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).

Part Number Q00066-00F Cleaning & Disinfection of ZONARE Transducers 2012-10

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CE

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



Shipping: Temperature Limits



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Displays the ZONARE serial number



Refer to the ZONARE Ultrasound System Safety Manual and Operator's Manual 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 Safety Manual for the Intended Use.

Warnings and Cautions

Refer to the corresponding ZONARE Ultrasound System Safety Manual for a complete list of Warnings and Cautions associated with the use of the ZONARE Transducers and Ultrasound System.

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.

NOTE: Do not use any cleaner or disinfectant on the transducer pins.

External-use transducers (curved array, linear array, and phased array): **ZONARE** recommends cleaning the transducers using the **Wipe Method** after each patient exam.

Endocavity probes: **ZONARE** recommends performing the **Immersion Method** of disinfection after each patient exam.

Cleaning & Disinfecting

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.

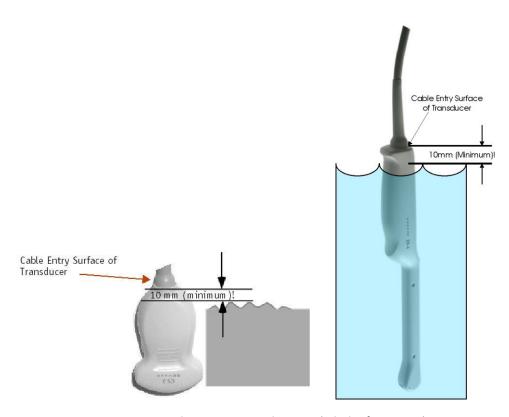


Figure 1: Immersion Level Limits for Transducers

ZONARE-Approved Transducer Disinfectants

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

Immersion Solutions

CIDEX	CIDEX OPA (nonglutaraldehyde)
Anioxyide 1000	CIDEX Plus
Metricide – 14 day	

Wipe Solutions

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

Disinfectants Approved for P8-3TEE Transducer

Immersion Solutions

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

Wipe Solutions

T-Spray	T-Spray II
Enzol/ Cidezyme	



- 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 nonrecommended cleaning or disinfectant solution, incorrect solution strength, or immersing the transducer deeper or longer than indicated can damage the transducer.
- 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*.

NOTE: For the EV probe, use a soft brush for thorough cleaning of all surfaces and crevices of the biopsymounting features on the EV handle.



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, reference the *User Manual* for more details.