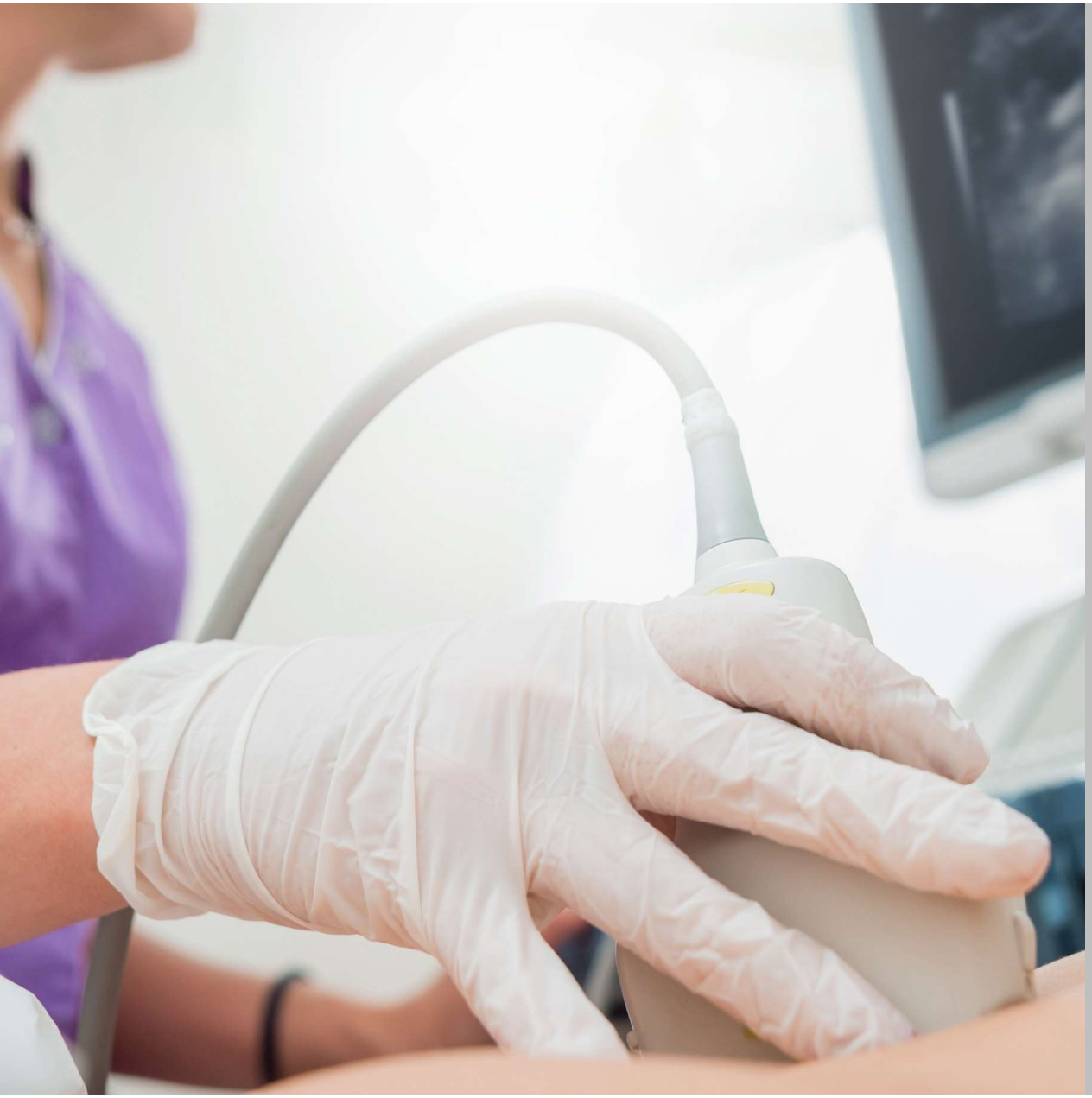


The Unknown Risk of Ultrasound probes and how to mitigate

Helen Campbell

In association with Ultrasound Infection Prevention Toolkit

Is there a department where ultrasound probes are not used?

- When considering probes there are certain departments that stand out.
- Risk assessments and SOPs linking into a quality system should already be established.
- These should/will have been produced with the help of infection prevention.
- They should include, level of disinfection needed, compatibility of chemicals, location of the cleaning/disinfection and training of staff.

