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

Ultrasound is among the imaging techniques that involves the greatest interaction between physician and patient. This greatly benefits diagnostics, allowing continuous interaction and a fruitful exchange of information between doctor and patient.

Unfortunately, in these times of emergency due to COVID-19, this previously positive aspect of ultrasound now has a potentially negative aspect. Unless it is carried out safely, it could present an increased risk of infection among physicians and patients. This is even more dangerous if it occurs inside hospitals or emergency areas, where the patient has not been fully investigated and the most favorable conditions for COVID-19 transmission are then established. Hence the need to provide specific instructions for the sanitization of ultrasound devices (probe + system).

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 manual relating to the reprocessing of non-critical probes (all convex, linear, phased models in use on intact epidermis).

The prescriptions and products/ reprocessing methods, contained in the Probe & Consumable manual code 141003500 version R17 or higher, remain unchanged for the semi-critical probes (endocavitary, bi-plane and TEE) and for the critical probes (intra-operative or laparoscopic). If used in a COVID-19 risk environment, all these probes should be subjected to the COVID-19 disinfection treatment indicated below for non-critical probes before reprocessing.

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General protection
and disinfection guidelines

SIRM, SIUMB, and FISM have issued guidelines [1] for the procedure of ultrasound examinations to ensure execution guaranteeing the safety of both operators and patients in the conditions during these critical times.

The settings **"outpatient"** on patients classified as oncological/urgent (non-COVID path):

- All patients should be considered at risk of COVID-19 transmission.
- The probe, covered with a cover or glove, must be sanitized with a suitable disinfectant agent after each patient.

The setting **"COVID-19 under investigation"** (patients awaiting COVID-19 assessment test), SIRM, SIUMB, and FISM recommend:

- Coverage of the ultrasound system with a washable keyboard cover or plastic and of the probe with a cover or glove. The probe cover must be changed after each patient to prevent transmission of the infection.
- In addition, disinfect the probe and ultrasound system after the end of the procedure in readiness for a new procedure.

The setting **"COVID-19 already established"** SIRM, SIUMB, and FISM recommend:

- Coverage of the ultrasound system with a washable keyboard cover or plastic and of the probe with a cover or glove. The probe cover must be changed after each patient to prevent transmission of the infection.
- In addition, disinfect the probe and ultrasound system after the end of the procedure in readiness for a new procedure.

In relation to findings of real situations in departments and the risk assessments, it is concluded that the recommendations of SIRM, SIUMB, and FISM should be implemented in an even more restrictive way in terms of disinfecting the devices, and to proceed in the following ways.

- The setting **"COVID-19 under investigation"** takes place in the manner recommended by SIRM, SIUMB, and FISM but with an additional risk minimization condition: to replace the probe cover and ultrasound system cover and to sanitize both after each patient (practically every patient is to be considered a "procedure" as the status of the next patient is unknown).
- The setting **"outpatient"** on patients classified as oncological/urgent is to be implemented, for greater safety, as provided for the Setting "COVID-19 under investigation."
- The setting **"COVID-19 already established",** in the case of patients not in the COVID-19 ward, follows the same rules established for the COVID case under investigation. For patients in the COVID department, it is sufficient to implement complete coverage of the ultrasound and, where possible, of the probe. Remove covers and proceed to disinfect the ultrasound system and probe immediately after the end of the procedure (sequential execution of examinations on all patients) to be ready for a new procedure.

COVID-19 **disinfection products**

The products suitable for disinfection are identified on the basis of their disinfectant efficacy on viruses, and in particular on those of COVID type [2,3,4,5], as specific studies on COVID-19 do not yet exist.

Furthermore, we must take into account the additional boundary conditions determined by the actual realities in which healthcare workers are operating today:

- Disinfection times must be as fast and effective as possible, also because more than one examination series per day may be required and the system cannot be blocked for a long time.
- The disinfection procedure must be simple, agile, and as far as possible on site to be performed by any healthcare professional simply by following the instructions for use.
- The hospital cannot afford to obtain new agents or systems (also because they are difficult to find today) and therefore the one that is most easily available in any health facility must be used.

