

# **Guidelines for cleaning, disinfection, and sterilization of transducers**

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This manual describes the cleaning, disinfection, and sterilization procedures for the ultrasound transducer.  
For the operating precautions and procedures for the transducers, refer to the operation manual for each transducer.

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## **Trademarks**

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# 1. Safety Precautions

## 1.1 Meaning of Signal Words

In this manual, the signal words **DANGER**, **WARNING**, **CAUTION**, and *NOTICE* are used regarding safety and other important instructions. The signal words and their meanings are defined as follows. Please understand their meanings clearly before reading this manual.

Signal word	Meaning
<b>⚠DANGER</b>	<b>Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.</b>
<b>⚠WARNING</b>	<b>Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.</b>
<b>⚠CAUTION</b>	<b>Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.</b>
<i>NOTICE</i>	Indicates a potentially hazardous situation which, if not avoided, may result in property damage.

## 1.2 Safety Precautions

Observe the following precautions to ensure the safety of patients as well as operators when performing cleaning, disinfection, or sterilization of the transducer.

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**⚠WARNING** **Never immerse the transducer connector or any other non-waterproof sections into liquids such as water or cleaning solution. Immersion may cause electric shock. Refer to the tables and figures in section 3 for the immersible range of each transducer model.**

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**⚠CAUTION** **1. Precautions concerning cleaning, disinfection, and sterilization.**

**1) Observe the following precautions to prevent infection.**

- **Wear protective gloves when performing cleaning.\***
- **Wear sterile protective gloves when performing disinfection or sterilization.\***
- **Wear new protective gloves each time cleaning, disinfection, and sterilization are performed.**
- **Clean the transducer before and after examination. Disinfect or sterilize the transducer as required.**
- **Note that local regulations may require that the transducer be disinfected before sterilization.**
- **Sterilize the transducer and biopsy adaptor before and after an ultrasound-guided biopsy procedure is performed. Failure to do so may result in the transducer and biopsy adaptor becoming sources of infection.**

\* Refer to the FDA's March 29, 1991 Medical Alert on Latex Products.

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**⚠ CAUTION**

- 2) After cleaning, rinse the transducer thoroughly with purified water to remove all chemical residues. After disinfection, rinse the transducer thoroughly with sterile or deionized water to remove all chemical residues.  
Chemical residues on the transducer may be harmful to the human body.
  - 3) After chemical cleaning or chemical disinfection, thoroughly dry the transducer surface.
  - 4) The efficacy of the cleaning solutions, disinfectants, and sterilizing gases is not guaranteed by Canon Medical Systems. Contact the manufacturers for information on the activity of the products.
  - 5) To ensure the prevention of infection, confirm the effectiveness of each chemical for cleaning, disinfection, or sterilization based on the criteria (such as effective period, number of times of use, discoloration, and results of using the effectiveness test kit) described in the documentation provided by the relevant manufacturer.
  - 6) Do not clean, disinfect, or sterilize the transducer using chemicals or methods other than those specified in this guide. If chemicals or methods other than those specified in this guide are used, the transducer may not be properly cleaned, disinfected, or sterilized or may be damaged.
  - 7) Observe the following precautions to prevent transducer malfunction.
    - Only soft materials such as soft cloth or soft gauze should be used when removing ultrasound gel from the transducer or wiping water or disinfectant from the transducer surface after cleaning or disinfection. Use of hard or abrasive cloth or gauze may damage the transducer.
    - The transducer must not be immersed in a chemical solution for more than three hours.
    - Do not permit the transducer to become overheated (more than 60°C (140°F)) during cleaning, disinfection, and sterilization.
    - The cleaning, disinfection, or sterilization conditions, such as the temperature and pressure, differ depending on the product. In addition, some products cannot be subjected to disinfection or sterilization procedures. Confirm the detailed conditions by referring to the tables and figures in section 3.
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### 1.3 Chemical Hazard (for USA only)

Observe the following instruction in order to protect patients and operators from inflammation or poisoning by chemical substances.

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**⚠️ WARNING:** This product can expose you to chemicals including lead and lead compounds, which are known to the State of California to cause cancer, and phthalates, which are known to the State of California to cause birth defects or other reproductive harm.  
For more information go to [www.p65warnings.ca.gov](http://www.p65warnings.ca.gov).

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### 1.4 Precautions Concerning Restriction of Sale or Use (for USA only)

United States law restricts this device to sale or use by, or on the order of a physician.

## 2. Cleaning, Disinfection, Sterilization

This section describes the methods for cleaning, disinfection, and sterilization.