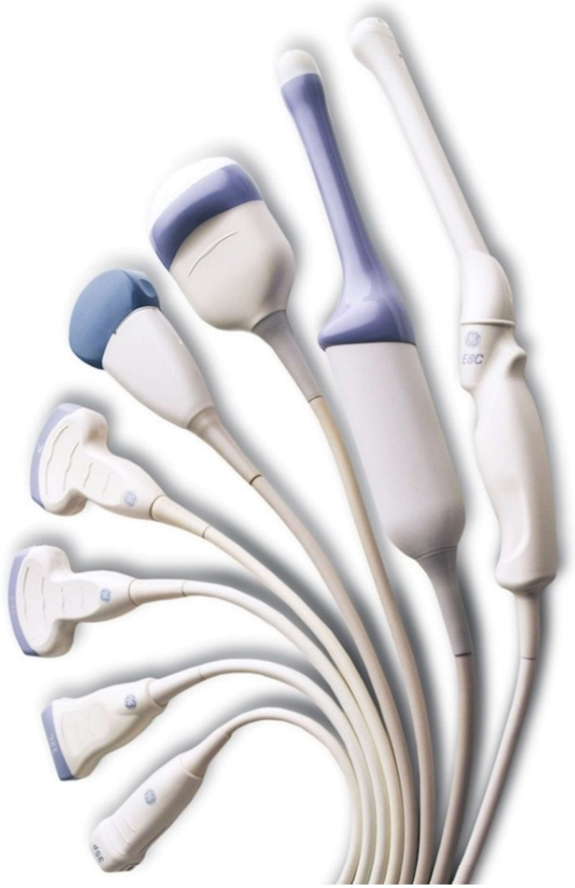
When is a probe borrowed by another department?

What about areas that borrow probes?

- Do they bring them back to the department for cleaning?
- Are they kept moist after use?
- Are the patient details recorded against the scope?
- Is the jell compatible with the cleaning/disinfection process?

If the probes are returned cleaned

- Are they aware of the cleaning/disinfection requirements?
- Is the cleaning /disinfection process recorded?
- Are the chemicals compatible?



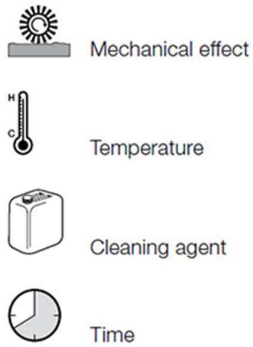
Sinners Circle
Dr Herbert Sinner German chemical engineer 1959

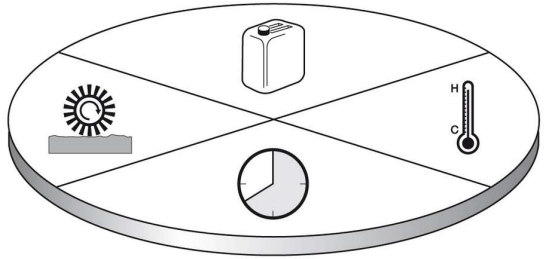
Mechanical

- This is the action of cleaning:
  - physical pressure
  - Movement over the surface with cleaning material – clean to dirty

Cleaning agent

- Detergent
- Instructions for Use “IFU’s” from the manufacture
- Compatibility with ultrasound probe
- Efficiency on contamination/soil
  - Different types of contamination/soil (organic & non-organic)
- The amount of chemical used
- Contact – scratches, worn areas





Temperature

- Does the detergent have a temperature range?
  - Endozymatic detergent has specific temperature / time requirements

Time

- Contact time – does the detergent take time to work

Changes in decontamination due to patients' condition

What happens when a patent presents for an external scan but has a rash/broken skin?

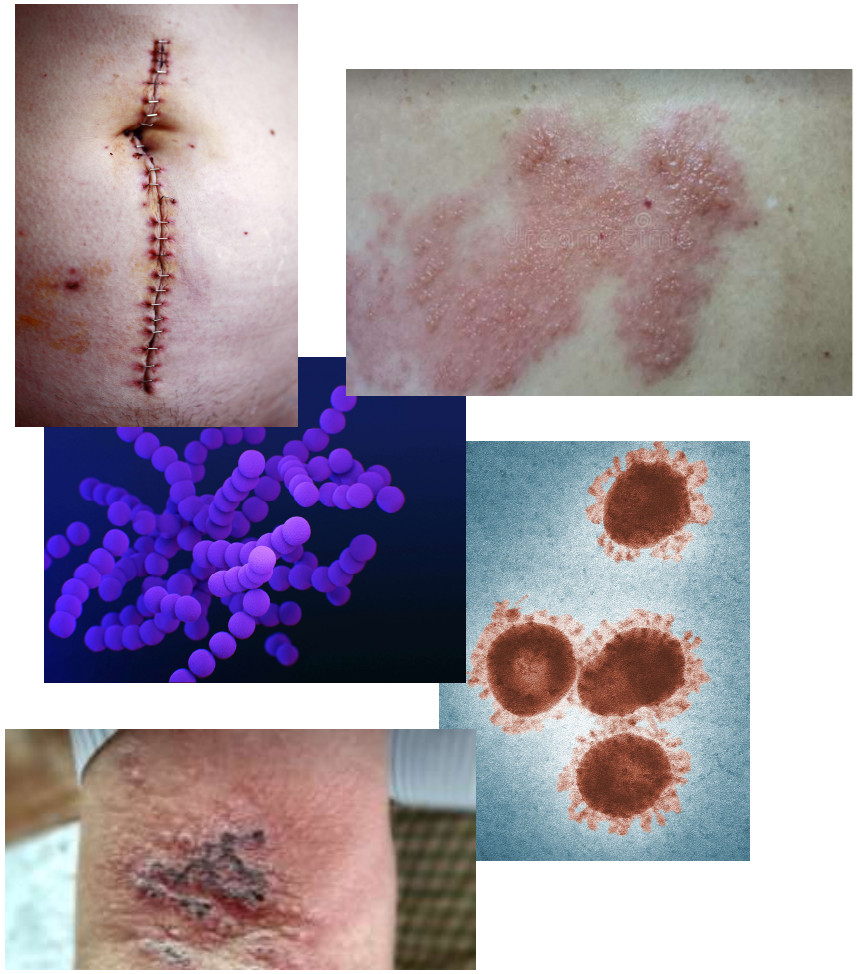
Is there a change to the cleaning/disinfection method?

