

Probing Questions

A decontamination journey

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In association with



Background

- I have worked within the decontamination world for 30+ years. Initially as a nurse, then within theatre services and finally within the direct provision of decontamination services.
- During this time I have been involved in both the use and decontamination of ultrasound probes.
- Decontamination guidance has developed over time from when it was a locally agreed process to now where it is regulated by national guidelines.
- Several events and documents have had a direct impact on the guidance and regulations now adopted for the decontamination of reusable invasive medical devices (RIMD) including ultrasound probes.

Probing Question: How did we get here?

1957

- **Spaulding classification:**
A strategy for sterilization or disinfection of inanimate objects based on the degree of risk involved in their use

2004

- **Hine Report:**
Independent review of endoscope decontamination in Northern Ireland

2012

- **Creutzfeldt-jakob Disease (CJD):**
Minimise transmission risk of CJD and vCJD in healthcare settings

2016

- **Health Technical Memorandum (HTM) 01-06:**
Management and decontamination of flexible endoscopes

2017

- **British Society of Gastroenterology (BSG):**
Guidance on decontamination of equipment for gastrointestinal endoscopy

Probing Question: What is the Spaulding Classification System?

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

Probing Question:

What does this all mean for Ultrasound probe decontamination?

Current Guidelines in UK

- UK Health Technical Memorandum 01-06
- Wales WHTM 01-06
- BMUS: Guidelines for Professional Ultrasound Practice
- BMUS: SCoR Ultrasound transducer decontamination- best practice summary
- NHS Scotland: Guidance for the decontamination of semi-critical ultrasound probes

Probing Question:

What does this all mean for Ultrasound probe decontamination?

- Where there is **no specific guidance** document relating to Ultrasound probes decontamination
 - Decontamination practices/guidelines for other medical devices should be adopted
 - Ultrasound probes are classified as medical devices
 - Adherence to Best Practice is expected
- In terms of patient safety, **Best Practice** should be evident in all aspects of the decontamination process.
- Adopting Best Practice standards involves the creation of robust systems including
 - standardisation of processes and
 - operating procedures.
- This can pose challenges for services
- The Infection Prevention (IP) Toolkit can assist with this

Probing Question: Where do we go from here?

- The clinicians who use ultrasound probes are keen to adopt guidance and best practice standards that improves patient safety and clinical outcomes, but are sometimes unsure how to get things started.
- Ultrasound probes can be used by many specialties, which are not centrally managed, and this can pose significant challenges in locating probes and standardising decontamination protocols.
- It is important to forge partnerships between clinicians and decontamination experts to benefit the patient
- It is also important to forge partnerships with other clinicians to create standardised protocols within your facilities.
- The Infection Prevention (IP) Toolkit provides an important resource in this process.

Probing Questions asked by Clinicians

- How do I find and identify my ultrasound probes?
- How do I identify the probe use and the appropriate decontamination method?
- How do I identify and manage the risk involved in the decontamination process?
- How do I bring all this information together within an operating procedure?



Introducing the IP Toolkit

The IP Toolkit is a **free peer created and reviewed resource**.

Developed and brought to life by a collective of clinical decontamination experts in the UK and Ireland, who all share a passion for best practice and open & shared learning:

Claire Jones-Manning Deputy Head of Operations & Decontamination Lead (England)

Elizabeth Collins Clinical Lead Infection Prevention (England)

Helen Campbell Decontamination Consultant (England)

John Prendergast Authorised Engineer (Decontamination)(Wales)

Anthony Sullivan External Decontamination Services Manager (England)

Niamh O'Callaghan Hospital Sterile Services Clinical Nurse Manager & Decontamination Lead (Ireland)

Linda Cooper Decontamination Project Lead (Northern Ireland)

Support for the development was provided by Nanosonics Ltd.