### 2.1 Cleaning

<<Items to be used: Protective gloves, cleaning solution or cleaning wipes, purified water, clean soft cloth or gauze, single-use sponge\*>>

\* The single-use sponge must not include any abrasive parts or contain any abrasive cleanser.

- (1) Wear protective gloves to prevent infection.  
Wear new protective gloves each time cleaning is performed.
- (2) If an accessory that can be disassembled (e.g., biopsy adaptor) is provided, disassemble it.  
For details concerning such parts, refer to the operation manual for the transducer.
- (3) Wash off all organic materials (such as blood or other bodily fluids) from the transducer under purified water. A single-use sponge can be used for washing. Do not use a brush, because it may damage the transducer.
- (4) In accordance with the tables and figures in section 3, immerse the transducer in a cleaning solution or wipe the transducer using wipes to dissolve or remove all remaining organic materials. Use a single-use sponge if necessary. If dried organic materials are present on the transducer, immerse it in the cleaning solution for a prolonged period.
- (5) Remove all residual organic materials and cleaning solution from the transducer by rinsing it under purified water. Confirm that all organic materials and cleaning solution have been completely removed. Do not reuse the purified water.
- (6) Dry the surface of the transducer using clean soft cloth or gauze. Do not use heat to dry the transducer.  
Handle the cleaning solution or wipes as described in the documentation provided by the relevant manufacturer. To maintain the effectiveness of the cleaning solution or wipes, ensure that the concentration, temperature, and other conditions specified in the documentation provided by the manufacturer are met. To confirm the effectiveness of the cleaning solution or wipes, use the criteria (such as effective period, number of times of use, discoloration, and results of using the effectiveness test kit) described in the documentation provided by the manufacturer.
- (7) Confirm that the transducer shows no signs of damage, deformation, or peeling.

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## 2.2 Disinfection

Before disinfection, the transducer must be cleaned.

Note that local regulations may require that the transducer be disinfected before sterilization.

<<Items to be used: Sterile protective gloves, disinfectant, sterile water or deionized water, sterile soft cloth or gauze>>

- (1) Wear sterile protective gloves to prevent infection.  
Wear new sterile protective gloves each time disinfection is performed.
- (2) Disinfect the transducer using the chemicals listed in section 3 "List of Chemicals".
- (3) Rinse the transducer thoroughly with sterile or deionized water, as described in the documentation provided by the manufacturer, in order to remove all residual disinfectant. (Rinsing is not necessary when gas disinfection is performed using Trophon EPR or Trophon 2.) Do not reuse the sterile or deionized water.
- (4) Dry the surface of the transducer using sterile soft cloth or gauze.  
Do not use heat to dry the transducer.  
Handle the disinfectant as described in the documentation provided by the relevant manufacturer.  
To maintain the effectiveness of the disinfectant, ensure that the concentration, temperature, and other conditions specified in the documentation provided by the manufacturer are met. To confirm the effectiveness of the disinfectant, use the criteria (such as effective period, number of times of use, discoloration, and results of using the effectiveness test kit) described in the documentation provided by the manufacturer.
- (5) Confirm that the transducer shows no signs of damage, deformation, or peeling.

## 2.3 Sterilization

Before sterilization, the transducer must be cleaned.

Note that local regulations may require that the transducer be disinfected before sterilization.

<<Items to be used: Sterile protective gloves, sterilant>>

\* Some types of transducers cannot be sterilized or the sterilization conditions may differ.

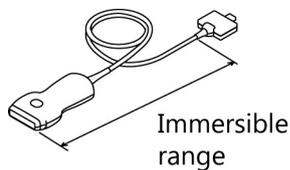
- (1) Wear sterile protective gloves to prevent infection.  
Wear new sterile protective gloves each time sterilization is performed.
- (2) Sterilize the transducer using the chemicals listed in section 3 "List of Chemicals".  
\* Place the transducer in a sterilization packing case and then place it in the sterilizer.
- (3) After gas sterilization, perform aeration to remove all gas residues on the transducer surface.
- (4) Confirm that the transducer shows no signs of damage, deformation, or peeling.

### 3. List of Chemicals

This section lists the chemicals used when washing, disinfecting, or sterilizing the transducer. Refer to the lists for the available chemicals.

In addition, refer to the manuals for the chemicals for the handling details.

- PLU-704SDT etc.



Never immerse the non-waterproof sections of the transducer (indicated on the tag attached to the cable) into liquids such as water or cleaning solution. Immersion may cause electric shock.