Is the same cleaning schedule/method used?

- If so, what are the risks?
- Who completes the risk assessment or is there one completed?

What method of assessment is used?

- This should change from a non-critical to a semi-critical procedure



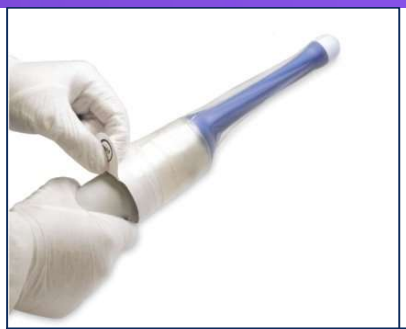
Sheathing a probe

There are many types of sheath for probes:

- Single use
- Sterile
- Different quality of sheaths

Does a sheath ever breach?

What cleaning method is used if the sheath splits?



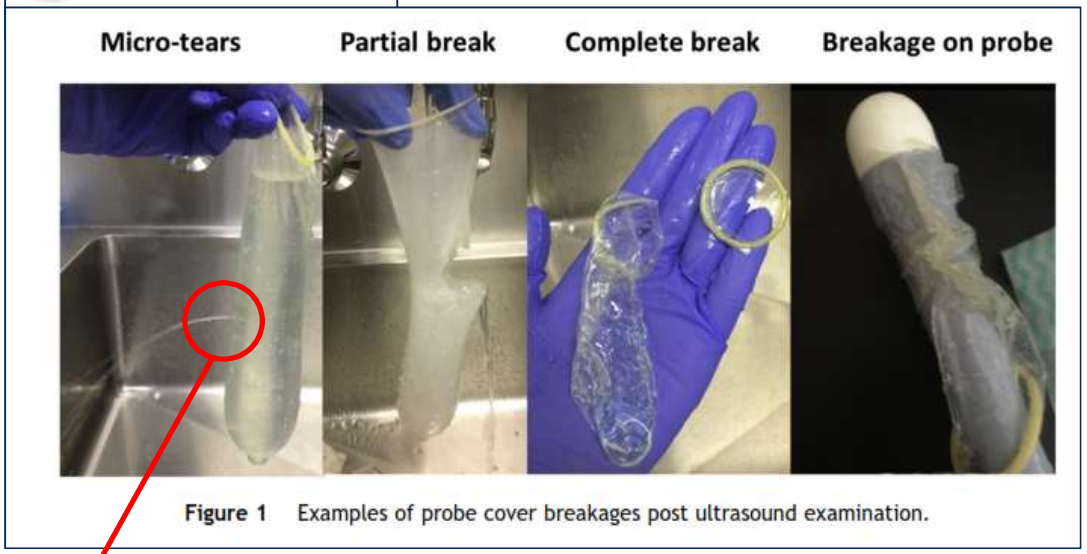


Figure 1 Examples of probe cover breakages post ultrasound examination.

Image from Basseal 2019 [1]

Micro-tear not visible to the eye

1.Basseal JM, et al. Infection, Disease & Health. 2019.

Who checks the probes?

Is it the operator?

Is it the User?

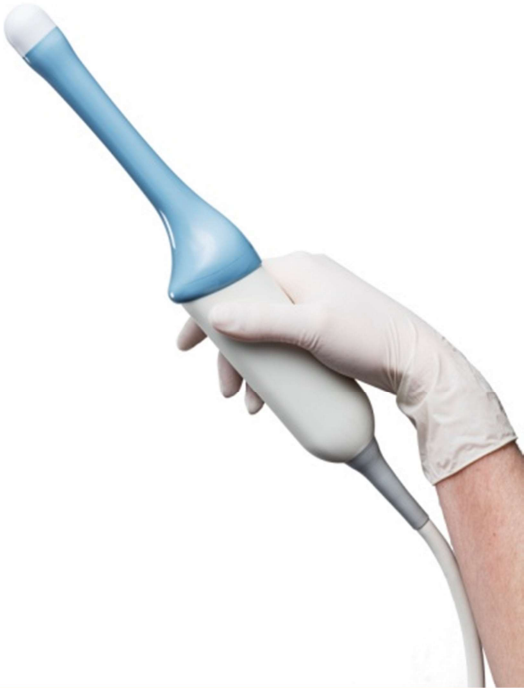
Is it the Healthcare assistant?

