Infection Prevention Toolkit

Prevention of Infection during Ultrasound Probe Use and Reprocessing

http://www.ultrasoundinfectionprevention.org.au/

Foreword

This Australian toolkit has been adapted from the original U.S. toolkit which was assembled in consultation with clinical experts with backgrounds in infection prevention and instrument reprocessing. The objective in developing this toolkit has been to provide a relevant resource regarding infection prevention during the use and reprocessing of ultrasound probes in Australia.

Australia-specific adaptions have been made by **Cathryn Murphy** *RN Bach. Photog. MPH. PhD. CIC. FAPIC, FSHEA, CICP-E.*

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Approach and Principles

These tools have been assembled based on best practice national standards,[1-3] guidelines[4-6] and accreditation criteria[1] with the goal of reducing infection risks associated with ultrasound use in the interest of patient safety. Guidelines referenced in this toolkit are evidence based, have been developed with infection prevention representation and have followed a formal guideline development process, including a public comment period. These tools are intended to guide the development of institutional policies and procedures, with an understanding that each institution can vary in the patient groups cared for, settings and the types of care provided.

Toolkit Contents

Tool 1: Part A - Locate

This list of strategies can help locate ultrasound machines in your facility. Locating ultrasound machines can be a challenging task, as they may move around, be uncatalogued, or may be unknown to personnel with responsibility for probe use and reprocessing.

Tool 1: Part B - Profile

After locating ultrasound machines with the Locate tool, this audit tool can be used to observe and assess procedure-specific ultrasound policy and practice. First record the procedure and department, then work through the profile form. The questions guide the user through their policy and an observation checklist is provided to record actual practice. The tool leads the user to an action plan if there is no policy, or if there are discrepancies among policy, practice and guidelines.

Tool 2: Algorithm

This tool is organized by department and provides a range of typical procedures that may be encountered in that department. Probe use and reprocessing requirements based on the NHMRC[5,6] and ASUM/ ACIPC[4] guidelines and AS/NZ[2,3] standards are presented as a decision making algorithm. The flow chart can be printed out and displayed throughout office and procedure rooms, and used as a quick reference chart for healthcare workers to determine whether practice is compliant with available guidelines.

Tool 3: Example Risk Assessment

This tool contains four editable templates designed to guide the assessment of potential hazards that may be encountered during the use and reprocessing (cleaning, disinfection, storage) of ultrasound probes. A sample risk matrix is provided with further instructions for completion. A facility should aim to mitigate all significant harm to the lowest risk rating. If that is not possible, the existing workflow and/or products should be reconsidered.

Tool 4: Policy Development Framework

This tool is a policy development framework designed to help develop infection prevention policies for all settings where ultrasound technology is used and probes are reprocessed. It can be used to develop a universal hospital policy or a department specific policy and has been developed based on major guidelines,[4-6] standards[1-3] and evidence based scientific literature.

Funding

The development of this toolkit has been supported by Nanosonics Ltd. Nanosonics Ltd strives to improve the safety of patients, clinics, their staff and the environment by transforming the way infection prevention practices are understood and conducted and introducing innovative technologies that deliver improved standards of care.

Important Note

This toolkit contains general guidance. Consider this guidance in light of the user's own professional advice and specific regulations, guidelines, policies and procedures of each region, institution and department. This tool does not replace manufacturer instructions for use (IFUs) nor does it replace institutional policy/workflows, but it is intended to be used in conjunction with them. This Important Note applies to all parts of this toolkit.

Disclaimer

Nanosonics will not accept responsibility of any kind for reliance on this tool or related materials and opinions including any death or injury to persons. The information, materials and opinions contained here are for general information purposes only, are not intended to constitute legal or other professional advice and should not be relied on or treated as a substitute for specific advice relevant to particular circumstances. We make no warranties, representations or undertakings about the content (including, without limitation, the quality, accuracy, completeness or fitness for any particular purpose of such content). This Disclaimer applies to all parts of this tool and every department.

References

1. Australian Commission on Safety and Quality in Health Care (ACSQHC). National Safety and Quality Health Service Standards.2nd ed. In. Sydney: ACSQHC; 2017.
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4. Australasian College of Infection Prevention and Control (ACIPC) and Australiasian Society for Ultrasound in Medicine (ASUM). Guidelines for Reprocessing Ultrasound Transducers. *Australasian Journal of Ultrasound in Medicine*. 2017;20(1):30-40.
5. National Health and Medical Research Council (NHMRC). Australian Guidelines for The Prevention and Control of Infection in Healthcare. In. Canberra: Commonwealth of Australia; 2010.
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Tool 3

Risk Assessment

This tool contains four completely editable templates designed to assess potential harm from hazards that may be encountered during the use and reprocessing (cleaning, disinfection, storage and transport) of ultrasound probes. There is a sample risk matrix and further instructions provided. A facility should aim to mitigate all significant risks to the lowest risk rating and if this is not possible, the existing workflow and/or products should be reconsidered.

