

Transducer Cleaning & Disinfection Guide

Products

ZS3 Ultrasound System

Z.One PRO Ultrasound System

mindray

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

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Symbol	Definition or description
	Information that may relate to safety of the patient, the operator, or the equipment
	Waste Electrical & Electronic Equipment Standard. Meets the WEEE Standard. For more information, contact Technical Support.
	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
	Consultation of Operator Manual Required
	Authorized Representative in the European Community
	Catalog Number of Item
	Shipping & Storage: Temperature Limits
	Shipping & Storage: Humidity limits
	Shipping & Storage: Pressure 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

Intended Use

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

Cautions and Warnings

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

CAUTIONS

- Cleaners and disinfectants identified in this manual are recommended because of their chemical compatibility with product materials, as well as their biological efficacy (reduction in the number of microorganisms) or cleaning (removal of organic and inorganic material) on the transducers when using the instructions provided herein. It is important that these instructions are followed carefully to properly clean and disinfect the transducer. Always refer to the guidelines and recommendations of the disinfectant or cleaner 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 documented in Table 1. Additionally, use caution to avoid getting fluid on transducer connector electrical contact area. Do not use any cleaner or disinfectant on the connector electrical contacts.
- Do not use the carrying case for storing the transducer. If the carrying case is used for storage, it may become a source of infection.
- The transducer and accessories supplied with it are not delivered disinfected. Disinfection before use is required.
- A legally marketed sterile transducer sheath and sterile gel must be installed over the transducer before performing intra-cavity, intraoperative or biopsy procedures. Protective barriers may be required to minimize disease transmission. Transducer sheaths are available for use with all clinical situations where infection is a concern.

To order transducer sheaths, contact:

CIVCO Medical Instruments Co.

Tel: 1.319.656.4447

Email: info@civco.com

Website: <http://www.civco.com>

- When using a transducer sheath, be sure to cover the transducer with a new (unused) transducer sheath to prevent infection during examination. If the package of a transducer sheath is open or broken, the sterilization of the transducer sheath may not be sufficient. DO NOT use such a transducer sheath.
- DO NOT use an expired transducer sheath. Before using transducer sheaths, verify whether the term of validity has expired.
- The transducer sheath may contain natural rubber latex and talc that can cause allergic reactions in some individuals.

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 Technical Support.
- 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.

Cleaning and Disinfection Overview

Cleaning and disinfection refer to two distinct processes. According to the Centers for Disease Control and Prevention (CDC) "Guideline for Disinfection and Sterilization in Healthcare Facilities" (2008):

"Cleaning is the removal of visible soil (e.g. organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic material that remains on the surfaces of instruments interfere with the effectiveness of these processes."

"Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores."

Low-Level Disinfection — Destruction of most bacteria, some viruses, and some fungi. Low-level disinfection will not necessarily inactivate *Mycobacterium tuberculosis* or bacterial spores.

High-Level Disinfection (HLD) — Destruction/removal of all microorganisms except bacterial spores.

"Sterilization describes a process that destroys or eliminates all forms of microbial life and is carried out in healthcare facilities by physical or chemical methods." At this time, the transducers are not qualified for use with commercial sterilization products or methods.

Selecting a Disinfection Method

Transducers can be divided into three categories based on their intended use. Some transducers may fall into more than one category (e.g. transducers use for biopsy procedures). When selecting a disinfectant, determine the required level of disinfection based on intended use and possibility of cross-contamination.

Contacts intact skin: Transducers that only come into contact with clean, intact skin are considered noncritical devices and require cleaning after every use. Cleaning may be followed by a low-level disinfectant spray or wipe.

Contacts mucous membranes: This category includes all endocavity transducers - intravaginal, transrectal, and transesophageal (TEE). These semi-critical transducers must be cleaned with an appropriate cleaner after use followed by high-level disinfection. Refer to H-046-011007-00 TEE Transducer Care and Maintenance for instructions on cleaning and disinfecting TEE transducers.

Contacts otherwise sterile tissue or blood: These transducers are considered critical and include all intraoperative transducers and all transducers that may come into contact with blood, such as during biopsy procedures. These transducers must be cleaned with an appropriate cleaner after each use, followed by a high-level disinfection or sterilization process. Sterilization is required if the transducer contacts sterile tissue or blood without a sterile sheath; high-level disinfection is acceptable if a sterile sheath and sterile gel are used in accordance with the instructions provided with the transducer sheath (see the FDA guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers," updated Sept 9, 2008).

