

Disinfectants for System Surfaces

The following disinfectants can be used to disinfect all surfaces of the system (including probe holders) except for the monitor and touchscreen.

Product Name	Manufacturer	Type
Sani-Cloth Bleach Germicidal Disposable Wipe	PDI	Wipe
Tristel Duo ULT	Tristel Solutions Limited	Foaming soap
Sporox II	Sultan Healthcare	Liquid
Rely+On™ Perasafe	DU PONT	Powder
Anioxyde 1000	Anios	Liquid
MetriCide OPA Plus	Metrex	Liquid



CAUTION:

- ▶ Using an inappropriate disinfection procedure may damage the system. Make sure that you check the disinfectant's expiry date.
- ▶ Mix the disinfectant solution to the strength specified on the instruction of the disinfectant manufacturer.

Disinfectants for Monitor Surface

The following disinfectants can be used to disinfect the monitor and touchscreen.

Product Name	Manufacturer	Type
Sani-Cloth Bleach	PDI	Wipe
Sporox	DSHealthcare Inc.	Liquid
Anioxyde 1000	Laboratoires Anios	Liquid
Metricide-OPA Plus	Metrex	Liquid
Cidex Plus	Advanced Sterilization Products	Liquid
Cleanisept Wipes	Dr. Schumacher GmbH	Wipe



- CAUTION:** When using a disinfectant, wipe it carefully with a soft cloth.

Cleaning and Disinfecting Probes

All probes must be cleaned and disinfected after each use.



WARNING:

- ▶ Always wear a protective face mask and gloves when cleaning and disinfecting probes.
- ▶ After cleaning and disinfecting probes, inspect their housing, strain relief, lens, and seal for damage or any functional degradation.
- ▶ Using an inappropriate cleaning or sterilizing agent may damage the probe.

► Information on Detergent, Disinfectant, and Ultrasound Gel

■ Classification of Disinfectants

To maintain the performance of ultrasound probes, proper maintenance is required. Ultrasound probes are classified as critical, semi-critical, or non-critical devices based on the FDA guidance* and the 'Hygiene Requirements for Medical Devices Reprocessing' included in the Guideline produced by the Robert Koch Institute (RKI) in Germany. Therefore, you must use a cleaning, disinfection, or sterilization method appropriate for each classification.

Classification Criteria	Contact Area	Application Probe	Level Selection
Non-critical device	Intact skin	Curved, Linear, and Phased array probes	Low level disinfectant
Semi-critical device	Mucous membrane and damaged skin	Endocavity, TEE	High level disinfectant or sterilization
Critical device	Blood, sterile tissue, etc.	Intraoperative	Sterilization

* Guidance for Industry and FDA Staff - Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers - Appendix D

* It is recommended that only high-level disinfectants are used to disinfect endocavity probes.

An appropriate detergent, disinfectant, or ultrasound gel should be used for all probes. Please refer to the Samsung Medison website and the User Guide. All probes are tested in accordance with the IPX 7 standard.

- ▶ User Guide: This is provided as a booklet upon purchase of the product.

Validated High Level Disinfection Instruction for Samsung Endo Cavity transducers

■ Tristel Duo – High Level Disinfection Method

1. Personal Protection

- ▶ Personal protection must always be worn when handling possibly contaminated ultrasound probes. Personal protection at least includes gloves and eye protection.
- ▶ Once you are wearing personal protection, you are ready to begin the cleaning and disinfection process.

2. Cleaning the Probe

- ▶ The first step in the high-level disinfection process is thorough cleaning. Possibly contaminated probes must be thoroughly cleaned before they can be disinfected.
- ▶ Hold the probe and put one aliquot of Tristel duo in the indentation of the probe ①
- ▶ Use a swap to spread the Tristel Duo liquid in the indentation(s) ②
- ▶ Put 2 aliquots of Tristel Duo on a Tristel Dry Wipe and clean the transducer from handgrip to the tip of the probe ③
- ▶ Use another dry swap to dry and clean the indentation(s) ④



3. Disinfecting the Probe

- ▶ Tristel Duo incorporates two separate compartments that contain the Tristel Base and the Tristel Activator solutions that create chlorine dioxide when mixed (1:1). Tristel Duo foam is generated by depressing the incorporated pump.
- ▶ Change your gloves
- ▶ Hold the probe and put one aliquot of Tristel duo in the indentation of the probe
- ▶ Use a swap to spread the Tristel Duo liquid in the indentation(s)
- ▶ Put 2 aliquots of Tristel Duo on a Tristel Dry Wipe and disinfect the transducer with rotations from handgrip to the tip of the probe. Leave the disinfectant on the probe for at least 30 seconds
- ▶ Use another dry swap to dry the indentation(s)
- ▶ Leave the surface to dry to ensure a 30 second contact time.



- ▶ Discard the used wipes, swaps and gloves to clinical waste, do not macerate. Do not re-use.
- ▶ Disinfected probe should be used immediately or stored in a manner to minimize recontamination.

