

SAMSUNG

Cleaning and Disinfecting the Ultrasound System - System/Monitor/Probe

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1. 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 the areas listed.

– [Disinfectants_Matrix List](#) : Please refer to the attached Excel file.

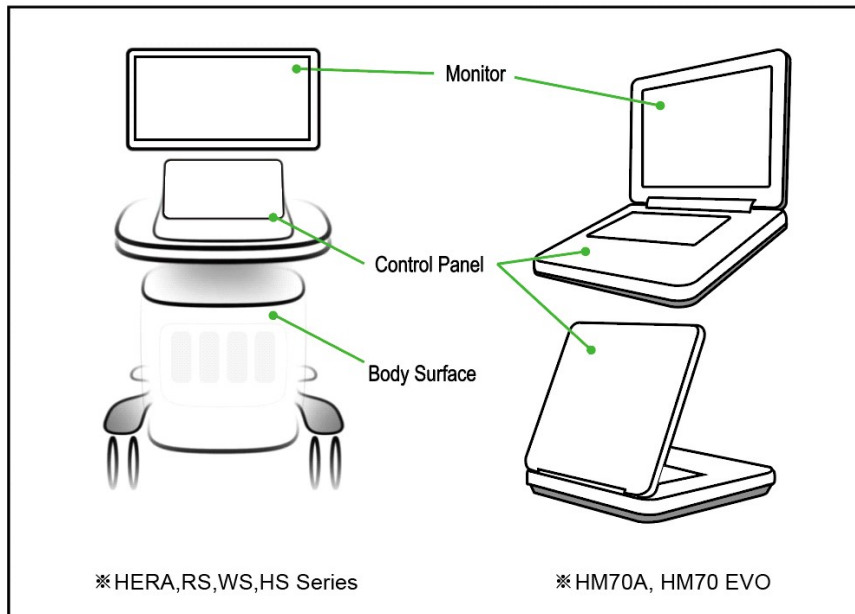


CAUTION

- Using a non-compatible disinfection procedure may result in damage to the system. Ensure to check the expiration date of the disinfectant prior to use.
- 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 surfaces 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.
- Multiple uses of the disinfectants may cause discoloration over time.
- Disinfectant residue may cause product malfunction. After using the disinfectant on the product, please ensure to remove any remaining disinfectant with a soft cloth before operating the product.



NOTE



2. 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 probe disinfection, 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.

– **Disinfectants_Matrix List** : Please refer to the attached Excel file.



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

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). Therefore, you should use the cleaning, disinfection, and sterilization methods appropriate for each classification. Proper maintenance is also required to maintain the performance of ultrasound probes.

Choose the Correct Probe-Care Method in the Below Table.

