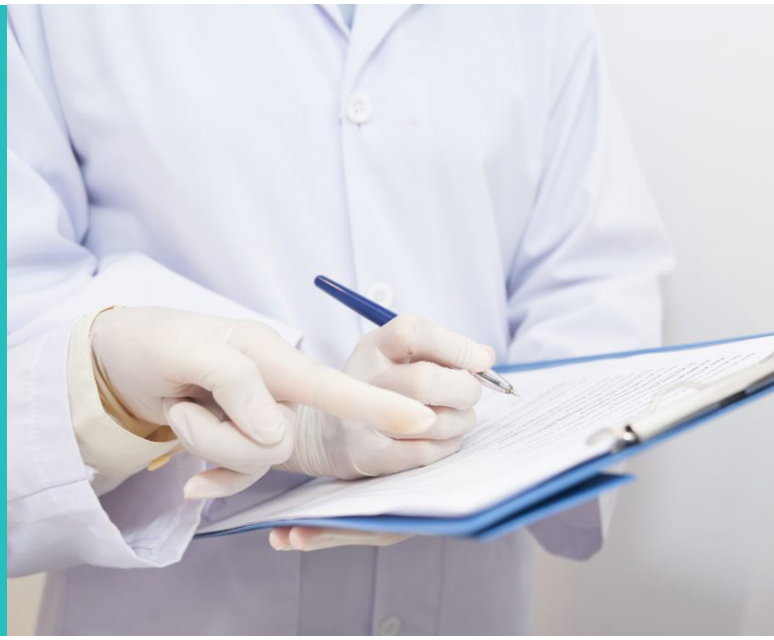
The importance of traceability in the high level disinfection (HLD) of ultrasound probes

Critical Summary

- United States medical device reprocessing standards require facilities to collect reprocessing cycle information, medical device identifiers, procedure information and patient details. The linking of the medical device and reprocessing information to the patient is referred to as tracking, or traceability.
- National standards and guidelines require medical devices classified as semi-critical and critical according to the Spaulding classification be traced to support patient safety.
- Digitization can help reduce manual administrative burden, the risk of operator error and incomplete record keeping.
- In the event of an outbreak or infection prevention breach, a reliable traceability system becomes instrumental for a facility in investigating, identifying and notifying affected patients.



American National standards and evidence-based guidelines require facilities to collect reprocessing cycle information, medical device identifiers, and then link this to the patient record.[1,2] This is referred to as tracking, or traceability.

When is traceability required in ultrasound probe reprocessing?

Sterilization and HLD of semi-critical and critical medical devices, including ultrasound probes, must have full traceability to the patient according to AAMI/ANSI ST58 and evidence based guidelines from the Association of PeriOperative Nurses (AORN).[1,2] The Joint Commission assess HLD processes with reference to National standards.[3]

Semi-critical ultrasound probes contact non-intact skin or mucous membranes and require a minimum of HLD (e.g. transvaginal ultrasound, scanning across non-intact skin).[1,4,5] Critical probes enter or contact sterile tissue or the bloodstream, and require sterilization (e.g. surgical probes).[1,4,5] If critical probes cannot be sterilized, they can undergo HLD and require use with a sterile sheath.[4]

Ultrasound presents unique challenges as its versatility and portability have resulted in its expanded use across healthcare.[6] The same probe could be used as a non-critical device, and later as a semi-critical device requiring HLD and traceability to the patient. It is important facility policies specify the information that must be collected to enable traceability of medical devices to patients.

Why is traceability required?

In 2018, The Joint Commission released a safety alert concerning noncompliance with standard IC.02.02.01 which requires organizations to reduce the risk of infections associated with medical equipment, devices and supplies. One of the findings included:

'Lack of monitoring or documentation of sterilization or HLD of equipment, which makes it difficult to track the use of equipment on a specific patient, complicating the patient notification process when an outbreak occurs.[7]'

Traceability is essential in an outbreak investigation to determine the extent of patient notifications and device recalls.[1,2] In a non-outbreak setting, it allows a facility to demonstrate they meet their duty of care to surveyors for reimbursement, and to patients.[2] Facilities can be ordered to halt patient examinations by health authorities if documentation demonstrating ultrasound probe reprocessing compliance is lacking.

Implementing traceability

The information contained in Figure 1 needs to be captured and linked for every semi-critical or critical ultrasound probe use.[1,2] Traceability can be completed manually (e.g., log-books), or by incorporating digitization (e.g. RFID scanning and electronic records).