❖ CIDEX® OPA Solution – High Level Disinfection Method

1. Personal Protective Equipment

- ▶ Personal protective equipment must always be worn when handling contaminated instruments and equipment. Personal protective equipment includes gloves, eye protection and fluid-repellent gown.
- ▶ Once you are wearing personal protective equipment, you are ready to begin the disinfection process.

2. Clean Instruments

- ▶ The first step in the high-level disinfection process is thorough cleaning. Contaminated probes must be thoroughly cleaned with a detergent prior to disinfection, especially take care of ridges and biopsy guide mountings.
- ▶ Following cleaning, rinse probe surface with large amounts of fresh water to remove residual detergent.

3. Using CIDEX® OPA Solution

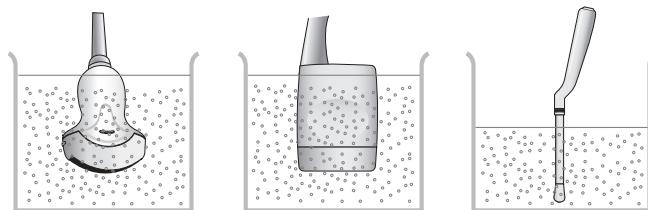
- ▶ Before using the solution, be sure to read the directions for use on the bottle label and package insert. The shelf life of an unopened bottle of CIDEX® OPA Solution is two years. The solution requires NO activation.

4. Test

- ▶ Concentration of this product during its reuse life must be verified by the CIDEX® OPA Test Strip prior to each use to determine that the concentration of ortho-phthalaldehyde is above the MEC of 0.3%.
- ▶ CIDEX® OPA Solution shall not be used beyond 14 days.

5. Disinfect

- ▶ Prepare a ready-to-use CIDEX® OPA (Ortho-phthalaldehyde) solution with a concentration of at least 0.55% using the manufacturer's instructions.
- ▶ Fill tray, basin or tall container with Cidex OPA at ambient room temperature (approximately 20-25°C) to a level allowing immersion of the probe up to the immersion line as shown below.



- ▶ Cover the CIDEX® Solution Tray with a secure lid. Soak probe for 12 minutes at 20–25°C to achieve high-level disinfection.
- ▶ Immerse probes in Cidex OPA at least until the immersion limits and ensure no air or bubbles are trapped. Allow soaking for minimum twelve (12) minutes.
- ▶ Excessive soaking time is not recommended as it may result in residues that result in patient allergic reaction or tissue discoloration.
- ▶ Cidex OPA solution shall not be reused beyond 14 days. Cidex OPA solution shall not be reused if concentration of active ingredient is below Minimum Effective Concentration of ortho-phthalaldehyde (0.3% w/v).

6. Rinse

- ▶ Remove probes from the solution and thoroughly rinse all surfaces up to the immersion line in shown in three (3) times with fresh sterile water, each time for a minimum of one (1) minute.

7. Dry

- ▶ Thoroughly dry all surfaces of the probe using a sterile, lint-free wipe or cloth, changing wipes/cloths when necessary to ensure the probe is completely dry. Visually inspect the probe to ensure all surfaces are clean and dry. Repeating drying steps if any moisture is visible.
- ▶ Disinfected probe should be used immediately or stored in a manner to minimize recontamination.

8. Dispose

- ▶ CIDEX® OPA Solution can be discarded down hospital and office drains or in accordance with local regulations.

■ Trophon – High Level Disinfection Method

1. a Preparing the Probe

- Wearing gloves, clean and dry the probe BEFORE commencing the high level disinfection process as per the probe manufacturer's instructions.

2. b Clean Instruments

- The first step in the high-level disinfection process is thorough cleaning. Contaminated probes must be thoroughly cleaned with a detergent prior to disinfection, especially take care of ridges and biopsy guide mountings.
- Following cleaning, rinse probe surface with large amounts of fresh water to remove residual detergent.

3. Loading The Disinfectant Cartridge

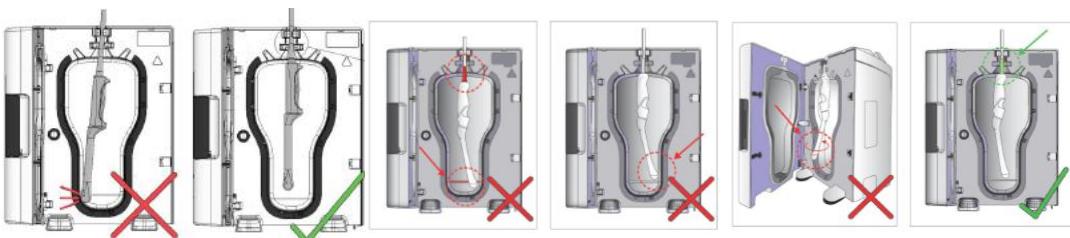
- A Trophon disinfectant cartridge needs to be inserted into the Trophon EPR before a high level disinfection cycle can commence. Refer to the Trophon user manual for detailed instructions on how to insert and/or replace Trophon disinfectant cartridges.

