Implementing an Ultrasound Infection Prevention Toolkit

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In association with Ultrasound Infection Prevention Toolkit

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What's your speciality?

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Whose responsibility is to ensure transducers safety?

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Transducer safety and infection prevention: Whose responsibility?

- Manufacturers and suppliers: equipment functioning, contamination risks and best practices for mitigating risks, and then consistent and reliable in providing clear and concise Instructions For Use (IFU) to mitigate risk.

- Healthcare facilities: should establish policies, standard operating procedures, sonographer training programs and refresher courses, and provide workflows that offer sonographers the time and resources to follow best practice infection control, disinfection, and safety procedures.

- Sonographers: should stay current on manufacturers' IFU and other guidance for infection prevention and control and follow established infection control, disinfection, and safety procedures in all instances to ensure the facility has the capability and capacity to adequately clean and reprocess the transducer.

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The best practices for transducer reprocessing includes

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Probe decontamination vs reprocessing

The best practices for transducer reprocessing include the:

- proper use,
- handling
- cleaning, sterilization or disinfection,
- transport and storage

of transducers used in diagnostic/interventional medical sonography

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What are the ancillary equipment that require cleaning along with the ultrasound probe?

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Probe decontamination vs reprocessing

The importance of infection prevention and control principles applies equally to the ultrasound machine and any ancillary equipment used during the procedure. It may include

- cables,
- keyboards,
- beds,
- chairs,
- IV poles,
- oxygen systems,
- cord.

Guidelines

United Kingdom and Ireland		
British Medical Ultrasound Society & Society & College of Radiographers	Guidelines For Professional Ultrasound Practice	2018
Health Facilities Scotland/Health Protection Scotland	NHSScotland Guidance for Decontamination of Semi-Critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes	2017
Health Service Executive Ireland	HSE Guidance for Decontamination of Semi-critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes	2016

Guidelines

Europe		
European Society of Radiology	Infection prevention and control in ultrasound - best practice recommendations from the European Society of Radiology Ultrasound Working Group	2017
European Committee for Medical Ultrasound Safety	Best Practice recommendations for cleaning and disinfection of ultrasound transducers whilst maintaining transducer integrity	2017
Svensk Förening för Obstetrik och Gynekologi (Sweden)	SFOG råd angående transducerskydd och desinfektion av ultraljudsprober vid all gynekologisk och obstetrisk ultraljudsundersökning inom öppen och slutenvård	2019
Hoge Gezondheidsraad / Conseil Supérieur de la Santé (Belgium)	Aanbevelingen inzake de infectiepreventie en het beheer van warmtegevoelige endocavitaire endoscpen en medische hulpmiddelen	2019
Ministère des Solidarités et de la Santé (France)	Proposition technique du groupe de travail national. Prevention du risque infectieux associe aux actes d'echographie endocavitaire: 28	2019
Werkgroep Infectie Preventie (Netherlands)	Reiniging, desinfectie en sterilisatie van medische hulpmiddelen voor hergebruik niet-kritisch, semi-kritisch of kritisch gebruik: 56	2017
Stuurgroep Flexibele Endoscopen Reiniging en Desinfectie (Netherlands)	Kwaliteitshandboek Reiniging en Desinfectie Flexibele Endoscopen: 118	2016
Kommission für Krankenhaushygiene und Infektionsprävention (Germany)	Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten. Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz: 66	2012
Direzione Sanitaria AUSL Pescara (Italy)	Linee Guida per la “Corretta gestione di Procedure Assistenziali e Igienico-Sanitarie in Setting di Cura Ospedalieri e Territoriali”: 88	2009

Implementing the IP Toolkit @ Mater

Role of an IP Toolkit?

