TOSHIBA

2B701-812EN*H

Guidelines for cleaning, disinfection, and sterilization of transducers

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.

Safety Precautions

1. Meaning of Signal Words

   In this manual, the signal words **DANGER**, **WARNING**, **CAUTION** 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
⚠**DANGER**	**Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.**
⚠**WARNING**	**Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.**
⚠**CAUTION**	**Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.**
CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in property damage.

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.

⚠CAUTION:

Federal law restricts this device to sale by or on the order of a physician.

⚠WARNING:

1. **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 figures on the last page for the immersible range of each transducer model.
2. **This product may contain chemicals known to the State of California to cause cancer, birth defects or other reproductive harm. Wash hands after handling.**

⚠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.**
- **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.**

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 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 TOSHIBA. Contact the manufacturers for information on the activity of the products.

⚠CAUTION:

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) 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 table on the last page.**

NOTE:

The mouthpiece supplied with the TEE transducer can be autoclaved (temperature: 134°C, holding time: 18 min). Confirm that "AUTOCLAVABLE" is indicated on the mouthpiece.

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) 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.

(3) In accordance with the table on the last page, 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.

(4) 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.

(5) Dry the surface of the transducer using clean soft cloth or gauze. Do not use heat to dry the transducer.

Handle the cleaning solution as or wipes 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.

(6) Confirm that the transducer shows no signs of damage, deformation, or peeling.

Disinfection

Before disinfection, the transducer must be cleaned.

<<Items to be used: Sterile protective gloves, disinfectant, sterile 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 disinfectants or disinfection devices shown in the table on the last page.

(3) Rinse off all residual disinfectant from the transducer with sterile or deionized water. Confirm that the disinfectant has been completely removed. 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.

Sterilization

Before sterilization, the transducer must be cleaned.

<<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 on the last page.

    * 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.

Precautions for use

- Wear protective gloves when performing cleaning.*
- Wear sterile protective gloves when performing disinfection or sterilization.*
- Wear new protective gloves each time cleaning, disinfection, or sterilization is performed.
- After chemical cleaning, rinse the transducer thoroughly with purified water and then dry it.
- After chemical disinfection, rinse the transducer thoroughly with sterile water or deionized water and then dry it.

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

Efficacy and effectiveness of the cleaning, disinfection, and sterilizing agents

- Contact the manufacturer of the relevant chemical for the efficacy of each cleaning, disinfection, or sterilizing agent.
- Determine the effectiveness of each agent based on the criteria described in the documentation supplied with the agent.

