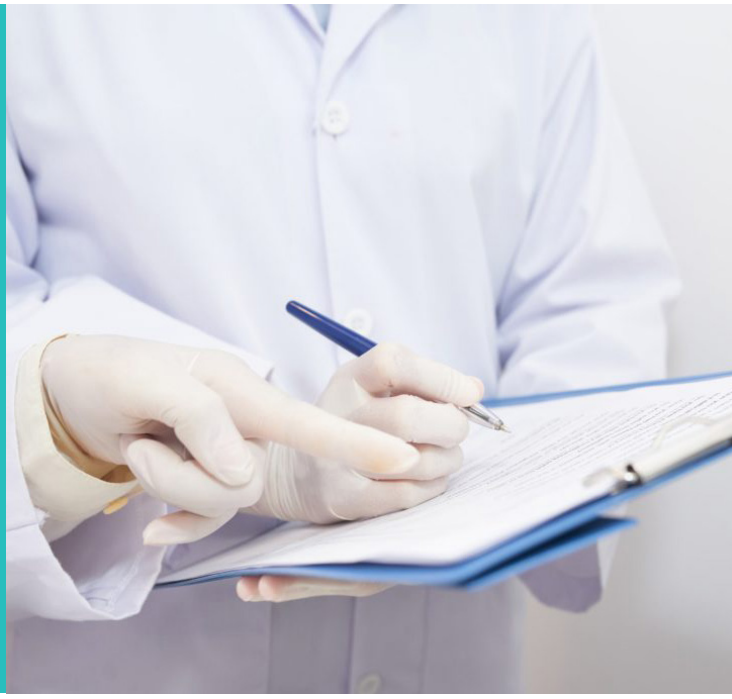
The importance of traceability in the high level disinfection (HLD) of ultrasound probes

Critical Summary

- Australian and New Zealand 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.
- Digitisation 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.



Australian and New Zealand Standards 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?

Sterilisation and HLD of semi-critical and critical medical devices, including ultrasound probes, must have full traceability to the patient according to the Australian National Safety and Quality Health Service (NSQHS) Standards, AS/NZS 4187 and the ACIPC-ASUM guidelines.[1-3]

Semi-critical ultrasound probes contact non-intact skin or mucous membranes and require a minimum of HLD (e.g. trans-vaginal ultrasound, scanning across non-intact skin).[2] Critical probes contact sterile tissue or the bloodstream, and require sterilisation (e.g. surgical probes).[2] If critical probes cannot be sterilised, they can undergo HLD and require use with a sterile sheath.[2,3]

Ultrasound presents unique challenges as its versatility and portability have resulted in its expanded use across healthcare.[4] 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?

Traceability is essential in an outbreak investigation to determine the extent of patient notifications and device recalls.[1-3] In a non-outbreak setting, it allows a facility to demonstrate they meet their duty of care to patients and for healthcare accreditation purposes. 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.[1-3] Traceability can be completed manually (e.g., log-books), or by incorporating digitisation (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.

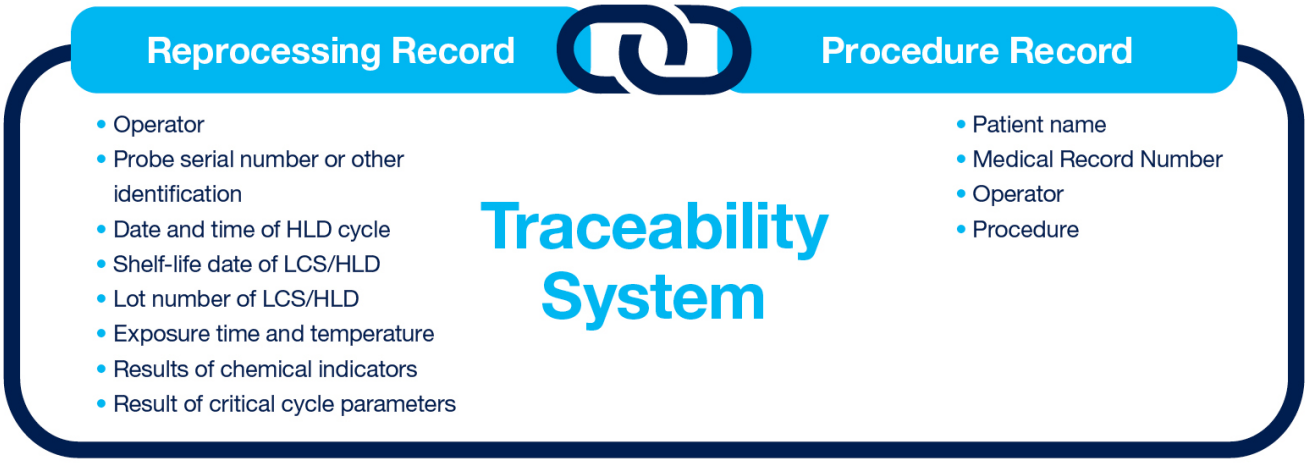


Figure 1. A traceability system links the information from the reprocessing cycle to the patient. The above information needs to be collected and linked to the patient for every HLD cycle. Adapted from the NSQHS Standards, AS/NZS 4187 and the ACIPC-ASUM guidelines.[1-3]

Benefits of digitisation to traceability in ultrasound

"HSOs should be working towards an electronic tracking/process record system." -AS/NZS 4187:2014 pg 72

Digitisation ensures information capture and labelling is standardised 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 can also streamline compliance practices to ensure that sensitive patient data is protected from unauthorised use.

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 digitisation 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. Australian Commission on Safety and Quality in Health Care (ACSQHC). National Safety and Quality Health Service Standards. Action 3.17. Second Edition. 2020. **2.** Standards Australia (AS) and Standards New Zealand (NZS). AS NZS 4187 2014: Reprocessing of reusable medical devices in health service organisations. 2014.**3.** Australasian College for Infection Prevention and Control (ACIPC), Australasian Society for Ultrasound in Medicine (ASUM). Guidelines for Reprocessing Ultrasound Transducers. Australasian Journal of Ultrasound in Medicine. 2017;20(1):30-40. **4.** Carrico RM, et al. Am J Infect Control. 2018;46(8):913-20.

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