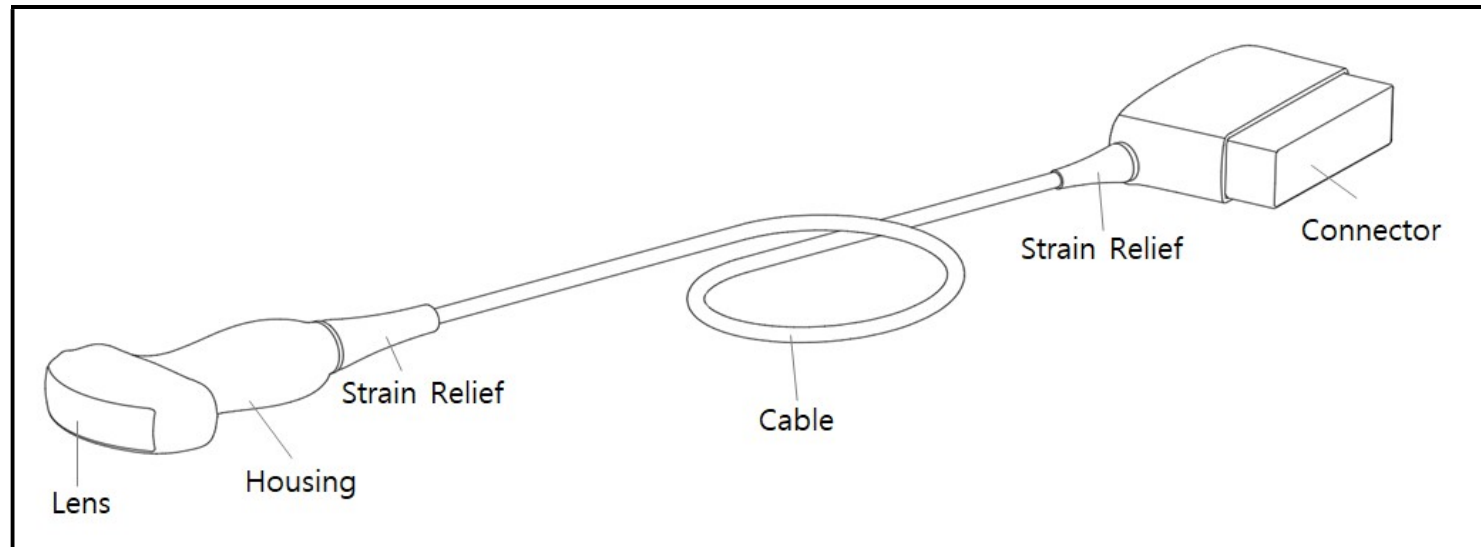
Classification Criteria	Contact Area	Application Probe	Level Selection
Non-critical devices	Intact skin	Curved, Linear, and Phased array probes	Low level disinfection
Semi-critical devices	Mucous membrane, damaged skin	Endocavity, MPTEE	High level disinfection or sterilization
