SAMSUNG

# Cleaning and Disinfecting the Ultrasound System

## System/Monitor/Probe

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# Disinfectants for System Surfaces (With Monitor)

The following disinfectant matrix indicates which disinfectants are compatible with specific system areas.

Please be cautious to avoid damage by only using approved disinfectants on areas listed.

| No | Product Name | Active Ingredient | Manufacturer | Type | Body Surface | Control Panel | Monitor |
|---|---|---|---|---|---|---|---|
| 1 | Accel® INTERVention™ Wipes | Hydrogen peroxide | Diversey | Wipe | ○ | * | ○ |
| 2 | Accel® Prevention Wipes | Hydrogen peroxide | Diversey | Wipe | * | ○ | |
| 3 | ANIOSURF Premium NPC | Quaternary Ammonium (N-Alkyl) | Laboratoires Anios | Liquid | ○ | ○ | ○ |
| 4 | Avert Sporicidal disinfectant cleaner | Sodium hypochlorite | US Headquarters Diversey, Inc. | Liquid | | ○ | |
| 5 | AZO detergent wipe | Isopropanol (70%) | Synergy Health Ltd | Wipe | * | ○ | |
| 6 | Azomax | 2methyl-2h-isothiazol-3-one polyhexamethylene biguanide | Synergy Health Ltd | Wipe | * | ○ | |
| 7 | CLEANISEPT® WIPES FORTE | Quaternary Ammonium (N-Alkyl) | Dr.Schumacher GmbH | Wipe | ○ | * | ○ |
| 8 | Clinell Detergent Wipes (Yellow) | Lauryl Polyglucose, Butoxydiglycol | GAMA Healthcare Ltd | Wipe | ○ | * | |
| 9 | Clinell Sporicidal wipes | Citric acid | GAMA Healthcare Ltd | Wipe | ○ | ○ | |
| 10 | Clinell Universal Santitising wipes (Clinell Universal Wipes) | Quaternary Ammonium (N-Alkyl) | GAMA Healthcare Ltd | Wipe | * | ○ | ○ |
| 11 | Clorox Healthcare® Bleach Germicidal Wipes | Sodium Hypochlorite | The Clorox Company | Wipe | ○ | ○ | ○ |
| 12 | Clorox regular (Clorox regular1: water10) | Sodium Hypochlorite | The Clorox Company | Liquid | ○ | ○ | ○ |
| 13 | CN'F | Alcohol | Neo Medical | Liquid | * | ○ | ○ |

| No | Product Name | Active Ingredient | Manufacturer | Type | Body Surface | Control Panel | Monitor |
|---|---|---|---|---|---|---|---|
| 14 | Dispatch@ Hospital Cleaner Disinfectant Towels with Bleach | | The Clorox Company | Wipe | ○ | ○ | |
| 15 | Ecolab Actichlor Tablets | Adipic acid, Sodium Carbonate | Ecolab | Tablet | ○ | ○ | |
| 16 | ED Wipes | Quaternary Ammonium (N-Alkyl) | MH healthcare | Wipe | ○ | ○ | ○ |
| 17 | Enzysept PLUS Wipes | Quaternary Ammonium (N-Alkyl) | Wooil C&Tech | Wipe | ○ | ○ | ○ |
| 18 | Ethanol 80% | Ethanol 80% | All manufacture | Liquid | * | ○ | |
| 19 | Incidin™ Oxy Wipe | Hydrogen peroxide | ECOLAB | Wipe | * | ○ | ○ |
| 20 | Meliseptol Wipes Sensitive | Quaternary Ammonium (N-Alkyl) | B. Braun Medical AG | Wipe | * | ○ | |
| 21 | Oxivir® Tb Wipes | Hydrogen peroxide | Diversey | Wipe | * | ○ | ○ |
| 22 | Perasafe | Citric acid | LANXESS Deutschland GmbH | Powder | ○ | ○ | ○ |
| 23 | PROTEX® ULTRA DISINFECTANT WIPES | Quaternary Ammonium (N-Alkyl) | Parker Laboratory Inc. | Wipe | ○ | ○ | ○ |
| 24 | saFecide Medical wipes | Alcohol | Liebecos | Wipe | * | ○ | ○ |
| 25 | saFecide Sensitive wipes | Quaternary Ammonium (N-Alkyl) | Liebecos | Wipe | * | ○ | ○ |
| 26 | Sani-Cloth® Active wipes | | PDI | Wipe | ○ | * | |
| 27 | Sani-Cloth® bleach Germicidal Disposable Wipe | Sodium Hypochlorite | PDI | Wipe | ○ | ○ | ○ |
| 28 | Sani-Cloth® Detergent wipes | | PDI | Wipe | * | ○ | |
| 29 | Sani-Cloth® HB Germicidal Disposable Wipe | Quaternary Ammonium (N-Alkyl) | PDI | Wipe | * | ○ | ○ |

