Esaote Ultrasound Systems Cleaning and Disinfection in the Event of COVID-19 Emergency

Foreword

This document is issued as an emergency process in response to the outbreak of Coronavirus Disease 2019 (COV-ID-19) with the aim of preventing virus transmission and to clarify on-site cleaning and disinfection of Esaote Ultrasound Systems.

A similar document has been prepared specifically for Esaote Ultrasound Probes (see References).

These guidelines are only a reference for use in the current COVID-19 pandemic. They complement, and do not replace, the indications already contained in the existing manuals included with your Esaote Ultrasound System.

Ultrasound system cleaning and disinfection procedure

General recommendations

Cleaning and disinfection should be in compliance with the general instructions of the infection control depart-

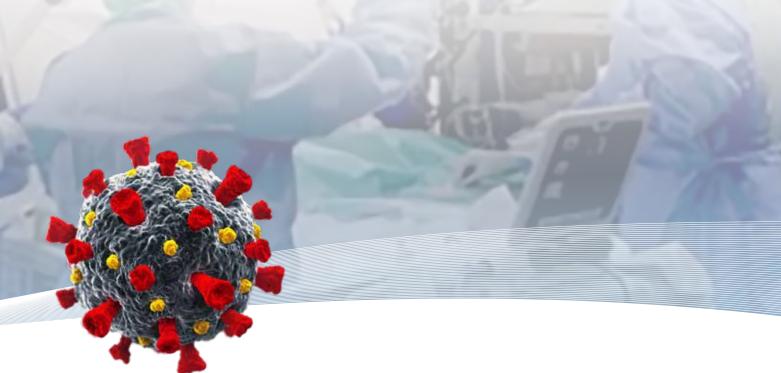
Wear single use Personal Protective Equipment (PPE) such as a face mask, eye protection, apron and sterile gloves according to local guidelines; at the end of the procedure dispose of PPE as instructed by local infection control directives.

Remove any non-essential accessory equipment from the Ultrasound System, such ECG cables, disposable ECG stickers, paperwork, gel and any other items to facilitate thorough cleaning and disinfection and to minimize risks for cross contamination.

Recommended products for cleaning and disinfection

The recommended products for cleaning and disinfecting are the following and belong to the: *List N: Disinfectants for Use Against SARS-CoV-2*, by the Environmental Protection Agency (EPA).

	EPA Registration Number	Product Name	Company	Formulation Type
	9480-5	Sani-cloth Active Germicidal Disposable Cloth	Professional Disposables International Inc	Wipe
	46781-13	Caviwipes 1	Metrex Research	Wipe
	46781-6	Cavicide	Metrex Research	Ready to use



Cleaning and disinfection procedure

Proceed as follows:

- 1. Turn the system power OFF and disconnect the power cable plug from the power outlet.
- 2. Use the selected product directly if it comes in a wipe format or moisten a piece of soft cloth and squeeze it lightly (e.g. in the case of Cavicide), and wipe the surfaces of the unit. Refer to the disinfectant manufacturer's instructions. Thoroughly clean and remove any residual material and stains.
- 3. After chemical disinfection, allow the surface of the system to dry completely. Do not heat the unit to dry
- 4. Check that the disinfected parts are not damaged or

After disinfecting the system, ventilate the room before turning ON the system.

Cleaning and disinfection procedure with readily available products

Since availability of the recommended products may not be guaranteed, a disinfection procedure using products that are readily available in hospitals and health facilities is recommended. Follow the general recommendations given above for cleaning and disinfection with step 2 modified as follows:

• Moisten a piece of soft cloth with ethanol in 60 to 70% solution, squeeze it lightly, and wipe the surface of the unit. Be careful not to allow the solution to enter the unit. Refer to the disinfectant manufacturer's instructions. Thoroughly clean and remove any residual material and stains. Isopropyl alcohol (70 vol%) or sodium hypochlorite (0.2% solution) may be used in place of ethanol.

After disinfecting the system, ventilate the room before turning ON the system.

This procedure is intended as an emergency process and it does not replace the cleaning and disinfection instructions given in the user manuals. The long term effects of this procedure have not been tested and may compromise the durability of paints and marks on the system. Since sodium hypochlorite is more aggressive, touchscreens and monitors should be cleaned using ethanol or isopropyl alcohol where available.

Use of plastic covers for the Ultrasound Systems

Plastic covers for the Ultrasound System, its touchable parts (knobs, screen) are commercially available and may be considered in order to reduce bioburden on these "high touch" surfaces with hard-to-clean grooves and slots.

The operator has to pay attention not to cover the screen in a way that reduces the view for the echocardiographer. This may reduce the quality of the study and increase scan duration. Similarly, the keyboard should be fully operative during the investigation.

The use of plastic covers can be applied only on Ultrasound Mobile Systems with the precaution not to cover any fan of the system to avoid overheating and subsequent damage. Do not apply on Ultrasound Portable Systems, unless they are put on a cart. In any case the System must be switched off and plastic covers have to be removed and disposed of as soon as the examination is completed, according to the relevant local guidelines. The operator must not obstruct the system's cooling air inlet. Please contact Esaote support for further information about their locations.

References

Please refer to the websites and documentation below for more information

World Health Organization (WHO)



Infection prevention and control during health care when novel coronavirus (nCoV) infection is suspected https://www.who.int/publications-detail/infectionprevention-and-control-during-health-care-when-novelcoronavirus-(ncov)-infection-is-suspected-20200125

> Centre for Disease Control (CDC) USA Interim Guidance for Healthcare Facilities: Preparing for Community Transmission of COVID-19 in the United States



https://www.cdc.gov/coronavirus/2019ncov/hcp/guidance-hcf.html?CDC_AA refVal=https%3A%2F%2Fwww.cdc. gov%2Fcoronavirus%2F2019-ncov%2Fhealthcarefacilities%2Fguidance-hcf.html

Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings



https://www.cdc.gov/coronavirus/2019-ncov/ hcp/infection-control-recommendations. html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc. gov%2Fcoronavirus%2F2019-ncov%2Finfectioncontrol%2Fcontrol-recommendations.html



Environmental Protection Agency (EPA) USA https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2

List N: Disinfectants for Use Against SARS-CoV-2



ESAOTE Ultrasound Systems Manuals www.esaote.com

IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, Ed. 3.1

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