**How to Choose when to HLD your Ultrasound Probe**

**Risk Based Classification for Disinfection**

It is very important that reusable medical devices are safely reprocessed (cleaned, disinfected/sterilized) between each patient to prevent infection transmission.

Classifying ultrasound probes based on risk associated with intended use provides a rational framework for associated decontamination methods (sterilize, high level disinfection and low level disinfection).

One such framework is the Spaulding Classification for determining the associated decontamination method required for reusable medical instruments according to the degree of infection transmission risk.

Devices that only contact intact skin are considered ‘non-critical’ requiring low level disinfection (inactivates bacteria, some fungi and some viruses). Devices that contact unhealthy skin or mucous membranes are considered ‘semi-critical’ requiring high level disinfection (inactivates bacteria, fungi, viruses with a few spores remaining). Devices which contact or enter sterile tissue, body fluids or vasculature are considered ‘critical’ requiring sterilization (inactivates all viable microorganisms).

Guidelines released locally by the Royal Society & College of Radiographers and the British Medical Ultrasound Society, Ireland’s Health Service Executive, NHS Scotland and regionally by the European Committee for Medical Ultrasound Safety and the European Society of Radiology, all make use of the widely adopted Dr. Spaulding Classification (or derivatives thereof) to form a consensus for when to high level disinfect ultrasound probes based on their use and patient contact sites. 2-7 Table 1 overleaf summarizes their recommendations.

While the Spaulding Classification is a good general classification system for devices, ultrasound probes have specific usage and reprocessing factors that also need to be considered (Table 1).

| DR. SPAULDING CLASSIFICATION | PROBE CAN CONTACT | DISINFECTION\| STERILIZATION REQUIREMENTS | EXAMPLES OF PROCEDURES |
|---|---|---|---|
| **CRITICAL** | ➢ Sterile Area<br>➢ Tissues<br>➢ Blood<br>➢ Body Cavities | Sterilization + (cover optional. If used, cover must be sterile)<br><br>Or<br><br>HLD + Sterile Cover | ○ Intraluminal<br>○ Intraoperative<br>○ Biopsy<br>○ Puncture Techniques<br>○ Non-Invasive probe-guided cannulation/venipuncture **<br>○ Non-Invasive probe guided wound assessment |
| **SEMI-CRITICAL*** ** | ➢ Internal organs via non-sterile natural orifices<br>➢ Blood contact expected occurs during procedure<br>➢ Mucous membranes<br>➢ Non-intact, broken skin | HLD + cover (preferable sterile) | ○ Transoesophageal echocardiography (TOE)<br>○ Transvaginal ultrasound (TV)<br>○ Transrectal ultrasound (TR)<br>○ Non-invasive probe-guided cannulation/venipuncture<br>○ Non-invasive probe-guided wound assessment |
| **NON-CRITICAL Non-Invasive**** ** | ➢ Only Healthy Intact Skin | Cleaning and or Low or Intermediate Level Disinfection (cover optional) | ○ Abdominal ultrasound, healthy skin<br>○ Pelvic ultrasound healthy skin |

Many ultrasound probes cannot be sterilized and accordingly most guidelines permit high level disinfection in lieu of sterilization for 'critical' probes so long as a sterile sheath is also used. Both endocavitary and surface probes are often used in conjunction with a sheath or condom. Importantly, guidelines state that use of a sheath (or condom) does not replace the need for disinfection as sheaths (and condoms) can have microscopic tears and can break during use.

It is important that this classification system is applied before the procedure commences. This means that information about what tissues or body sites may be contacted, is required in advance, so that an

appropriately disinfected or sterilized probe can be selected. Furthermore, there is a strong preference in guidelines for automated, validated reprocessing procedures.

**The Essential for Acceptable Reprocessing**

Ultrasound usage in the United Kingdom has increased significantly with diagnostic procedures in England rising over 24% from 7 million to 9.3 million over five years.

Ultrasound probes, as with all reusable medical devices, carry infection risks and a number of infections have been attributed to improper use and reprocessing. A fatal hepatitis B infection contracted during a transoesophageal procedure led to a Medicines and Healthcare products Regulatory Agency alert requesting all users to review their decontamination procedures.

Furthermore, a retrospective cohort study by NHS Scotland and Health Protection Scotland demonstrated an infection risk when high level disinfection was not performed for endocaviatry procedures. The study found that patients undergoing transvaginal scans with low level disinfection probes, were 41% more likely to have positive bacterial cultures compared to matched patients not undergoing ultrasound procedures.

The need for standardized infection control procedures is paramount to improving patient outcomes in healthcare settings. With increasing applicability of ultrasound and subsequent increase in ultrasound procedures, infection control becomes increasingly more important.

Proper application of the Dr. Spaulding Classification system and adherence to local guidelines will ensure an adequate level of disinfection is performed and will protect patients from infection risk.

*Reference: MM08-12-UK-FY Spaulding Clinical BulletinLR*

Prepared by:
**Virgilio "Tom" Jackson Casinares**,
PhD.H | CSSD International Certified American, European and Middle Eastern
**Juan Carlos Floresca**,
BSN, CRCST, CIS, CER, Dubai DHA CSSD Certified, DHCC CSSD Certified
**Rommel Failana**,
RN, CRCST, UAE MOH CSSD Certified