



Ultrasound Infection Prevention Toolkit

Ver. 1.0



Prevention of infection during
ultrasound probe use and reprocessing

Tool 3 Risk Assessment

www.ultrasoundinfectionprevention.org.uk/

This tool contains four completely editable templates designed to assess for 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.

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Instructions

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

There are three types of risks to consider:

- Patient safety
- Operator safety
- Environmental risk

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.

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/Sterilisation
- Example Risk Assessment Template for Storage
- Example Risk Assessment Template for the use of Ultrasound for Medical Procedures

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Example Risk Assessment Template for Ultrasound Probe Cleaning

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

Risk type	Risk description	Potential harm(s)	Likelihood	Severity	Risk rating	Example mitigations (if risk rating >low)	Risk rating after mitigation
Biological/ Chemical/ Electrical	Cleaning agent/process is not deemed compatible by ultrasound equipment manufacturer.	<ul style="list-style-type: none"> Damage to ultrasound equipment leading to compromised image quality and potential misdiagnosis or injury to patients. 	Possible	Moderate	Medium	<ul style="list-style-type: none"> Ensure cleaning agent selected is compatible with the probe by consulting the manufacturer IFU. Document declarations of compatibility Conduct a risk assessment if not compatible and maintain device in spec to a higher level/frequency than is within the IFU Ensure cleaning process is done in accordance with IFU; this will cover the electrical part of the risk 	Low
Biological	Cross-contamination of clean/dirty areas during cleaning after patient exam.	<ul style="list-style-type: none"> Spreading contamination to subsequent patients. 	Possible	Significant	High	<ul style="list-style-type: none"> 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 are used for clean and dirty probes. If transport containers are being reused, ensure they are disinfected after soiled transport. 	Low

Risk type	Risk description	Potential harm(s)	Likelihood	Severity	Risk rating	Example mitigations (if risk rating >low)	Risk rating after mitigation
Biological	Insufficient probe cleaning resulting from incorrect cleaning protocol followed.	<ul style="list-style-type: none"> Potential infection to subsequent patients due to failed cleaning/disinfection. 				<ul style="list-style-type: none"> 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. Review practise, update training and implement quality improvement plan if required Follow cleaning efficacy testing regime advised by your Infection Prevention Control/Decontamination teams 	Low
Biological	Not following probe model-specific manufacturer IFUs for cleaning unique features of probe (e.g. grooves or indentations)	<ul style="list-style-type: none"> Potential infection to subsequent patients due to failed cleaning/disinfection. 				<ul style="list-style-type: none"> Following manufacturer 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 transoesophageal echocardiography probes)	<ul style="list-style-type: none"> Damage to ultrasound equipment potentially leading to compromised image quality and misdiagnosis or injury to patients. 				<ul style="list-style-type: none"> Identify any probes that have additional probe specific tests and ensure manufacturer IFUs followed when conducting tests. Ensure operators are aware of additional requirements for specific probe models. Routine training updates. 	Low
Chemical/ Biological	Chemical/biological exposure to cleaning agent (e.g. enzymes, detergents, chemicals).	<ul style="list-style-type: none"> Potential chemical injury. 				<ul style="list-style-type: none"> 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 are met. 	Low
Physical	Improper cleaning of probe (e.g. unsealed surface probe soaked beyond window, unsealed intracavity probe handle soaked).	<ul style="list-style-type: none"> Damage to ultrasound equipment potentially leading to compromised image quality and misdiagnosis or injury to patients. 				<ul style="list-style-type: none"> 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

Risk type	Risk description	Potential harm(s)	Likelihood	Severity	Risk rating	Example mitigations (if risk rating >low)	Risk rating after mitigation
Physical	Improper installation of sinks and cleaning tools.	<ul style="list-style-type: none"> Physical injury to end-users. 				<ul style="list-style-type: none"> Ensure that installation of sinks and other cleaning tools are undertaken by a skilled professional and are installed as per manufacturer instructions. 	Low
Environmental	By-products unsafe for disposal in sink.	<ul style="list-style-type: none"> Damage to the environment. 				<ul style="list-style-type: none"> 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/Sterilisation

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

Risk type	Risk description	Potential harm(s)	Likelihood	Severity	Risk rating	Example mitigations (if risk rating >low)	Risk rating after mitigation
Chemical/ Physical	Disinfection/sterilisation process not deemed compatible by ultrasound equipment manufacturer leading to damage to ultrasound equipment.	<ul style="list-style-type: none"> Damaged equipment could lead to compromised image quality and misdiagnosis or injury to patients. 				<ul style="list-style-type: none"> Ensure the disinfection/sterilisation process is deemed suitable by the manufacturer and follow the manufacturer's IFU regarding disinfection or sterilisation. 	Low
Biological	Key parameters not met during disinfection / sterilisation of probe leading to failed cycle: <ul style="list-style-type: none"> Incorrect disinfectant/sterilant contact time Incorrect disinfectant/sterilant temperature Cycle validation not incorporated in disinfection/sterilisation process 	<ul style="list-style-type: none"> Pathogens may remain on the probe and potentially create infection risk to subsequent patients. 				<ul style="list-style-type: none"> Following the IFU with respect to disinfection/sterilisation protocol. Using a validated, automated disinfection/sterilisation method that is also deemed compatible with the probe manufacturer. Commissioned/routinely validated as per national guidance and manufacturers IQ/OQ/PQ regimes. Conduct routine process audits of manual processes. Using indicators or other monitors to indicate whether the sterilisation/disinfection cycle has been completed successfully. Using labels on sterilised/disinfected probes to indicate the level of reprocessing undertaken on probe. 	Low