Critical devices	Blood,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

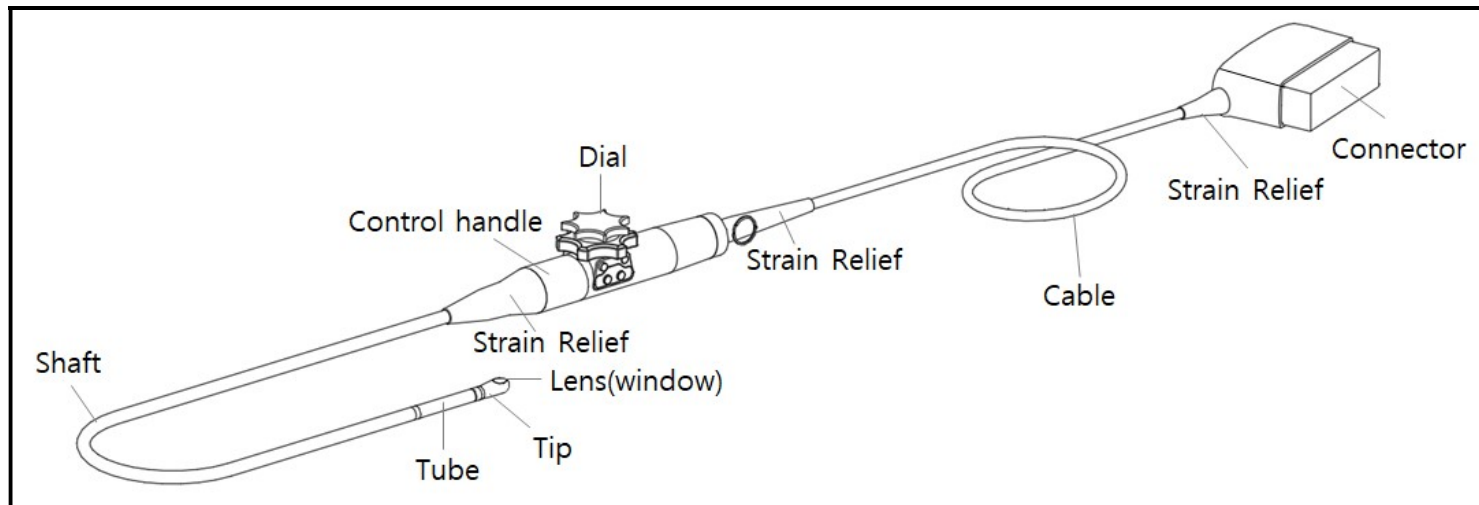
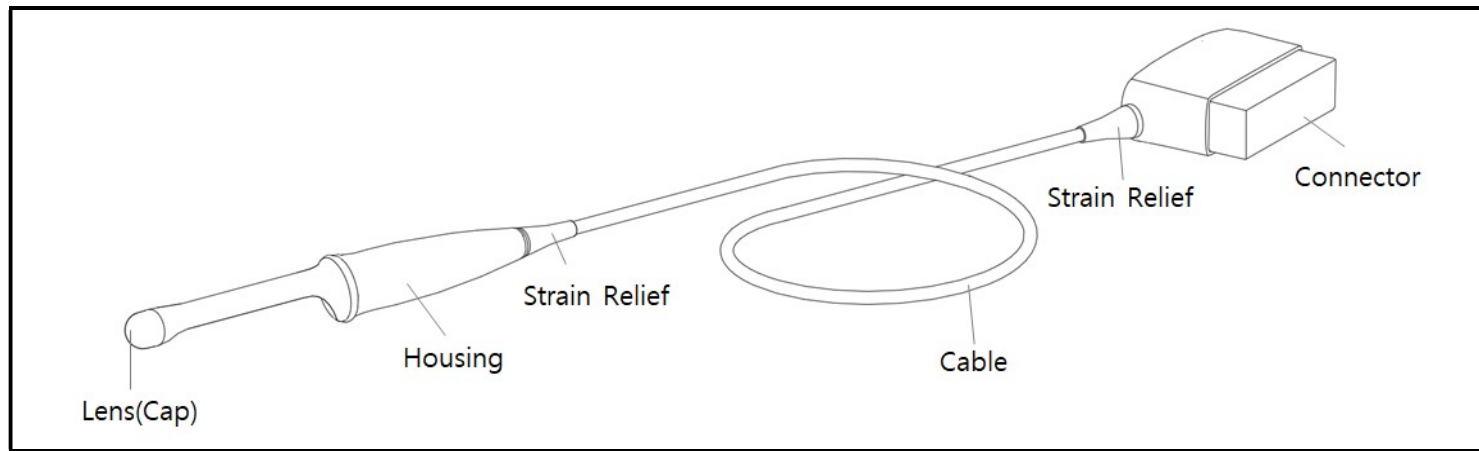
※ Guidance for Industry and FDA Staff – Marketing Clearance of Diagnostic Ultrasound Systems and Transducers - Appendix E

