Ultrasound Infection Prevention

Risks, Challenges and Solutions

APIC Greater Atlanta Chapter Meeting

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Disclosures

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Learning objectives

- Review recent research documenting infection risk from ultrasound procedures.
- Determine the reprocessing requirements for ultrasound probes, used in a variety of procedures, by applying the Spaulding classification, CDC and FDA guidelines.
- Discuss the significance of available evidence demonstrating the high frequency of contact between the ultrasound probe and sterile puncture site in a variety of percutaneous interventions.
- Explain the application of the ultrasound IP Toolkit components ('Locate and Profile', 'Algorithm', 'Risk Assessment' and 'Policy' tools) to ensuring that patients are safe from infection risk.

What is ultrasound?

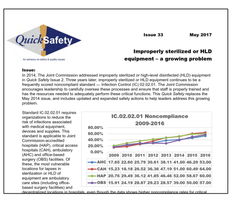
- Ultrasound probes are heat sensitive reusable medical devices used to visualise the anatomy in a variety of procedures.
- Ultrasound probes can require LLD, HLD or sterilization depending on the patient contact site. The same probe may require LLD for one procedure, then HLD for another procedure.
- Ultrasound probes come in a variety of shapes and sizes for a variety of procedures

External / Surface Probes
e.g. Doppler, linear, curvilinear, intraoperative probes

Endocavitary Probes
e.g. transvaginal, transrectal, transesophageal probes

Risk from ultrasound procedures

2017, USA. Joint Commission. 74% of all immediate threats to life were from improper sterilization or HLD of devices



Quick Safety
An advisory on safety & quality issues

Issue 33 May 2017

Improperly sterilized or HLD equipment – a growing problem

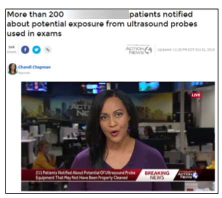
Issue:
In 2014, The Joint Commission addressed improperly sterilized or high-level disinfected (HLD) equipment in *Quick Safety* Issue 2. Three years later, improperly sterilized or HLD equipment continues to be a frequently scored noncompliant standard — Infection Control (IC) 02.02.01. The Joint Commission encourages leadership to carefully oversee these processes and ensure that staff is properly trained and has the resources needed to adequately perform these critical functions. This *Quick Safety* replaces the May 2014 issue, and includes updated and expanded safety actions to help leaders address this growing problem.

Standard IC.02.02.01 requires organizations to reduce the risk of infections associated with medical equipment, devices and supplies. This standard is applicable to Joint Commission-accredited hospitals (HAP), critical access hospitals (CAH), ambulatory (AHC) and office-based surgery (OBS) facilities. Of these, the most vulnerable locations for lapses in sterilization or HLD of equipment are ambulatory care sites (including office-based surgery facilities) and decentralized locations in hospitals, even though the data shows higher noncompliance rates for critical

IC.02.02.01 Noncompliance 2009-2016

	2009	2010	2011	2012	2013	2014	2015	2016
AHC	17.65	22.60	25.79	30.61	38.11	41.00	46.29	53.00
CAH	15.23	18.18	26.52	36.36	47.19	51.00	60.49	64.00
HAP	20.76	29.49	36.12	41.85	46.46	52.00	58.67	60.00
OBS	15.91	24.19	28.87	29.23	28.57	39.00	50.00	57.00

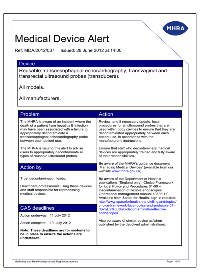
2018, USA. Facilities being cited for improper ultrasound probe reprocessing.