Cleaning & Disinfecting

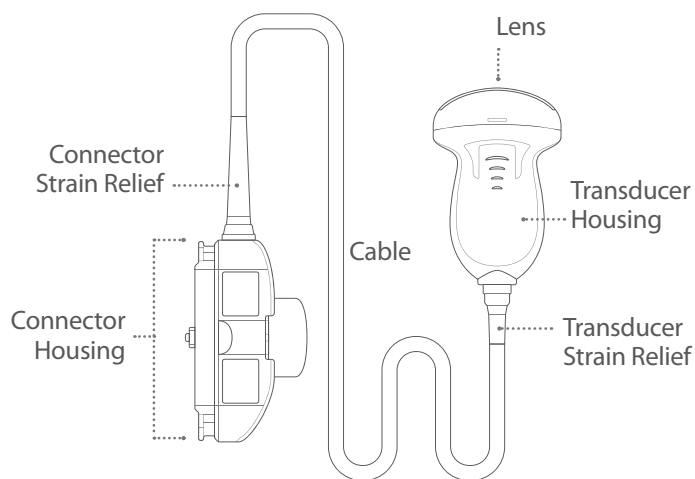
The following sections describe the approved methods to clean or high-level disinfect transducers, except for TEE transducers. Refer to H-046-011007-00 TEE Transducer Care and Maintenance for instructions on cleaning and disinfecting TEE transducers. The following figure depicts the components of an ultrasound transducer (non-TEE).

Cleaning Instructions



Transducers must be thoroughly cleaned after each use. Cleaning is a critical step to allow for effective disinfection.

Note: The instructions below should be used in conjunction with the cleaning agent manufacturer's instructions for use. These guidelines ensure the transducers are not damaged during the cleaning process and ensure effectiveness of the cleaning process.



1. Wear gloves to reduce contamination transfer and infection.
2. Except for wipe or spray cleaning, disconnect the transducer from the Cart or Scan Engine/Scan Module. If present, remove the transducer cover/sheath and discard.
3. Use a damp soft cloth to remove particulates, ultrasound coupling gel, or body fluids.
4. Choose an appropriate cleaning agent. Approved cleaners are listed in this document in **Table 2** and include cleaning wipes and sprays (listed as type disinfectant in **Table 2**), mild detergents, enzymatic cleaners and specially designed enzymatic sponges.
5. Follow the cleaning agent manufacturer's instructions for preparation and use of the cleaner. When cleaning the transducer, never allow any type of fluid to enter the connector strain relief or connector electrical contact area. Use one of the following methods:
 - Soaking: Soak the transducer in the cleaning fluid for a minimum of 1 minute or according to manufacturer instructions until the transducer is visibly clean. Light mechanical cleaning with a soft cloth may be necessary to remove dried on material or material trapped in seams or biopsy guide features.



To prevent possible damage to the electronics of the transducer, never immerse the transducer beyond the point documented in **Table 1**. Additionally, use caution to avoid getting fluid on the transducer connector electrical contact area. Do not use any cleaner or disinfectant on the connector electrical contacts

- Sponges: Use a pre-soaked enzymatic sponge product to wipe all surfaces of the transducer and transducer strain relief/cable if necessary for a minimum of 1 minute or according to manufacturer instructions until the transducer is visibly clean.
 - Wipes or Sprays: Use a transducer cleaning wipe product or soft cloth moistened with cleaning spray (in accordance with manufacturer instructions) and wipe all surfaces of the transducer and transducer strain relief/cable if necessary for a minimum of 1 minute or according to manufacturer instructions until the transducer is visibly clean.
6. Rinse thoroughly with room temperature tap water to remove remaining particulate and cleaning residue for 30 seconds. Alternatively for transducers that cannot be easily immersed, use a damp cloth to wipe surfaces of the transducer and cable until visibly clean.
 7. Air-dry (or towel dry) the transducer with a soft, clean cloth.
 8. Examine the transducer for damage, such as cracks, splitting, holes, or fluid leaks. If damage is evident, discontinue use of the transducer and contact Technical Support.