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Suitable and easier to access products

Human coronaviruses can remain infectious on inanimate surfaces (such as metal, glass or plastic) up to 9 days (although, presumably, with a reduced charge, but there are still no specific confirmation studies in this regard) [3]. Surface disinfection with 0.1% sodium hypochlorite or 62-71% ethanol (ethyl alcohol) significantly reduces the infectivity of coronavirus on surfaces within 1 minute of exposure [2,3,4,5]. We expect a similar effect against SARS-CoV-2 (COVID-19) [2,3].
Consequently, the following products, with the warnings indicated and being those with the easiest availability in each facility, are recommended as the most suitable:

Sodium hypochlorite in 0.2% solution with 5 minutes of contact

In literature [2,3,4,5] it is reported in a substantially unanimous way that sodium hypochlorite in solution at a concentration of 0.1% significantly reduces coronavirus infection on surfaces with an exposure time of 1 minute. Higher times and concentrations guarantee higher efficacy, but at the same time the product is potentially aggressive to medical devices that are made from plastics and porous silicones, as is the case of ultrasound probes. An optimal compromise to guarantee good efficacy (guaranteeing a reduction higher than Log4 indicated in the literature [2], staying within the margins of concentration also in relation to the volatility of the product which reduces the titration) and, at the same time, good compatibility with the device (i.e. risk of deterioration within at least 1-2 years compared to the intensive close use of required sanitizations) is to use it in 0.2% solution with a contact time of 5 minutes.

For such a solution preparation, any product containing sodium hypochlorite can be used by diluting the concentration until the indicated concentration of 0.2% is obtained (for example with commercial Amuchina containing 2% sodium hypochlorite, a blend must be prepared containing 1 part Amuchina to 9 parts water). Sodium hypochlorite exposed to air is volatile, it is therefore recommended to prepare what is strictly necessary and to change it at least every 8 hours.

Attention: unless you use the pure product, given the volatility of the product if exposed to air, the packaging of the commercial product used to prepare the solution must be kept closed and its exposure to the air limited as much as possible. If the commercial product from which the solution is prepared is not in an intact package and it is not known how long it has been open or it is known that it has been open for 5-6 days, raise the sodium hypochlorite solution concentration up to 0.5% to compensate for the loss of commercial product titration.

Ethanol in 62-71% solution with 1 minute of contact

In the literature [2,3,4,5] it is reported, in a substantially unanimous way, that ethanol (ethyl alcohol) in solution at 62-71% concentration significantly reduces the coronavirus infection on surfaces with an exposure time from 1 minute. This requirement comes with a warning that the product is highly aggressive in the case of the silicones, the material of the probe head. **It is therefore recommended not to use it on the probe head** but preferably on the cable, connector, and grommet. In any case, if it is used to disinfect the probe head, internal tests carried out confirm that limited use is possible as there are no alterations up to at least 100 treatment cycles. On the other hand, given the short contact time required, it can be applied by simply wetting the parts to be treated uniformly with a sprayer and allowing it to dry, without needing to immerse the device in the solution. If it accidentally comes into contact with electrical contacts, it will not damage them. In fact, the CDC USA [4] recommends using a 70% alcohol solution in the form of a spray or soaked wipes to disinfect electronic devices if no manufacturer's instructions are available. The solution is stable and does not require any special storage precautions but, in any case, must always be kept in a closed container.

Other **suitable** products

For other suitable commercial products that can be used in place of those indicated above, please refer to the list published by EPA United States [6], to date the only public body known to have published an official list of products recognized as valid for the disinfection of COVID-19 (human coronavirus).