Introducing the IP Toolkit

The 4 editable tools are available free of charge,
and are downloadable from the IP toolkit webpage:

www.ultrasoundinfectionprevention.org.uk



Tool 1

Locate & Profile



Tool 2

Algorithm



Tool 3

Risk Assessment



Tool 4

Policy Development Framework

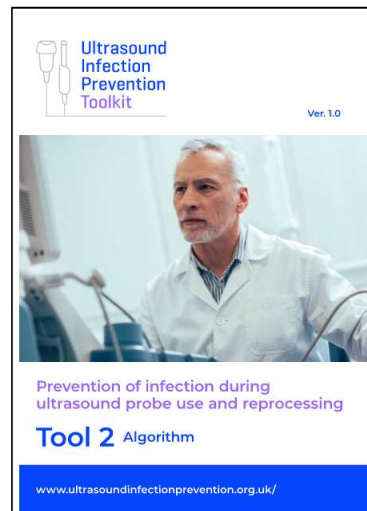
Introducing the IP Toolkit

Tool 1: Locate and Profile



Use this tool to **observe, assess and create an action plan** where discrepancies are observed between guidelines, practice and standard operating procedures.

Tool 2: Algorithm



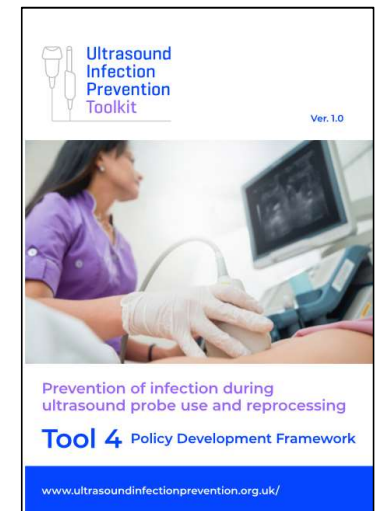
Use this tool to **identify correct probe reprocessing requirements** based on guidelines, organized by department.

Tool 3: Risk Assessment



Use this tool to **assess potential hazards that may be encountered** during the use and reprocessing (e.g., cleaning, disinfection storage and traceability) of ultrasound probes.

Tool 4: Policy Development Framework



Use this tool to **develop an ultrasound infection prevention policy** for your facility.



Introducing the IP Toolkit: TOOL 1 LOCATE & PROFILE

Part A: Locate

- 4 strategies to identify all ultrasound probes across the facility

Part B: Profile

- Templates to profile the type of probes and the practice observed across the facility:
 - type of probe
 - probe manufacturer
 - current procedures
 - required decontamination status
 - available documentation
e.g. operating procedures, instructions for use

Part C: Action plan

- Template to document a set of actions from the audit carried out in Part B



TOOL 1 LOCATE & PROFILE

Part A Locate

| Strategy | Rationale | How | Limitations |
|---|--|--|--|
| 1. Locate where ultrasound machines are by searching the organisation's asset register. | The HCO's assets registry department maintains an asset register of equipment used throughout the facility. The asset register links the ultrasound machine to department locations. | Ask HCO's assets registry department to provide a complete list of ultrasound probes and consoles from their asset register. Identify the service they belong to and the department in which they are located. | <ul style="list-style-type: none">• Not all ultrasound machines may be listed on the register.• Asset registers may be incomplete (e.g. due to mergers/acquisitions, purchases being made by local departments, trial equipment being used, replacement of old equipment, equipment shared between several departments or other reasons). |
| 2. Locate where ultrasound consumables are being used (e.g. gel, probe sheaths/covers). | All ultrasound probes are used with ultrasound gel which is essential for imaging quality. Some ultrasound probes are used with sheaths/covers. Locating ultrasound gel and probe covers will lead to the departments using ultrasound probes. | Approach the procurement and/or logistics team to request they search purchase orders and inventory lists for each service department/facility, and provide a report of material. | <ul style="list-style-type: none">• It may be difficult to obtain purchase orders and inventory, particularly if a central system is not in place.• Some consumables may be ordered centrally and distributed, or may be ordered and purchased locally (e.g. by individual departments or units).• It may be difficult to identify consumables due to multiple brands/suppliers. |