Instructions

The following pages contain four template risk assessments for ultrasound probe cleaning, disinfection, storage and use in medical procedures.

Combine and edit the templates to complete a full assessment of your chosen reprocessing workflow. Not all rows may be relevant depending on your chosen workflows and products and other rows may be required depending on your specific situation.

Use the risk matrix provided (Table 1) to determine the risk rating for each hazard. Rate the likelihood (almost certain to highly unlikely) and severity (negligible to critical) for each hazard and harm and use the matrix to determine the overall risk rating (low to extreme).

The example mitigations are provided in the template and are designed to reduce all hazards to low risk. If the mitigations cannot be put in place, the facility should reconsider its existing workflow and products.

This tool can be used to risk assess existing and proposed processes.

Table 1: Risk matrix for determining risk ratings.

Likelihood x Severity	Negligible	Minor	Moderate	Significant	Critical
Almost certain	Medium	High	High	Extreme	Extreme
Likely	Low	Medium	High	High	Extreme
Possible	Low	Medium	Medium	High	High
Unlikely	Low	Low	Medium	High	High
Highly unlikely	Low	Low	Low	Medium	High

Risk Assessment Templates

- Example Risk Assessment Template for Cleaning
- Example Risk Assessment Template for Disinfection/Sterilization
- Example Risk Assessment Template for Storage
- Example Risk Assessment Template for Use of Ultrasound for Medical Procedures

Institution:	*Department:*	*Document Number:*	*Written by:*	*Date:*
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Example Risk Assessment Template for Ultrasound Probe Cleaning

Product/Process:_____ **Room Locations:**_____

Hazard Type	Hazard	Potential harm(s)	Likelihood of hazard occurring and resulting in harm	Harm severity	Risk	Example mitigations (if risk rating >low)	Risk after mitigation
Biological/ Chemical/ Electrical	Cleaning agent/process is not deemed compatible by ultrasound equipment manufacturer.	• Damage to ultrasound equipment leading to compromised image quality and potential misdiagnosis or injury to patients.	**Possible**	**Moderate**	**Medium**	• Ensure cleaning agent selected is compatible with the probe by consulting the manufacturer IFU.	**Low**
Biological	Cross contamination of clean/dirty areas during cleaning after patient exam.	• Spreading contamination to subsequent patients.	**Possible**	**Significant**	**High**	• Ensure a one way workflow from dirty to clean. • Ensure segregation of clean, sterile and contaminated items. • If probes need to be transported to another room for reprocessing, ensure separate transport containers for clean and dirty probes. • If transport containers are being reused, ensure they are disinfected after soiled transport.	**Low**
Biological	Insufficient probe cleaning resulting from incorrect cleaning protocol followed.	• Potential infection to subsequent patients due to failed cleaning/disinfection.				• Following manufacturer IFU for cleaning with regards to key parameters. • Perform a visual inspection post-cleaning to ensure no moisture, bodily fluid, gel or other visible bioburden remains.	**Low**

Biological	Not following probe model specific manufacturer IFUs for cleaning unique features of probe (e.g., grooves or indentations)	• Potential infection to subsequent patients due to failed cleaning/disinfection.				• Follow manufacture IFU for cleaning with regards to cleaning of grooves and/or indentations.	**Low**
Biological	Not conducting additional probe specific tests as per manufacturer IFU (e.g., leak test for transesophageal echocardiography probes)	• Damage to ultrasound equipment potentially leading to compromised image quality and misdiagnosis or injury to patients.				• Identify any probes that have additional probe specific tests and ensure manufacturer IFU is followed when conducting tests. • Ensure end-users are aware of additional requirements for specific probe models.	**Low**
Chemical/ Biological	Chemical/biological exposure to cleaning agent (e.g., enzymes, detergents, chemicals).	• Potential chemical injury.				• Ensure PPE is available and is being used by end users when cleaning according to manufacturer IFUs and policy. • Ensure adequate ventilation and environmental requirements met.	**Low**
Physical	Improper cleaning of probe (e.g., unsealed surface probe soaked beyond window, unsealed intracavity probe handle soaked).	• Damage to ultrasound equipment potentially leading to compromised image quality and misdiagnosis or injury to patients.				• Ensure manufacturer IFU for cleaning is followed and end-users are aware of special requirements for specific probe models. • Visually inspect probes before use to ensure there is no visible damage or cracks.	**Low**
Physical	Improper installation of sinks and cleaning tools.	• Physical injury to end-users.				• Ensure that installation of sinks and other cleaning tools are undertaken by a skilled professional and are installed as per manufacturer instructions.	**Low**
Environm-ental	By-products unsafe for disposal in sink.	• Damage to the environment.				• Dispose unsafe by-products in correct disposal units (e.g., biohazards disposed in contaminated waste containers.)	**Low**