Records should be kept for a period of time specified by the specific state or local statutes, or legal considerations. If not specified, record retention should be determined in conjunction with the facility's risk management and infection prevention and control committees.[1,2]

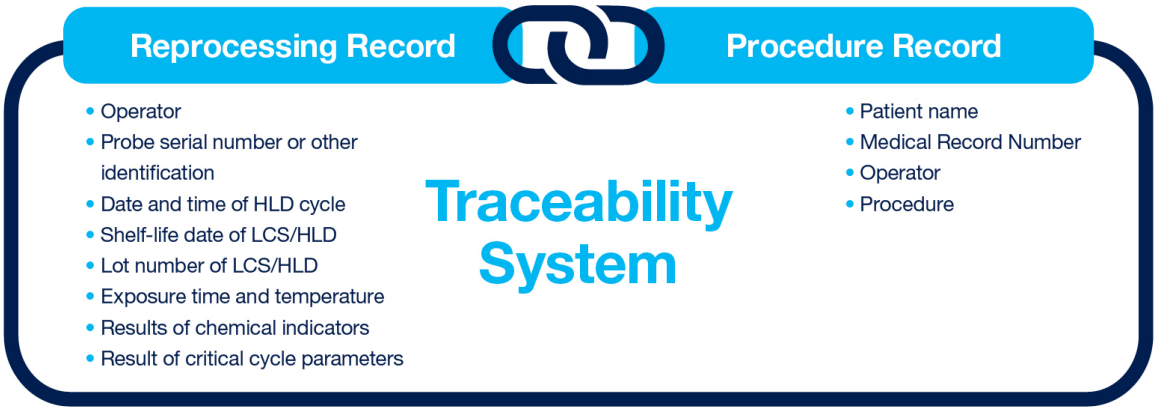


Figure 1. A traceability system links the information from the reprocessing cycle to the patient. The above information needs to be collected and linked to the patient for every HLD cycle. Adapted from AAMI ST58 and AORN Guidelines for periOperative practice.[1,2]

Benefits of digitization to traceability in ultrasound

> "Digitization of the process will allow quick access to load information, thus facilitating a quick response. In addition, this documentation provides evidence of a department's quality control program. Electronic records of process monitoring results, including specific load item identification are recommended because of their better legibility, accuracy, traceability, security and data integrity." - AAMI ST58 pg 47

Digitization ensures information capture and labelling is standardized across the entire ultrasound probe reprocessing workflow (e.g. using RFID technology and printers). This can help reduce manual administrative burden, the risk of operator error and incomplete record keeping. Digital records permit paperless linkage to the patient record which can be backed up securely. Digital solutions streamline compliance with The Health Insurance Portability and Accountability Act (HIPAA) to ensure that sensitive patient data is protected from unauthorized use.[8]

Conclusion

In healthcare, a robust traceability system can be used as a tool for investigating and identifying the affected patients in the event of an outbreak or infection prevention breach. Implementing digitization into traceability workflows can ensure record security, accuracy and efficient capture across the ultrasound infection prevention workflow.

Contact us today for your specific educational needs on traceability or understanding when to HLD at your facility.

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References 1. AAMI ST58:2013 Chemical sterilization and high-level disinfection in health care facilities. **2.** Association of periOperative Registered Nurses (AORN). High-Level Disinfection. AORN Guidelines for periOperative practice. Online: AORN, Inc; 2018. **3.** The Joint Commission (TJC) 2016. High-Level Disinfection (HLD) and Sterilization BoosterPak. Available at: http://www.jointcommission.org/assets/1/6/TJC_HLD_BoosterPak.pdf **4.** CDC 2008. Guideline for Disinfection and Sterilization in Healthcare Facilities. **5.** FDA 2019. Marketing Clearance of Diagnostic Ultrasound Systems and Transducers. 2019. **6.** Carrico RM, et al. Am J Infect Control. 2018;46(8):913-20. **7.** The Joint Commission (TJC). Improperly sterilized or HLD equipment – a growing problem. 2017 **8.** Office of the Assistant Secretary for Planning and Evaluation (ASPE) 1996. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996. Date accessed: 03/02/2021. Available at: https://aspe.hhs.gov/report/health-insurance-portability-and-accountability-act-1996

Nanosonics Limited 14 Mars Road, Lane Cove, NSW 2066, Australia, T: +61 2 8063 1600 E: info@nanosonics.com.au www.nanosonics.com.au

USA & Canada. Nanosonics Inc. 7205 E 87th Street, Indianapolis, IN 46256, USA T: 1-844-TROPHON 1-844-TROPHON 1-844-876-7466 E: info@trophon.com W: www.trophon.us

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