| No | Product Name | Active Ingredient | Manufacturer | Type | Body Surface | Control Panel | Monitor |
|---|---|---|---|---|---|---|---|
| 30 | SciCan Optim 33TB Surface CleaneDisinfectant Wipes | Hydrogen peroxide | SciCan | Wipe | * | ○ | |
| 31 | Sono Ultrasound Wipes | Quaternary Ammonium (N-Alkyl) | Advanced Ultrasound Solutions Inc. | Wipe | * | ○ | ○ |
| 32 | Super Sani-Cloth® Germicidal Disposable Wipe | Quaternary Ammonium (N-Alkyl) | PDI | Wipe | * | ○ | ○ |
| 33 | Super Sani-Cloth® Plus Wipes | | PDI | Wipe | * | ○ | |
| 34 | Surfa'safe | Quaternary Ammonium (N-Alkyl) | Laboratoires Anios | Liquid (Spray) | ○ | ○ | ○ |
| 35 | terralin® liquid | Alcohol | Schülke & Mayr GmbH | Liquid | * | ○ | |
| 36 | Tristel duo | Chlorine dioxide | Tristel Solutions Ltd. | Foam | * | ○ | ○ |
| 37 | Tristel Sporicidal Wipe | Chlorine dioxide | Tristel Solutions Ltd. | Wipe | * | ○ | ○ |
| 38 | Trophon® companion cleaning wipes | Quaternary Ammonium (N-Alkyl) | Nanosonics Limited | Wipe | * | ○ | |
| 39 | T-Spray II | Quaternary Ammonium (N-Alkyl) | Pharmaceutical Innovations, Inc. | Liquid (Spray) | ○ | ○ | ○ |
| 40 | Tuffie large detergent wipes | Ethylan CPG, Betain 810 | Vernacare | Wipe | * | ○ | |
| 41 | Virkon S | Potassium peroxymonosulfate | Lanxess Corporation | Powder | ○ | ○ | |
| 42 | Wip'Anios Excel wipes | Quaternary Ammonium (N-Alkyl) | Laboratoires Anios | Wipe | ○ | ○ | ○ |
| 43 | Yuhanrox regular (Yuhanrox regular1: water10) | Sodium Hypochlorite | Yuhan clorox | Liquid | ○ | ○ | ○ |

| | |
|---|---|
| ○ | Compatible |
| * | If the disinfectant is used on non-approved area, it may result in surface cracking or discoloration. |

**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.
- Air dry the device according to the disinfectant manufacturer's instruction, or remove water from all surface of the device using a sterile, lint-free cloth.
- Examine the device for damage such as cracks, splitting, sharp edges, or projections. If such damage is found, discontinue use of the device and contact your Samsung Medison representative.
- Repeated use of disinfectants may cause discoloration.

# 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 the Probe

All probes must be cleaned and disinfected after each use. Cleaning is an important procedure that must be carried out before disinfecting the probe. For information on cleaning and disinfecting the probe, 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.

As ultrasound probes are classified into critical, semi-critical or non-critical devices based on the standards of FDA guidance* and the Hygiene Requirements for the Reprocessing of Medical Devices from Germany guideline of Robert Koch Institute (RKI), proper cleaning and disinfection or sterilization methods for that classification should be used. 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.