The Joint Commission (TJC). Improperly sterilized or HLD equipment – a growing problem. 2017. Available at: https://www.jointcommission.org/assets/1/23/qs_33a_2017.pdf

Updated on Oct 31, 2018 11:29 pm: https://www.wtae.com/article/more-than-200-upmc-jameson-patients-notified-about-potential-exposure-from-ultrasound-probes-used-in-exams/24498056

Risk from ultrasound procedures



MHRA

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 types of reusable ultrasound probes.	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 of their responsibilities. Be aware of the MHRA's guidance document 'Managing Medical Devices' (available from our website www.mhra.gov.uk). Be aware of the Department of Health's publications (England only): Choice Framework for local Policy and Procedures 01-06 – Decontamination of flexible endoscopes: Operational management manual 13536:1.0. Available from Space for Health, sign-in required: http://www.spaceforhealth.nhs.uk/England/topics/choice-framework-local-policy-and-protocols-01-06-%E2%80%93-decontamination-flexible-endoscopes Also be aware of similar advice as/when published by the devolved administrations.

Action by
Trust decontamination leads.
Healthcare professionals using these devices and staff responsible for reprocessing medical devices.

CAS deadlines
Action underway: 11 July 2012
Action complete: 19 July 2012
Note: These deadlines are for systems to be in place to ensure the actions are undertaken.

Medicines and Healthcare products Regulatory Agency Page 1 of 4

2012, UK. Patient death from hepatitis B infection thought to have been transmitted via endocavitary ultrasound

Probe was not properly disinfected.

MHRA (similar to FDA) released an alert to review all ultrasound disinfection practices in UK.

Medicines and Healthcare products Regulatory Agency (UK). Medical Device Alert: Reusable transoesophageal echocardiography, transvaginal and transrectal ultrasound probes (transducers) (MDA/2012/037). 2012.

Risk from ultrasound procedures

Risk of infection following semi-invasive ultrasound procedures in Scotland, 2010 to 2016: A retrospective cohort study using linked national datasets

David Scott, Eilidh Fleicher, Hayley Kane, Willem Malcolm, Kimberley Kavanagh, A Lan Banks and Annette Reaks

2018, Scotland. Study demonstrated epidemiological link between improper endocavitary probe disinfection with LLD and increased infection risk.

- 30 days after a **TV scan** (results highly significant):
  - Patient is **41% more likely to have positive bacterial cultures**
  - Patient is **26% more likely to be prescribed antibiotics**
- 30 days after a **TR scan** (results highly significant):
  - Patient is **3.40x more likely to have positive bacterial cultures**
  - Patient is **75% more likely to be prescribed antibiotics**
- 30 days after a **TOE scan**:
  - Patient is **4.92x more likely to have positive bacterial cultures** (result highly significant)
  - Patient is **5% more likely to be prescribed antibiotics** (not significant)

Scott D et al. Ultrasound. 2018 Aug;26(3):168-177.

Risk from ultrasound procedures

2016-2018. Outbreaks have occurred in external ultrasound probe guided procedures, linked to contaminated ultrasound gel.

Multiple patients effected across many facilities, following ultrasound guided CVC insertion, nerve blocks, arthrocentesis, amniocentesis, among many more.[1-3]

1. Shaban RZ, et al. American journal of infection control. 2017;45(9):954-58.
2. Abdelfattah R, et al. Journal of Hospital Infection. 2018;98(3):289-94.
3. Cheng A, et al. Clinical Microbiology and Infection. 2016;22(4):382. e1-e11.

Overview of ultrasound probe reprocessing

Traceability
The ability to verify the history, location, or application of an item by means of documented recorded identification.
Semi-critical and critical probes must be traced.

Cleaning
A process which involves physical removal of soil from the surfaces of devices to prepare the items for safe handling and/or further decontamination.

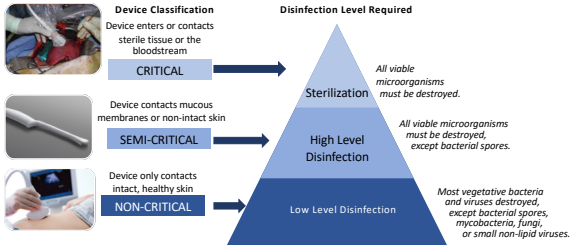
Disinfection
Process by which pathogenic microorganisms are destroyed in order to prevent patient to patient transmission.