- Proper infection prevention and control practices are necessary to protect patients and sonographers.
- Contaminated transducers and ultrasound gel have been associated with infection outbreaks, including those in the bloodstream, urinary tract, respiratory tract, biopsy sites, and wounds.
- There are also documented cases of hepatitis B and C with some resulting in patient death
- These infections were attributable to a failure to follow evidence-based and reproducible infection prevention and control practices (e.g., proper transducer cleaning and disinfection, appropriate transducer cover, sterile gel).
- Situational risk include sonographers (or managers) being unfamiliar with best practices for transducer reprocessing

Implementation of IP toolkit and its Components

Tool 1

Locate & Profile

Tool 2

Algorithm

Tool 3

Risk Assessment

Tool 4

Policy Development Framework

- This toolkit has been 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 resource regarding infection prevention during the use and reprocessing of ultrasound probes.

Implementing the IP Toolkit : TOOL 1 A - LOCATE

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Could you please list the departments where ultrasound-guided procedures are performed in your organisation?

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Implementing the IP Toolkit : TOOL 1 A - LOCATE

Strategy 1	Strategy 2	Strategy 3	Strategy 4
Locate where ultrasound machines are by searching the organization's asset register.	Locate where ultrasound consumables are being used (e.g., gel, probe sheaths/covers).	Survey departments to identify where ultrasound is used.	Identify billable ultrasound procedures in financial records.
Ask the Clinical/Biomedical Engineering department to provide a complete list of ultrasound probes and consoles from their asset register. Identify the department in which they are located.	Approach materials management, purchasing or supply chain management and request they search purchase orders and inventory lists for each department/the facility, and provide a report of material.	Approach departments and ask about their ultrasound use. Methods include but are not limited to departmental/facility wide email, physically visiting or phoning each department and/or patient care unit	Identify ultrasonography billing codes, ask finance department for a list of billing records that involve ultrasound procedure item codes and determine which departments are billing for those items.

Experiences in TOOL 1 A - LOCATE

Strategy 1	Strategy 2	Strategy 3	Strategy 4
Locate where ultrasound machines are by searching the organization's asset register.	Locate where ultrasound consumables are being used (e.g., gel, probe sheaths/covers).	Survey departments to identify where ultrasound is used.	Identify billable ultrasound procedures in financial records.
Not every ultrasound machines were listed Asset registers may be incomplete due to local purchases/trial equipment Borrowing special probes from nearby private hospital	Central system in place Received the list of all areas where consumables are being used (e.g., gel, probe sheaths/covers	Difficulty in accessing information from various departments Workload Delayed response time for emails Time consuming	Not all procedures were coded as USG guided procedure. The finance system is not set up to readily perform the searches HIPE coding – the data base system is incomplete.

Experiences in TOOL 1 A - LOCATE

Strategy 1	Strategy 2	Strategy 3	Strategy 4
Locate where ultrasound machines are by searching the organization's asset register.	Locate where ultrasound consumables are being used (e.g., gel, probe sheaths/covers).	Survey departments to identify where ultrasound is used.	Identify billable ultrasound procedures in financial records.

The Best Approach : Combine all 4 strategies to generate the maximum data set

TOOL 1 B - PROFILE

Probing Questions.

1. Policy: Does the facility/department have a policy for performing ultrasound procedures?

2. Read the Policy: How does the policy indicate the probe should be reprocessed as per the Spaulding classification?

3. Assess the Policy: Is the policy consistent with manufacturer instructions for use and guideline recommendations for the listed procedures?

4. Observe Practice: How is the probe reprocessed and used by the end users for each procedure?

5. Assess Practice: Is the observed practice compliant with your policy?

6. Action Plan Required: Does the policy needs updating? Does users require training? Is tracking/traceability in place?

TOOL 1 LOCATE & PROFILE
Part B Profile: Departments & Ultrasound systems

a) Department and ultrasound systems

Department	Date	Assessor / Auditor	Operator(s) present
OBGYN	22/9/21	Jane Doe	Joe Bloggs