※ 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 to use 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.

- ※ All disinfection methods for Semi-critical probes that are marked with ♦ in the attached Excel file have been validated by Samsung Medison for biological effectiveness.
- **User Guide:** This is provided as a booklet upon purchase of the product.
- **Disinfectants_Matrix List :** Please refer to the attached Excel file.





3. Using Ultrasound Gel

For successful acoustic signal transmission, ultrasound gels or couplant must be applied.



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 users.
- Only use the ultrasound gels approved by Samsung Medison. Using unapproved gels may result in damage to the probe and void the warranty.
- Completely remove the remaining ultrasonic gel on the probe surface after using the probe. Residues from the ultrasonic gel may result in contamination and discoloration.
- Do not use ultrasound gels or couplant that contain any of the following ingredients:
 - Oil-based lotion type couplants, Mineral oil, Olive oil, Lubricant oil, Paraffin-based grease, Dimethylsilicone, Alcohol such as methanol, Ethanol or ethanol, or isopropanol, Acetone, Dioctylphthalate, Aromatic substances, Iodine compounds, Aloe Vera



CAUTION

- The tip of the gel tube may cause damage to the probe lens.
- 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.



4. Validated High-Level Disinfection Instruction for Probe

☐ Tristel Duo ULT: Wiping Method for Endocavity Probes

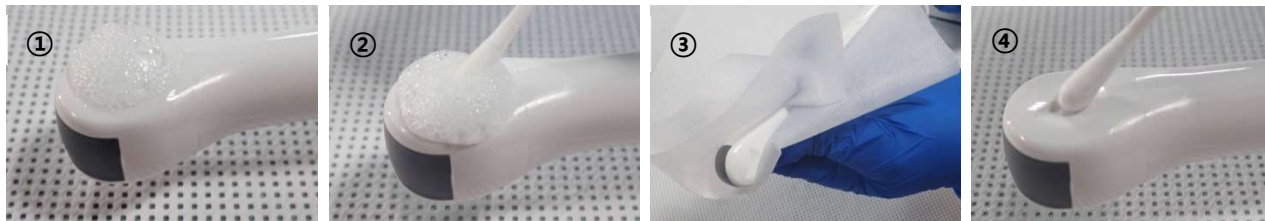
1. Cleaning the Probe

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 probe lens.

- 3) Hold the probe and put one pump of Tristel Duo ULT in the crevices of the probe. (See Figure 1 ①)
- 4) Use a swab to spread the Tristel Duo ULT Foam in the crevices. (See Figure 1 ②)
- 5) Put two pumps of Tristel Duo ULT on a Tristel Dry Wipe and clean from housing to the lens of the probe. (See Figure 1 ③)
- 6) Use another dry swab to dry and clean the crevices. (See Figure 1 ④)
- 7) After cleaning, thoroughly dry the probe.



[Figure 1]

2. Using Tristel Duo ULT

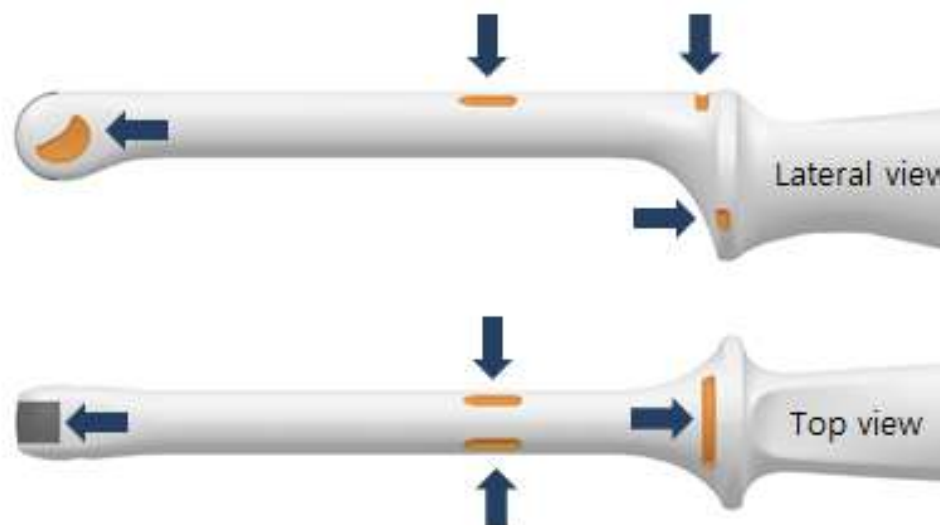
Follow Tristel Duo ULT manufacturer's instructions for preparation, temperature, solution strength, and duration of contact. Ensure that the solution strength and duration of contact are appropriate for the intended clinical use of the device. Be sure to observe the solution expiration date.

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 ①)
- 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 ②)
- 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 ③)



[Figure 2]



[Figure 3 - crevices]

4. Dry

- 1) Leave the surface to dry, ensuring at least 30 seconds of dry 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 the 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.
- ※ Regulation and restriction of Semi-critical probe wipe type disinfection may differ per country. Please check local regulations before using wipe disinfection on Semi-critical probe.

☐ **CIDEX® OPA : 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 High-Level Disinfection(HLD) process, clean the probes thoroughly all cleaners and disinfections listed in the cleaning and disinfection guide are in accordance to the manufacturer's instructions.

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

- 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

- 1) Before using the CIDEX® OPA, be sure to read the usage instructions.

NOTE: The shelf life of an unopened bottle of CIDEX® OPA is two years. The CIDEX® OPA requires NO activation.

NOTE: In accordance to the CIDEX® OPA Manufacturer's usage instructions, Prepare the use CIDEX® OPA with a concentration of at least 0.55%.