What training has taken place, is this recorded and how long is this information kept?

Is there a dedicated area for cleaning/disinfecting the probes?

- Does this area have the facilities needed?

Are all staff aware of the cleaning/disinfection process?



“There has never been an infection from using ultrasound probes?”

There is a possible risk of cross contamination.

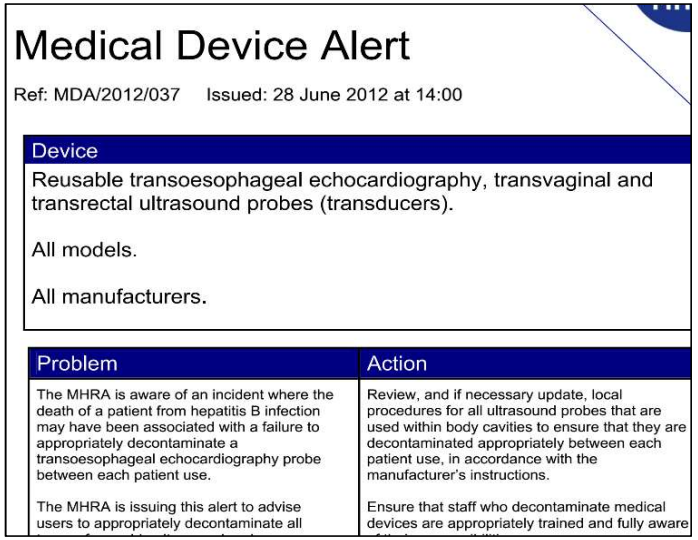
MHRA alert (MDA/2012/037) MHRA UK 2012. Medical Device Alert: Reusable transoesophageal echocardiography, transvaginal and transrectal ultrasound probes (transducers) (MDA/2012/037).

A TOE probe transmitted Hep B to subsequent patients and one patient died as a result.

Issues:

- The probe was not leak tested
  - On investigation a hole was found
- The probe was manually cleaned
  - There was no record of contact times
- Training
  - No refresher training
  - Training was on generic scopes
- There was no dedicated decontamination area (best practice within the UK)
  - Cleaning / disinfection took place in the procedure room

Traceability to patients was accurate with the hospital picking up the next 10 patients that the scope was used on.



Medical Device Alert

Ref: MDA/2012/037 Issued: 28 June 2012 at 14:00

Device
Reusable transoesophageal echocardiography, transvaginal and transrectal ultrasound probes (transducers). All models. All manufacturers.

Problem	Action
The MHRA is aware of an incident where the death of a patient from hepatitis B infection may have been associated with a failure to appropriately decontaminate a transoesophageal echocardiography probe between each patient use. The MHRA is issuing this alert to advise users to appropriately decontaminate all	Review, and if necessary update, local procedures for all ultrasound probes that are used within body cavities to ensure that they are decontaminated appropriately between each patient use, in accordance with the manufacturer’s instructions. Ensure that staff who decontaminate medical devices are appropriately trained and fully aware

Scottish study on semi-invasive (semi-critical) 2010-2016

Scottish study[1]:

Risk of infection following semi-invasive ultrasound procedures in Scotland, 2010 to 2016

Government followed 330 500 gynaecology patients' journeys retrospectively over 7 years. 60 698 patients had undergone TV scans.

Evidence was collected from community antibiotic prescriptions within 30 days of the procedure. (Scott, D., et al. Ultrasound. 2018;26(3): 168-177)

Risk varies depending on the procedure but the indicated
absolute risk increase was 0.05 -2.25%

90.5% of facilities **were not performing high level disinfection (HLD)** on these probes.

A national survey in 2012 showed variation on how probes were being cleaned / disinfected with only 9.5% using high-level disinfection (HLD), similarly a survey within Europe found 14.7% using HLD

In 2016 guidance was issued by the Scottish health board recommending the use of (**HLD**) for all semi-critical procedures.

Concluded failure to follow new Scottish guidelines (HLD endocavitary probes) would be placing patients at unacceptable risk of harm.

(1) Scott D, et al. Ultrasound. 2018;26(3):168-77.