	Ultrasound machines identification	Manufacturer(s)
1	XSF-741321846541-512	ABC
2		
3		
4		

b) Probes and procedures

Probe name	Probe type (surface / endo-cavitary)	Probe ID*	Probe Serial Number	Probe Manufacturer	Procedure(s)	Spaulding Classification (non critical / semi-critical / critical)
Abdominal Probe	SURFACE	DEPT 001	ABCDE	XXXXX	ABDOMINAL SCANNING	NON-CRITICAL

c) Documentation

Questions	Answers			Comments
Does the facility/department have SOP(s) for reprocessing ultrasound probes?	☐ Yes	☑ No	☐ Not specified	
Do the operators have access to the US probe(s) IFU?	☑ Yes	☐ No	☐ Not specified	
Is the reprocessing system manual?	☐ Yes	☑ No	☐ Not specified	
Is the reprocessing system automated?	☑ Yes	☐ No	☐ Not specified	
If yes to the automated question above: Has the automated reprocessor been validated, serviced and tested in line with national and international standards and following the manufacturer's recommendation?	☑ Yes	☐ No	☐ Not specified	
Where are the validation and service reports stored?	☑ Yes	☐ No	☐ Not specified	

TOOL 1 LOCATE & PROFILE
Part B Profile: Probe processing procedure audit

Step	Observations				Comments
Post-procedure cleaning (bed-side)	☐ No	☑ Yes	Method used:	☐ Not specified	
Containment of contaminated probe	☑ No	☐ Yes	Method used:	☐ Not specified	Immediate HLD with product X
Cleaning	☐ No	☑ Yes	Method used: Y wipes	☐ Not specified	
Disinfection type	☐ LLD	☑ HLD	Method used: Product X	☐ Not specified	
Disinfection method	☐ Manual	☑ Automated	Method used: Product X	☐ Not specified	
Terminal process step	☐ LLD	☑ HLD	☐ sterilisation	☐ Not specified	
Cover use	☐ None	☐ Single-use non-sterile	☑ Sterile	☐ Not specified	
Gel use	☐ Multi-use bottle	☐ Single-use non-sterile	☑ Single-use sterile	☐ Not specified	Multiuse gel not used
Multi-use Gel max usage	☐ 1 day	☐ > 1 day	Please specify:	☑ Not specified	
Reprocessing Traceability	☐ No traceability	☑ Manual	☐ Electronic	☐ Not specified	
Post processing storage	☐ No	☑ Yes	Method used:	☐ Not specified	Storage cover on console
Time limit defined?	☐ No	☑ Yes	Time limit:	☐ Not specified	
Other steps(s) (please specify)					

TOOL 1 LOCATE & PROFILE @ Mater

Paper based audit tool was changed to electronic audit tool

Benefits:

- Easy to use
- Avoid paper usage
- Standardized data collection
- Immediate data availability – excel/csv format
- Saves time
- Enhances the efficiency and productivity.

Findings

- No policy available in many departments
- Policy out of date
- Inconsistencies within the policy
- Lack of training
- Limited traceability
- Non-compliance to the policy

Findings: Non-compliance to the policy

Disinfection Level

Critical

Semi-Critical

User training

Traceability

Multi –use 5 L Gel

Non-critical

Policy

Area 8 – 100%

Finding:

Observations	Count	%
Gel not removed from probe	33	73%
Incorrect method of disinfection chosen based on Spaulding classification	18	40%
Cable not cleaned	17	38%
Plug not cleaned	25	56%
Control panel not cleaned	23	51%
U/S holder on console not cleaned	25	56%

What Was Incorrect About Technique

Blood And Gel Remain On Probe For Next Operator To Use

U/S Holder On Console Visibly Dirty And Used To Hold Decontaminated Probes

Probe is contaminated with dried gel

What Was Incorrect About Technique

Gel not removed from probe pre disinfection and has dried to the surface of the probe.