Of these commercial products, it is recommended to select only the commercial products (identified by the product name and product manufacturer in the list) that are based on the following active ingredients (applied to the sanitization of both the probe head and the cable – be careful with the connector because these ingredients can damage the electrical contacts):

Quaternary ammonium

Sodium hypochlorite

Ethanol (with the limitations indicated above for the 62-71% range of concentration)

Hydrogen peroxide

Do not use products with one of the active ingredients indicated, if they do not correspond to a commercial name and manufacturer name indicated in the list, as they are not validated compatible by EPA.
It is not recommended to use products for which a contact time of more than 5 minutes is required as they are difficult to apply in spray or wipe mode and require too much time for the contact procedure by immersion in the disinfectant.
The attached list is indicative of the status as of April 1, 2020, for the updated list refer to the link indicated in the reference [6].

Not recommended disinfectants

These are disinfectants based on active ingredients suitable for COVID-19, but they could create compatibility problems or endanger the use of our devices.

Peracetic acid

Due to the significant aggressiveness of this substance, which leads to an excessive reduction in the lifetime of the probe, particularly in conditions of frequent use, the use of all products based on this active principle is not recommended. The exception is for Perasafe Rely + On, but only for the probes for which compatible use of Perasafe Rely + On has been validated by Esaote (see Probe & Consumable manual code 141003500 version R17 or higher, attachment C).

Glutaraldehyde

Use not recommended due to the high toxicity.

Disinfectants with **limited efficacy**

Based on the findings in the literature [2,3] the following active ingredients have proven to be less effective (or achieve efficacy but with much longer times than those indicated by the manufacturer in normal use) against human coronavirus and, therefore, are not to be considered suitable for a COVID-19 disinfection.

Orthophthalaldehyde (Cidex OPA, 0.55%)

It takes over 10 minutes to achieve a reduction greater than Log3.

Benzalkonium chloride
(in a concentration between 0.05% and 0.2%)

It takes 10 minutes to 3 days to reach a reduction greater than Log3.

Chlorhexidine (0.02%)

After 10 minutes of activity it does not go beyond a Log1.5.

Ultrasound probe
disinfection procedure

It is necessary to disinfect not only the **probe head (A)** but also the entire **cable (B)** and in some cases also the **connector (C)** to ensure an effective disinfection of non-critical probes (linear, phased array, convex) **(fig. 1)**.

Figure 1 - Essential parts of the ultrasound probe

Most probe models cannot be immersed together with the cable so it will be necessary to disinfect the cable separately from the head **(fig. 2-fig. 5)**. Refer to Annex A of the Probe & Consumable manual code 141003500 version R17 or higher (and briefly summarized in **Table 1** below) for the models with IPX7 waterproof rating that can be immersed up to the connector **(C)**.