Risk type	Risk description	Potential harm(s)	Likelihood	Severity	Risk rating	Example mitigations (if risk rating >low)	Risk rating after mitigation
Biological	Traceability not incorporated in disinfection process.	<ul style="list-style-type: none"> Inability to recall ultrasound device or recall patients that may have been harmed due to process failure. 				<ul style="list-style-type: none"> Maintain logbook in the cleaning area to document and record each disinfection or sterilisation cycle, including date and time, end-user information and disinfection/sterilisation 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.	<ul style="list-style-type: none"> Increases risk of infection for subsequent patients. 				<ul style="list-style-type: none"> Ensure one-way workflow - 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.	<ul style="list-style-type: none"> Chemical injury to end-users. 				<ul style="list-style-type: none"> Have appropriate PPE available for end-users to utilise when performing disinfection/sterilisation. Eliminate the need for handling toxic disinfecting agents. Conduct COSHH Control of Substances Hazardous to Health assessments (UK) CARA Chemical Agent Risk Assessment (Ireland). If required, suitable ventilated environments that are verified as part of a validation regime. Assess air change rates as per chemical supplier's recommendations. Follow SOPs for safe disposal of chemicals. 	Low

Risk type	Risk description	Potential harm(s)	Likelihood	Severity	Risk rating	Example mitigations (if risk rating >low)	Risk rating after mitigation
Chemical/ Biological	<p>Incorrect rinsing protocol applied to probe post-disinfection/sterilisation, for example:</p> <ul style="list-style-type: none"> • Incorrect water quality used for rinsing (e.g. non-sterile water after liquid chemical sterilisation) • Insufficient duration or cycles of rinsing 	<ul style="list-style-type: none"> • 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. 				<ul style="list-style-type: none"> • Ensure that the IFU for rinsing post-disinfection/sterilisation is followed regarding water quality and duration/cycles. • Plan and conduct regular IPC audits. • Ensure ongoing training. • Ensure correct level of water quality (e.g. sterile water, potable, deionised or reverse osmosis treated water) for terminal rinsing is accessible nearby if it is required. 	Low
Environmental	By-products unsafe for disposal in sink.	<ul style="list-style-type: none"> • Damage to the environment. 				<ul style="list-style-type: none"> • Dispose unsafe by-products in correct disposal units (e.g. biohazards disposed in contaminated waste containers). • Using a disinfection/sterilisation process that does not include the production of harmful by-products. 	Low
Electrical/ Chemical	Unsafe installation of disinfection/sterilisation equipment.	<ul style="list-style-type: none"> • Physical injury to end-users. 				<ul style="list-style-type: none"> • 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 reprocessing system.	<ul style="list-style-type: none"> • Damage to ultrasound equipment leading to compromised image quality and potential misdiagnosis or injury to patients. • Physical injury to end-users. 				<ul style="list-style-type: none"> • Ensure that installation of sinks and other cleaning tools are undertaken by a skilled professional and are installed as per manufacturer instructions. 	Low
Electrical/ Chemical	Preventative maintenance of automated disinfectant not performed.	<ul style="list-style-type: none"> • Risk of device failure or negative impact to the performance of the device. 				<ul style="list-style-type: none"> • Ensure that device preventative maintenance is performed as prescribed by manufacturer IFU and is documented. • Visual checks by the operator are carried out at routine intervals. 	Low

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Example Risk Assessment Template for Ultrasound Probe Transport and Storage

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

Risk type	Risk description	Potential harm(s)	Likelihood	Severity	Risk rating	Example mitigations (if risk rating >low)	Risk rating after mitigation
Biological	Recontamination of probe after disinfection during storage.	<ul style="list-style-type: none"> Risk of infection to subsequent patients. 				<ul style="list-style-type: none"> Minimise handling and transport post disinfection. Ensure that probes are stored in designated clean, dry area when not in use. For example: <ul style="list-style-type: none"> On the ultrasound console while the probe is covered by a clean probe cover (cover manufactured in ISO certified clean room) In regular cabinet made from appropriate materials non-shedding and easily cleanable (e.g. stainless steel) 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