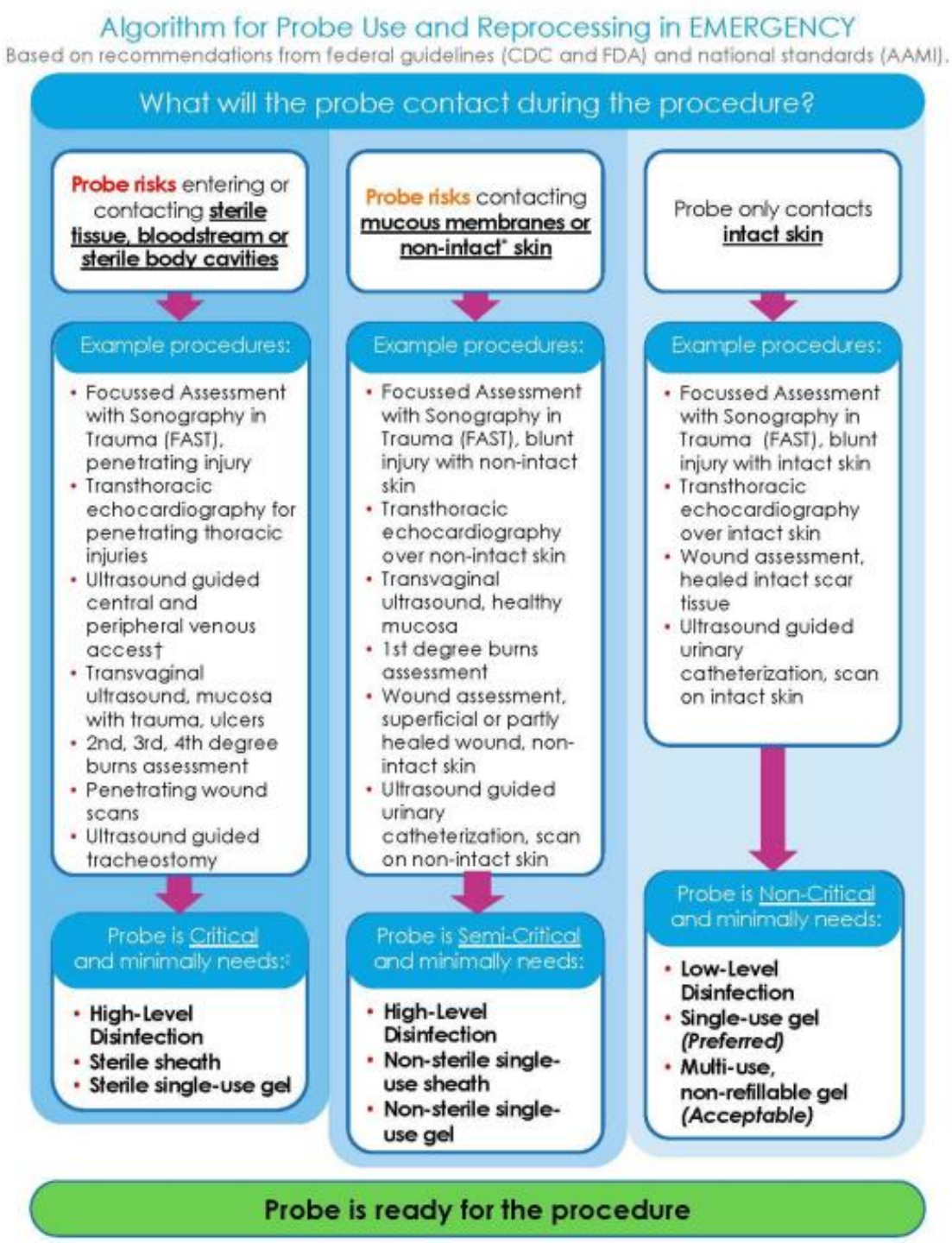
Gel not removed from orientation marker on probe pre disinfection will render decontamination of this area ineffective

Part 1 C : Action Plan/Outcomes:

- Development of hospital SOP on reprocessing of ultrasound probe
- Development of algorithms
- Discontinue the 5L gel
- Training for all Sonographers
- Implementing Traceability systems
- Regular audit and feedback
- Risk register

Toolkit : Tool 2 – Algorithm Development

This tool 2 facilitate the user to develop algorithms for transducer reprocessing as per the Spaulding classification for individual department.