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Example Risk Assessment Template for Ultrasound Probe Disinfection/Sterilization

Product/Process:_____ **Room Locations:**_____

Hazard Type	Hazard	Potential harm(s)	Likelihood of hazard occurring and resulting in harm	Harm severity	Risk	Example mitigations (if risk rating >low)	Risk After Mitigation
Chemical/ Physical	Disinfection/sterilization process not deemed compatible by ultrasound equipment manufacturer leading to damage to ultrasound equipment.	• Damaged equipment could lead to compromised image quality and misdiagnosis or injury to patients.				• Ensure the disinfection/sterilization process is deemed suitable by the manufacturer and follow the manufacturer's IFU regarding disinfection or sterilization.	**Low**
Biological	Key parameters not met during disinfection/sterilization of probe leading to failed cycle: • Incorrect disinfectant/sterilant contact time • Incorrect disinfectant/sterilant temperature • Cycle validation not incorporated in disinfection/ sterilization process	• Pathogens may remain on the probe and potentially create infection risk to subsequent patients.				• Follow the manufacturer's instructions for use with respect to disinfection/sterilization protocol. • Use a validated, automated disinfection/sterilization method that is also deemed compatible with the probe manufacturer. • Use indicators or other monitors to indicate whether the sterilization/disinfection cycle has been completed successfully. • Use labels on sterilized/disinfected probes to indicate the level of reprocessing undertaken on probe.	**Low**

Biological	Traceability not incorporated in disinfection process.	• Inability to recall ultrasound device or recall patients that may have been harmed due to process failure.				• Maintain logbook in the cleaning area to document and record each disinfection or sterilization cycle including date and time, end-user information and disinfection/sterilization completion and success status. Ensure that reprocessing records are linked to patient records. • Review logbooks on a regular basis and check for incomplete or missing information. • Maintain records for a duration in compliance with institutional policy, procedures and manufacturer IFUs • Apply same mitigations for electronic records.	**Low**
Biological	Cross contamination of clean/dirty areas.	• Increases risk of infection for subsequent patients.				• Ensure a one way workflow from dirty to clean. • Ensure segregation of clean, sterile and contaminated items. • If probes need to be transported to another room for reprocessing, ensure separate transport containers for clean and dirty probes.	**Low**
Chemical	Chemical exposure to disinfection agent.	• Chemical injury to end-users.				• Have appropriate PPE available for end-users to utilize when performing disinfection/sterilization. • Eliminate the need for handling toxic disinfecting agents.	**Low**
Chemical/ Biological	Incorrect rinsing protocol applied to probe post-disinfection/sterilization, for example: • Incorrect water quality used for rinsing (e.g., non-sterile water after liquid chemical sterilization) • Insufficient duration or cycles of rinsing	• Damage to ultrasound equipment leading to compromised image quality and potential misdiagnosis or injury to patients. • Patient injury resulting from exposure to sterilant or HLD chemical				• Ensure that the manufacturer instructions for rinsing post-disinfection/sterilization are followed regarding water quality and duration/cycles. • Ensure correct level of water quality (e.g., sterile water, potable, deionized or reverse osmosis treated water) for terminal rinsing is accessible nearby if it is required.	**Low**

Environmental	By-products unsafe for disposal in sink.	• Damage to the environment.				• Dispose unsafe by-products in correct disposal units (e.g., biohazards disposed in contaminated waste containers). • Using a disinfection/sterilization process that does not include the production of harmful by-products.	**Low**
Electrical/ Chemical	Unsafe installation of disinfection/sterilization equipment.	• Physical injury to end-users.				• Ensure that installation of sinks and other cleaning tools are undertaken by a skilled professional and are installed as per manufacturer instructions.	**Low**
Physical Injury	Improper installation of automated disinfector.	• Damage to ultrasound equipment leading to compromised image quality and potential misdiagnosis or injury to patients.				• Ensure that installation of sinks and other cleaning tools are undertaken by a skilled professional and are installed as per manufacturer instructions.	**Low**
		• Physical injury to end-users.					
Electrical/ Chemical	Preventative maintenance of automated disinfector not performed.	• Risk of device failure or negative impact to the performance of the device.				• Ensure that device preventative maintenance is performed as prescribed by manufacturer IFU and is documented.	**Low**

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Example Risk Assessment Template for Ultrasound Probe Storage

Product/Process:_____ **Room Locations:**_____

Hazard Type	Hazard	Potential harm(s)	Likelihood of hazard occurring and resulting in harm	Harm severity	Risk	Example mitigations (if risk rating >low)	Risk After Mitigation