Risk type	Risk description	Potential harm(s)	Likelihood	Severity	Risk rating	Example mitigations (if risk rating >low)	Risk rating after mitigation
Biological	Mixing up of LLD and HLD probes during storage. Disinfected probes during storage.	<ul style="list-style-type: none"> Risk of infection to subsequent patients. 				<ul style="list-style-type: none"> Ensure that storage areas for probes requiring different levels of disinfection are kept separate and are clearly labelled, notifying end-users. Use of designated locations for clean/dirty activities. Routinely audited by IPC/Decontamination Lead. 	Low
Biological	Exceed the validated storage time.	<ul style="list-style-type: none"> Risk of infection for subsequent patients. 				<ul style="list-style-type: none"> Label indicates the storage time (automated system). If manual, reprocess before using the probe again. Plan and conduct regular IPC audits. Ensure ongoing training. 	Low
Biological	Probe is not stored according to manufacturer instructions or is stored wet or near sources of moisture.	<ul style="list-style-type: none"> 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. 				<ul style="list-style-type: none"> Ensure that probes are stored in designated clean, dry area when not in use. For example: <ul style="list-style-type: none"> 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. Appropriate cover designated for use 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

Risk type	Risk description	Potential harm(s)	Likelihood	Severity	Risk rating	Example mitigations (if risk rating >low)	Risk rating after mitigation
Biological	Physical stress to probe during transport.	<ul style="list-style-type: none"> Damage to ultrasound equipment leading to compromised image quality and potential misdiagnosis or injury to patients. 				<ul style="list-style-type: none"> 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. As agreed with the multi-disciplinary team (IPC and Decontamination lead) 	Low
Biological	Contamination of probe during transport from storage location (e.g., contaminated container).	<ul style="list-style-type: none"> Recontamination of instrument and subsequent infection of patients. 				<ul style="list-style-type: none"> 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 cleaned and disinfected after soiled transport. Compliance with the Carriage of Dangerous Good (CDG) act²⁹ (UK) or Carriage of Uncleaned Reusable Invasive Medical Devices by Road Regulation²³ (Ireland) should be observed in the event of transporting a soiled probe off-site to another establishment for decontamination/repair. 	Low

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Example Risk Assessment Template for Ultrasound Probe Use Requirements

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

Risk type	Risk description	Potential harm(s)	Likelihood	Severity	Risk rating	Example mitigations (if risk rating >low)	Risk rating after mitigation
Biological	Probe with incorrect level of disinfection/sterilisation used on patient (e.g. LLD probe used during a sterile procedure).	<ul style="list-style-type: none"> Risk of infection to subsequent patients. 				<ul style="list-style-type: none"> 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/sterilisation cycle, including date and time, end-user information and disinfection/sterilisation 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.	<ul style="list-style-type: none"> Risk of infection to subsequent patients. 				<ul style="list-style-type: none"> 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: sterilise probe or HLD probe and use with sterile sheath. 	Low
Biological	Semi-critical or critical probe only LLD and used with a sterile or non-sterile sheath.	<ul style="list-style-type: none"> Risk of infection to subsequent patients. 				<ul style="list-style-type: none"> Provide department guidelines to end-users about compliant use of semi-critical and critical ultrasound probes: minimally HLD probe and use with sterile sheath (preferably sterilise critical probes). 	

Risk type	Risk description	Potential harm(s)	Likelihood	Severity	Risk rating	Example mitigations (if risk rating >low)	Risk rating after mitigation
Biological	Sterile gel is not used for procedures where there is risk of contact with sterile tissue or the vascular system or bloodstream.	<ul style="list-style-type: none"> Risk of infection to subsequent patients. 				<ul style="list-style-type: none"> 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 or non-sterile single-use gel is not used for procedures where there is risk of contact with mucous membranes or non-intact skin.	<ul style="list-style-type: none"> Risk of infection to subsequent patients. 				<ul style="list-style-type: none"> 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. 	Low
Biological	Microbial growth in multiuse gel bottles.	<ul style="list-style-type: none"> Risk of infection to subsequent patients. 				<ul style="list-style-type: none"> Ensure that multiuse gel bottles are not expired. Preferentially use single-use gel (sterile) for every patient where possible. Gel bottles stored as per agreed IFU (e.g., temperature/humidity control, out of sunlight and clearly labelled with agreed expiry date). 	Low

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Example Mitigation Plan Template

If the risk mitigation requires an extensive observation, a significant change, or several steps, this template allows to document the change process and the final outcome.

Identified Hazard: _____

Identified Risk Level _____ **= Likelihood of hazard:** _____ **x harm severity** _____

Action Plan			Progress Update	Re-audit	
Auditor/assessor: Date:			Auditor/assessor: Date:	Auditor/assessor: Date:	
Action(s) required	Person responsible	Priority High Medium Low	Status	Outcome	Action Effectiveness <i>(How do you prove that the actions have been effective?)</i>

Mitigated Risk Level _____ **= Likelihood of hazard:** _____ **x harm severity** _____

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