TOOL 1 LOCATE & PROFILE

Part A Locate

| Strategy | Rationale | How | Limitations |
|--|---|--|---|
| 3. Survey departments to identify where ultrasound is used. | End users are the best placed to know where ultrasound is being used. | <p>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 leadership.</p> <p>Also, the assumption is that most Emergency departments, Critical Care Units and Operating departments will use USS (ultrasound scan) during procedures.</p> <p>It might be worthwhile to make contact with a clinical specialist i.e. critical care scientist who could advise of locations that routinely use USS for cannulations etc.</p> | <ul style="list-style-type: none">• It may be time consuming to reach all departments.• It may be difficult to identify staff with full knowledge of ultrasound use in their department. |
| 4. Identify ultrasound procedures in HCO coding systems records. | Ultrasound procedures should be coded. If ultrasound procedure item codes are obtained, they can then be used to identify which departments or providers are performing those procedures. | Identify ultrasonography procedure codes; coding and information department for a list of ultrasound procedure item codes and determine which departments are performing those procedures. | <ul style="list-style-type: none">• Coding may not provide department specific information.• The coding system may not be set up to readily perform these searches.• Not all services using ultrasound probes for diagnosis or treatment will record these as ultrasound procedures . |



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 | | |
| 5 | | |
| 6 | | |



TOOL 1 LOCATE & PROFILE

Part B Profile: Probes & Procedures

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 | DEPT001 | ABCDE | XXXXX | ABDOMINAL SCANNING | NON-CRITICAL |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |



TOOL 1 LOCATE & PROFILE

Part B Profile: Documentation

c) Documentation

| Questions | Answers | | | Comments |
|---|---|--|--|----------|
| Does the facility/department have SOP(s) for reprocessing ultrasound probes? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | <input type="checkbox"/> Not specified | |
| Do the operators have access to the US probe(s) IFU? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Not specified | |
| Is the reprocessing system manual? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | <input type="checkbox"/> Not specified | |
| Is the reprocessing system automated? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> 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? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Not specified | |
| Where are the validation and service reports stored? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Not specified | |



TOOL 1 LOCATE & PROFILE

Part B Profile: Probe processing procedure audit

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



TOOL 1 LOCATE & PROFILE

Part B Profile: Assess practice & audit conclusion

Assess Practice

| Questions | Answers | | | Comments |
|--|--|--|--|----------|
| Is the observed practice fully compliant with the SOP? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | <input type="checkbox"/> Not specified | |
| Where are the training records stored? | Please specify: <i>Electronically</i> | | <input type="checkbox"/> Not specified | |
| Are the operators trained for this procedure? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Not specified | |
| Type of training | <input checked="" type="checkbox"/> Internal | <input type="checkbox"/> External | <input type="checkbox"/> Not specified | |

Audit Conclusion

| Comments |
|--|
| <i>This practice is non-compliant as no SOP is available</i> |



TOOL 1 LOCATE & PROFILE

Part C Action plan

| Action Plan | | | | Progress Update | Re-audit | |
|-----------------------|--|--------------------|-----------------------------------|--------------------------------------|--|--|
| Auditor/assessor: | | | | Auditor/assessor: | Auditor/assessor: | |
| Date: | | | | Date: | Date: | |
| Deviations identified | Actions required | Person responsible | Priority High Medium Low | Status | Outcome | Action effectiveness (How do you prove that the actions have been effective?) |
| SOP to be created | 1. Review IFU | XX | High | 1. IFU reviewed | SOP conform with IFU | |
| | 2. Create a standardised procedure | XX | High | 2. SOP created | SOP is available in folder for all staff | Perform process audits once a year |
| | 3. Communicate SOP to all relevant staff | Y.Y. | Medium | 3. Awareness training rolled out | All relevant staff have been asked to describe the SOP | |
| | 4. Update training folders | Y.Y. | Medium | Staff training folders to be updated | | |

IP Toolkit: Next Steps

After using **Tool 1** to **Locate and Profile** all ultrasound probes

The team knows:

- What ultrasound systems & probes you have and their locations.
- What procedures these ultrasound probes are used for and their required decontamination status
- What documentation exists and what needs to be created.