Storage
A process that prevents recontamination of reprocessed devices, ensuring they are available for reuse.

Next patient use

CDC 2008 – Guideline for Disinfection and Sterilization in Healthcare Facilities.
AAMI ST58:2013 - Chemical sterilization and high-level disinfection in health care facilities.

Spaulding classification



CDC & FDA: Sheaths don't replace reprocessing

'**Do not use a lower category of disinfection or cease to follow the appropriate disinfectant recommendations when using probe covers** because these sheaths and condoms can fail.' (pg. 89)

CDC 2008. Guideline for Disinfection and Sterilization in Healthcare Facilities

'For clinical applications of a semi-critical or critical nature (e.g., intraoperative, transrectal, transvaginal, transesophageal, or biopsy procedures), labeling should recommend, when appropriate, the use of sterile, legally marketed probe sheaths. **Note that the use of sheaths does not change the type of reprocessing that is recommended after each use.**' (pg. 17)

'The probe used in a semi-critical application should be cleaned and sterilized or at least receive high level disinfection after use even if a sheath was used. Probes used for critical applications should be cleaned and sterilized after use **even if a sterile sheath was used. Sheaths can fail during use and the level of resulting contamination may not be easily visible**.' (pg. 57)

FDA 2008. Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.

Ultrasound is complex

People
- Doctors
- Nurse Practitioners
- Physician Assistants
- Students
- Technicians
- Sonographers
- Radiologists
- Physical Therapists
  - Allied Health
  - etc.…

Places
- OBGYN/MFM
- Interventional radiology
- Emergency
- Cardiology
- Surgery
- Anesthesiology
- Gastroenterology
  - Musculoskeletal
  - Nephrology
  - etc…

Procedures
- Transvaginal scans
- Transrectal scans
- External surface scans
- Intraoperative scans
- Biopsies
- Drainages
- Aspirations
  - Injections
    - Cannulations
    - etc.…

Probes are widely used in invasive procedures and can involve contact with sterile tissue or mucous membranes

Complex to manage

Varied practices in ultrasound reprocessing across healthcare


American Journal of Infection Control

Ultrasound probe use and reprocessing: Results from a national survey among U.S. infection preventionists

2018, USA. Survey finds ultrasound use is far more widespread than expected.

Ultrasound is used in almost every healthcare department.

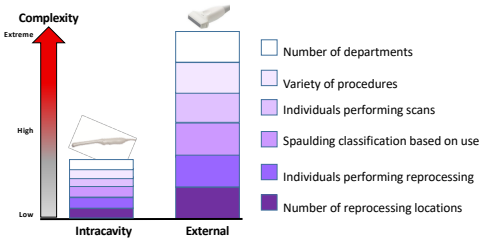
Variability in ultrasound probe disinfection practices for the same procedure across the nation.

How do we begin to standardize probe reprocessing policy and practice rationally?

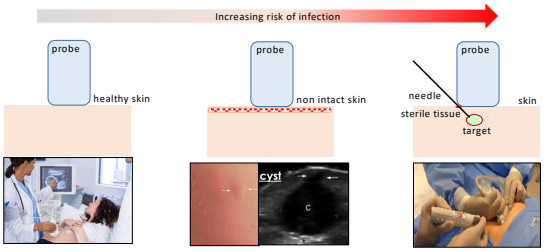
Carrico et al. American Journal of Infection Control 46 (2018) 913-20.

