Sanitization of probe and ultrasound systems in the event of COVID-19 emergency

Ultrasound is among the imaging techniques that involves the greatest interaction between physician and patient. This has always been a strong point and of greater impact on diagnostics, allowing continuous interaction and a fruitful exchange of information between doctor and patient. Unfortunately, in this moment of emergency due to the COVID-19 infection dissemination, this, that it has always been the positive element of the ultrasound, becomes an important potentially negative element. If performed not safely, it will determine an increased risk of infection among physician and patient. This is even more dangerous if it occurs inside hospitals, in emergency areas, where the patient is not yet fully investigated and then the most favorable conditions for COVID-19 diffusion are determined. 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 COVID19 pandemic situation. 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, TRT and TEE) and for the critical probes (intra-operative or laparoscopic). If used in a COVID19 risk environment, all this probes, before reprocessing, should be subjected to the COVID19 sanitization treatment indicated below for non-critical probes.

General protection and sanitation 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 determined by this critical moment.

For Setting “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 gel after each patient.

For Setting “COVID under investigation” (patients awaiting COVID assessment test), SIRM, SIUMB and FISM recommend:

- Coverage with washable keyboard cover or plastic film of the ultrasound system and with a cover or glove the probe. The probe cover must be changed after each patient to prevent transmission of the infection.
- Further, sanitize probe and ultrasound system after end of procedure to be ready for new procedure.

For Setting “already established COVID” SIRM, SIUMB and FISM recommend

- Coverage with washable keyboard cover or plastic film of the ultrasound system and with a cover or glove the probe. The probe cover must be changed after each patient to prevent transmission of the infection.
- Further, sanitize probe and ultrasound system after end of procedure to be ready for new procedure.

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

- The Setting “COVID 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 quickly 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 under investigation”.
- The Setting “already established COVID, in the case of patients not in the COVID 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 sanitize the ultrasound system and probe quickly at the end of the procedure (sequential execution of exams to all patients) to be ready for a new procedure.

COVID 19 sanitizing products

The products suitable for sanitization are identified on the basis of their disinfectant efficacy on viruses, and in particular on those COVID type [2,3,4,5], as specific studies on COVID19 do not yet exist.

Furthermore, we must take into account the additional boundary conditions determined by the effective 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.

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). 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 (COVID19).

Consequently the following products, with the warnings indicated and being those with the easiest availability in each structure, 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 already at a concentration of

0.1% significantly reduces coronavirus infection on surfaces already with an exposure time of 1 minute. Higher times and concentrations guarantee higher efficacy but at the same time the product is potentially aggressive for medical devices using plastics and porous silicones as it is the case of ultrasound probes. An optimal compromise to guarantee good efficacy (guaranteeing a reduction higher than Log 4 indicated in the literature [2], staying within the margins of concentration also in relation to the volatility of the product which reduces the title) and, at the same time, good compatibility with the product (i.e. risk of deterioration at least within 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 a such 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, it must be prepared a blend containing 1 part of Amuchina and 9 parts of 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 limited as much as possible its exposure to the air. 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 opened or it is known that it has been opened since at least 5-6 days, raise the sodium hypochlorite solution concentration up to 0.5% to compensate for the loss of commercial product title.**

- **Ethanol in 60-70% 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 already at 60-70% concentration significantly reduces the coronavirus infection on surfaces already with an exposure time of 1 minute. This requirement is maintained 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 dispensed 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 impacts electrical contacts, it will not damage them. In fact, the CDC USA [4] recommends, for electronic products, if no manufacturer's instructions are available, to use a 70% alcohol solution in the form of a spray or soaked wipes to disinfect them. The solution is stable and does not require any special storage precautions but in any case always 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 COVID19 (Humancoronavirus).

Of these commercial products, it is recommended to select only the commercial products (identified by the product name and product manufacturer in the list) based on the following active principles (applicable both to the sanitation of the probe head and the cable, attention to the use on the connector because they can damage the electrical contacts):

- Quaternary ammonium
- Sodium hypochlorite
- ethanol (with the limitations indicated above for the 60/70% range of concentration)

Do not use products with one of the active ingredients indicated, if they do not comply with 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 it is 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 01/04/2020, for the updated list refer to the link indicated in the reference [6].

Not recommended disinfectants

They are disinfectants based on active principle suitable for COVID19 but they could create compatibility problems or risk of use on our devices.

- **Peracetic acid**. Due to the significant aggressiveness of this substance which leads to an excessive reduction in the life time of the probe, particularly in conditions of frequent use, the use of all products based on this active principle is not recommended except 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.
- **Hydrogen peroxide (hydrogen peroxide).** There are conflicting indications on efficacy, contact times and concentration that suggest not to use it for COVID19 disinfection until unambiguous confirmations are made available.

Disinfectants with limited efficacy

Based on the findings in the literature [2,3] the following active ingredients have proven to be less effective (or reach efficacy but with much longer times than those indicated by the manufacturer in normal use) against Human Coronavirus and therefore, even more so , are not to be considered suitable for a COVID19 disinfection.

