contamination of endocavitary ultrasound probes under routine conditions”.<sup>14</sup>

## What is HLD?

HLD one of three disinfection levels used in hospitals and clinics for reprocessing ultrasound probes. It results in the complete elimination of all microorganisms in or on a probe, except for large numbers of bacterial spores.<sup>8,15</sup>



## When should HLD be used?

HLD should be performed on ultrasound probes that are used in semi-critical procedures, as defined by the Spaulding Classification (see above diagram) which forms the basis for multiple US and international guidelines. Applying the correct level of disinfection is based on the procedure the probe is going to be used for on the next patient and the degree of risk for infection.

Ultrasound probes used in examinations that may have a remote chance of contacting cracked or other non-intact skin and bodily fluids (including blood) should be minimally high level disinfected.<sup>8,16</sup>

If a heat-sensitive device cannot be sterilized due to the potential damage to the device then it can, at a minimum, be high level disinfected.

###

## References

1. CDC Health Alert Network September 11, 2015. Available from: <http://emergency.cdc.gov/han/han00382.asp>.
2. Leroy S. Infectious risk of endovaginal and transrectal ultrasonography: systematic review and meta-analysis. *Journal of Hospital Infection* (2012), <http://dx.doi.org/10.1016/j.jhin.2012.07.014>
3. Casalegno et. Al.: High Risk HPV Contamination of Endocavity Vaginal Ultrasound Probes: An Underestimated Route of Nosocomial Infection?, *PLOS ONE*, Oct 2012, Volume 7, Issue 10.
4. Ma et al.: Transvaginal ultrasound probe contamination by the human papillomavirus in the emergency department, *Emerg Med J*, 2012.
5. M'Zali et al. Persistence of microbial contamination on transvaginal ultrasound probes despite low-level disinfection procedure. *PLoS One* 2014;9:e93368.
6. GOV.UK Medical Safety Alert; Reusable transoesophageal echocardiography, transvaginal and transrectal ultrasound probes (transducer) – failure to appropriately decontaminate. (<https://www.gov.uk/drug-device-alerts/medical-device-alert-reusable-transoesophageal-echocardiography-transvaginal-and-transrectal-ultrasound-probes-transducers-failure-to-appropriately-decontaminate>).
7. Health Protection Scotland, NHS National Services Scotland. NHSScotland Risk Based Recommendations for the Decontamination of Semi-Invasive Ultrasound Probes: Risk of infection following semi-invasive ultrasound procedures in Scotland, 2010 to 2016. Version 1.0. October 2017. Accessible at: <http://www.hps.scot.nhs.uk/pubs/detail.aspx?id=3366>.
8. Rutala WA, Weber DJ, HICPAC. Guideline for Disinfection and Sterilization in Healthcare Facilities. USA: Centers for Disease Control (CDC); 2008. Rutala W.A. et al., (Available at: <https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines.pdf>)
9. Highett M, Claman P. High rates of perforation are found in endovaginal ultrasound probe covers before and after oocyte retrieval for in vitro fertilization-embryo transfer. *J Assist Reprod Genet.* 1995;12(9):606-9.
10. Amis S, Ruddy M, Kibbler CC, Economides DL, MacLean AB. Assessment of condoms as probe covers for transvaginal sonography. *J Clin Ultrasound.* 2000;28(6):295-8.
11. Milki AA, Fisch JD. Vaginal ultrasound probe cover leakage: implications for patient care. *Fertil Steril.* 1998;69(3):409-11.
12. Stormont JM, Monga M, Blanco JD. Ineffectiveness of latex condoms in preventing contamination of the transvaginal
13. Masood J, Voulgaris S, Awogu O, Younis C, Ball AJ, Carr TW. Condom perforation during transrectal ultrasound guided (TRUS) prostate biopsies: a potential infection risk. *Int Urol Nephrol.* 2007;39(4):1121-4.
14. Kac G, Podglajen I, Si-Mohamed A, et al. Evaluation of ultraviolet C for disinfection of endocavitary ultrasound transducers persistently contaminated despite probe covers. *Infect Control Hosp Epidemiol* 2010;31:165–17.
15. Federal Drug Administration. Guidance for Industry and FDA Reviewers: Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants. 2000.
16. American Institute of Ultrasound in Medicine. Guidelines for cleaning and preparing external and internal-use ultrasound probes between patients. AIUM Official Statement. Online at: <http://www.aium.org/officialStatements/57>. Accessed March 8, 2016.