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## Disinfectants Matrix

| No. | Classification | Name | Type | Disinfectant Level | Manufacture | Active Ingredient | 3D: CV1-8A CV1-8AD | 3DC2-6 | 3D2-6 3D2-6ET | V2-6 | 3D4-8 3D4-8ET | V4-8 | VE4-8 | VN4-8 | 3D4-9 3D4-9ES | V5-9 | EV3-10B | LV3-14A V6-12 | EV2-10A | Convex: C1-4EC | CS1-4 | SC1-6 | CA1-7A CA1-7AD | C2-4/20 | C2-4ES | C2-5 | CA2-6BM | C2-6 C2-6IC | CN2-8 | C2-8 C2-8ED | CA2-8A CA2-8AD CF2-8 | CA2-9A CA2-9AD | C3-7EP | CA3-10A | CA4-9/ 10ED | CN4-9 | C5-8 CF4-9 | CA1-7S | Endocavity: EC4-9 | EC4-9IS | ER4-9/10ED | EV4-9/10ED | EVN4-9 | VR5-9 | EA2-11B | EA2-11AR EA2-11AV | E3-12A | Linear: LA2-9A L4-7 | L3-8 | L3-12A LA3-14A LA3-14AD | LA3-16A LA3-16AD LF5-13 | LA3-16AI LS6-15 | LA4-18B LA4-148BD | LM4-15B | LN5-12/ 40 | LN5-12 | LF5-12 | L5-12/ 50 | LS5-13 | L5-13/50 | L5-13 L5-13IS | L7-16 L7-16IS | LA2-14A | Phased Array: P1-4 | PA1-5A | PM1-6A | PN2-4 | P2-4AH | P2-4BA PE2-4 | SP3-8 | PA3-8B P3-8 P3-8CA | PA4-12B P4-12 | CW: DP2B | CW2.0 | CW 4.0 | CW6.0 | DP8B | TEE: MMPT3-7 MPT3-7 |
|---|---|---

# Disinfectants Matrix

| No. | Classification | Name | Type | Disinfectant Level | Manufacture | Active Ingredient | 3D | | | | | | | | | | | | Convex | | | | | | | | | | | |

# Validated High Level Disinfection Instruction for Samsung Transducers

## Tristel Duo ULT: Wiping Method for Endocavity Probes

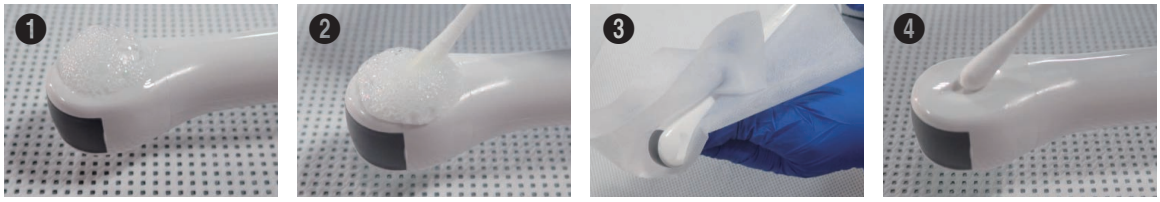
### 1. Cleaning the Probe

**NOTE:** Always use protective equipment such as face mask, eyewear, and gloves when cleaning and disinfecting probes.

1) If applicable, remove the biopsy adapter, needle guide or protective sheath from the probe.
2) Before conducting the HLD process, clean the probes thoroughly.

**NOTE:** Do not use paper or abrasive products when cleaning the probe. They can damage the lens of the probe.

3) Hold the probe and put one pump of Tristel Duo ULT in the crevices of the probe. (See Figure 1 ❶)
4) Use a swab to spread the Tristel Duo ULT Foam in the crevices. (See Figure 1 ❷)
5) Put two pumps of Tristel Duo ULT on a Tristel Dry Wipe and clean the transducer from housing to the lens of the probe. (See Figure 1 ❸)
6) Use another dry swab to dry and clean the crevices. (See Figure 1 ❹)
7) After cleaning, thoroughly dry the probe.