- **Orthophthalaldehyde (Cidex OPA, 0.55%).** It takes over 10 minutes to achieve a reduction greater than Log3.0.
- **Benzalkonium chloride (in a concentration between 0.05% and 0.2%).** It takes 10 minutes to 3 days to reach a reduction greater than Log3.0.
- **Chlorhexidine (0.02%).** After 10 minutes of activity it does not go beyond a Log1.5.

Inappropriate methods

Sterilization methods (Sterrad, Steris, ETO and similar ones). All sterilization methods are obviously effective methods, by definition, but their use is limited by several practical operational difficulties. They require the transfer of the device to the sterilization center but the transfer from any COVID or suspected COVID setting requires that the device itself be made safe before carrying it out. This condition is not acceptable for practicality and timing. In fact, for critical probes, which must be sterilized in all cases before reuse, the indication given in the preamble is to carry out sanitation COVID19 before proceeding with the transfer to the sterilization center.

UV methods (Germitec or similar). Machines that use UV-C do not allow to disinfect cables. Furthermore, there are no efficacy tests for COVID19. The only info comes from Duan and others [7] who found that ultraviolet radiation for 60 minutes on crops of different coronaroviruses results in an undetectable level of

viral infection. The method is therefore effective but 60 minutes of time is too much and normally the sanitary facilities are not equipped with UV-C machines for disinfection. For more if they are not available at the Setting we have the same transfer problems raised by the sterilization methods.

TROPHON method. Different principle, less time than UV-C method but COVID effectiveness is not validated. In addition, the same limitations (non-disinfectable cables) and problems of use (transfer to the place of installation) of UV methods apply.

Ultrasound probe sanitization 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)

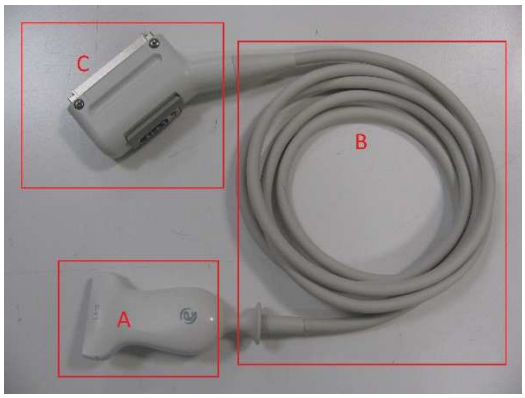

Figure 1 - Essential parts of the ultrasound probe

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

Recommended operating method of sanitization

1. Carry out sanitization by wearing disposable personal protective equipment (PPE) according to local guidelines. Dispose of the gloves as infected residue 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 among the infected residues. For use in the established Setting COVID19, all tests can be performed on patients without using the probe cover and without sanitizing between one patient and another, taking care of a scrupulous sanitation at the end of the sequence of examinations. Probe coverage, instead, is an essential additional safety requirement in case of Setting “outpatient” and Setting “COVID under investigation”.
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 among the infected residues.
5. Remove residual detergent residue from the probe using wipes soaked in purified water. Dispose of the wipes among the infected residues 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 among the infected residues.
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 60/70% ethanol solution (but limited use is recommended) or one of the products mentioned in the paragraph "Other suitable products" can be used.


Figure 2 - Example of probe head immersed in disinfectant

8. At the same time you are disinfecting the probe head by immersion, disinfect the cable (B) and connector (C), preferably by spraying a 60/70% 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 to spray all the non-immersed part up to the connector having it laid on a surface (fig. 3), turn gently so as not to overturn the immersed probe head (fig. 4), also spray the part that was laid so as to cover with the spray the whole surface not immersed (fig. 5). Allow the liquid to dry taking care that it takes place no earlier than 1 minute. 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, be 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 the indicated contact time.


Figure 3 – Spray on facade


Figure 4 – turn the cable looop


Figura 5 – Spray on the other side

9. In case the cable is immersible point 7 includes as the probe head (A) as the cable (B) (figure 6), while the 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.


Figure 6 – Example of head and probe cable immersed in disinfectant

10. Thoroughly rinse the probe head (A) and the cable (B) with a tissue soaked in sterile or deionized water. Dispose of used tissue soaked among the infected residues.
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 from infected residues.

Table 1 - List of submersible probes with the whole cable.

C 2-9	L3-11	P 1-5
IH 6-18	L4-15	P 3-11
IL 4-13	L8-24	PA250

Ultrasound system sanitization procedure

For use in any setting where the presence of COVID19 infection cannot be first excluded, the use of washable covers for the ultrasound system is required. This is necessary because the presence of ravines in the system structure makes it problematic to ensure the uniformity of contact of any spray or nebulization that can be sprayed on the system. For the same reason, the use of wipes would not be sufficient to reach all the points to be sanitized and obviously an electronic system cannot be immersed in a disinfectant liquid.

At the end of the procedure it is suggested to spray the cover by using alcohol-based wipes or sprays containing at least 70% ethyl alcohol and leave to act for 1 minute before removing it. This lowers the risk of viral contact infection when removing the cover.

Dispose of used cover in infected residues.

If necessary, spray alcohol-based sprays containing at least 70% ethyl alcohol, taking care to avoid the accumulation of liquids and let them dry before proceeding to the next use (should take place in about 2 minutes).

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