- 2) Before using CIDEX® OPA every time, must be verified by CIDEX® OPA test strip to see if ortho-phthalaldehyde concentration is above 0.3% Minimum Effective Concentration(MEC).

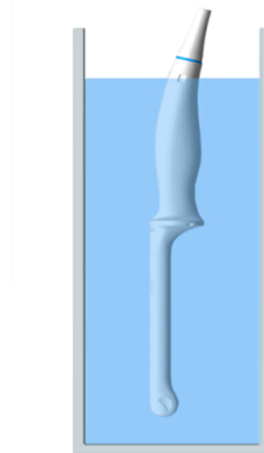
NOTE: CIDEX® OPA must be discarded after 14 days, even if the CIDEX® OPA test strip indicates a concentration above the Minimum Effective Concentration(MEC).

3. Disinfecting the Probe

- 1) Change your gloves.
- 2) Immerse the probe into the CIDEX® OPA 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 CIDEX® OPA for 12 minutes.



[Figure 4]

4. Rinse

- 1) Thoroughly rinse the probe by fully immersing it in sterile 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 sterile water each time.

5. Dry

- 1) Remove water from all surfaces of the 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) Visibly examine the probe and cable for any potential damage such as cracks, splitting, sharp edges or projections. If any damage is observed then discontinue the use of the device and contact your local Samsung Medison representative.

NOTE: Register the disinfection data according to local regulations for traceability.

☐ **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

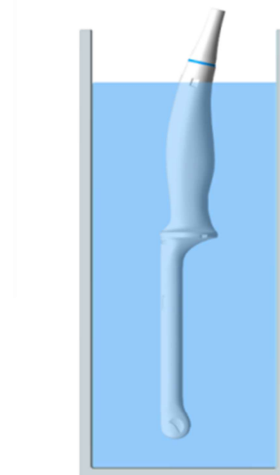
Follow Metricide™ OPA Plus manufacturer's instructions for preparation, temperature, solution strength, and duration of contact. Ensure that the solution strength and duration of contact are appropriate for the intended clinical use of the device. Be sure to observe the solution expiration date.

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) 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.

NOTE: Register the disinfection data according to local regulations for traceability.

☐ trophon® EPR/trophon®2: Automated High-Level Disinfection System 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.

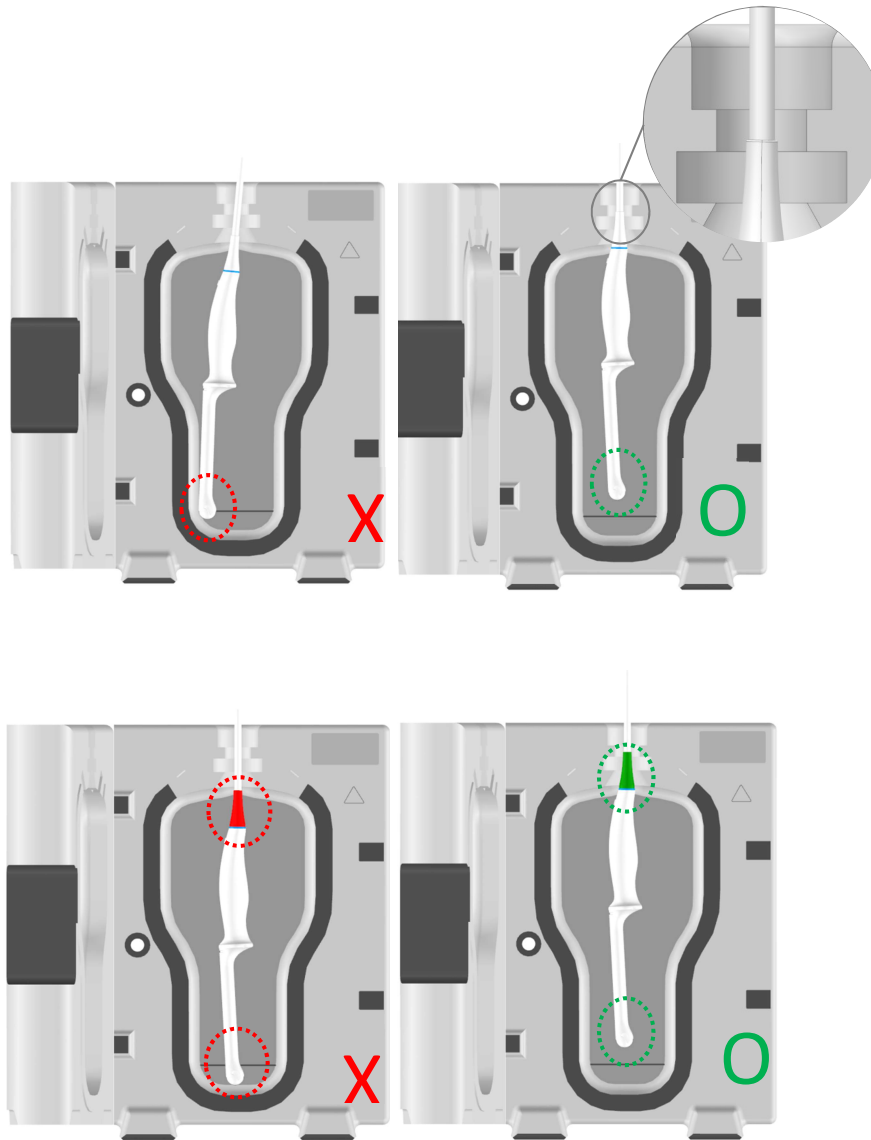
- 3) If necessary, follow the rinse (and neutralization) instructions from the cleaner or disinfectant manufacturer for rinsing the probe.
- 4) After cleaning, thoroughly dry the probe.