External Ultrasound Probe Reprocessing

External probe reprocessing is more complex than endocavitary probe reprocessing



Example procedures with external ultrasound probes



Scan across healthy skin
eg routine pregnancy

Scan across unhealthy skin
eg epidermal cyst scan

Percutaneous intervention
eg biopsy

The Spaulding Classification

- CDC, FDA, AORN guidelines and AAMI standards use this framework to define requirements for device disinfection and sterilization in healthcare settings.[1-6]
- Healthcare facilities must correctly apply this framework for accreditation (covered in CMS infection control worksheet and TJC standards).[7,8]
- It is a rational approach to disinfection and sterilization of resuable devices based on risk[1,9]
- Framework is so clear and logical that it has been successfully used since its inception in 1968 by reprocessing experts to determine the appropriate level of disinfection or sterilization.[1]

1. Rutala WA, Weber DJ, HICPAC, CDC. Guideline for Disinfection and Sterilization in Healthcare Facilities. 2008.
2. FDA 2000. Content and Format of Premarket Notification (510(k)) Submissions for Liquid Chemical Sterilants/High Level Disinfectants.
3. FDA 2008. Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.
4. FDA 2015. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.
5. AORN. Guidelines for Perioperative Practice
6. CTSE 2013 Chemical sterilization and high-level disinfection in health care facilities.".
7. CMS 2014 Memo re: [illegible]
8. TJC IC Standards Digest
9. Spaulding EH. Chemical disinfection of medical and surgical materials. in Lawrence C, Block SS, editors. Disinfection, sterilization, and preservation. Philadelphia (PA): Lea & Febiger; 1968. p. 517-31.

The Spaulding Classification

Device enters or contacts sterile tissue or the bloodstream
→ CRITICAL

"The first category is that of critical items, so called because the risk is great. They are either introduced beneath the surface of the body or attached to another object which is, i.e., transfer forceps, scalpel blades, cardiac catheters and plastic components of the heart-lung oxygenator."

Device contacts mucous membranes or non-intact skin
→ SEMI-CRITICAL

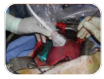
"Materials in the second category are semicritical items...They make direct contact with mucous membranes, but these tissues are intact and therefore constitute barriers to infection."

Device only contacts intact, healthy skin
→ NON-CRITICAL

"The third category consists of noncritical items which do not make contact with the patient or, if they do, only with unbroken skin."

Spaulding EH (1968). Chemical disinfection of medical and surgical materials. Disinfection, sterilization, and preservation. Lawrence C, Block SS. Philadelphia (PA), Lea & Febiger: 517-531.

The Spaulding Classification



Device Classification

Device enters or contacts sterile tissue or the bloodstream

CRITICAL

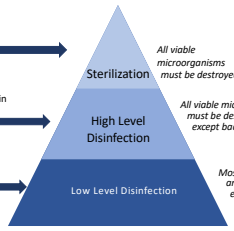
Device contacts mucous membranes or non-intact skin

SEMI-CRITICAL

Device only contacts intact, healthy skin

NON-CRITICAL

Disinfection Level Required



All viable microorganisms must be destroyed.

All viable microorganisms must be destroyed, except bacterial spores.

Most vegetative bacteria and viruses destroyed, except bacterial spores, mycobacteria, fungi, or small non-lipid viruses.

1. CDC 2008. Guideline for Disinfection and Sterilization in Healthcare Facilities.
2. Spaulding EH. Chemical disinfection of medical and surgical materials. In:Lawrence C, Block SS, editors. Disinfection, sterilization, and preservation. Philadelphia (PA): Lea & Febiger; 1968. p. 517-31.

CDC: minimum HLD for probes used in surgery

Ultrasound probes used during surgical procedures also can contact sterile body sites. These probes can be covered with a sterile sheath to reduce the level of contamination on the probe and reduce the risk for infection. However, because the sheath does not completely protect the probe, the probes should be sterilized between each patient use as with other critical items. **If this is not possible, at a minimum the probe should be high-level disinfected and covered with a sterile probe cover.**' (pg. 19)

CDC 2008. Guideline for Disinfection and Sterilization in Healthcare Facilities

FDA reprocessing recommendations for probes used in surgery and in biopsies

'For clinical applications of a **semi-critical or critical nature (e.g., intraoperative**, transrectal, transvaginal, transesophageal, **or biopsy procedures**), labeling should recommend, when appropriate, the use of sterile, legally marketed probe sheaths. Note that the use of sheaths does not change the type of reprocessing that is recommended after each use.' (pg. 17)

