

**ZONARE**  
**ZONARE Transducers**  
**Cleaning & Disinfection**

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CAUTION: Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner (USA).

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## Symbols



Draws attention to information that may relate to safety of the patient, the operator, or the equipment



Waste Electrical & Electronic Equipment Standard.  
ZONARE meets the WEEE Standard. For more information, contact ZONARE Inc.



Refers to a type BF patient-applied part (B= body, F= floating applied part)



Refers to a type CF patient-applied part (C= cardiac, F= floating applied part)



Manufacturer



Date of manufacture



Consult Operator Manual



Authorized Representative in the European Community



Catalog Number of Item



Shipping: Temperature Limits

**Rx Only**

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner (USA).



Serial Number of Item



Refer to the ZONARE Ultrasound System Safety Manual, Operator's Manual or Instructions for Use for a description of the system including compatible transducers and operating instructions.

## Intended Use

ZONARE Transducers are intended for use with ZONARE's Ultrasound Systems. Refer to the corresponding ZONARE Ultrasound System Manual(s) for the Intended Use.

## Cautions and Warnings

Refer to the corresponding ZONARE Ultrasound System Manual(s) or Instructions for Use for a complete list of Warnings and Cautions associated with the use of the ZONARE Transducers and Ultrasound System.



### CAUTIONS

- Disinfectants identified are recommended because of their chemical compatibility with product materials, not their biological effectiveness. For biological effectiveness of a disinfectant, see the guidelines and recommendations of the disinfectant manufacturer.
- During immersion disinfection, never immerse the transducers longer than 45 minutes. Damage may occur to the transducer housing and/or components if disinfection times exceed these recommended limits.
- Using a non-recommended cleaning or disinfectant solution, incorrect solution strength, or immersing the transducer deeper or longer than indicated can damage the transducer. Damages linked to the use of disapproved chemicals are not covered under product warranty or service contract.
- To prevent possible damage to the electronics of the transducer, never immerse the transducer beyond the point (10 mm below the top edge of the transducer housing) shown in [Figure 1](#). Additionally, use caution during disinfection process to avoid getting fluid on transducer pins. Do not use any cleaner or disinfectant on the transducer pins.
- Nanosonics Trophon® High-Level Disinfection method has been qualified for use on the E9-4 Transducer running software version 4.7.323L or higher on the z.one ultra Ultrasound System and all software versions on the ZS3 Ultrasound System. Running software versions prior to 4.7.323L on the z.one ultra after using the Trophon® EPR disinfection system can result in acoustic output levels exceeding FDA limits. Note: The software version on the z.one ultra can be verified by pressing the service key.



### WARNINGS

- Always examine transducers for damage, such as cracks, splitting, holes, or fluid leaks. If damage is evident, discontinue use of the transducer and contact **ZONARE**.
- Prior to initiating any disinfection process, disconnect the transducer from the Ultrasound System.
- To avoid electrical shock prior to cleaning any device, turn off the system and unplug from AC power outlet. Do not allow disinfectant to contact metal surfaces. Always use protective eyewear and clothing when cleaning or disinfecting device.
- Disinfectant wipes and topical spray products are not FDA cleared high-level disinfectants and do not provide adequate protection should the transducer become cross-contaminated.

## General Cleaning

ZONARE Transducers are not provided cleaned and/or disinfected. The user must clean and/or disinfect ZONARE transducers prior to use, as appropriate.

When choosing a disinfectant, determine the required level of disinfection based on intended use and possibility of cross-contamination.

## Cleaning & Disinfecting

Note: The instructions below should be used in conjunction with the Cleaning and/or Disinfection agent manufacturer's instruction for use. These provide guidelines to ensure ZONARE transducers are not damaged during the cleaning and/or disinfection process.