Figure 2 - Example of probe head immersed in disinfectant

Figure 3 - Spray on surface

Figure 4 - Spray the other side

Figure 5 - Example of head and probe cable immersed in disinfectant

Recommended operating method for disinfection

1. Carry out disinfection wearing disposable personal protective equipment (PPE) in accordance with local guidelines. Dispose of the gloves as infectious waste at the end of the process.
2. A disposable sponge can be used for washing.
3. Detach the probe from the ultrasound system and remove any probe covers by disposing of them as infectious waste. For use in the "established COVID-19" setting, all tests can be performed on patients without using the probe cover and without sanitizing between one patient and the next one, ensuring scrupulous sanitization at the end of the sequence of examinations. By contrast, probe coverage is an essential additional safety requirement in case of "outpatient" and "COVID-19 under investigation" settings.
4. Clean the probe using cleaning wipes to dissolve or remove any remaining organic materials. Cleaning is to be carried out on parts that have residues of organic and non-organic materials (for example contact gel). Dispose of the wipes as infectious waste.
5. Remove detergent residue from the probe using wipes soaked in purified water. Dispose of the wipes as infectious waste after checking that all foreign materials and detergent have been completely removed.
6. Dry the probe surface with a disposable soft cloth or clean gauze. Do not use heat to dry the transducer. Dispose of used cloth or gauze as infectious waste.
7. Disinfect the probe head **(A)** by immersing it **(see example in fig. 2)** up to the immersion limit indicated in the manual for the specific type of probe in an aqueous solution of sodium hypochlorite (0.2%) for five minutes. Alternatively, the 62-71% ethanol solution (but limited use is recommended) or one of the products mentioned in the paragraph "Other suitable products" can be used.
8. At the same time as you are disinfecting the probe head by immersion, disinfect the cable **(B)** and connector **(C)**, preferably by spraying a 62-71% ethanol solution, taking care not to wet the metal parts of the connector. To carry out the operation, while the probe head is immersed in the disinfection liquid, it is recommended that all the non-immersed parts up to the connector are laid on a surface and sprayed **(fig. 3)**. Turn gently so as not to overturn the immersed probe head and spray the part that was underneath so as to cover all the surfaces that are not immersed **(fig. 4)**. Allow the liquid to dry, taking care that this does not happen before one minute passed. Alternatively you can use the aqueous solution of sodium hypochlorite (0.2%) by spraying it as indicated for ethanol (but taking care that it remains wet for at least 5 minutes, possibly repeating the spraying process) and, in this case, being careful not to wet the metal parts of the connector, which could oxidize. Another alternative is to use one of the products mentioned in the paragraph "Other suitable products" if it can be sprayed and ensuring.
9. If the cable is immersible, point 7 includes the cable **(B)** well as the probe head **(A) (fig. 5)**, while point 8 concerns only the connector **(C)**. Refer to the attached table 1 to find out which probes are submersible with the entire cable or refer to Annex A of the Probe & Consumable manual code 141003500 version R17 or higher.
10. Thoroughly rinse the probe head **(A)** and the cable **(B)** with a tissue soaked in sterile or deionized water. Dispose of used soaked tissue as infectious waste.
11. Dry the surface of the probe head **(A)** and the cable **(B)** with a sterile disposable soft cloth or gauze. Do not use heat to dry the transducer. Dispose of used cloth or gauze as infectious waste.

Table 1 - List of submersible probes with the whole cable		
C 1-8	L 3-11	P 1-5
IH 6-18	L 4-15	P 3-11

Ultrasound Systems cleaning and disinfection procedure

Refer to the Esaote document ref. 160000199 **Esaote Ultrasound Systems – Cleaning and Disinfection in the Event of COVID-19 Emergency**

References

Please refer to the websites and documentation below for more information

[1] **SIRM, SIUMB, and FISM guidelines on behavioral modalities for carrying out an ultrasound examination in this pandemic moment.**

[2] G. Kampf, D. Todt, S. Pfaender, E Steinmann **Persistence of coronaviruses on inanimate surfaces and their inactivation with biocidal agents**. *Journal of Hospital Infection 104 (2020) 246e251*

[3] Anthony F. Henwood. **Coronavirus disinfection in histopathology**, *ISSN: 0147-8885 (Print) 2046-0236 (Online) Journal of Histotechnology*

[4] **Coronavirus Disease 2019 (COVID-19) Cleaning and Disinfection for Households, United States CDC (Centers for Disease Control and Prevention)**

[5] **DISINFETTANTI PIÙ COMUNI E MODALITÀ D'USO** from the Casalpusterlengo Civil Protection website *http://www.casaleinforma.it/pcivile/pulizia/disinfettanti.htm*

[6] **List N: Products with Emerging Viral Pathogens AND Human Coronavirus claims for use against SARS-CoV-2** Date Accessed: 04/01/2020 United States EPA. *Discharge updated list at www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2*

[7] Duan SM, Zhao XS, Wen RF, et al. **Stability of SARS coronavirus in human specimens and environment and its sensitivity to heating and UV irradiation**. *Biomed Environ Sci. 2003 Sep;16(3):246–255.*

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