[Figure 1]

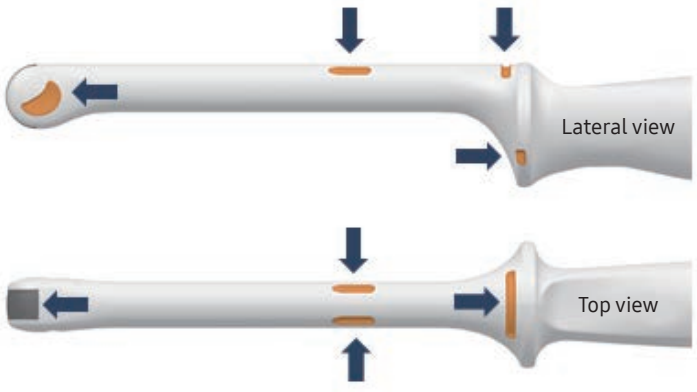
### 2. Using Tristel Duo ULT

Follow Tristel Duo ULT manufacturer's instructions for preparation, temperature, solution strength, and duration of contact. Ensure that the solution strength and duration of contact are appropriate for the intended clinical use of the device. Be sure to observe the solution expiration date.

## 3. Disinfecting the probe

1) Change your gloves.
2) Hold the probe and put one pump of Tristel Duo ULT in the crevices of the probe. (See Figure 2 ❶)
3) Use a swab to spread the Tristel Duo ULT Foam in the crevices. Leave the disinfectant on the probe for at least 30 seconds. (See Figure 2 ❷)
4) Put two pumps of Tristel Duo ULT on a Tristel Dry Wipe and disinfect the transducer from housing to the lens of the probe. Leave the disinfectant on the probe for at least 30 seconds. (See Figure 2 ❸)


[Figure 2]




[Figure 3 – Crevices]

## 4. Dry

1) Leave the surface to dry to ensure at least 30 second contact time.
2) Use the probe immediately or store the probe properly (e.g. in a sterile bag) to prevent any further contamination.

## 5. Management

1) Register the disinfection data for traceability according to local regulations.
2) Examine the probe and cable for damage such as cracks, splitting, sharp edges, or projections. If such damage is found, discontinue use of the device and contact your Samsung Medison representative.

※ Using disinfection wipes for devices requiring high-level disinfection may be prohibited in some countries such as USA.

## Metricide OPA Plus: Immersion Method for Endocavity Probes

### 1. Cleaning the Probe

**NOTE:** Always use protective equipment such as face mask, eyewear, and gloves when cleaning and disinfecting probes.

1) If applicable, remove the biopsy adapter, needle guide or protective sheath from the probe.
2) Before conducting the HLD process, clean the probes thoroughly with wiping or immersion method as per the instructions of the chosen detergent manufacturer.

**NOTE:** Do not use paper or abrasive products when cleaning the probe. They can damage the lens of the probe.

3) If necessary, follow the rinse (and neutralization) instructions from the cleaner or disinfectant manufacturer for rinsing the probe.
4) After cleaning, thoroughly dry the probe.

### 2. Using Metricide OPA Plus

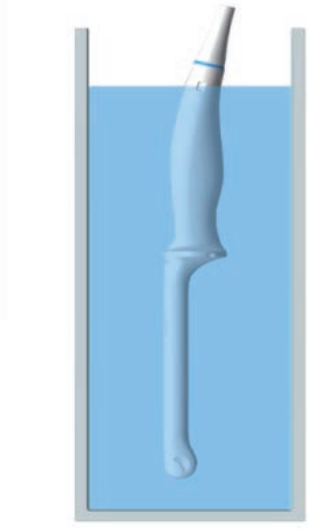
Follow Metricide OPA Plus manufacturer's instructions for preparation, temperature, solution strength, and duration of contact. Ensure that the solution strength and duration of contact are appropriate for the intended clinical use of the device. Be sure to observe the solution expiration date.

### 3. Disinfecting the Probe

1) Change your gloves.
2) Immerse the probe into the Metricide OPA Plus solution. (See Figure 4)

**NOTE:** Ensure that all air bubbles are removed from the surface of the probe by agitating.

3) Allow the probe to soak in the Metricide OPA solution for 12 minutes.



[Figure 4]

## 4. Rinse

1) Thoroughly rinse the probe by fully immersing it in pure water to the point in the figure above. (See Figure 4)
2) Remove all air bubbles from the surface of the probe and allow the probe to set for a minimum of 1 minute.
3) Repeat the Step 1) and 2) of Rinse two more times for a total of 3 rinses using a fresh batch of pure water each time.

## 5. Dry

1) Remove water from all surfaces of probe with a sterile lint-free cloth.
2) Use the probe immediately or store the probe properly (e.g. in a sterile bag) to prevent any further contamination.