Biological	Recontamination of probe after disinfection during storage.	• Risk of infection to subsequent patients.				• Minimise handling and transport post disinfection.
						• Ensure that probes are stored in designated clean, dry area when not in use. For example:
						  ○ On the ultrasound console while the probe is covered by a clean probe cover (cover manufactured in ISO certified clean room)
						  ○ In regular cabinet while probe is covered by a clean probe cover
						• Store according to probe manufacturer instructions.
						• In the event there was known or suspected contamination of the probe during storage, ensure that the probe is reprocessed again prior to use.
							Low

Biological	Mixing up of low level disinfected and high level disinfected probes during storage.	• Risk of infection to subsequent patients.				• Ensure that storage areas for probes requiring different levels of disinfection are kept separate and are clearly labelled notifying end-users.	**Low**

Biological	Probe is not stored according to manufacturer instructions or is stored wet or near sources of moisture.	• Damage to ultrasound equipment leading to compromised image quality and potential misdiagnosis or injury to patients. • May promote pathogen growth, resulting in infection transmission risk				• Ensure that probes are stored in designated clean, dry area when not in use. For example: a) In an air filtered cabinet b) In the ultrasound console while the probe is covered by a clean probe cover (cover manufactured in ISO certified clean room) c) In regular cabinet while probe is covered by clean probe cover. • Store according to probe manufacturer instructions. • In the event there was known or suspected contamination of the probe during storage, ensure that the probe is reprocessed again prior to use.	**Low**
Biological	Physical stress to probe during transport.	• Damage to ultrasound equipment leading to compromised image quality and potential misdiagnosis or injury to patients.				• Use designated transport routes to facilitate easy manoeuvring and avoid high areas of traffic. • Use a transport system that secures probes and prevents them from falling during transport between locations.	**Low**
Biological	Contamination of probe during transport from storage location (e.g., contaminated container).	• Recontamination of instrument and subsequent infection of patients.				• Use designated dirty/clean containers when transporting probes to prevent cross-contamination. • Ensure that clean probes are only transported in clean containers. • If transport containers are being reused, ensure they are disinfected after soiled transport.	**Low**

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Example Risk Assessment Template for Ultrasound Probe Use Requirements

Product/Process:_____ **Room Locations:**_____

Hazard Type	Hazard	Potential harm(s)	Likelihood of hazard occurring and resulting in harm	Harm severity	Risk	Example mitigations (if risk rating >low)	Risk After Mitigation
Biological	Probe with incorrect level of disinfection/sterilization used on patient (e.g., LLD probe used during a sterile procedure).	• Risk of infection to subsequent patients.				• Provide department guidelines to end-users regarding probe Spaulding classification - 'critical', 'semi-critical' or 'non-critical' - and the subsequent level of disinfection required before use. • Refer to a maintained logbook and check the probe's last disinfection/sterilization cycle including date and time, end-user information and disinfection/sterilization completion and success status prior to patient use. • Have a probe labelling or visual cue system in place for storage of probes so LLD and HLD probes are not mixed up.	**Low**
Biological	Critical probe is HLD however not used with a sterile sheath.	• Risk of infection to subsequent patients.				• Ensure adequate inventory of sterile sheaths are supplied at point of use for end-users. • Provide department guidelines to end-users about compliant use of critical ultrasound probes: sterilize probe, or HLD probe and use with sterile sheath.	**Low**
Biological	Semi-critical or critical probe only LLD and used with a sterile sheath.	• Risk of infection to subsequent patients.				• Provide department guidelines to end-users about compliant use of semi-critical and critical ultrasound probes: minimally HLD probe even if a sheath is used (preferably sterilize critical probes).	**Low**

Biological	Sterile gel is not used for procedures where there is risk of contact with sterile tissue, or the vascular system.	• Risk of infection to subsequent patients.				• Provide departmental guidelines to end-users to enable them to determine when use of sterile or non-sterile, single use packets, or multi use bottle gel is appropriate. • Ensure there is adequate supply of single use sterile gel in applicable settings. • Avoid the use of refillable gel bottles and gel warmers where possible.	**Low**
Biological	Sterile single use gel is not used for procedures where there is risk of contact with mucous membranes or non-intact skin.	• Risk of infection to subsequent patients.				• Provide departmental guidelines to end-users to enable them to determine when use of sterile or non-sterile, single use packets, or multi use bottle gel is appropriate. • Ensure there is adequate supply of single use sterile gel in applicable settings. • Avoid the use of refillable gel bottles and gel warmers where possible.	**Low**
Biological	Microbial growth in multiuse gel bottles.	• Risk of infection to subsequent patients.				• Ensure that multiuse gel bottles are not expired. • Preferentially use single use gel (sterile) for every patient where possible.	**Low**