2. Preparing trophon® EPR/trophon®2

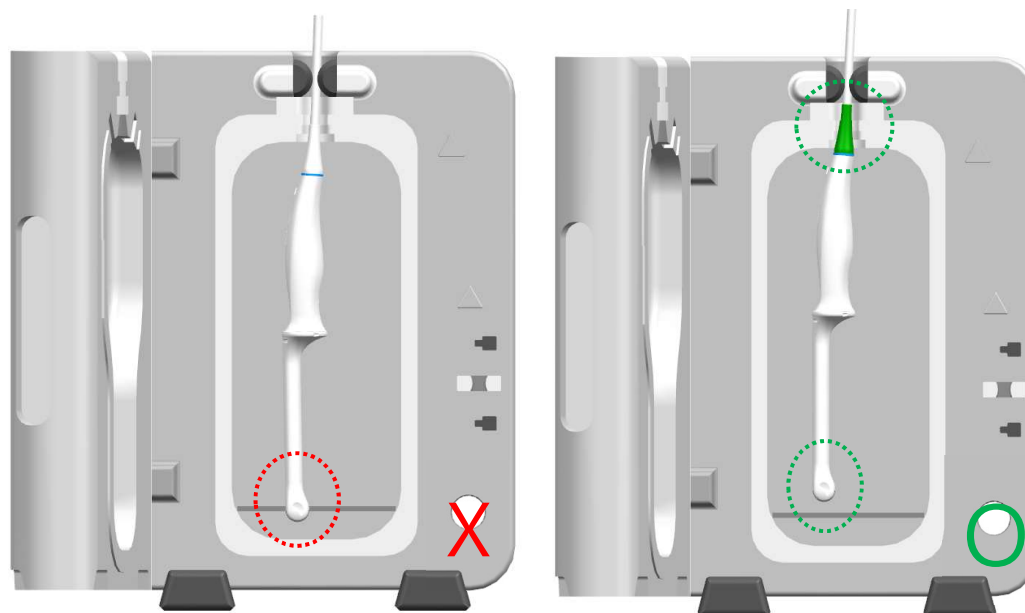
- 1) Refer to trophon® EPR/trophon®2 Instructions for use for proper use of the device, including correct positioning of the probe.

NOTE: Incorrect positioning of the probe may result in: Unsuccessful HLD cycles. (See Figures 5, 6.)