## 6. Management

1) Register the disinfection data for traceability according to local regulations.
2) Examine the probe and cable for damage such as cracks, splitting, sharp edges, or projections. If such damage is found, discontinue use of the device and contact your Samsung Medison representative.

## Trophon EPR, Trophon 2: Disinfection System Method for Endocavity Probes

### 1. Cleaning the Probe

**NOTE:** Always use protective equipment such as face mask, eyewear, and gloves when cleaning and disinfecting probes.

1) If applicable, remove the biopsy adapter, needle guide or protective sheath from the probe.
2) Before conducting the HLD process, clean the probes thoroughly with wiping or immersion method as per the instructions of the chosen detergent manufacturer.

**NOTE:** Do not use paper or abrasive products when cleaning the probe. They can damage the lens of the probe.

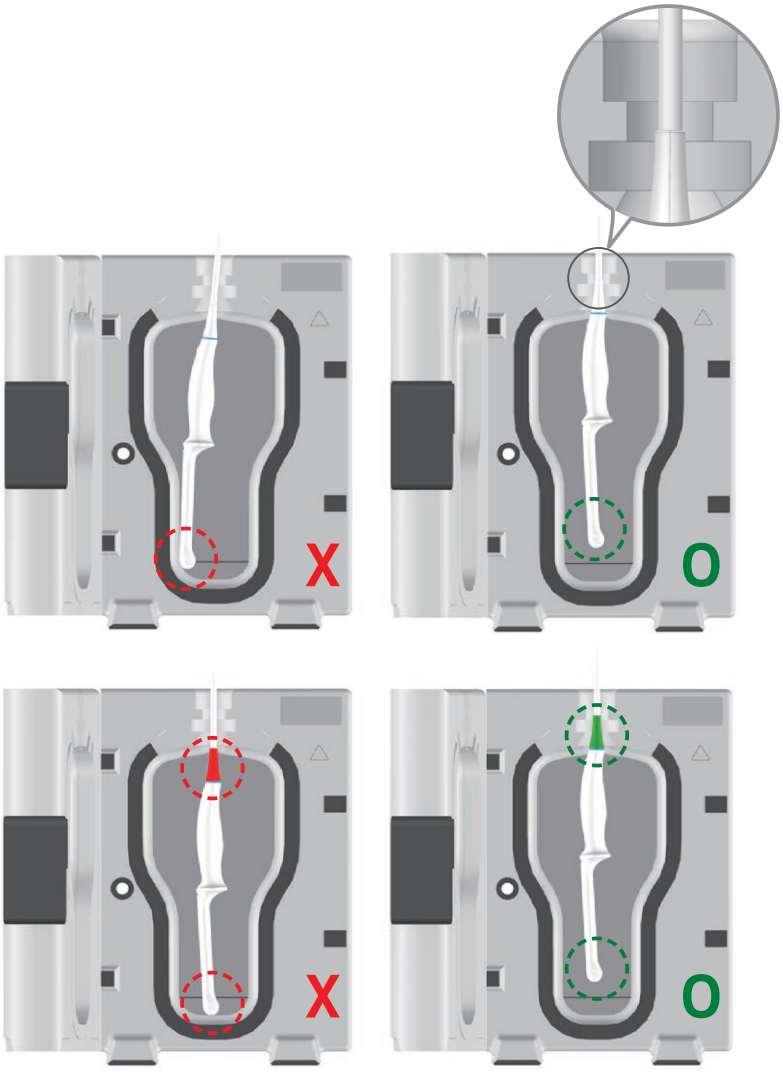
3) If necessary, follow the rinse (and neutralization) instructions from the cleaner or disinfectant manufacturer for rinsing the probe.
4) After cleaning, thoroughly dry the probe.