Disinfection Instructions

When choosing a disinfectant, determine the required level of disinfection based on intended use and possibility of cross-contamination. All semi-critical and critical transducers require high-level disinfection before they can be used on another patient.

Warning: 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.

Note: The instructions below should be used in conjunction with the disinfectant agent manufacturer's instructions for use. These guidelines ensure that the transducers are not damaged during the disinfection process and ensure effectiveness of the disinfection process.

Low-level disinfection of non-critical transducers

Low level disinfection on non-critical transducers is achieved with appropriately labeled wipes and topical sprays. Biological effectiveness of these disinfectants has not been independently tested on the transducers. See guidelines and recommendations of the disinfectant manufacturer for use and efficacy information.

1. Wear gloves to reduce contamination transfer and infection.
2. Clean the transducer following the instructions in "Cleaning Instructions."
3. Choose an appropriate low-level disinfectant. Approved disinfectants (chemically compatible) are listed in this document in Table 2 and include quaternary ammonium chlorides, ethylene glycols and hydrogen peroxides.
4. Follow the disinfectant agent manufacturer's instructions for preparation and use of the disinfectant.
5. Wipe or spray the transducer, strain relief, cable and connector housing with the disinfectant, following the manufacturer's instructions for duration of wipe/disinfectant contact to achieve desired results. Do not apply the disinfectant any longer than necessary. Do not allow any type of fluid to enter the connector strain relief or connector electrical contact area.
6. Allow the transducer to air-dry.
7. Examine the transducer for damage, such as cracks, splitting, holes, or fluid leaks. If damage is evident, discontinue use of the transducer and contact Technical Support.

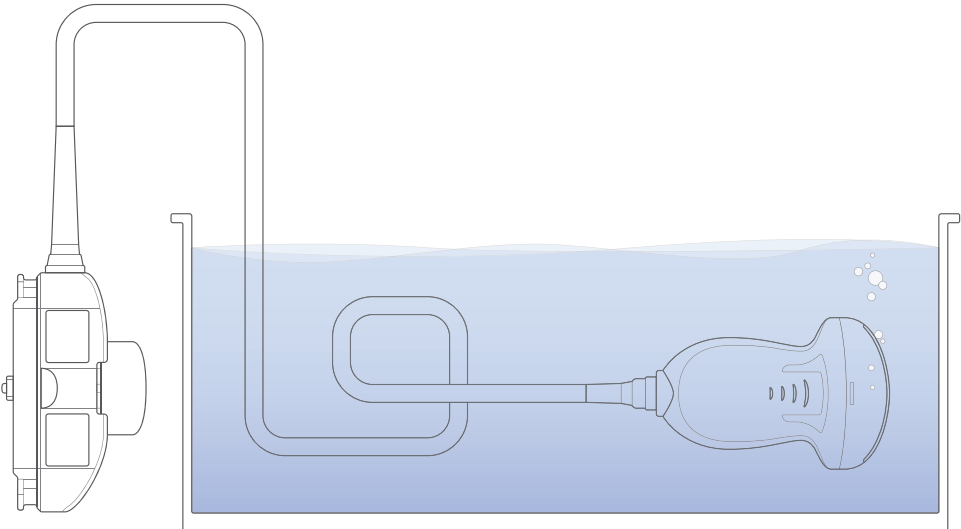
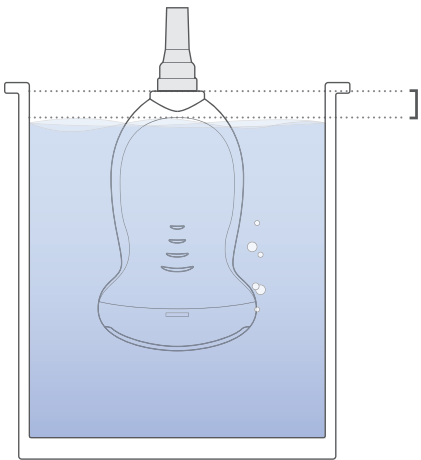

High-Level Disinfection of Semi-Critical and Critical Transducers

High level disinfection of semi-critical and critical transducers is achieved with appropriately labeled HLD solutions and disinfectant systems. See guidelines and recommendations of the disinfectant manufacturer for appropriate use.