MC, 71 years, admitted to ED with sepsis. H/o poor venous access, SHO inserted a cannula with the help of Ultrasound surface probe. According to Spaulding classification, the probe should receive:

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MC, was transferred from ED to ITU for management of sepsis and vascular access nurse placed a central line using ultrasound. According to Spaulding classification, the probe should receive:

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MC, required an abdominal ultrasound to identify the source of infection. According to Spaulding classification, the probe should receive:

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Spaulding Classification

The internationally adopted framework for disinfection and sterilization of medical devices.

Spaulding Classification	Medical Device Contacts	Risk of Infection Transmission	Disinfection Level
Critical	Sterile tissue or the bloodstream	High	Sterilization*
Semi-critical	Mucous membranes or non-intact skin	Medium	High Level Disinfection (HLD)
Non-critical	Intact skin only	Low	Intermediate level (ILD) or Low level disinfection (LLD)

*** Critical ultrasound probes can be high level disinfected and used with a sterile sheath if sterilization is not possible**

Introducing the IP Toolkit: Tool 3 Risk Assessment

- This tool contains 4 editable templates designed to assess potential harm from hazards that may be encountered during the use and reprocessing of ultrasound probes.
- The risk matrix helps to rate the risk

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

Using Tool 3: example risk spreadsheet

- When a hazard has been identified, determine the risk rating by using the risk matrix:
  Likelihood x **Severity** = **Risk**

  Likelihood = the chance that the hazard will occur and result in harm

  Severity = seriousness of harm

Table 1: Risk matrix for determining risk ratings.

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

Example Risk Assessment Template for Ultrasound Probe Cleaning

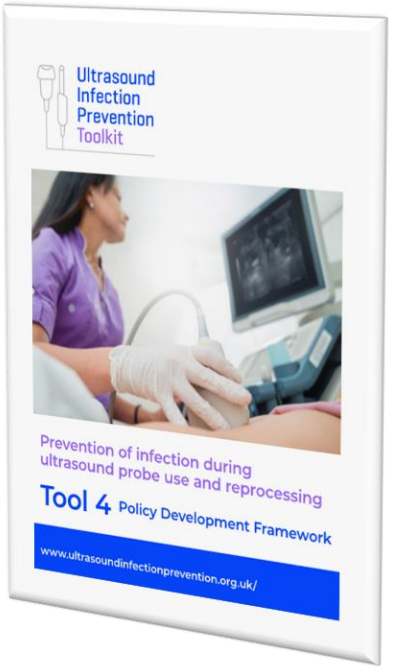
Product/Process:_____ **Room Locations:**_____

