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.
- Australian and New Zealand 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?

Sterilisation and high-level disinfection (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. transvaginal 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]

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.[1-3]

Traceability is essential in an outbreak investigation to determine the extent of patient notifications and device recalls.[1-3] 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.[4] 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 patients and is necessary for healthcare accreditation purposes.

Benefits of digitisation to traceability in ultrasound

Traceability can be completed manually (e.g. logbooks) or by incorporating digitisation (e.g. radio frequency identification (RFID) scanning and electronic records). Digitisation ensures standardised 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 unauthorised use.

Implementing traceability for wireless probes

Australian and New Zealand standards require that for each semi-critical and critical use of a wireless probe, data should be captured that can be used to identify the patient, the procedure and the reprocessing history of the device used.[1-3] A suggested minimum data set is included in Figure 1.

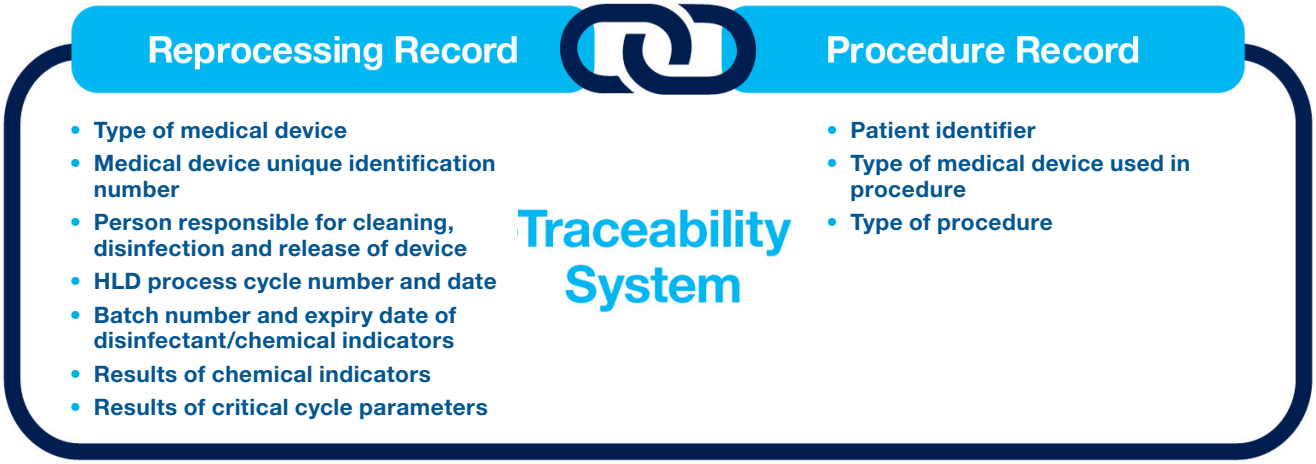

Figure 1. A traceability system links the information from the reprocessing cycle to the patient. The above information is a suggested minimum data set to collect and link to the patient for every HLD cycle. Adapted from AS/NZS 4187 and the ACIPC-ASUM guidelines.[2,3]

Traceability with the trophon2® device

The trophon2 device offers a digitised 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 digitisation 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. 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.** Géry A, et al. J Hosp Infect. 2021 May;111:184—188.

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MM02021-ANZ-CB V01 Oct22