This gives an action plan to move forward to the next stage of the process. Which is **Tool 2: Algorithm**

IP Toolkit: Next Steps

Tool 2: Algorithm

- Contains the correct processing requirements
- Based on guidelines
- Organised by department

All tools are available @

www.ultrasoundinfectionprevention.org.uk



Tool 1
Locate & Profile



Tool 2
Algorithm



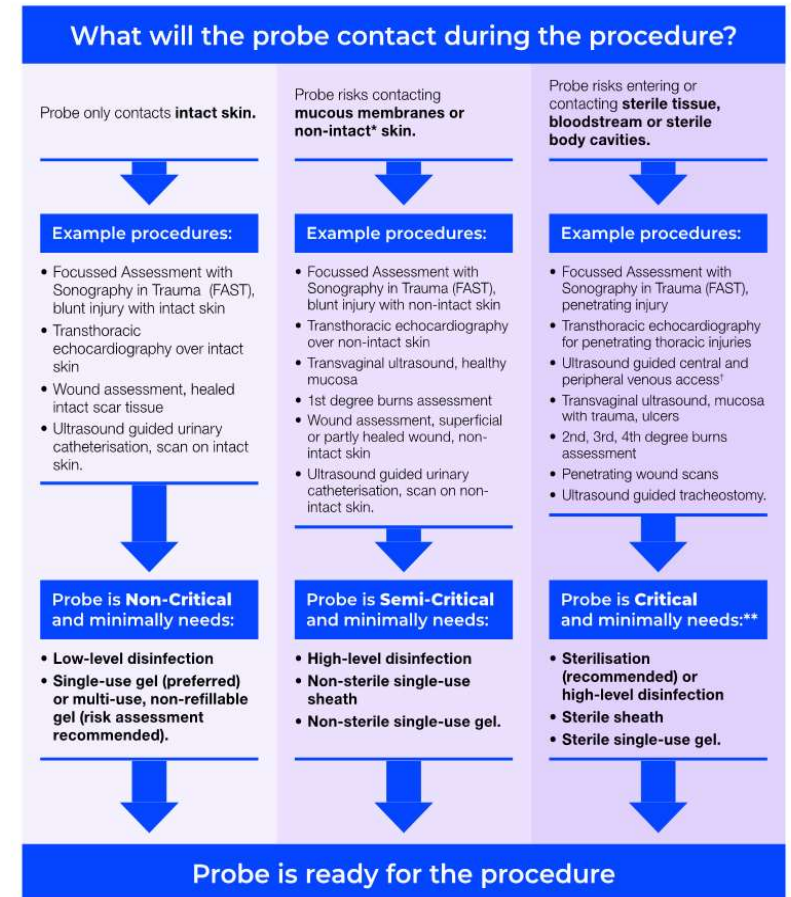
Tool 3
Risk Assessment



Tool 4
Policy Development Framework

Algorithm for probe use and reprocessing in EMERGENCY

Based on recommendations from the SCoR/BMUS, HSE Ireland, NHS Scotland, ESR, ECMUS and WFUMB.