Serratia marcescens outbreak[1] - Caen France (2018)

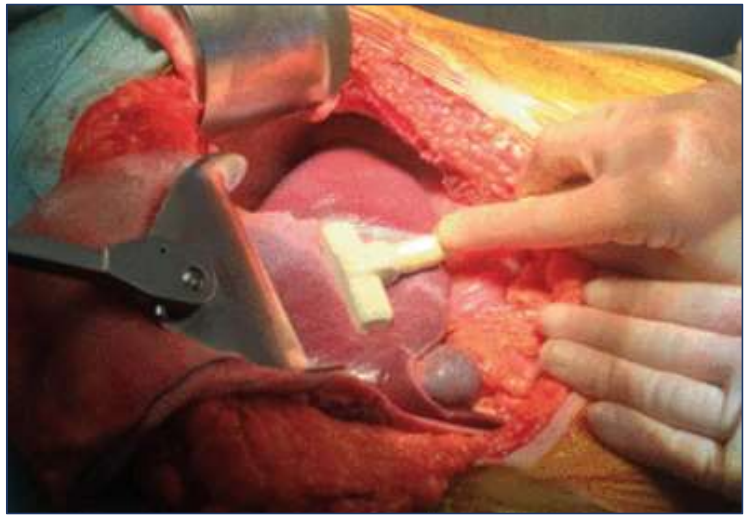
Hospitals Infection control team noticed an increase in infections within patients undergoing digestive surgery.

- Common factor for 8 patients – theatre attended with use of ultrasound probe.
- Theatre closed, surface and environmental samples taken.
- Medical devices checked with samples taken.
- Result – nothing found.
- Additional investigation found there was a loose seal, from the probe, to the cable.
- Samples taken with a positive result.

Learning outcomes:

- Probe was not sheathed – clinicians request to enable clearer view.
- High level of surgical activity – fast turn round times.
- Lack of Training in both the procedure and cleaning/decontamination of probe.

This led to an alert and the withdrawing of the probe



(1) Gery, et. al. J Hosp Infect. 2021 May;111:184-188. doi: 10.1016/j.jhin.2020.12.025.

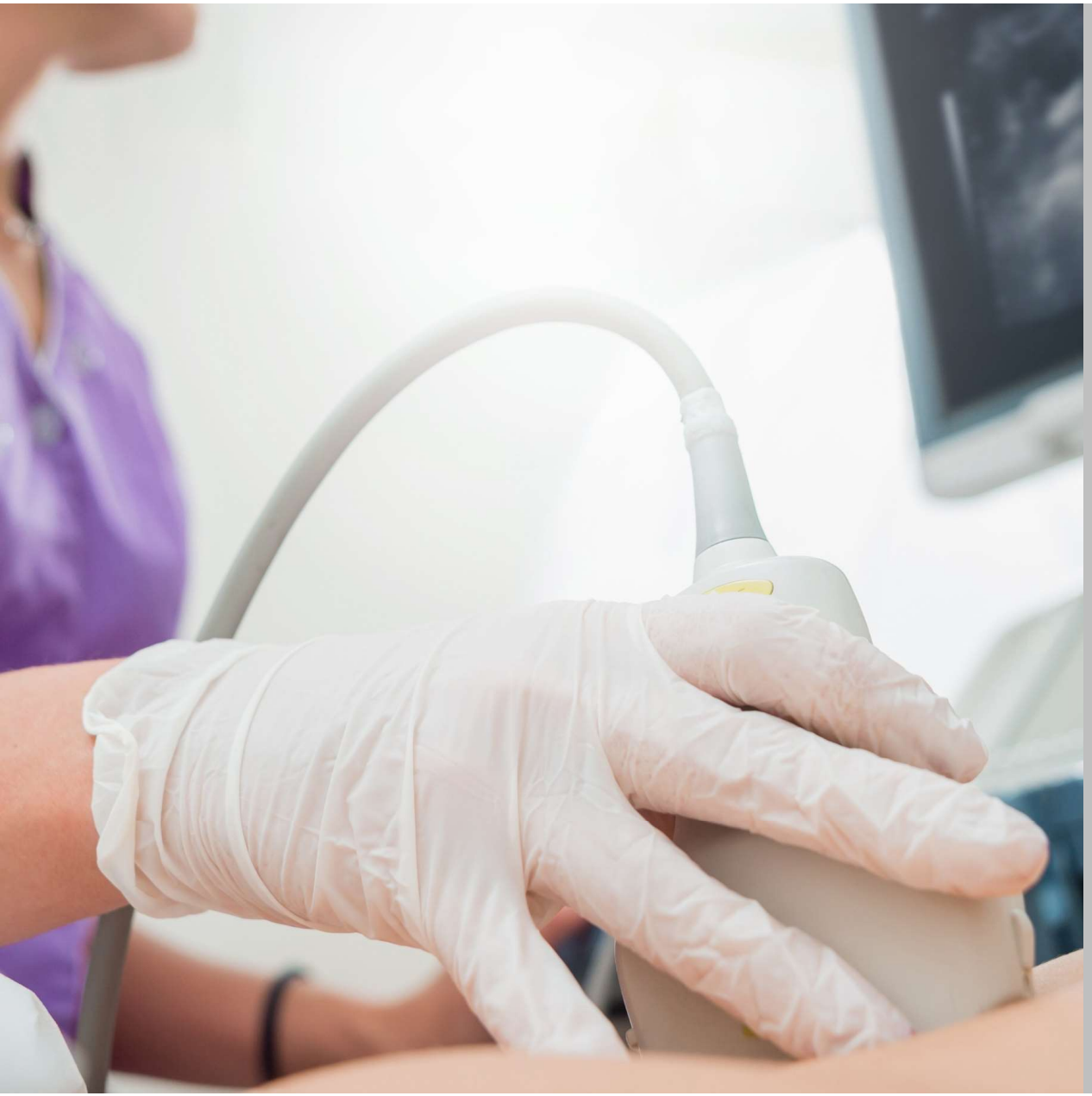
Recognising infections from ultrasound probes