'**The probe used in a semi-critical application should be cleaned and sterilized or at least receive high level disinfection** after use even if a sheath was used. **Probes used for critical applications should be cleaned and sterilized after use** even if a sterile sheath was used. Sheaths can fail during use and the level of resulting contamination may not be easily visible.' (pg. 57)

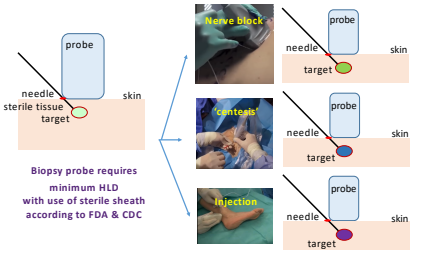
FDA 2008. Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.

Other guidelines

- American Institute of Ultrasound in Medicine (AIUM) changed their guidelines in March 2018 from HLD to LLD for percutaneous intervention
- Contradicts FDA, CDC and Spaulding
- AIUM includes a caveat – "If there is reason to believe that the probe cover may become compromised, the probe must be high-level disinfected prior to the procedure"
- A survey found that 25.4% of interventional radiologists had experienced a needle stick injury in the past year; 75.5% of cases were attributed to operator error[1]

1. Reddy P et al. J Vasc Interv Radiol. 2009;20(8):1070-4 e5.

Application of FDA, CDC and Spaulding to other procedures



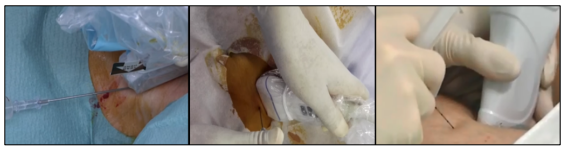
Following Spaulding's rationale, if the probe contacts sterile tissue, then these probes are critical devices.

'Virtual Observation' analysis study

- Purpose of this study was to investigate whether contact with puncture site occurred in routine procedures
- Video stills were analysed from educational YouTube content. The first 100 videos from each procedure search were analysed with selection criteria applied (e.g. probe and needle need to be clearly visible and performed on a real patient).
- Following Spaulding's rationale, if the probe contacts sterile tissue, then these probes are critical use devices. If probe contacts broken sin, probes are semi critical use devices.

Methods – Category definition and assignment

Category A | Category B | Category C



Clear contact between probe and needle puncture

Probe and needle in very close proximity (< 10 mm)

Probe and needle not in very close proximity (> 10 mm)

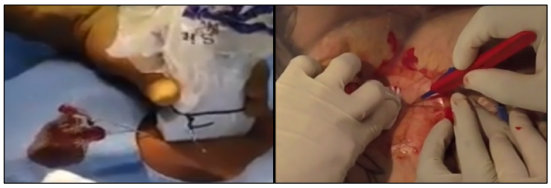
Results – High risk of contact between probe and puncture in 90% of procedures

Table 1: Proximity category assignment results by procedure.

Ultrasound guided procedure category	Search string	Met inclusion criteria (n)	A:* n (%)	B:† n (%)	C:‡ n (%)
Biopsy	Ultrasound guided biopsy	21	9 (43%)	10 (48%)	2 (10%)
Nerve block (NB)	Ultrasound guided nerve block	29	9 (31%)	12 (41%)	8 (28%)
Drainage	Ultrasound guided drainage	10	5 (50%)	4 (40%)	1 (10%)
Central venous catheter insertion (CVC)	Ultrasound guided central venous catheter	18	9 (50%)	8 (44%)	1 (6%)
Peripheral venous access	Ultrasound guided peripherally inserted central catheter <search 1> Ultrasound guided peripheral IV <search 2>	36	21 (58%)	13 (36%)	2 (6%)
	Total, Average: n (%)		53 (50%)	47 (40%)	14 (10%)

* Category A: Clear contact between ultrasound probe and needle or puncture site.
† Category B: Ultrasound probe is in very close proximity (<10mm).
‡ Category C: Ultrasound probe is not in close proximity (>10mm).