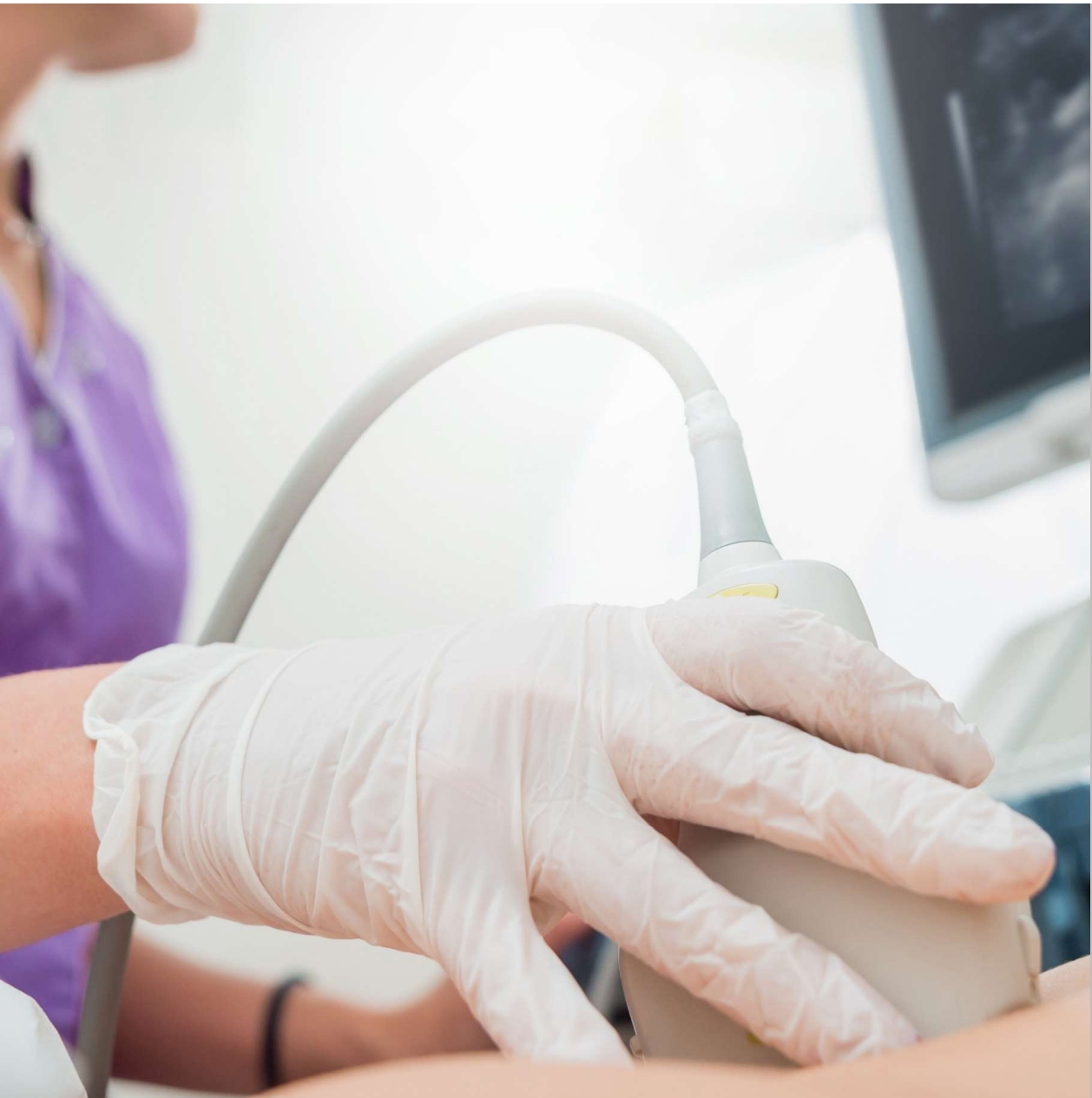


NOTE: Example procedures have been provided as examples based on interpretation of the Spaulding Classification. Some procedures may fall into other categories depending on the specific clinical situation and on which tissues may be contacted. Additionally, the probe cable and ultrasound console are generally considered non-critical surfaces and should be cleaned and undergo LLD between patients as part of the room turnover process. Check with manufacturer to determine whether chosen disinfectant is compatible with the probe and cable.

*Non-intact skin: Areas of the skin that have been opened by cuts, abrasions, dermatitis, chapped skin or unhealthy skin etc.

†It is important that patients continue to receive ultrasound guidance for peripheral IVs, midlines and PICCs as evidence shows increased risk of infection where ultrasound guidance is not performed. Where HLD would prevent the use of ultrasound for these procedures, the relative risks need to be considered. See Section 5.2.1 in Tool 4 – Policy Development Framework for more information.

**European and global ultrasound guidelines states that the probes should be sterilised between each patient use as with other critical items. If this is not possible, SCoR/BMUS and ESR recommend the probe should minimally be high-level disinfected and covered with a sterile probe cover.



Thank You

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