Being aware there *is* a risk of passing on infection when using ultrasound probes

- Dirty to clean route for devices
- Cleaning (you can not disinfect if the device is not clean)
- Spaulding classification
  - Method of disinfection
- Storing after disinfection

If there is a problem you will need;

- Accurate traceability of patient, scope, cleaning (detergent, lot number, staff member), disinfection method (chemical, contact time, staff member etc.)
- Training records of staff (operator and staff member doing the cleaning and disinfection)



Introducing the Ultrasound Infection Prevention Toolkit

In association with Ultrasound Infection Prevention Toolkit

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

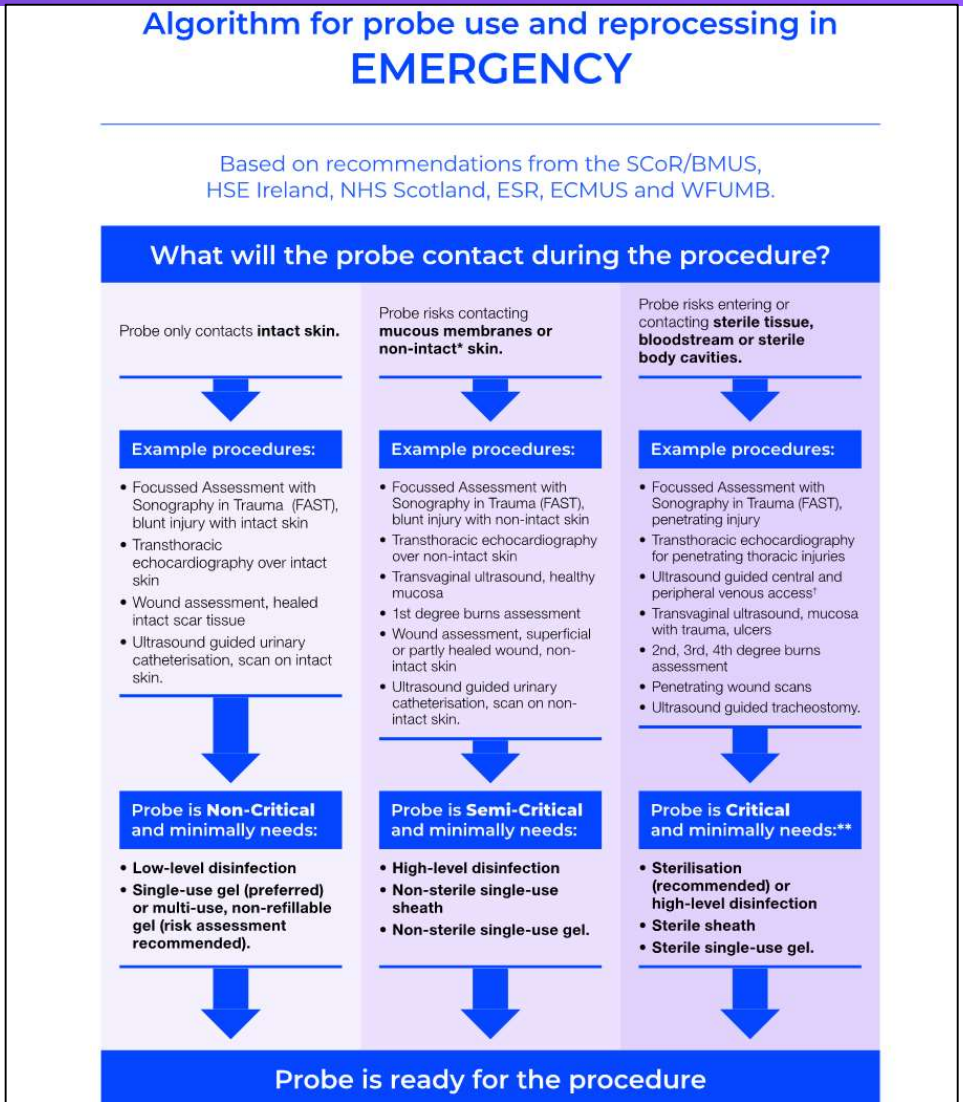
Introducing the IP Toolkit: Tool 2 Algorithm

This tool is **organised by department** and provides a **range of typical procedures** that may be encountered in that department.