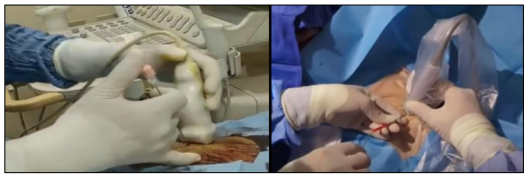
Results – Examples of clear contact (Category A)



Internal jugular vein central venous catheter insertion

Central venous catheter insertion

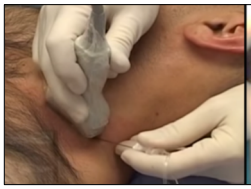
Results – Examples of clear contact (Category A)



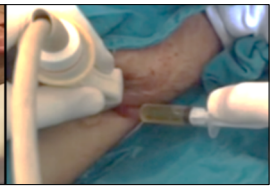
Liver abcess drainage

Pericardiocentesis

Results – Examples of clear contact (Category A)



Interscalene block



Thoracentesis

Takeaways from virtual observation

- Analysis shows regular contact between needle and probe
- Important for facilities to review and observe their use of ultrasound to guide procedures and apply Spaulding
- When developing policies, prioritize evidence based guidelines and standards promulgated by standards development agencies recognized by TJC and CMS.
- Where risks to the patient exist, reviews and risk assessments should be conducted to maximise patient safety.

Practicalities of implementation in vascular access

- There are some procedures where routine HLD of probes used in percutaneous interventions would be more difficult
- Example: mobile vascular teams – there is currently no practicable solution for mobile HLD
- Institutions should review what they should do for these procedures
- AVA guidelines recommend LLD + sheath, however include a caveat that recommends HLD:

> "14. In the event ongoing process monitoring identifies cleaning and disinfectant failure(s), adverse patient outcomes that may be attributable to transducer reprocessing methods, or user techniques that demonstrate risk to the use of Low Level Disinfection (e.g., needlestick injuries, damage to transducer/probes, punctures of sheaths during procedures) existing approaches should be re-evaluated with consideration of operational and organizational changes including centralization of cleaning and disinfection, use HLD, or other changes that serve to protect the safety of the patient. "

AVA 2018. Transducer Disinfection for Assessment and Insertion of Peripheral and Central Catheters for Vascular Access Teams and Clinicians.

Practicalities of implementation

- This is a complex issue that needs collaboration between IPs, reprocessing experts, risk management experts, quality experts, patient safety experts, department heads and staff.
- Working together to discuss, observe procedures and review or write policy takes time.
- A group of experts has developed some tools to help IPs initiate these processes to work toward the common goal of patient safety.

Solutions

Ultrasound Infection Prevention toolkit

www.ultrasoundinfectionprevention.org

Introducing the Ultrasound IP Toolkit

- Four free practical tools designed by a group of concerned IPs and device reprocessing experts to help users meet existing evidence-based guidelines and standards.
- Editable to comply with institutional, local, state and regional policies/guidelines.

Contributors

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Accessing the toolkit

www.ultrasoundinfectionprevention.org

Instructional video by Amy Nichols RN MBA CIC presented at APIC 2018 National Conference

35

Accessing the toolkit

www.ultrasoundinfectionprevention.org

Download all 4 tools as a zip file

Download tools individually

Option to sign up for updates as more tools are posted

36

Tool 1 – First locate ultrasound machines

Strategy	Rationale	How	Limitations
1. Locate where ultrasound machines are by searching the organization's asset register.	Clinical/Biomedical Engineering department maintains an asset register of equipment used throughout the facility. The asset register links the ultrasound machine and associated service contracts to department locations.	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.	• 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 is being used 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 probes covers will lead to the departments using ultrasound probes.	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.	• 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).
3. Survey departments to identify where ultrasound is used.	End users are the best placed to know where ultrasound is being used.	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.	• 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 billable ultrasound procedures in financial records.	Ultrasound procedures should be billed. If ultrasound procedure item codes are obtained, they can then be used to identify which departments or providers are billing for those items.	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.	• Billing may not provide department specific information. • The finance system may not be setup to readily perform these searches. • It may be difficult to determine which item codes are associated with ultrasound procedures or probes.