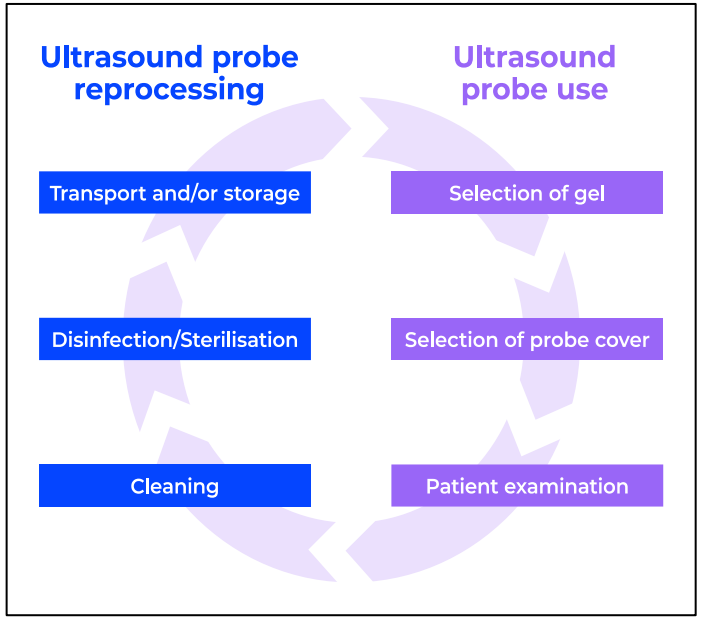
Risk type	Risk description	Potential harm(s)	Likelihood	Severity	Risk rating	Example mitigations (if risk rating >low)	Risk rating after mitigation
Biological/ Chemical/ Electrical	Cleaning agent/process is not deemed compatible by ultrasound equipment manufacturer.	• Damage to ultrasound equipment leading 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. • 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.	• 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 are used for clean and dirty probes. • If transport containers are being reused, ensure they are disinfected after soiled transport.	**Low**

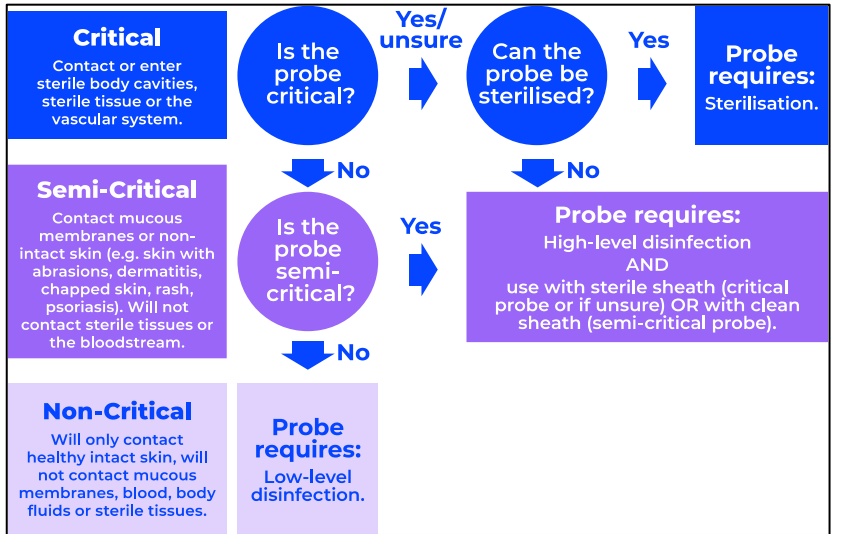
If the hazard presents a medium, high or extreme risk, the suggested mitigations should be considered to reduce the risk to low.