# Cleaning

Country of origin :

Any : Any country

FRA : France

DEU : Germany

GBR : United Kingdom

USA : United States

JPN : Japan

AUS : Australia

Chemical name/type	Enzyme			
	Trade name	CIDEZYME®	3M™ Rapid Multi-Enzyme cleaner	ANIOSYME DD1 *1
Manufacturer	J&J	3M Company	Laboratories ANIOS	DR. WEIGERT GmbH & Co. KG
Country of origin	Any	Any	FRA	DEU
Concentration (Dilution ratio)	0.8% (125)	1% (100)	0.5% (200)	1% (100)
Time	1 min.	10 min.	5 min.	10 min.
Temperature	Room temperature		Room temperature	
Humidity	Normal humidity		Normal humidity	
Model name	Pressure	Normal pressure		Normal pressure
PVU-375SDT, PVU-382SDT, PLU-704SDT, PLU-1004SD	OK	OK	OK	OK

OK : Use of the chemical is permitted.  : Use of the chemical is not permitted.

Enzyme					Isopropyl alcohol/ Ethylene glycol monobutyl ether	Alkyl dimethyl benzyl ammonium chloride/2-ethanol/ Alkyl polysaccharide/ Ethylenediamine tetraacetic acid
Tristel Pre-Clean Wipes *1	MetriZyme®	Klenzyme®	Instru-Zyme® Gel	Endozime® Xtreme Power *1	CaviWipes™	Intercept® Wipes
Tristel Solutions Limited	Metrex Research, Inc.	STERIS Corporation	Summit Medical	RUHOF Corporation	Metrex Research, Inc.	MEDIVATORS Inc.
GBR	USA	USA	USA	USA	USA	USA
Working solution	0.77% (130)	0.8% (125)	Working solution	0.2% (500)	Working solution	Working solution
Wiping only	5 min.	5 min.	Wiping only	2 min.	Wiping only	
Room temperature		Room temperature			Room temperature	
Normal humidity		Normal humidity			Normal humidity	
Normal pressure		Normal pressure			Normal pressure	
OK	OK	OK	–	OK	–	–

\*1: Not for use in the USA.

## Low/Middle-Level Disinfection -1 (Except for USA)

Note that local regulations may require that the transducer be disinfected before sterilization.

Country of origin :
Any : Any country
FRA : France
DEU : Germany
GBR : United Kingdom
USA : United States
JPN : Japan
AUS : Australia

	Chemical name/type	Didecyl dimethyl ammonium chlorides/ Quaternary ammonium compounds	Didecyl dimethyl ammonium chlorides
	Trade name	CLEANISEPT® WIPES	WIP'ANIOS Excel
	Manufacturer	Dr. Schumacher GmbH	Laboratories ANIOS
	Country of origin	DEU	FRA
	Concentration (Dilution ratio)	Working solution	Working solution
	Time	Wiping only	Wiping only
	Temperature	Room temperature	Room temperature
	Humidity	Normal humidity	Normal humidity
	Pressure	Normal pressure	Normal pressure
Model name	PVU-375SDT, PVU-382SDT, PLU-704SDT, PLU-1004SD		
		OK	-

OK : Use of the chemical is permitted. - : Use of the chemical is not permitted.

Glyoxal/Glutaral/ Didecyl dimethyl ammonium chlorides
Lysoformin® 3000
Lysoform Disinfection Ltd.
DEU
2% (50)
15 min.
Room temperature
Normal humidity
Normal pressure
-

## Low/Middle-Level Disinfection -2 (High-level disinfection is also required in the USA.)

Note that local regulations may require that the transducer be disinfected before sterilization.

Country of origin :
Any : Any country
FRA : France
DEU : Germany
GBR : United Kingdom
USA : United States
JPN : Japan
AUS : Australia

	Chemical name/type	Ethanol	Isopropyl alcohol	Isopropyl alcohol/ Ethylene glycol monobutyl ether	Sodium hypochlorite
	Trade name	Ethanol	Isopropyl alcohol	CaviWipes™	Dispatch® Hospital Cleaner Disinfectant Towels with Bleach
	Manufacturer	Any manufacturer	Any manufacturer	Metrex Research, Inc.	The Clorox Company
	Country of origin	Any	Any	USA	USA
	Concentration (Dilution ratio)	80% (original solution)	70% (original solution)	Working solution	0.65% (working solution)
	Time	Wiping only	Wiping only	Wiping only	Wiping only
	Temperature	Room temperature	Room temperature	Room temperature	Room temperature
	Humidity	Normal humidity	Normal humidity	Normal humidity	Normal humidity
Model name	Pressure	Normal pressure	Normal pressure	Normal pressure	Normal pressure
PVU-375SDT, PVU-382SDT, PLU-704SDT, PLU-1004SD		OK	OK	OK	OK

OK : Use of the chemical is permitted.  : Use of the chemical is not permitted.