### 2. Preparing Trophon EPR, Trophon 2

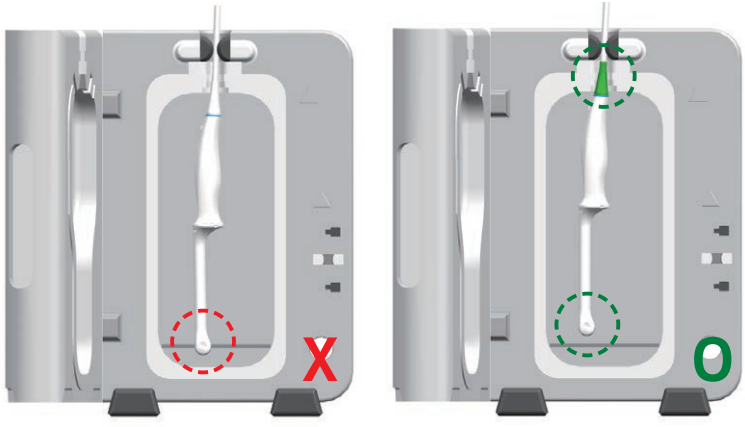
**NOTE:** Refer to the user instructions of the Trophon EPR, Trophon 2 for details of proper use, storage and disposal of waste.

1) Place the probe in Trophon EPR, Trophon 2 following the user instructions of Trophon EPR, Trophon 2.

**NOTE:** Improper positioning of the probe can damage the probe due to the increased temperature of the wall and high-level disinfection may not be achieved. (See Figures 5, 6)




[Figure 5 – Trophon EPR]




[Figure 6 – Trophon 2]

## 3. Disinfecting the Probe

1) Change your gloves.
2) Start the disinfection process and wait until the end of the cycle. (The standard cycle takes 7 minutes)
3) Wear a new set of clean gloves and always remove the probe immediately at the end of the cycle from the Trophon EPR, Trophon 2.

**NOTE:** After completion of the disinfection process, the surface temperature of the probe and chamber may have increased. Always use protective equipment such as face mask, eyewear, and gloves.

## 4. Rinse & Dry

1) Remove hydrogen peroxide from all surfaces of the probe with a sterile lint-free cloth.

**NOTE:**

- Aggressive wiping or scrubbing can damage the probe. Use a gentle wiping motion for the probe lens, the strain relief, and the areas surrounding the strain relief.
- When wiping the probe, hold the housing. Do not suspend the probe by the cable. This can damage probes.

2) Use the probe immediately or store the probe properly (e.g. in a sterile bag) to prevent any further contamination.

## 5. Management

1) Register the disinfection data for traceability according to local regulations.
2) Examine the probe and cable for damage such as cracks, splitting, sharp edges, or projections. If such damage is found, discontinue use of the device and contact your Samsung Medison representative.

## Cidex OPA: Immersion Method for MPTEE Probe

### 1. Cleaning the Probe

**NOTE:** Always use protective equipment such as face mask, eyewear, and gloves when cleaning and disinfecting probes.

1) If applicable, remove the biopsy adapter, needle guide or protective sheath from the probe.
2) Before conducting the HLD process, clean the probes thoroughly with wiping or immersion method as per the instructions of the chosen detergent manufacturer.

**NOTE:**

- Do not use paper or abrasive products when cleaning the probe. They can damage the lens of the probe.
- Immerse only the portion of the probe between the tip at the end of the probe and the area marked as 100cm. (See Figure 7)

3) If necessary, follow the rinse (and neutralization) instructions from the cleaner or disinfectant manufacturer for rinsing the probe.
4) After cleaning, thoroughly dry the probe.

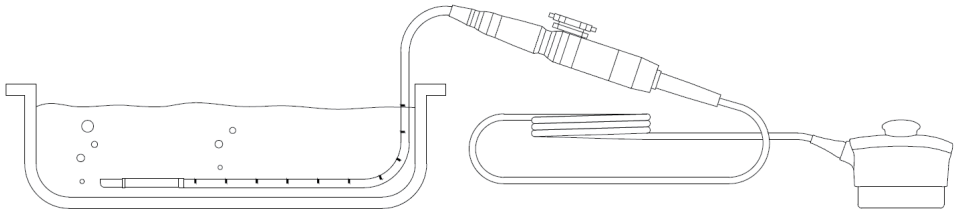
### 2. Using Cidex OPA

Follow Cidex OPA manufacturer's instructions for preparation, temperature, solution strength, and duration of contact. Ensure that the solution strength and duration of contact are appropriate for the intended clinical use of the device. Be sure to observe the solution expiration date.