37

- Example strategies are listed
- Ordered by assumed effectiveness
- All can be used in combination to locate all your machines

Tool 1 – Profile procedure policy and practice

Tool 1: Part B – Profile

Profile policy and practice for each ultrasound procedure at your facility.

Procedure	Department	Room	Date	Assessor

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

□ Yes. **Go to Q2.** □ No. **Go to Q4.**

2. Read Your Policy. How does the policy indicate the probe should be reprocessed and used for this particular procedure?

Reprocessing:	□ Sterilized	□ HLD	□ LLD/ILD	□ Not specified
Cover use:	□ Sterile	□ Single use non-sterile	□ None	□ Not specified
Gel use:	□ Single use sterile	□ Single use non-sterile	□ Multiuse bottle	□ Not specified

3. Assess Your Policy. Is the policy consistent with manufacturer instructions for use and guideline recommendations for this procedure? Refer to Tool 2 for procedure specific information.

□ Yes □ No, but policy contains justification for deviation □ No

- Checklist guides user through reviewing policy and procedures
- Visit department and read policy
- Record how policy directs user to disinfect and use probe
- Determine if policy complies with guidelines (see Tool 2)

Tool 1 – Profile procedure policy and practice

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

Reprocessing:	□ Sterilized	□ HLD	□ LLD/ILD
Cover use:	□ Sterile	□ Single use non-sterile	□ None
Gel use:	□ Single use sterile	□ Single use non-sterile	□ Multiuse bottle

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

□ Yes □ No □ No policy in place

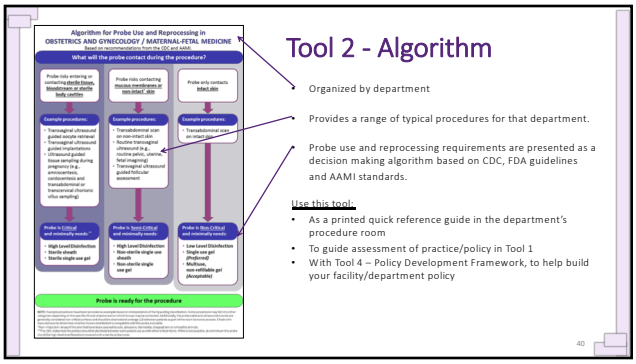
6. Were any shaded options selected?

□ Yes. **Go to Q7.** □ No. Congratulations, your policy and practice are compliant. No further action needed. File this form, ensure ongoing training for all users.

7. Action Plan Required. Your policy needs updating or users are not trained according to your policy/procedure. Note action and effectiveness review date below for each shaded option.

Effectiveness Review Date: ___/___/_____

- Observe how users reprocess and use probe in practice
- If shaded boxes selected, action plan required due to discrepancies between policy, practice and guidelines



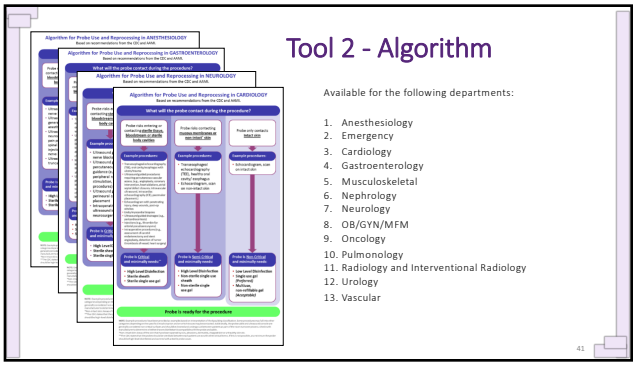
Tool 2 - Algorithm

- Organized by department
- Provides a range of typical procedures for that department.
- Probe use and reprocessing requirements are presented as a decision making algorithm based on CDC, FDA guidelines and AAMI standards.

