Sustainable Competence in Advancing Healthcare

ECR 2017 | EUROPEAN CONGRESS OF RADIOLOGY
Vienna/Austria | March 1-5

WG 3 - ESR WORKING GROUP ON ULTRASOUND

Minimizing the risk of cross infection: How to keep patients safe in ultrasound

ECR 2017

Thursday 2 March 2017 Vienna @ 8:30

INDUSTRY PERSPECTIVE

Nicole Denjoy
COCIR Secretary General

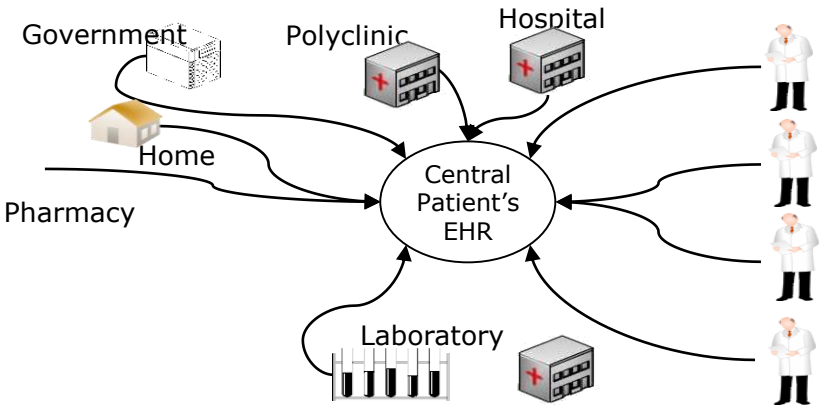
INDUSTRY SECTORS COVERED BY COCIR

COCIR is a non-profit trade association, founded in 1959 and having offices in Brussels and China, representing the medical technology industry in Europe

COCIR covers 4 key industry sectors:

- Medical Imaging
- Radiotherapy
- Health ICT
- Electromedical

Our Industry leads in state-of-art advanced technology and provides integrated solutions covering the complete care cycle



30 COCIR COMPANY MEMBERS

14 COCIR NATIONAL TRADE ASSOCIATIONS MEMBERS

AGORIA no future without technology — BELGIUM

FiHTA — FINLAND

snitem creating the tools for medical progress — FRANCE

bvitg — GERMANY

ZVEI: — GERMANY

ETOSZ ASSOCIATION OF HEALTH TECHNOLOGY SUPPLIERS AND MEDICAL DEVICE MANUFACTURERS — HUNGARY

ASSOBIOMEDICA — ITALY

apormed tecnologias para a saúde — PORTUGAL

FHI MEDICAL TECHNOLOGY — THE NETHERLANDS

Holland HealthTech — THE NETHERLANDS

federación española de empresas de tecnología sanitaria fenin — SPAIN

SWEDISH Medtech — SWEDEN

TIP GÖR DER — TURKEY

AXREM — UNITED KINGDOM

COCIR AT INTERNATIONAL LEVEL

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

2016: DITTA MoU with the World Bank
2015: DITTA was granted a NGO status with WHO
2014: DITTA has official liaison with AHWP

SUMMARY

1. Standards on disinfection
2. Regional and national regulations and guidance
3. Ultrasound probes classification
4. Approval of disinfectants and processes
5. Manufacturers' instructions for users
6. COCIR recommendations to users

STANDARDS ON DISINFECTION

IEC 60601-1 Ed 3.1 and IEC 60601-2-37** Ed 2.1*

- 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).

**IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
***IEC 60601-2-37 : Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment*

STANDARDS ON DISINFECTION

IEC 60601-1 Ed 3.1 and IEC 60601-2-37 Ed 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.

STANDARDS ON DISINFECTION

Other standards

- **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.

- **AAMI TIR No. 12—2010:** Designing , Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers.