Quaternary ammonium chlorides		Quaternary ammonium chlorides/ Isopropyl alcohol		Decyldimethyloctylammonium chloride/ Dimethyldioctylammonium chloride/ Didecyldimethylammonium chloride/ Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides	Hydrogen peroxide
Protex™ Ultra Disinfectant Wipes	Sani-Cloth® AF3, Sani-Cloth® AF	Sani-Cloth® Plus	Super Sani-Cloth®	SONO Ultrasound Wipes	Oxivir 1 wipes
Parker Laboratories, Inc.	Professional Disposables International, Inc.	Professional Disposables International, Inc.		Advanced Ultrasound Solutions Inc.	Diversey, Inc.
USA	USA	USA		USA	USA
0.232% (working solution)	0.28% (working solution)	0.25% / 14.85% (working solution)	0.5% / 55% (working solution)	Working solution	0.5% (working solution)
Wiping only	Wiping only	Wiping only	Wiping only	Wiping only	Wiping only
Room temperature	Room temperature	Room temperature	Room temperature	Room temperature	Room temperature
Normal humidity	Normal humidity	Normal humidity	Normal humidity	Normal humidity	Normal humidity
Normal pressure	Normal pressure	Normal pressure	Normal pressure	Normal pressure	Normal pressure
OK	OK	OK	OK	OK	OK

## High-Level Disinfection -1 (Except for USA)

Note that local regulations may require that the transducer be disinfected before sterilization.

Country of origin :
Any : Any country
FRA : France
DEU : Germany
GBR : United Kingdom
USA : United States
JPN : Japan
AUS : Australia

	Chemical name/type	Hydrogen peroxide, Peracetic acid	Chlorine dioxide		
	Trade name	PeraSafe™ *1	Tristel Fuse for Instruments	Tristel Sporidical Wipes/ Tristel Rinse Wipes	Tristel Duo ULT
Manufacturer	DuPont	Tristel Solutions Limited			
Country of origin	Any	GBR			
Concentration (Dilution ratio)	1.62% (61.7)	0.012% (1 sachet in 5 liters of water)	Working solution		
Time	10 min.	5 min.	Wiping only		
Temperature	Room temperature	Room temperature			
Humidity	Normal humidity	Normal humidity			
Model name	Pressure	Normal pressure	Normal pressure		
PVU-375SDT, PVU-382SDT, PLU-704SDT, PLU-1004SD	OK	OK	OK	OK	OK

OK : Use of the chemical is permitted.  : Use of the chemical is not permitted.

Succindialdehyde		Peracetic acid		Ortho-phthalaldehyde	Sodium percarbonate/ Citric acid	Peracetic acid, Hydrogen peroxide, Acetic acid		
gigasept® FF (new)		NU-CIDEX®	Anioxyde 1000	Opal™	Clinell® Sporicidal wipes	gigasept® PAA concentrate		mikrozyd® PAA wipes
Schülke & Mayr GmbH		J&J	Laboratories ANIOS	Whiteley Medical	GAMA Healthcare Ltd.	Schülke & Mayr GmbH		
DEU		GBR	FRA	AUS	GBR	DEU		
5% (20)		0.35% (working solution)	0.15% (working solution)	0.57% (Working solution)	Working solution	2% (a double-chambered bottle into 5 liters of water)		Working solution
15 min.* <sup>2</sup>	60 min.* <sup>3</sup>	5 min.	30 min.	6 min.	Wiping only	5 min.* <sup>4</sup>	15 min.* <sup>3</sup>	Wiping only
Room temperature		Room temperature		Room temperature	Room temperature	Room temperature		
Normal humidity		Normal humidity		Normal humidity	Normal humidity	Normal humidity		
Normal pressure		Normal pressure		Normal pressure	Normal pressure	Normal pressure		
-	-	OK	OK	OK	-	OK	OK	OK

\*1: PeraSafe™ may be classified as a sterilizing agent or as a high-level disinfectant depending on the local regulations.

\*2: For bacteria and fungi

\*3: For virucidal

\*4: For mycobactericidal

## High-Level Disinfection -2

Note that local regulations may require that the transducer be disinfected before sterilization.