To determine the correct level of reprocessing required for particular ultrasound probe, first determine the patient contact site.

Alternatively, if the procedure is already listed in the department algorithm, find the procedure to determine the possible patient contact site.

Follow the algorithm down the page to determine whether the probe needs low level disinfection, high level disinfection or sterilisation when used in that application.



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.

Using Tool 3: example risk assessment

Finance questioned the high cost of repairing probes in a department.
An audit was requested to look at the use, cleaning/disinfection and storage of the probe.
The department regularly audited their processes having accurate signed SOPs and training records.
The probe company was asked for a copy of their IFU's, it was found that the wipe the department was using to clean the probe was not compatible with the probe.
The wipe had been changed to one used throughout the hospital due to cost pressures within the department/hospital, it had been **assumed** that the chemicals used were the same.

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

Using Tool 3: example risk assessment

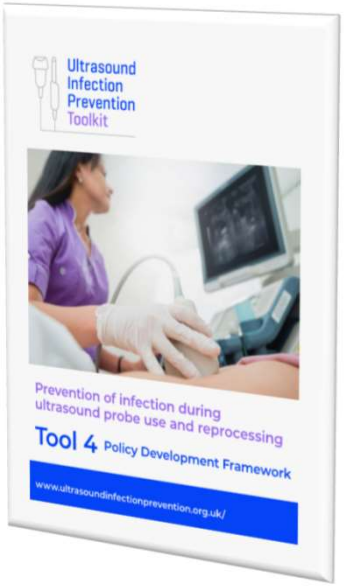
The continence clinic scans multiple patients in a morning, they wipe with a detergent/disinfection wipe depending upon what is available on the day. This has been the practice for many years with no problems.
A return patient informs the Nurse during the procedure that she had a skin infection develop a few days after her last appointment requiring antibiotics and asked if it could have come from the probe. This was the start of an investigation;
1. Was there a SOP? 2. What was the probe cleaned with? 3. Who cleaned the probe?

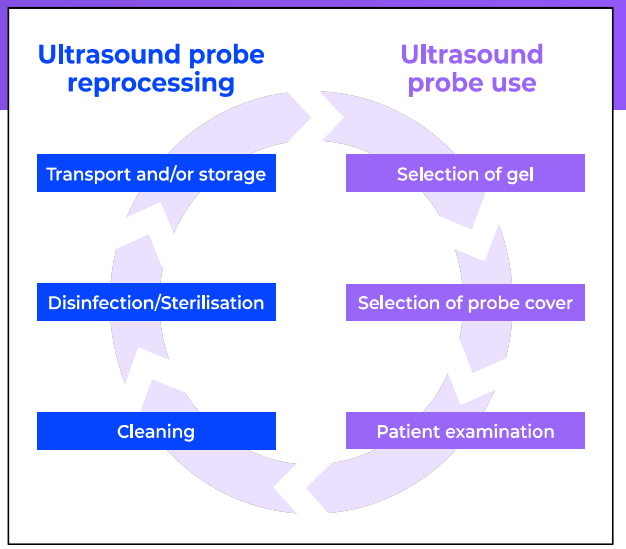
Yes there was an basic SOP **but** it was undated and kept in the office. This SOP did not stipulate HLD or LLD.
The other two questions could not be answered, there was no traceability of method or cleaning/chemicals used e.g. lot numbers or name recoded against the cleaning of the probe (if it's not recorded it's not been done).
The department was asked to review the process, update the SOP and complete a risk assessment to sit on the Trusts risk register.

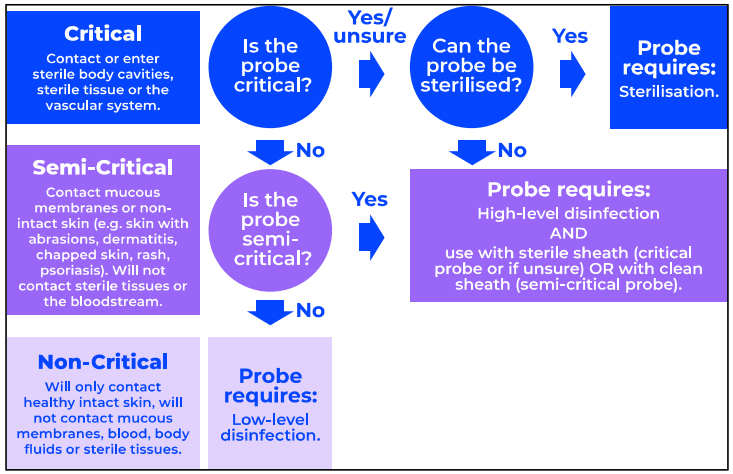
Risk type	Risk description	Potential harm(s)	Likelihood	Severity	Risk rating	Example mitigations (if risk rating >low)	Risk rating after mitigation
Biological	Probe with incorrect level of disinfection/ sterilisation used on patient (e.g. LLD probe used during a HLD procedure).	Risk of infection to subsequent patients.	Medium	Medium	Medium	• 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 cycle, including date and time, end-user information and disinfection 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