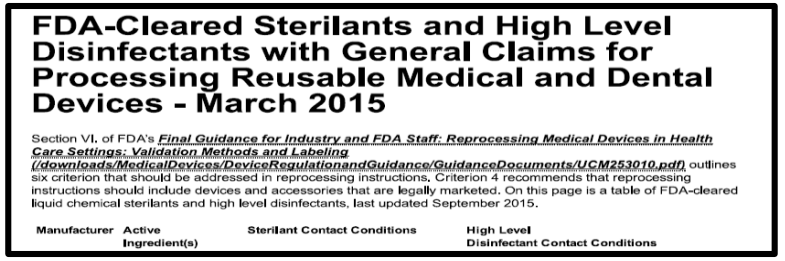
DISINFECTION

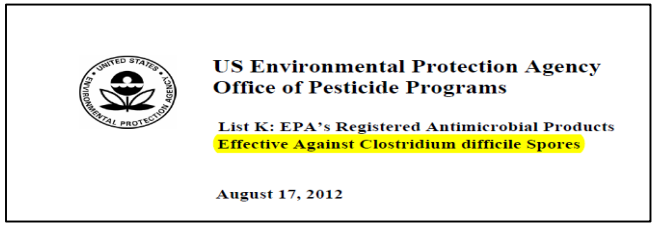
Examples of Regional and national regulations/guidance

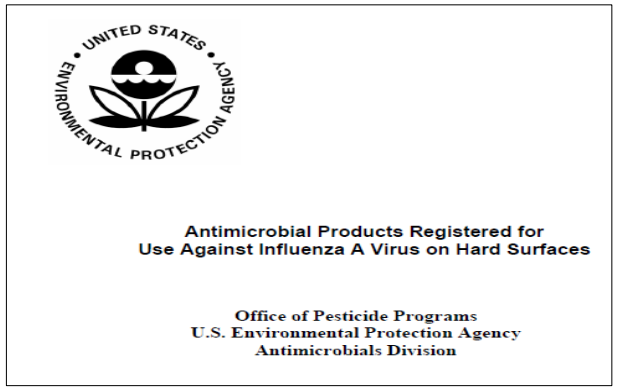
- **European Medical Devices Directive** 93/42/EEC and 2007/47/CE: CE marking is the manufacturer's declaration that the product meets the requirements of the applicable EC directives.
- **FDA Guidance:** Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Guidance for Industry and Food and Drug Administration Staff
- **EPA and FDA lists of disinfectants**

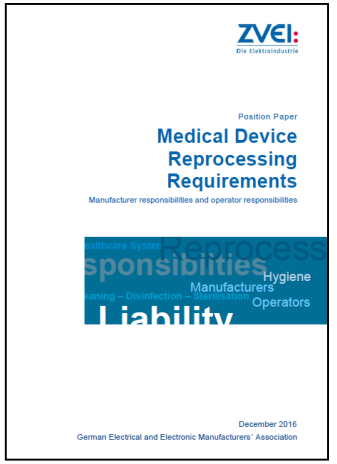
<u>Industry Guidance examples:</u>

- **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









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.

Examples of lists of validated chemicals for disinfection

APPROVAL OF DISINFECTANTS AND PROCESSES

IEC 60601-1 Ed 3.1 and IEC 60601-2-37 Ed 2.1

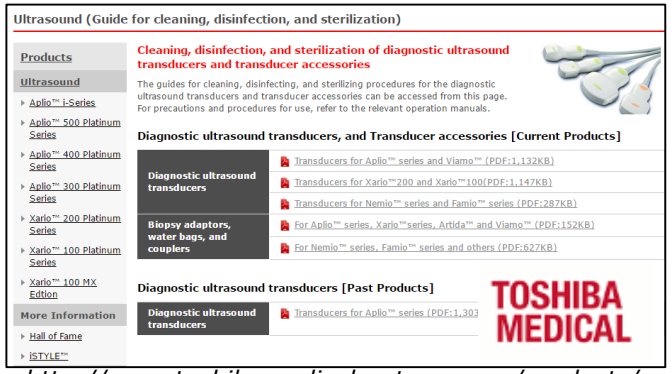
11.6.6 Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

- 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.

