

# **Guidelines for Cleaning, Disinfection, and Sterilization of Xario 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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**CANON MEDICAL SYSTEMS CORPORATION**

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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) After gas sterilization, degas the transducer. Gas residues on the transducer may be harmful to the human body.
  - 5) 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.
  - 6) 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.
  - 7) 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.
  - 8) 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.

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## 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 cleaning, 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.

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- NOTE**
1. When multiple model names included in the List of Chemicals are referred to, note that they are abbreviated. For example, "PSU-25BT and PSU-30BT" is abbreviated as "PSU-25BT/30BT".
  2. For the transducers supported by each diagnostic ultrasound system, refer to the operation manual supplied with the diagnostic ultrasound system.
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# Cleaning

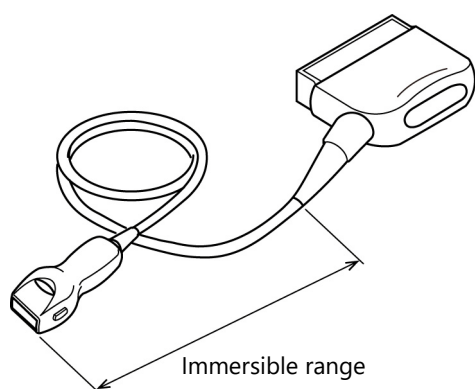
Country of origin :  
 Any : Any country  
 FRA : France  
 DEU : Germany  
 GBR : United Kingdom  
 USA : United States  
 JPN : Japan  
 AUS : Australia

Chemical name/type	Enzyme			
	Trade name	3M™ Rapid Multi-Enzyme cleaner	ANIOSYME DD1 *	neodisher® mediclean *
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	
Pressure	Normal pressure		Normal pressure	
Model name	Immersion range			
PSU-25BT/30BT/70BT PVU-375BT/382BT	Type A	OK	OK	OK
PSU-50BT PVU-712BT	Type A	OK	OK	OK
PVU-674MV	Type A	OK	–	–
PLU-704BT	Type A	OK	OK	OK
PVU-745BTV	Type A	OK	OK	OK
PVU-745BTF/745BTH/770ST PVL-715RS	Type A	OK	OK	OK
PVU-674BT/781VT/781VTE PLU-1005BT	Type A	OK	OK	OK
PLU-1204BT	Type A	OK	OK	OK
PVU-681MVL	Type A	OK	OK	OK
PVU-350BTP	Type A	OK	OK	OK
PLU-308BTP	Type A	OK	OK	OK
PLU-1202BT	Type A	OK	OK	OK
PLU-705BTF/705BTH	Type A	OK	OK	OK

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

\*: Not for use in the USA.

- Type A (PSU-25BT etc.)



Never immerse the non-waterproof sections of the transducer into liquids such as water or cleaning solution. Immersion may cause electric shock.

Enzyme					Isopropyl alcohol/ Ethylene Glycol Monobutyl Ether	Alkyl dimethyl benzyl ammonium chloride/2-ethanol/ Alkyl polysaccharide/ Ethylenediamine tetracetic acid
Tristel Pre-Clean Wipes *	MetriZyme®	Klenzyme®	Instru-Zyme® Gel	Endozime® Xtreme Power*	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	OK	OK	OK
OK	OK	OK	OK	OK	OK	OK
–	–	–	–	OK	OK	OK
OK	OK	OK	OK	OK	OK	OK
OK	OK	OK	OK	OK	OK	OK
OK	OK	OK	OK	OK	OK	OK
OK	OK	OK	OK	OK	OK	OK
OK	OK	OK	OK	OK	OK	OK
OK	OK	OK	OK	OK	OK	OK
–	OK	–	OK	OK	–	–
OK	OK	OK	OK	OK	OK	OK
OK	OK	OK	–	OK	OK	–
OK	OK	OK	–	OK	OK	–