### 3. Disinfecting the Probe

1) Change your gloves.
2) Immerse the probe into the Cidex OPA solution. (See Figure 7)

**NOTE:** Immerse only the portion of the probe between the tip at the end of the probe and the area marked as 100cm.



[Figure 7]

**NOTE:**

- Ensure that all air bubbles are removed from the surface of the probe by agitating.
- Do not allow sharp objects to touch the lens. Do not touch the lens unnecessarily. This can damage the lens.

3) Allow the probe to soak in the Cidex OPA solution for 12 minutes.

## 4. Rinse

1) Thoroughly rinse the probe by fully immersing it in sterile pure water to the point in the figure above. Immerse only the portion of the probe between the tip at the end of the probe and the area marked as 100cm. (See Figure 7)
2) Remove all air bubbles from the surface of the probe and allow the probe to set for a minimum of 1 minute.
3) Repeat the Step 1) and 2) of **Rinse** two more times for a total of 3 rinses using a fresh batch of sterile pure water each time.

## 5. Dry

1) Remove water from all surfaces of probe with a sterile lint-free cloth.
2) Use the probe immediately or store the probe properly (e.g. in a sterile bag) to prevent any further contamination.

## 6. Management

1) Register the disinfection data for traceability according to local regulations.
2) Examine the probe and cable for damage such as cracks, splitting, sharp edges, or projections. If such damage is found, discontinue use of the device and contact your Samsung Medison representative.

## Gigasept® PAA concentrate: Immersion Method for MPTEE Probe

### 1. Cleaning the Probe

**NOTE:** Always use protective equipment such as face mask, eyewear, and gloves when cleaning and disinfecting probes.

1) If applicable, remove the biopsy adapter, needle guide or protective sheath from the probe.
2) Before conducting the HLD process, clean the probes thoroughly.

**NOTE:**

- Do not use paper or abrasive products when cleaning the probe. They can damage the lens of the probe.
- Immerse only the portion of the probe between the tip at the end of the probe and the area marked as 100cm. (See Figure 8)

3) Wipe the MPTEE probe with 5 Tristel Dry Wipes soaked with 8 ml 1.6% CIDEZYME and wipe for 3 minutes.
4) Thoroughly clean the probe with a detergent especially taking care of the junctions of the flexible part and the crevices on the transducer. (See Figure 8)
5) Rinse the MPTEE probe for 1 minute with water.

[Figure 8]

### 2. Using Gigasept® PAA concentrate

Prepare a Gigasept® PAA concentrate with a concentration of at least 2% using the manufacturer's instructions.

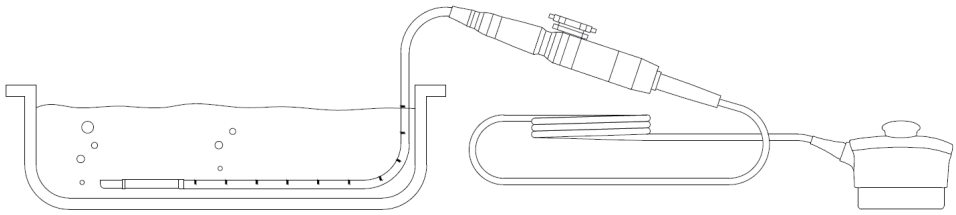
### 3. Disinfecting the Probe

1) Change your gloves.
2) Place the MPTEE probe in the 2% Gigasept® PAA concentrate. (See Figure 9)

**NOTE:** Immerse only the portion of the probe between the tip at the end of the probe and the area marked as 100cm. (See Figure 9)

3) Ensure that all air is removed from the surface of the MPTEE probe.
4) Leave the MPTEE probe for 15 minutes in the solution.

**NOTE:** Gigasept® PAA concentrate shall not be reused beyond 12 hours.



[Figure 9]

## 4. Rinse

1) Remove the MPTEE probe from the solution and thoroughly rinse all surfaces up to the immersion point. (See Figure 9)
2) Repeat this process two more times with sterile water, each time for a minimum of 1 minute.

## 5. Dry

1) 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.
2) Use the probe immediately or store the probe properly (e.g. in a sterile bag) to prevent any further contamination.

## 6. Management

1) Register the disinfection data for traceability according to local regulations.
2) Examine the probe and cable for damage such as cracks, splitting, sharp edges, or projections. If such damage is found, discontinue use of the device and contact your Samsung Medison representative.