

## 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.

Locale	Product name	Active ingredient	Manufacturer	Type
EUROPE	Perasafe	Citric acid	LANXESS Deutschland GmbH	Powder
USA	Sani-Cloth® bleach Germicidal Disposable Wipe	Sodium Hypochlorite	PDI	Wipe
USA	T.Spray II	Quaternary Ammonium(N-Alkyl)	Pharmaceutical Innovations, Inc.	Spray
USA	PROTEX® ULTRA DISINFECTANT WIPES	Quaternary Ammonium(N-Alkyl)	Parker Laboratory Inc.	Wipe
EUROPE	Wip'Anios Excel wipes	Quaternary Ammonium(N-Alkyl)	Laboratoires Anios	Wipe
EUROPE	Surfa'safe	Quaternary Ammonium(N-Alkyl)	Laboratoires Anios	Liquid
KOREA	Yuhanrox regular (Yuhanrox regular1: water10)	Sodium Hypochlorite	Yuhan clorox	Liquid
USA	Clorox regular (Clorox regular1: water10)	Sodium Hypochlorite	The Clorox Company	Liquid
KOREA	Enzysept PLUS Wipes	Quaternary Ammonium(N-Alkyl)	Wooil C&Tech	Wipe
KOREA	ED Wipes	Quaternary Ammonium(N-Alkyl)	MH healthcare	Wipe
KOREA	ANIOSURF Premium NPC	Quaternary Ammonium(N-Alkyl)	Laboratoires Anios	Liquid
EUROPE	Virkon S	Pentapotassium, Succinic acid	LANXESS Deutschland GmbH	Powder
USA	Bleach Germicidal Wipes	Sodium Hypochlorite	The Clorox Company	Wipe

## Disinfectants for Monitor Surface

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

Locale	Product name	Active ingredient	Manufacturer	Type
EUROPE	Perasafe	Citric acid	LANXESS Deutschland GmbH	Powder
USA	Sani-Cloth® bleach Germicidal Disposable Wipe	Sodium Hypochlorite	PDI	Wipe
USA	T.Spray II	Quaternary Ammonium(N-Alkyl)	Pharmaceutical Innovations, Inc.	Spray
USA	PROTEX® ULTRA DISINFECTANT WIPES	Quaternary Ammonium(N-Alkyl)	Parker Laboratory Inc.	Wipe
EUROPE	Wip'Anios Excel wipes	Quaternary Ammonium(N-Alkyl)	Laboratoires Anios	Wipe
KOREA	Yuhanrox regular (Yuhanrox regular 1: water 10)	Sodium Hypochlorite	Yuhan clorox	Liquid
USA	Clorox regular (Clorox regular 1: water 10)	Sodium Hypochlorite	The Clorox Company	Liquid
KOREA	Enzysept PLUS Wipes	Quaternary Ammonium(N-Alkyl)	Wool C&Tech	Wipe
KOREA	ED Wipes	Quaternary Ammonium(N-Alkyl)	MH healthcare	Wipe
KOREA	ANIOSURF Premium NPC	Quaternary Ammonium(N-Alkyl)	Laboratoires Anios	Liquid
USA	Bleach Germicidal Wipes	Sodium Hypochlorite	The Clorox Company	Wipe



### 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.
- ▶ When using a disinfectant, wipe it carefully with a soft cloth.

# Using Ultrasound Gel

For successful acoustic signal transmission, please only use the ultrasound gels approved by Samsung Medison.



## WARNING:

- ▶ The use of inappropriate ultrasound gels could result in damage to the probe. Using damaged probes may result in electric shocks and other hazards to the patients and/or users.
- ▶ Do not use ultrasound gels or coupling media that contain any of the following agents:
  - Oils such as mineral oil, cooking oil, gasoline, solvents, rust inhibitors, lanolin, paraffin-based grease, ester, and excessive silicon-based release agents;
  - Alcohols, such as acetone, methanol, and plasticizer (dioctylphtalate), or denatured alcohol;
  - Glacial acetic acid and iodine; or
  - All types of lotion or gel that contain aromatic substances



## CAUTION:

- ▶ When applying the ultrasonic gel to the probe, make sure that the tip of the gel tube does not touch the surface of the probe lens.
- ▶ The tip of the gel tube may cause damage to the probe lens.



