The importance of traceability in the high-level disinfection of wireless ultrasound probes

Critical Summary

- Traceability is the process of linking reprocessing cycle information and medical device identifiers to a patient record.
- United States medical device reprocessing standards require ultrasound probes classified as semi-critical and critical devices to have full traceability to the patient.
- Traceability is especially important for wireless probes, due to their portability and potential use in semi-critical or critical procedures.
- 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.

When is traceability required in ultrasound probe reprocessing?

Sterilization and high-level disinfection (HLD) of semi-critical and critical medical devices, including ultrasound probes, must have full traceability to the patient according to United States national standards and evidence-based guidelines.[1,2]

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).[3] Critical probes contact sterile tissue or the bloodstream, and require sterilization (e.g. surgical probes).[3] If critical probes cannot be sterilized, they can undergo HLD and require use with a sterile sheath.[3]

Why is traceability important for wireless probes?

Wireless ultrasound presents unique challenges for traceability due to its versatility and portability. Wireless probes are often shared between rooms, departments or operators and can be used in a range of different procedures. For example, the same probe could be used as a non-critical device in an abdominal scan, and later as a semi-critical device for an ultrasound-guided biopsy. Institutes must ensure that wireless probes have full traceability to the patient for each semi-critical or critical use.[1,2]

The Joint Commission has 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 documentation of sterilization or HLD of equipment.[4] Traceability is essential in an outbreak investigation. For example, in an outbreak of *Serratia marcescens* attributed to an ultrasound probe used in a digestive surgery ward, 8 out of 9 patients who came into contact with the contaminated probe were infected.[5] Traceability records were instrumental in identifying previously missed cases.

In non-outbreak settings, traceability allows a facility to demonstrate they meet their duty of care to surveyors for reimbursement, and to patients. Facilities can be ordered to halt patient examinations by health authorities if documentation on ultrasound probe reprocessing compliance is lacking.

Benefits of digitization to traceability in ultrasound

Traceability can be completed manually (e.g. logbooks) or by incorporating digitization (e.g. radio frequency identification (RFID) scanning and electronic records). Digitization ensures standardized information across the entire workflow and can 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 can also streamline compliance practices to ensure that sensitive patient data is protected from unauthorized use.

Implementing traceability for wireless probes

The information contained in Figure 1 needs to be captured and linked for every semi-critical or critical ultrasound probe use.[1,2]

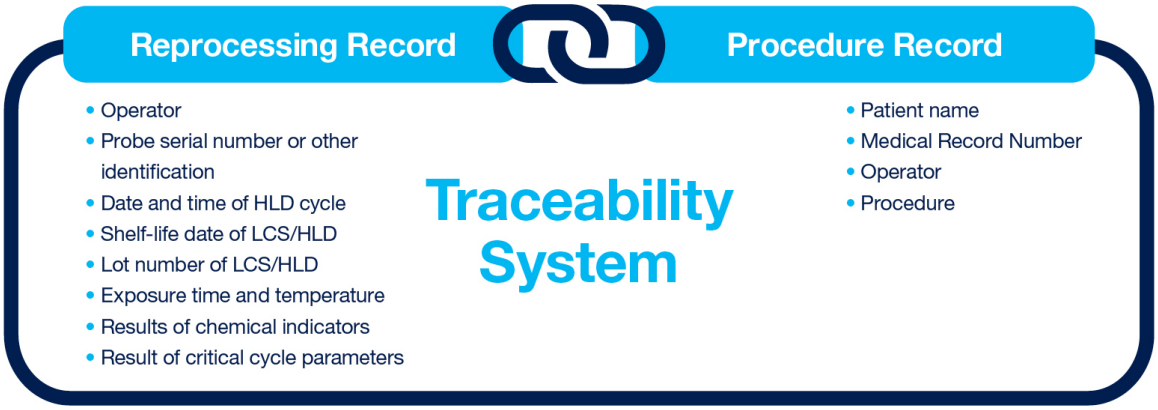

Figure 1. A traceability system links the information from the reprocessing cycle to the patient. The above information needs to be collected and linked to the patient for every HLD cycle. Adapted from AAMI ST58 and AORN Guidelines for periOperative practice.[1,2]

Traceability with the trophon2® device

The trophon2 device offers a digitized traceability solution based on RFID technology (AcuTrace®), which is now available for wireless ultrasound probes. AcuTrace can be used to trace wireless probes with the use of the trophon Wireless Ultrasound Probe Holder and a trophon AcuTrace Medical Instrument Tag.

All medical instruments intended to be reprocessed with a trophon2 device should be assigned a Medical Instrument Tag, to link each instrument to the HLD cycle.

Unlike traditional wired probes, wireless ultrasound probes do not have a cable to which the Medical Instrument Tag can be secured. It is recommended that the Medical Instrument Tag be attached to the top loop of the trophon Wireless Ultrasound Probe Holder to maintain traceability and reduce the risk of misplacing the tag.

Alternatively, healthcare professionals should consult facility protocols to determine how the Medical Instrument Tag and Holder can be integrated into clinical workflows to meet traceability requirements.

Conclusion

The ability to trace each semi-critical or critical use of an ultrasound probe to the patient is essential for wireless probes. A robust traceability system can be used as a tool for investigating and identifying 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 to learn about our traceability solutions or for your specific educational needs on ultrasound probe disinfection.

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References: 1. Association for the Advancement of Medical Instrumentation. AAMI ST58:2013 Chemical sterilization and high-level disinfection in health care facilities. **2.** Association of periOperative Registered Nurses (AORN). AORN Guidelines for Perioperative Practice. 2018. **3.** CDC 2008. Guideline for Disinfection and Sterilization in Healthcare Facilities. **4.** The Joint Commission (TJC), 2017. Improperly sterilized or HLD equipment - a growing problem. **5.** Géry A, et al. J Hosp Infect 2021; 111:184-188.

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