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







How to mitigate the risks: take aways

- Don’t assume
- Read the small print
- Record the risk assessment on the Trusts risk register.

All tools are available @

www.ultrasoundinfectionprevention.org.uk

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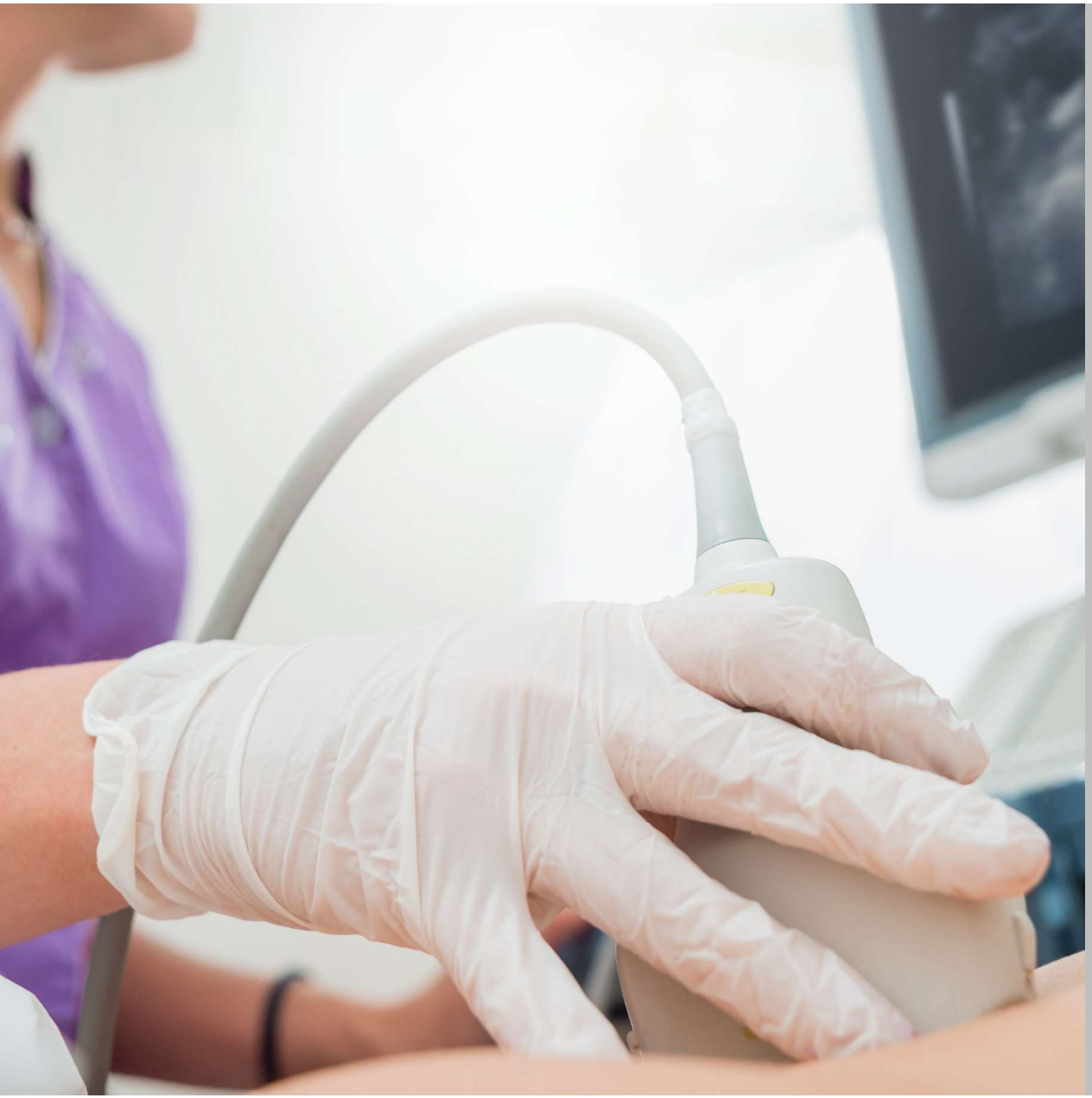

Thank You

www.ultrasoundinfectionprevention.org.uk

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