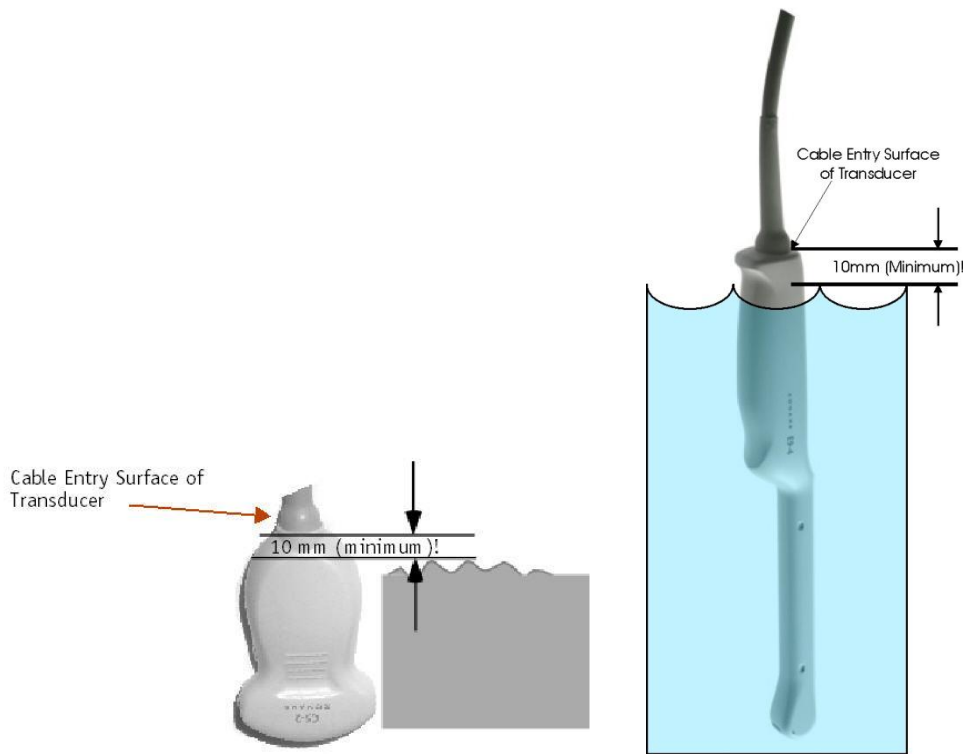
### **Wipe Method**

1. Disconnect the transducer from the Cart or Scan Engine/Scan Module. If present, remove the transducer cover/sheath and discard.
2. Use a soft cloth dampened with a mild soap (Liquinox) and water solution to remove particulate, ultrasound coupling gel, or body fluids.
3. Examine the transducer for damage, such as cracks, holes, or fluid leaks. If damage is evident discontinue use of the transducer and contact **ZONARE** Technical Support.
4. Next, **ZONARE** recommends the use of a disinfectant solution to wipe the transducer housing, strain relief and cable. Follow the disinfectant manufacturer's instructions for proper cleaning. A list of approved disinfecting solutions is listed below.
5. Air-dry (or towel dry) the transducer with a soft, clean cloth.

### **Immersion Method**

**NOTE: All transducers may be immersed except for AUX CW probes.**

1. Disconnect the transducer from the Cart or Scan Engine/Scan Module. If present, remove the transducer cover/sheath and discard.
2. Use a soft cloth dampened with a mild soap (Liquinox) and water solution to remove particulate, ultrasound coupling gel, or body fluids.
3. Examine the transducer for damage, such as cracks, splitting, holes, or fluid leaks. If damage is evident, discontinue use of the transducer and contact **ZONARE** Technical Support.
4. Mix the disinfectant solution according to the manufacturer's instructions for solution strengths and disinfecting times. A list of approved disinfecting solutions is listed below.
5. Immerse the transducer into the disinfecting solution, ensuring it is not immersed below the depth indicated in **Figure 1** (next page). Immersion time should be as recommended by the disinfectant manufacturer.
6. Wipe the surface of the transducer with a soft cloth dampened with a mild soap (Liquinox) and water solution.
7. Wipe the transducer again with a soft cloth soaked with fresh water to remove any residual cleaning solution prior to use on patients.
8. Air-dry (or towel dry) the transducer with a soft, clean cloth.



**Figure 1: Immersion Level Limits for Transducers**

### **High Level Disinfection**

1. Disconnect the transducer from the Cart or Scan Engine/Scan Module. If present, remove the transducer cover/sheath and discard.
2. Use a soft cloth dampened with a mild soap (Liquinox) and water solution to remove particulate, ultrasound coupling gel, or body fluids.
3. Examine the transducer for damage, such as cracks, holes, or fluid leaks. If damage is evident discontinue use of the transducer and contact **ZONARE** Technical Support.
4. Follow disinfectant manufacturer's instructions.

## ZONARE-Approved Transducer Disinfectants

**NOTE: All transducers may be immersed except for AUX CW probes.**

The following disinfectants are approved for all **ZONARE** transducers *except* the P8-3TEE:

### ***Immersion Solutions***

CIDEX	CIDEX OPA (nonglututaraldehyde)
Anioxyide 1000	CIDEX Plus
Metricide – 14 day	--

### ***Wipe Solutions***

T-SPRAY	T-SPRAY II
Sani-Cloth PLUS	CaviWipes
50% Isopropyl Alcohol LF	--

Disinfectants Approved for P8-3TEE Transducer

### ***Immersion Solutions***

Cidex OPA (non glututaraldehyde)	Cidex Plus®
Metricide Metricide 28® Metricide Plus 30®	Omnicide 14 N.S.® Omnicide 28
Steranios 2% Steranios 2% N.G.® Steranios 2% E.C.S.®	Gigasept AF Gigasept FF Gigasept PPA
Virkon	TD-5™
Wavecide-01	Gigasept AF Gigasept FF Gigasept PPA

### ***Wipe Solutions***

T-Spray	T-Spray II
Enzol/ Cidezyme	--

Additional High-Level Disinfection System for E9-4 Transducer *ONLY*:

### ***Nanosonics Trophon® EPR System***



Nanosonics' Trophon® EPR High-Level Disinfection method has been qualified for use on the E9-4 Transducer running software version 4.7.323L or higher on the z.one ultra Ultrasound System and all software versions on the ZS3 Ultrasound System. Running software versions prior to 4.7.323L or lower on the z.one ultra after using the Trophon® EPR disinfection system can result in acoustic output levels exceeding FDA limits. Note: The software version can be verified on the z.one ultra by pressing the Service Key.