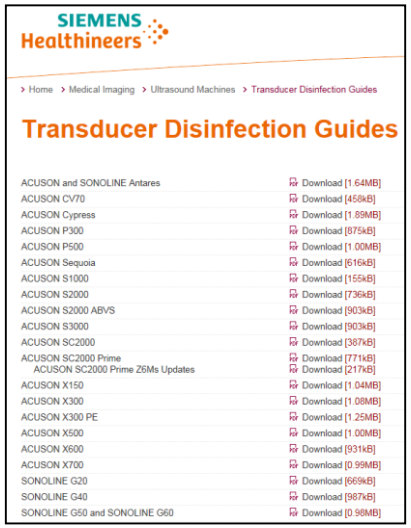
MANUFACTURERS' INSTRUCTIONS

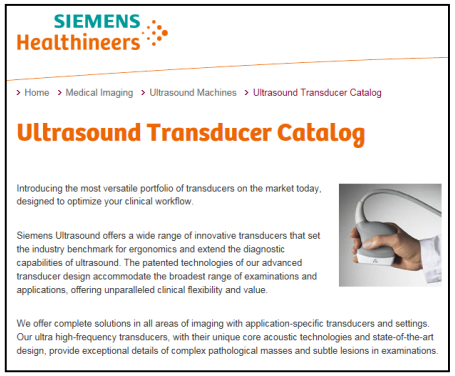
In addition to Instructions for Use, manufacturers have **specific websites and guidance** available for users. For example:

http://www.usa.philips.com/healthcare/resources/feature-detail/ultrasound-care-and-cleaning

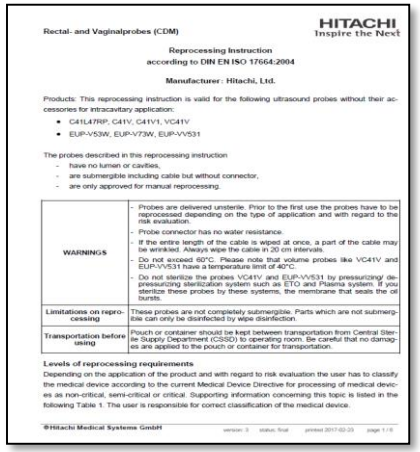


http://www.toshibamedicalsystems.com/products/us/cleaning/

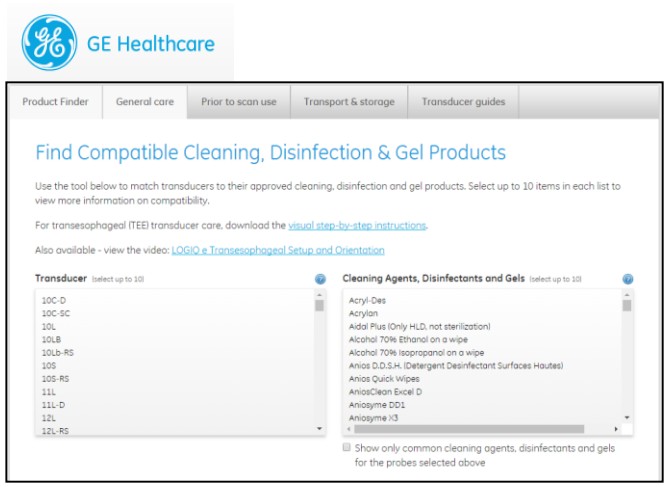




https://www.healthcare.siemens.com/ultrasound/transducer-disinfection-guides



HITACHI manual : "Reprocessing Instruction according to DIN EN ISO 17664:2004"



http://www3.gehealthcare.com/en/products/categories/ultrasound/ultrasound_probes

COCIR RECOMMENDATIONS TO USERS

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

COCIR

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Thank You!

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