- ☐ Residual disinfectant remaining on the probe's surface may lead to temporary bleaching or irritation of the skin, or both, if gloves are not worn.
- ☐ Check with your Samsung Medison representative to use probes not listed in the trophon® EPR/trophon®2 Compatible Ultrasound Probe list.
- ☐ Damage to the probe may occur if in contact with the chamber wall.



[Figure 5] trophon® EPR



[Figure 6] trophon®2

3. Disinfecting the Probe

- 1) Refer to trophon® EPR/trophon®2 Instructions for Use for proper use of the device, instructions on how to run a high-level disinfection cycle and removal of the probe.
- 2) Remove the probe in trophon® EPR/trophon®2 following the user instructions of trophon® EPR/trophon®2 for details of proper use.

NOTE: After HLD cycle completion, wear a new set of clean gloves and it is recommended to remove the probe as soon as possible.
(The chamber may have surface temperatures up to 60°C. Care should be taken not to touch the chamber.)

4. Dry

- 1) Use a dry, sterile lint-free cloth to wipe the probe after a disinfection cycle. Visually inspect the probe and remove any present disinfectant residue.

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.

NOTE: When wiping the probe, hold the housing. Do not suspend the probe by the cable. This can damage the 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) 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.

NOTE: Register the disinfection data according to local regulations for traceability.

☐ **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.

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 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.

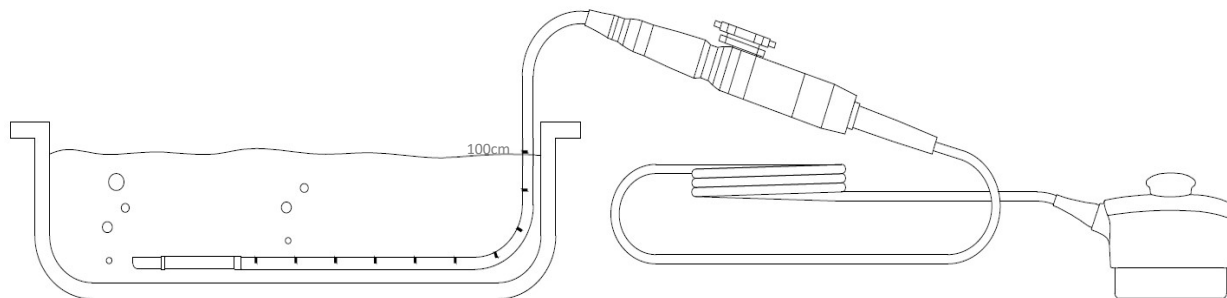
2. Using CIDEX® OPA

Follow the 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.

NOTE: 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 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 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) 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.

NOTE: Register the disinfection data according to local regulations for traceability.

□ 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.

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 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.

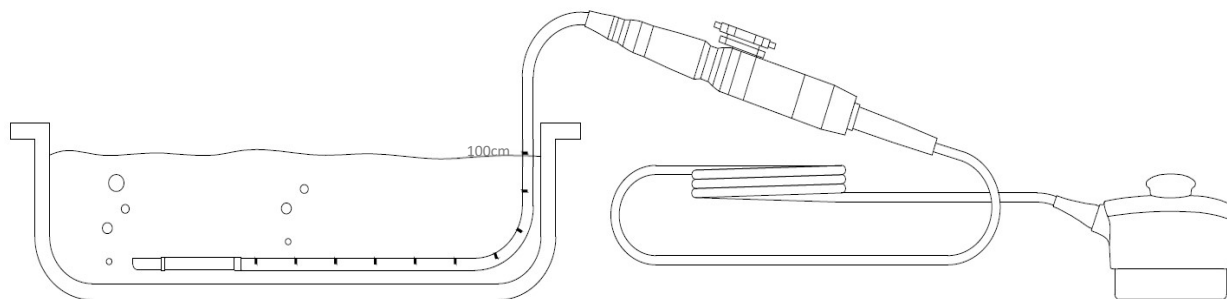
3. Disinfecting the Probe

- 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 working solution shall not be used more than 12 hours and/or have visible contamination.



[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) Rinse two more times with sterile water for a minimum of 1 minute each time.

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) 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.

NOTE: Register the disinfection data according to local regulations for traceability.