1. Wear gloves to reduce contamination transfer and infection.
2. Clean the transducer following the instructions in "Cleaning Instructions."
3. Choose an appropriate high-level disinfectant. Approved disinfectants are listed in this document in **Table 2** and include glutaraldehydes, hydrogen peroxides, and ortho-phthalaldehydes.
4. Follow the disinfectant agent manufacturer's instructions for preparation and use of the disinfectant or disinfectant system. When disinfecting the transducer, never allow any type of fluid to enter the connector strain relief or connector electrical contact area.
5. If the transducer is to be immersed in a disinfection agent, never immerse the transducer beyond the point documented in **Table 1**. Also with immersion disinfectants, make sure to eliminate air pockets by vigorously swishing the transducer in the solution at the start.
6. After disinfection, follow the disinfectant manufacturer's instructions regarding rinsing with water and subsequent drying. Avoid prolonged exposure to water in regions of the transducer that cannot be immersed (refer to **Table 1**).
7. Follow manufacturer's instructions to dry the transducer.
8. Examine the transducer for damage, such as cracks, splitting, holes, or fluid leaks. If damage is evident, discontinue use of the transducer and contact Technical Support.

Immersion Limits for Transducers

Table 1

<p>Immersion Level Limit for the following transducers:</p> <p>A2CW A5CW C4-1 C6-1 C6-2 C8-3 3D C9-3 C9-3sp C10-3 C18-5 E9-3 E9-3 3D E9-4 L8-3 L10-5 L14-5sp L14-5w L20-5 P4-1c</p>	
<p>Immersion Level Limit for the following transducers:</p> <p>C5-2 C9-4t L12-4v P10-4 P4-1</p>	<div><div><p>10mm</p><p>Minimum distance between cable connection and water level</p></div></div>

Approved Transducer Disinfectant and Cleaning Agents

Table 2

D = disinfectant

C = cleaner

HLD = high level disinfectant

● = approved

○ = indicates 1 year equivalent use testing instead of normal 5 year.

x = not approved

blank = not tested, not approved

	Sani-Cloth AF3 (gray)	Sani-Cloth HB (green)	Sani-Cloth Plus (red)	Cavicide Liquid	CaviWipes/CaviWipes XL	Dispatch Towels	PI-Spray II	Protex Spray	Protex Ultra Wipes	Accel TB Wipes	Sono Ultrasound Wipes	MetriZyme Liquid and MetriSponge	Revital-Ox Enzymatic Detergent	Prolystica 2X Enzymatic	Endozime and Endozime Sponge	Liquinox	Metricide	Metricide 28	Cidex	Revital-Ox Resert HLD	Trophon EPR	Cidex OPA	Metricide OPA Plus
Type	D	D	D	D	D	D	D	D	D	D	D	C	C	C	C	C	HLD	HLD	HLD	HLD	HLD	HLD	HLD
A2CW		●	●	●	○											●							
A5CW		●	●	●	○											●							
C4-1	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	✗	●	●
C5-2		○	○	○	○												○	○	○			○	○
C6-1														●	●	●						●	●
C6-2	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	✗	●	●
C8-3 3D		●	●	●	○							●		●	●	●	○	○	○	●		○	○
C9-3	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	✗	●	●
C9-3sp		✗	●	●								●	●	●	●	●	●	●	✗	●	●	●	●
C9-4t	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	✗	●	●
C10-3	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	✗	●	●
C18-5														●	●	●						●	●
E9-3		✗	✗	✗								●	●	●	●	●	●	●	●	●	●	●	●
E9-3 3D		●	●	●	○							●		●	●	●	○	○	○	●		○	○
E9-4		✗	●	●	○							●	●	●	●	●	●	●	●	●	●	●	●
L8-3	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	✗	●	●
L10-5	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	✗	●	●
L12-4v		○	○	○	○																	○	○
L14-5sp	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
L14-5w	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	✗	●	●
L20-5	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	✗	●	●
P4-1		○	○	○	○												○	○	○			○	○
P4-1c	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	✗	●	●
P10-4		○	○	○	○									○	○		○	○	○			○	○
P8-3TEE		○	○	○								○		○	○		○	○	○	●		○	○
P8-3mTEE		○	○	○								○		○	○		○	○	○	●		○	○
P9-3IC	SINGLE USE ITEM, NOT DISINFECTIBLE																						

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