Introducing the IP Toolkit: Tool 4 Policy Development Framework

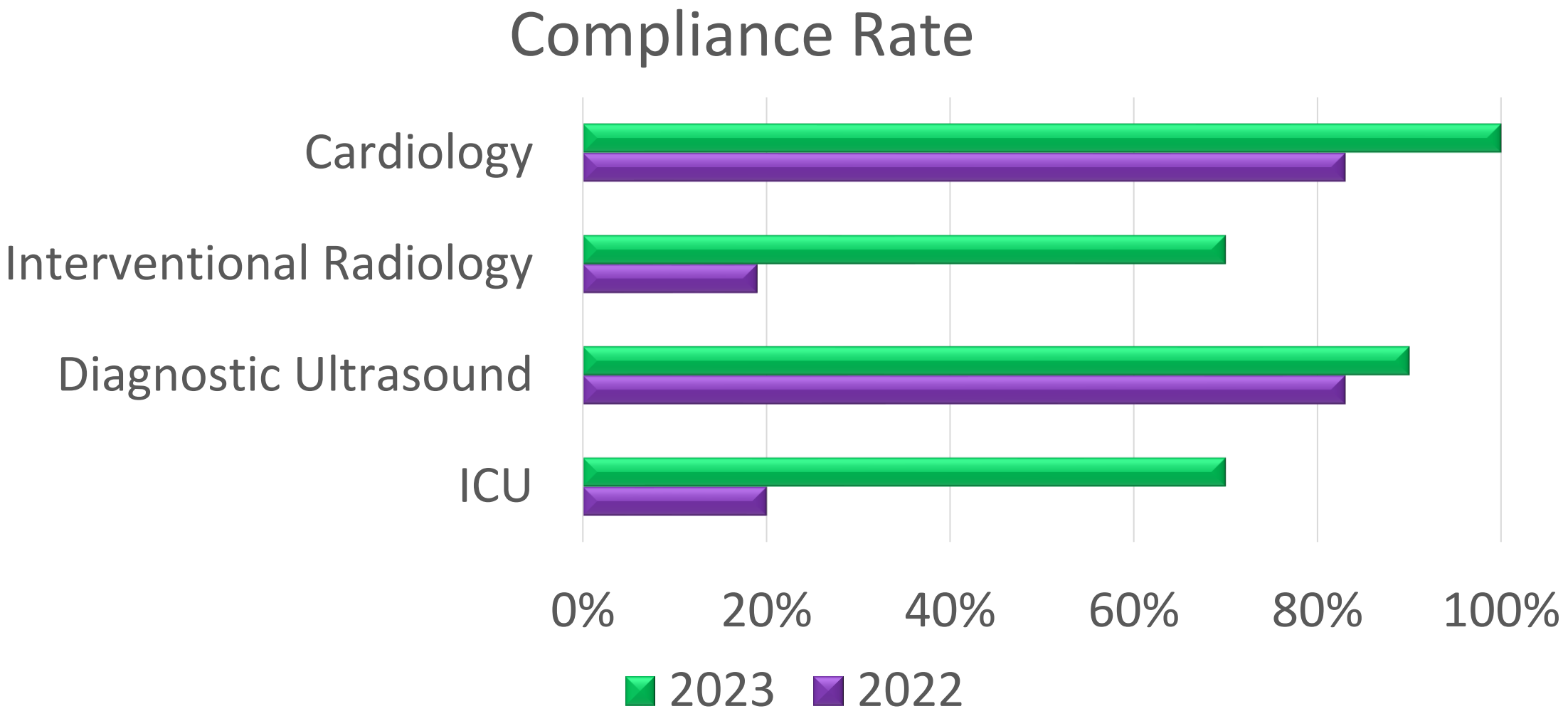
- This tool has been developed for healthcare personnel developing infection prevention policies for ultrasound probe use and reprocessing.
- It is designed as a SOP framework for application in all settings where ultrasound is used.
- This framework can be used to develop a universal hospital SOP or a department specific SOP
- It is based on relevant Guidelines, covering all reprocessing steps + validation and training







Ultrasound Probe reprocessing Audit 2023



take aways

- ✓ The toolkit gives good direction as to where to start the audit process by identifying the ultrasound machines in the clinical areas and getting a profile of the types of procedures there are used in.
- ✓ The audit questions are structured and includes all key elements of probe decontamination outlined in the HSE Ireland and UK guidelines.
- ✓ It is easy to follow and covers the procedure process from start to finish, including gel selection, covers used and post procedure handling of contaminated probes.
- ✓ The Algorithms provided, give detailed guides on how to classify the level of decontamination needed based on the procedure performed.
- ✓ The risk assessment allowed us to prioritise the risks identified to ensure changes required could be implemented. e.g. removal of all 5L multiuse gels from the clinical areas.
- ✓ The policy framework help use to put in place our own SOP within our organisation with the hope of compliance improvements upon re-audit.
- ✓ The tool is free to use and there are no obligations to the company.

take aways

All tools are available @ **www.ultrasoundinfectionprevention.org.uk**

Thank You

www.ultrasoundinfectionprevention.org.uk

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