

## **Risks of Improper Ultrasound Probe Reprocessing**

### **Background and Facts**

Effective high level disinfection (HLD) should eliminate fungi, bacteria, and viruses on an ultrasound probe. Traditional disinfection involves manual methods such as soaking in toxic chemicals, spraying or wiping, which can be ineffective, inefficient and environmentally unsound. Clinical evidence highlights the various cross contamination risks when ultrasound reprocessing is not performed properly.

### **Manual Disinfection Risks**

As well as being potentially inconsistent, manual processes can also be arduous for the operator, leading to a risk of error and a lack of compliance. Additionally, there is the risk of exposure to dangerous chemicals.

Clinical research confirms the drawbacks of traditional disinfection processes:

- A study that evaluated endoscopy reprocessing practices, including employee perceptions and occupational health issues, found there was “extensive non-adherence with reprocessing guidelines when manual methods were used.” Further, “automation resulted in better compliance with guidelines and reduced [health problems] associated with reprocessing.” Employee compliance to HLD recommendations was observed as only 1.4 percent for manual methods versus 75.4 percent for an automated process.<sup>1</sup>
- Manual disinfection of medical devices has been shown to lead to an increased risk of operator error if protocols are not followed correctly and poor protocol compliance can lead to an increased risk of infection transmission for patients.<sup>1,2</sup>
- A non-fatal case of hepatitis C and a fatal case of hepatitis B have been linked to improper ultrasound transducer disinfection.<sup>3,4</sup>

### **Probe Handle Risk**

Some ultrasound probes cannot be immersed in bulk liquids due to potential probe damage, so users avoid disinfecting the handle. Additionally, manual wipe-based disinfection systems may not specify disinfection of the probe handle and practice can vary between users.

While there is no specific guidance for ultrasound probe handle disinfection, a number of experts have noted it is imperative for the reprocessing guidelines to be updated.<sup>5,7</sup>

Clinical research confirms the necessity of proper handle disinfection:

- Residual bacteria, including pathogens such as methicillin resistant *Staphylococcus aureus* (MRSA), persist on more than 80 percent of handles that are not immersed during liquid soak disinfection.<sup>5</sup>

- The frequency of handle contamination was also confirmed in another study showing that over 80% of handles had residual contamination (after probe reprocessing) where handles were not disinfected.<sup>6</sup>
- Experts have discussed the potential for ultrasound probe handles to act as a reservoir for nosocomial pathogens, which could be transferred to the probe head, sheath or to a patient. This highlights the imperative need for guidelines and healthcare policies to be updated to ensure that the handle and probe are adequately disinfected after every patient use.<sup>7</sup>

### **Health Risks Using Traditional Bulk Liquid High Level Disinfectants**

Glutaraldehyde (GTA) and ortho-phthalaldehyde (OPA) are both used as high level disinfectants. GTA, and particularly OPA, can pose severe health and safety risks for patients and clinical staff who are exposed to them.

- In 2012 a study found that nurses with regular daily exposure to sterilizing agents (including glutaraldehyde) during pregnancy, are more than twice as likely to undergo late spontaneous abortion compared to nurses who are not exposed to these chemicals.<sup>8</sup>
- A study showed detrimental effects upon embryo development when culture media were exposed to surgical instruments sterilised with Cidex.<sup>9</sup>
- There is a body of published case reports showing that workers and patients have experienced respiratory problems, anaphylaxis, skin reactivity, and systemic antibody production with use of OPA.<sup>10-15</sup>

In addition to these health risks, both OPA and GTA have been shown ineffective against high-risk Human Papillomaviruses (HPVs) that can contaminate ultrasound probes.<sup>16,17</sup>

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## References

1. Ofstead, CL et al., Endoscope reprocessing methods: A prospective study on the impact of human factors and automation. *Gastroenterology Nursing*, 33:304–11, 2010.
2. Weber DJ, Rutala WA. Assessing the risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines. *Am J Infect Control*. 2013;41(5 Suppl):S67-71.
3. Ferhi K, Roupret M, Mozer P, Ploussard G, Haertig A, de La Taille A. Hepatitis C transmission after prostate biopsy. *Case Rep Urol*. 2013;2013:797248.
4. Medicines and Healthcare products Regulatory Agency (UK), Medical Device Alert Ref: MDA/2012/037.
5. Ngu A, McNally G, Patel D, Gorgis V, Leroy S, Burdach J. Reducing Transmission Risk Through High-Level Disinfection of Transvaginal Ultrasound Transducer Handles. *Infect Control Hosp Epidemiol*. 2015;36(5):581-4.
6. Buescher DL, Mollers M, Falkenberg MK, Amler S, Kipp F, Burdach J, et al. Disinfection of transvaginal ultrasound probes in a clinical setting: comparative performance of automated and manual reprocessing methods. *Ultrasound Obstet Gynecol*. 2016;47(5):646-51.
7. Alfa MJ. Intra-cavitary ultrasound probes: cleaning and high-level disinfection are necessary for both the probe head and handle to reduce the risk of infection transmission. *Infect Control Hosp Epidemiol*. 2015;36(5):585-6.
8. Lawson CC, Rocheleau CM, Whelan EA, Lividoti Hibert EN, Grajewski B, Spiegelman D, et al. Occupational exposures among nurses and risk of spontaneous abortion. *Am J Obstet Gynecol*. 2012;206(4):327 e1-8.
9. Ackerman, S.B., et al., Toxicity testing for human in vitro fertilization programs. *J In Vitro Fert Embryo Transf*, 1985. 2(3): p. 132-7.
10. H. Fujita, M. Ogawa, and Y. Endo. A case of occupational bronchial asthma and contact dermatitis caused by ortho-phthalaldehyde exposure in a medical worker," *J Occupational Health*, vol. 48, pp. 413–416, 2006.
11. W. N. Sokol. Nine episodes of anaphylaxis following cystoscopy caused by Cidex OPA (orthophthalaldehyde) high level disinfectant in 4 patients after cytoscopy. *J Allergy and Clinical Immunology*, vol. 114, pp. 392–397, 2004.
12. Cooper DE, White AA, Werkema AN, Auge BK. Anaphylaxis following cystoscopy with equipment sterilized with Cidex OPA (ortho-phthalaldehyde): a review of two cases. *J Endourol*. 2008;22(9):2181-4.
13. Suzukawa M, Yamaguchi M, Komiya A, Kimura M, Nito T, Yamamoto K. Ortho-phthalaldehyde-induced anaphylaxis after laryngoscopy. *J Allergy Clin Immunol*. 2006;117(6):1500-1.
14. Suzukawa M, Komiya A, Koketsu R, Kawakami A, Kimura M, Nito T, et al. Three cases of ortho-phthalaldehyde-induced anaphylaxis after laryngoscopy: detection of specific IgE in serum. *Allergol Int*. 2007;56(3):313-6.
15. Anderson SE, Umbright C, Sellamuthu R, Fluharty K, Kashon M, Franko J, et al. Irritancy and allergic responses induced by topical application of ortho-phthalaldehyde. *Toxicol Sci*. 2010;115(2):435-43.
16. Meyers J, Ryndock E, Conway MJ, Meyers C, Robison R. Susceptibility of high-risk human papillomavirus type 16 to clinical disinfectants. *J Antimicrob Chemother*. 2014;69(6):1546-50.
17. Ryndock E, Robison R, Meyers C. Susceptibility of HPV16 and 18 to high level disinfectants indicated for semi-critical ultrasound probes. *J Med Virol*. 2016;88(6):1076-80.