Use this tool:

- As a printed quick reference guide in the department's procedure room
- To guide assessment of practice/policy in Tool 1
- With Tool 4 – Policy Development Framework, to help build your facility/department policy

40



Tool 2 - Algorithm

Available for the following departments:

1. Anesthesiology
2. Emergency
3. Cardiology
4. Gastroenterology
5. Musculoskeletal
6. Nephrology
7. Neurology
8. OB/GYN/MFM
9. Oncology
10. Pulmonology
11. Radiology and Interventional Radiology
12. Urology
13. Vascular

41

Tool 3 – Example risk assessment

- Designed to assess potential hazards that may be encountered during the use and reprocessing of ultrasound probes
- Use to assess safety of existing processes and processes under consideration
- Consider new products/processes if mitigations cannot be reduced to low
- Not all rows in example may be relevant to your specific situation – those rows can be deleted and other rows can be added
- 4 templates: cleaning, disinfection, storage and use

Tool 3 – Example risk assessment

- An example risk matrix is provided
- Facility may have standard risk matrix which can be used

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

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

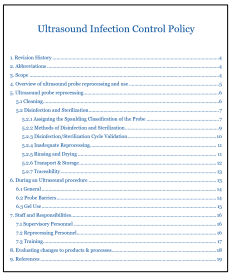
Severity = seriousness of harm

Likelihood x Severity = Risk

Tool 3 – Example risk assessment

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/sterilizatio n 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
	Key parameters not met during disinfection/ sterilization of probe leading to failed cycle: • Incorrect	Pathogens may remain on the				• Following the manufacturer's instructions for use with respect to disinfection/sterilization protocol. • Using a validated, automated disinfection/sterilization method that	

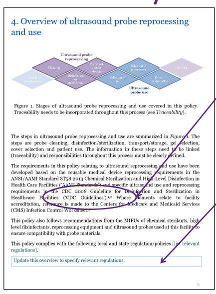
Tool 4 – Policy development framework


Ultrasound Infection Control Policy

- This tool provides the framework to help develop an ultrasound infection prevention policy
- Comprehensive document covering all aspects of probe reprocessing, probe use and staff training.
- Completely editable document to address different departments and facilities.
- Developed based on major evidence based guidelines, standards and scientific literature.

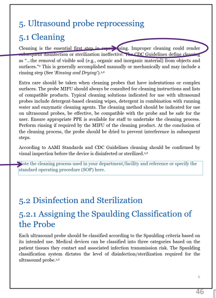
45

Tool 4 – Policy development framework


4. Overview of ultrasound probe reprocessing and use

Referenced

Blue instructional boxes to help you edit and customize for your facility or department


5. Ultrasound probe reprocessing

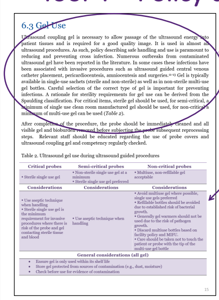
5.1 Cleaning

5.2 Disinfection and Sterilization

5.2.1 Assigning the Spaulding Classification of the Probe

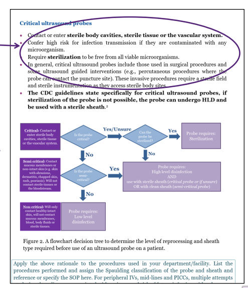
46

Tool 4 – Policy development framework


6.3 Gel Use

Provides background info on ultrasound reprocessing topic

Figures and tables summarizing considerations


Critical ultrasound probes

47

Summary

- There is risk from ultrasound procedures
- Risk is compounded by the complexity of ultrasound – variety of departments, procedures and end users
- Follow federal guidelines and national standards and apply the Spaulding classification to standardize your disinfection practices
- Download and use the toolkit to help assess, evaluate and create your facility policy

Ultrasound Infection Prevention toolkit

www.ultrasoundinfectionprevention.org

48

Ultrasound Infection Prevention

Risks, Challenges and Solutions

Thank you, Questions?