Country of origin :
Any : Any country
FRA : France
DEU : Germany
GBR : United Kingdom
USA : United States
JPN : Japan
AUS : Australia

Chemical name/type	Glutaraldehyde				
	Trade name	CIDEX®	CIDEX PLUS® 28 day solution	MetriCide®	MetriCide® 28
Manufacturer	J&J	J&J	Metrex Research, Inc.		
Country of origin	Any		USA		
Concentration (Dilution ratio)	2.4% (working solution)	3.4% (working solution)	2.6% (working solution)	2.5% (working solution)	3.4% (working solution)
Time	45 min.	20 min.	45 min.	90 min.	90 min.
Temperature	Room temperature		25°C (77°F)		
Humidity	Normal humidity		Normal humidity		
Model name	Pressure	Normal pressure		Normal pressure	
PVU-375SDT, PVU-382SDT, PLU-704SDT, PLU-1004SD		OK		OK	

OK : Use of the chemical is permitted.  : Use of the chemical is not permitted.

Glutaraldehyde		Ortho-phthalaldehyde	Hydrogen peroxide		Hydrogen peroxide	Hydrogen peroxide
WAVICIDE® -01	Sporicidin®	CIDEX® OPA	Trophon® EPR	Trophon® 2	SPOROX® II	Revital-Ox™ Resert® High Level Disinfectant
Medical Chemical Corporation	Contec Inc.	J&J	Nanosonics Limited		Sultan Healthcare	STERIS Corporation
USA	USA	Any	AUS		USA	USA
2.5% (working solution)	1.12% (working solution)	0.55% (working solution)	Use the disinfectant cartridges specifically designed for the disinfection device. There are no disinfection related parameters (temperature, humidity, pressure, or time) to be set by the operator.		7.5% (working solution)	2% (working solution)
45 min.	20 min.	12 min.			30 min.	8 min.
Room temperature	Room temperature	Room temperature			Room temperature	Room temperature
Normal humidity	Normal humidity	Normal humidity			Normal humidity	Normal humidity
Normal pressure	Normal pressure	Normal pressure			Normal pressure	Normal pressure
OK	OK	OK	OK*1	OK	OK	OK

\*1: Use a Trophon® EPR with transducer cable clamp "T-Clamp". Please contact your Trophon® EPR representative for further information.

## Sterilization

Note that local regulations may require that the transducer be disinfected before sterilization.

Country of origin :
Any : Any country
FRA : France
DEU : Germany
GBR : United Kingdom
USA : United States
JPN : Japan
AUS : Australia

	Chemical name/type	Ethylene oxide gas	Hydrogen peroxide plasma <sup>*1</sup>	
	Trade name	Ethylene oxide gas	STERRAD <sup>®</sup> 50/100S/200/NX	STERRAD <sup>®</sup> 100NX
	Manufacturer	Any manufacturer		J&J
	Country of origin	Any		Any
	Concentration (Dilution ratio)	10%	20%	Use STERRAD system cassettes specifically designed for the sterilizer.
	Time	Exposure time: 7 hours Aeration time: 12 hours	Exposure time: 3.5 hours Aeration time: 12 hours	Select [SHORT Cycle] for STERRAD 100S/200 and [STANDARD Cycle] for STERRAD NX. Select [EXPRESS Cycle]. There are no sterilization related parameters (temperature, humidity, pressure, or time) to be set by the operator.
	Temperature	50°C (122°F)	60°C (140°F)	There are no sterilization related parameters (temperature, humidity, pressure, or time) to be set by the operator.
	Humidity	50%		
	Model name	Pressure	980 hPa [gauge]	
	PVU-375SDT, PVU-382SDT, PLU-704SDT, PLU-1004SD	-	-	-
				OK <sup>*2, *3</sup>

OK : Use of the chemical is permitted. - : Use of the chemical is not permitted.

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- \*1: Note that the label on the transducer may fade. This is not an abnormality.
  - \*2: One transducer can be sterilized per sterilization cycle. Do not perform sterilization for more than one item at a time.
  - \*3: There may be sticky areas on the cable, however, this is not a fault. If there are sticky areas, wipe them with a soft cloth or gauze moistened with ethanol.

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## 4. Other Information

- For Europe

CANON MEDICAL SYSTEMS EUROPE B.V.



Zilverstraat 1, 2718 RP  
Zoetermeer, The Netherlands

<https://eu.medical.canon>

For other countries, please contact your local distributor.

- Legal manufacturer



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