## **Low/Middle-Level Disinfection (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

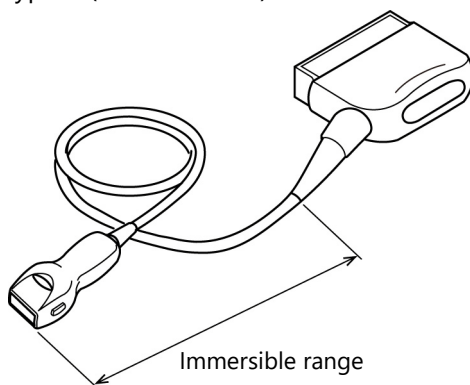
AUS : Australia

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
PSU-25BT/30BT/70BT	Immersible range	OK	OK	OK	OK
PVU-375BT/382BT					
PSU-50BT	Type A	OK	OK	OK	OK
PVU-712BT					
PVU-674MV	Type A	OK	OK	OK	OK
PLU-704BT	Type A	OK	OK	OK	OK
PVU-745BTV	Type A	OK	OK	OK	OK
PVU-745BTF/745BTH/770ST	Type A	OK	OK	OK	OK
PVL-715RS					
PVU-674BT/781VT/781VTE	Type A	OK	OK	OK	OK
PLU-1005BT					
PLU-1204BT	Type A	OK	OK	OK	OK
PVU-681MVL	Type A	OK	OK	OK	OK
PVU-350BTP	Type A	OK	OK	–	–
PLU-308BTP	Type A	OK	OK	OK	OK
PLU-1202BT	Type A	OK	OK	OK	OK
PLU-705BTF/705BTH	Type A	OK	OK	OK	–

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

- Type A (PSU-25BT etc.)



Never immerse the non-waterproof sections of the transducer into liquids such as water or cleaning solution. Immersion may cause electric shock.

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
OK	OK	OK	OK	OK	OK
OK	OK	OK	OK	OK	OK
OK	OK	OK	OK	OK	OK
OK	OK	OK	OK	–	–
OK	OK	OK	OK	OK	OK
OK	OK	OK	OK	OK	OK
OK	OK	OK	OK	OK	OK
OK	OK	OK	OK	OK	OK
–	–	–	–	–	–
OK	OK	OK	OK	OK	OK
OK	OK	OK	OK	OK	OK
–	OK	OK	OK	–	–

# High-Level Disinfection

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

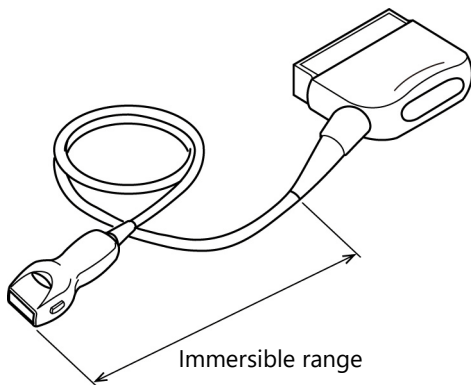
Country of origin :  
 Any : Any country  
 FRA : France  
 DEU : Germany  
 GBR : United Kingdom  
 USA : United States  
 JPN : Japan  
 AUS : Australia

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		
Pressure	Normal pressure		Normal pressure		
Model name	Immersion range				
PSU-25BT/30BT/70BT PVU-375BT/382BT	Type A	OK		OK	
PSU-50BT PVU-712BT	Type A	OK		OK	
PVU-674MV	Type A	OK		-	
PLU-704BT	Type A	OK		OK	
PVU-745BTV PLU-705BTF/705BTH	Type A	OK		OK	
PVU-745BTF/745BTH/770ST	Type A	OK		OK	
PVL-715RS	Type A	OK		OK	
PVU-674BT/781VT/781VTE PLU-1005BT	Type A	OK		OK	
PLU-1204BT	Type A	OK		OK	
PVU-681MVL	Type A	OK		OK	
PVU-350BTP	Type A	OK		OK	
PLU-308BTP	Type A	OK		OK	
PLU-1202BT	Type A	OK		OK	

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

\*: For transducers with a thin cable, use a Trophon® EPR with a serial number beginning with 24100 or higher or a transducer cable clamp "T-Clamp". Please contact your Trophon® EPR representative for further information.

- Type A (PSU-25BT etc.)



Never immerse the non-waterproof sections of the transducer into liquids such as water or cleaning solution. Immersion may cause electric shock.