4. Inserting the Chemical Indicator

- A Trophon Chemical Indicator must be used for each disinfection cycle. No other chemical indicators are approved for use in the trophon EPR. Each Chemical Indicator may only be used once. Place the Trophon Chemical Indicator into the holder. Refer to the Trophon Chemical Indicator IFU. You may then position the probe in the chamber.

5. Positioning the Probe

- When the Trophon is ready to use, screen message Load Probe and Indicator will be displayed.
- Open chamber door.
- Ensure the probe is correctly positioned in the chamber. The probe must not contact the chamber wall and must be positioned above the embossed line at the bottom of the chamber.



6. Closing the Chamber Door

- The door will automatically lock at the start of a high level disinfection cycle.

7. Disinfecting the Probe

- ▶ If the probe has been pre-cleaned and dried, press Yes using the soft key button. If Yes is selected, you will be prompted by the screen message: Press start to begin.
- ▶ The progress of the disinfection cycle is indicated on the LCD screen message: Disinfecting.
- ▶ The High Level Disinfection cycle will take 7 minutes to complete.

8. Removing the Probe

- ▶ NOTE: After completion of a successful high level disinfection cycle, the ultrasound probe and chamber may have surface temperatures up to 45°C and 60°C respectively. Care should be taken not to touch the chamber. The probe will feel warm to touch and is safe for handling and use with clean gloves on.
- ▶ Cycle Complete. Wear Gloves. Remove and Wipe Probe.
- ▶ Attention: Wear Gloves and Wipe Probe. (This message indicates that some hydrogen peroxide may not have been broken down into its constituents, oxygen and water and extra care should be taken when removing the probe).
- ▶ Wearing clean gloves, immediately remove the used Chemical Indicator from the trophon and verify the color change against the chart on the Chemical Indicator carton.
- ▶ Discard used Chemical Indicator.
- ▶ Remove the probe carefully using minimal contact after the cycle is complete. Avoid touching the probe against the chamber's hot surface. Avoid compromising the probe's disinfected surface before use.
- ▶ Wipe the probe with a clean, low lint, absorbent, single-use, dry sterile cloth/ wipe. Visually inspect the probe and ensure Any disinfectant residue present is removed.
- ▶ If a pass was verified by the Chemical Indicator color AND the trophon screen displayed cycle complete, the HDL has been successful.
- ▶ Discard gloves.
- ▶ Close the chamber door.
- ▶ Disinfected probe should be used immediately or stored in a manner to minimize recontamination.

*Note: Please refer to disinfectant manufacturer's user manual to find additional informations.

Gigasept PAA Concentrate – High Level Disinfection Method for TEE probe

1. Personal Protection

- ▶ Personal protective equipment must always be worn when handling possibly contaminated probes. Personal protective equipment includes gloves, eye protection and fluid-repellent gown.
- ▶ Once you are wearing personal protective equipment, you are ready to begin the disinfection process.

2. Cleaning the TEE Probe

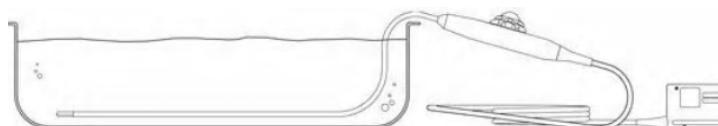
- ▶ The first step in the high-level disinfection process is thorough cleaning. Possibly contaminated probes must be thoroughly cleaned prior to disinfection.
- ▶ Thoroughly clean the probe with a detergent especially taking care of the junctions of the flexible part and the indentation on the scan head (see Figure 1).
- ▶ Wipe the TEE probe with 5 Tristel Dry Wipes soaked with 8 ml 1.6% CIDEZYME and wipe for 3 minutes.
- ▶ Rinse the TEE probe for 1 minute with a 1% sodium dodecyl sulphate (SDS) solution.



[Figure 1. TEE probe MMPT3-7 with contamination spots (arrows)]

3. Disinfecting the TEE Probe

- ▶ Prepare a Gigasept® PAA solution with a concentration of at least 2% using the manufacturer's instructions.
- ▶ Place the TEE probe in the 2% Gigasept® PAA solution as shown in Figure 2.
- ▶ Ensure that all air is removed from the surface of the TEE probe.
- ▶ Leave the TEE probe for at 15 minutes in the solution.



[Figure 2. Do not immerse beyond this point, 5cm from the strain relief]

- ▶ Gigasept® PAA solution shall not be reused beyond 12 hours.

4. Rinse

- ▶ Remove the TEE probe from the solution and thoroughly rinse all surfaces up to the immersion point as shown, repeat this process two more times with sterile water, each time for a minimum of one (1) minute.

5. Dry

- ▶ Thoroughly dry all surfaces of the probe using a sterile, lint-free wipe or cloth, changing wipes/cloths when necessary to ensure the probe is completely dry. Visually inspect the probe to ensure all surfaces are clean and dry. Repeat the drying steps if any moisture is still visible.
- ▶ Disinfected probe should be used immediately or stored in such a way that recontamination is prevented.

6. Disposal of the Disinfection Solution

- ▶ According to the manufacturer Gigasept® PAA Solution can be discarded down hospital- and office drains. Recommendation however is to check the local regulations first.