# Cleaning, Disinfecting, and Sterilizing Probes

All probes must be cleaned and disinfected after each use. Cleaning is an important procedure that must be carried out before disinfecting probes. For information about cleaning and disinfecting probes, please refer to 'Cleaning, Disinfecting, and Sterilizing the Probe' in the 'Probes' chapter of the user manual. Using an inappropriate disinfectant may damage the probe.



## WARNING:

- ▶ Always use protective equipment such as face mask, eyewear, and gloves when cleaning, disinfecting, and sterilizing probes.
- ▶ Inspect the housing, strain relief, lens and seal for damage, and check for any functional degradation after cleaning and disinfecting the probe.
- ▶ Using an inappropriate cleaning or disinfecting agent may damage the probe.

## Information on Detergent, Disinfectant, and Ultrasound Gel

### Reprocessing Method by Probe Type

To maintain the performance of ultrasound probes, proper maintenance is required.

Ultrasound probes are classified into critical, semi-critical, and non-critical medical devices, in accordance with FDA guidance\* and the Hygiene Requirements for the Reprocessing of Medical Devices set forth in the guidelines of the Robert Koch Institute (RKI) in Germany. Therefore, you should use the cleaning, disinfection, and sterilization methods appropriate for each classification.

#### Choosing the Correct Probe-Care Method in below Table

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

\* Guidance for Industry and FDA Staff – Marketing Clearance of Diagnostic Ultrasound Systems and Transducers - Appendix E

\* The FDA reprocessing guidance 'Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Guidance for Industry and Food and Drug Administration Staff' March 17, 2015, (<https://www.fda.gov/media/80265/download>)

The care method for your probes determines the appropriate disinfectant for your probe. An appropriate detergent, disinfectant or ultrasound gel should be used for all probes. For details about compatible detergent, disinfectants, and ultrasound gel, please see 'Disinfectants Matrix' on Samsung Medison website and the User Guide.

- ▶ 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 ❶
- ▶ Use a swab to spread the Tristel Duo liquid in the indentation(s) ❷
- ▶ Put 2 aliquots of Tristel Duo on a Tristel Dry Wipe and clean the transducer from handgrip to the tip of the probe ❸
- ▶ Use another dry swab to dry and clean the indentation(s) ❹



### 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 swab 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 swab to dry the indentation(s).
- ▶ Leave the surface to dry to ensure a 30 second contact time.



- ▶ Discard the used wipes, swab 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.

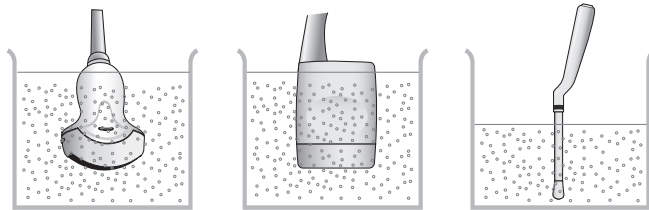
### 4. Test

- ▶ 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.

# 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

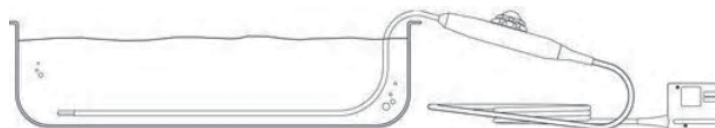
- ▶ The first step in the high-level disinfection process is thorough cleaning. Possibly contaminated probes must be thoroughly cleaned prior to disinfection.
- ▶ Thoroughly clean the probe with a detergent especially taking care of the junctions of the flexible part and the indentation on the scan head (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.