Glutaraldehyde		Ortho-phthalaldehyde	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
Normal humidity		Normal humidity			Normal humidity	Normal humidity
Normal pressure		Normal pressure			Normal pressure	Normal pressure
OK	OK	OK	OK*	OK	OK	OK
OK	OK	OK	OK*	OK	OK	OK
-	-	OK	OK	OK	-	OK
OK	OK	OK	OK*	OK	OK	OK
OK	OK	OK	OK*	OK	OK	-
OK	OK	OK	OK*	OK	OK	OK
OK	OK	OK	-	-	OK	OK
OK	OK	OK	OK	OK	OK	OK
OK	OK	OK	OK	OK	OK	OK
OK	-	OK	OK	OK	OK	OK
OK	OK	OK	-	-	-	-
OK	OK	OK	-	-	OK	OK
OK	OK	OK	OK	OK	OK	OK

## Sterilization

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

<div style="border: 1px solid black; padding: 5px;">                     Country of origin :                      Any : Any country                      FRA : France                      DEU : Germany                      GBR : United Kingdom                      USA : United States                      JPN : Japan                      AUS : Australia                 </div>	Chemical name/type	Ethylene oxide gas <sup>*1</sup>		Hydrogen peroxide plasma <sup>*2</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% <sup>*5</sup>	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 <sup>*4</sup> and [STANDARD Cycle] for STERRAD NX.  There are no sterilization related parameters (temperature, humidity, pressure, or time) to be set by the operator.	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)		
	Humidity	50%			
Model name	Pressure	980 hPa [gauge]			
PSU-25BT/30BT/70BT PVU-375BT/382BT	–	–	OK	OK <sup>*7, *8</sup>	
PSU-50BT PVU-712BT	–	–	–	–	
PVU-674MV	–	–	–	–	
PLU-704BT	–	–	OK	OK <sup>*7, *8</sup>	
PVU-745BTV	–	OK <sup>*6</sup>	OK	OK <sup>*7, *8</sup>	
PVU-745BTF/745BTH	–	OK <sup>*6</sup>	OK	OK <sup>*7, *8</sup>	
PVL-715RS	–	–	OK	–	
PVU-770ST	–	–	OK	OK <sup>*7, *8</sup>	
PVU-674BT PLU-1005BT	–	–	OK	OK <sup>*7, *8</sup>	
PLU-1204BT	–	–	OK	OK <sup>*7, *8</sup>	
PVU-681MVL	–	–	–	–	
PVU-350BTP <sup>*3</sup>	OK	OK <sup>*6</sup>	OK	OK <sup>*7, *8</sup>	
PLU-308BTP <sup>*3</sup>	OK	OK <sup>*6</sup>	OK	OK <sup>*7, *8</sup>	
PVU-781VT/781VTE	–	OK <sup>*6</sup>	OK	OK <sup>*7, *8</sup>	
PLU-1202BT	–	OK <sup>*6</sup>	OK	OK <sup>*7, *8</sup>	
PLU-705BTF/705BTH	–	OK <sup>*6</sup>	OK	OK <sup>*7, *8</sup>	

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

\*1: After sterilization, thoroughly degas the transducer to remove all gas residues on the transducer.

\*2: Note that the label on the transducer may fade. This is not an abnormality.

\*3: The biopsy adaptors, needle stopper, and depth gauge supplied with the transducer can be also sterilized by high-pressure steam sterilization (temperature: 134°C (273.2°F), holding time: 18 min).

\*4: For STERRAD 100S/200 for the USA, no Cycle option is provided.

\*5: Not for use in the USA.

\*6: These items have been confirmed to withstand 120 cycles of sterilization using the method described in this manual.

\*7: One transducer can be sterilized per sterilization cycle. Do not perform sterilization for more than one item at a time.

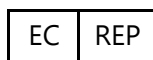
\*8: There may be sticky areas on the cable, however, this is not a fault. If there are sticky areas, wipe them with a soft cloth or gauze moistened with ethanol.

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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



Canon Medical Systems Corporation  
1385, Shimoishigami, Otawara-shi, Tochigi 324-8550, Japan