3rd WHO Global Forum on Medical Devices
Wednesday 10 May 2017, Geneva (Switzerland)

ISR session on Good practice in Ultrasound probe cleaning

Update on probe cleaning technologies

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DITTA is a non-profit trade association, created in 2000 and incorporated in 2012 represents more than 600 companies around the globe.

DITTA covers the following industry sectors:
1. Diagnostic imaging,
2. Radiation therapy,
3. Healthcare IT,
4. Electromedical
5. and Radiopharmaceuticals

Our Industry leads in state-of-art advanced technology and provides integrated solutions covering the complete care cycle.
7.9.2.12 For ME EQUIPMENT parts or ACCESSORIES that can become contaminated through contact with the PATIENT or with body fluids or expired gases during NORMAL USE, the instructions for use shall contain:

- details about cleaning and disinfection or sterilization methods that may be used; and
- list the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that such ME EQUIPMENT parts or ACCESSORIES can tolerate.
- a list of the pertinent parts, components and/or functions that should be checked after each cleaning, disinfection or sterilization cycle, and method(s) of inspection.

This requirement does not apply to any material, component, ACCESSORY or ME EQUIPMENT that is marked as intended for a single use unless the MANUFACTURER specifies that the material, component, ACCESSORY or ME EQUIPMENT is to be cleaned, disinfected or sterilized before use (see 7.2.1).
11.6.7 Sterilization of ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized shall be assessed and documented according to ISO 11135-1, ISO 11137-1 or ISO 17665-1 as appropriate. See also 7.9.2.12.

After these PROCEDURES, the ME EQUIPMENT, ME SYSTEM and their parts or ACCESSORIES are to show no signs of deterioration that could result in an unacceptable RISK (visual inspection) followed by the appropriate dielectric strength and LEAKAGE CURRENT tests and by inspection of the RISK MANAGEMENT FILE.
ISO 17664:2004: sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices. The principles of ISO 17664:2004 may be applied when considering the information to be supplied with medical devices which only require disinfection prior to re-use.

European Medical Devices Directive 93/42/EEC and 2007/47/CE: CE marking is the manufacturer’s declaration that the product meets the requirements of the applicable EC directives.

FDA Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Guidance for Industry and Food and Drug Administration Staff

EPA and FDA lists of disinfectants

Industry Guidance examples:

ZVEI: Medical Device Reprocessing Requirements: Manufacturer responsibilities and operator responsibilities

ZVEI: Specific guidance on reprocessing of special probes: Hygiene-Anforderungen bei der Aufbereitung von transvaginalen und transrektalen Ultraschallsonden

EPA and FDA lists of disinfectants
ULTRASOUND PROBES
CLASSIFICATION BASED ON SPAULDING SCHEME

Critical devices
Enter body tissue, surgical openings (e.g., surgical instruments)
Must be Sterilized; if not feasible, High Level Disinfection (HLD) with sterile cover
Laparoscopic, intra-operative transducers

Semi-critical devices
Contact mucous membranes (e.g., flexible endoscopes)
Should be Sterilized; if not feasible, High Level Disinfection
Trans esophagus, Transvaginal/Transrectal transducers

Non-critical devices
Contact intact skin (e.g., stethoscopes, electrocardiogram electrodes)
Intermediate Level Disinfection (ILD) or Low Level Disinfection (LLD)
Surface contact transducers

All devices must be cleaned first!
APPROVAL OF DISINFECTANTS AND PROCESSES

• There are several hundreds validated commercially available disinfectants from many manufacturers.
• Many regulations at global level makes hard to find the same disinfectant all over the globe.
• Global approval process for a disinfectant is very long for manufacturers, due to the high number of ultrasound probes (hundreds) and of disinfectants.
• Only a few disinfectants per year can be approved by manufacturers due to the extensive testing required.
• Specific formulations are approved as different additives in different formulations may not be compatible.
11.6.6 Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT, ME SYSTEMS and their parts, including APPLIED PARTS and ACCESSORIES, shall be capable of withstanding, without damage or deterioration of safety provisions, the cleaning or disinfection PROCESSES specified in the instructions for use. See also 7.9.2.12.

The MANUFACTURER shall evaluate the effects of multiple cleanings/disinfections as indicated in the instructions for use during the EXPECTED SERVICE LIFE of the ME EQUIPMENT, ME SYSTEM, their parts and ACCESSORIES and assure that these PROCESSES do not result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE.

Where compliance with this standard could be effected by cleaning or disinfecting the ME EQUIPMENT, ME SYSTEM and their parts and ACCESSORIES, they are cleaned or disinfected once in accordance with the methods specified including any cooling or drying period. After these PROCEDURES, the ME EQUIPMENT, ME EQUIPMENT parts or ACCESSORIES are to show no signs of deterioration that could result in an unacceptable RISK (visual inspection) followed by the appropriate dielectric strength and LEAKAGE CURRENT tests.

The RISK MANAGEMENT FILE is inspected to verify that the MANUFACTURER has evaluated the effects of multiple cleanings.
In addition to Instructions for Use, manufacturers have specific websites and guidance available for users. For example:

- Philips: Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers
- Philips: Care and Cleaning of Ultrasound Systems and Transducers
- Hitachi manual: “Reprocessing Instruction according to DIN EN ISO 17664:2004”
1. Only probes that have been effectively cleaned can be disinfected

2. Use only disinfectants approved by the manufacturer and indicated by the manufacturer himself. Failing to do so may result in damaging the probes.

3. Follow the disinfection process indicated by the manufacturer as it is validated to ensure proper disinfection even if a protective cover is used

4. Follow the manuals provided by the manufacturer

5. In case of doubt always contact the manufacturer and discuss about alternative chemicals or processes

6. In case alternative disinfectants or processes are used, the user shall conduct a risk assessment

7. For 3rd party probes the relative disinfectants and processes shall be used
THANK YOU!

www.globalditta.org