Model name*3	Usable chemicals																											
	Cleaning									Low/Middle-Level Disinfection*7					High-Level Disinfection											Sterilization	
Chemical name/type	Enzyme					Ethanol	Isopropyl alcohol	Isopropyl alcohol/ Ethylene glycol monobutyl ether	Alkyl dimethyl benzyl ammonium chloride/ 2-ethanol/ Alkyl polysaccharide/ Ethylenediamine tetraacetic acid	Sodium hypochlorite	Quaternary ammonium chlorides		Quaternary ammonium chlorides/ Isopropyl alcohol		Glutaraldehyde							Ortho-phthalaldehyde	Hydrogen peroxide			Ethylene oxide gas*1	Hydrogen peroxide plasma*2
Trade name	CIDEZYME®	MetriZyme®	Rapid Multi-Enzyme cleaner	Klenzyme®	Instru-Zyme™ Gel	Ethanol	Isopropyl alcohol	CaviWipes™	Intercept® Wipes	Dispatch® Hospital Cleaner Disinfectant Towels with Bleach	Sani-Cloth® AF3, Sani-Cloth® AF	Protex™ Disinfectant Wipes	Sani-Cloth® Plus	Super Sani-Cloth®	CIDEX®	CIDEX PLUS® 28 day solution	MetriCide®	MetriCide® 28	MetriCide® Plus 30	WAVICIDE® -01	Sporicidin®	CIDEX® OPA	SPOROX® II	Revital-Ox™ Resert® High Level Disinfectant	Trophon EPR™	Ethylene oxide gas	STERRAD® 50/100S/ 200/NX
Manufacturer	J&J	Metrex Research, Inc.	3M Company	STERIS Corporation	Summit Medical			Metrex Research, Inc	Minntech Corporation	The Clorox Company	Professional Disposables International, Inc.	Parker Laboratories, Inc.	Professional Disposables International, Inc.		J&J	J&J	Metrex Research, Inc	Metrex Research, Inc	Metrex Research, Inc	Medical Chemical Corporation	Sporicidin International	J&J	Sultan Healthcare	STERIS corporation	Nanosonics Limited		J&J
Concentration (Dilution ratio)	0.8% (125)	0.77% (130)	1% (100)	0.8% (125)	Working solution	80% (original solution)	70% (original solution)	Working solution	Working solution	0.65% (working solution)	0.28% (working solution)	0.232% (working solution)	0.25% / 14.85% (working solution)	0.5% / 55% (working solution)	2.4% (working solution)	3.4% (working solution)	2.6% (working solution)	2.5% (working solution)	3.4% (working solution)	2.5% (working solution)	1.12% (working solution)	0.55% (working solution)	7.5% (working solution)	2% (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.	10%	Use STERRAD system cassettes specifically designed for each sterilizer. There are no sterilization-related parameters (temperature, humidity, pressure, or time) to be set by the operator.
Time	1 min.	5 min.	10 min.	5 min.	Wiping only	Wiping only	Wiping only	Wiping only	Wiping only	Wiping only	Wiping only	Wiping only	Wiping only		45 min.	20 min.	45 min.	90 min.		45 min.	20 min.	12 min.	30 min.	8 min.		Exposure time: 7 hours Aeration time: 12 hours	
Temperature	Room temperature	Room temperature		Room temperature	Room temperature	Room temperature	Room temperature	Room temperature	Room temperature	Room temperature	Room temperature	Room temperature	Room temperature		Room temperature		Room temperature			Room temperature	Room temperature	Room temperature	Room temperature	Room temperature		50°C	
Humidity	Normal humidity	Normal humidity		Normal humidity	Normal humidity	Normal humidity	Normal humidity	Normal humidity	Normal humidity	Normal humidity	Normal humidity	Normal humidity	Normal humidity		Normal humidity		Normal humidity			Normal humidity	Normal humidity	Normal humidity	Normal humidity	Normal humidity		50%	
Pressure	Normal pressure	Normal pressure		Normal pressure	Normal pressure	Normal pressure	Normal pressure	Normal pressure	Normal pressure	Normal pressure	Normal pressure	Normal pressure	Normal pressure		Normal pressure		Normal pressure			Normal pressure	Normal pressure	Normal pressure	Normal pressure	Normal pressure		Operating pressure 980 hPa [gauge]	
PC-20M	Immersible range: OK / Type A: OK			OK	OK	–	OK	OK	OK	OK	OK	OK	OK		OK		OK			OK	–	–	OK	OK	–	–	–
PC-50M	Type A: OK			OK	OK	OK	OK	–	–	–	OK	–	OK		OK		–			OK	–	OK	–	–	–	–	–
PET-508MA*4	Type B: OK			–	–	OK	–	–	–	–	OK	–	–		OK		OK			OK	–	OK	–	–	–	–	–
PET-512MC*4	Type B: OK			–	–	–	–	–	–	–	OK	–	–		OK		OK			OK	–	OK	–	–	–	–	–
PET-511BTM*4 *5/510MB*4	Type C: OK			OK	–	OK	–	–	–	–	–	–	–		OK		OK			OK	OK	OK	–	–	–	–	–
PLT-1204AT/1204AX, PVT-375AX	Type D: OK			–	OK	OK	OK	–	–	–	–	–	–		OK		OK			OK	OK	OK	–	–	–	OK	OK
PLT-604AT/704AT/805AT PLT-1202S/1204BT/1204BX PVT-375AT/375BT/382BT/661VT PVT-375SC/674BT	Type D: OK			OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		OK		OK			OK	OK	OK	OK	OK	OK	OK	OK
PST-20CT/25AT/25BT PST-37CT/50AT/65AT PVT-745BTF/745BTH	Type D: OK			OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		OK		OK			OK	OK	OK	OK	OK	OK*6	OK	OK
PLT-308P*8, PVT-770RT	Type D: OK			OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		OK		OK			OK	OK	OK	OK	OK	–	OK	OK
PLT-705BTF/705BTH	Type D: OK			OK	OK	OK	OK	OK	OK	–	OK	–	OK		OK		OK			OK	OK	OK	OK	–	OK	OK	OK
PVT-745BTV	Type D: OK			OK	OK	OK	OK	OK	OK	–	OK	–	OK		OK		OK			OK	OK	OK	OK	–	OK*6	OK	OK
PVT-350BTP*8	Type D: OK			–	OK	OK	OK	–	–	–	–	–	–		OK		OK			OK	OK	OK	–	–	–	OK	OK
PLT-704SBT/705BT/1005BT PVT-781VT	Type D: OK			OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		OK		OK			OK	OK	OK	OK	OK	OK	–	OK
PLT-704ST/1204ST, PVT-375ST	Type D: OK			OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		OK		OK			OK	OK	OK	OK	OK	OK	–	–
PST-25ST/50BT, PVT-712BT	Type D: OK			OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		OK		OK			OK	OK	OK	OK	OK	OK*6	–	–
PST-25SX	Type D: OK			–	OK	OK	OK	–	–	–	OK	–	OK		OK		–			–	OK	OK	–	–	–	–	–
PST-30SBT	Type D: OK			OK	OK	OK	OK	OK	OK	–	–	–	–		OK		OK			OK	OK	OK	OK	–	OK*6	OK	–
PST-30BT	Type D: OK			OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		OK		OK			OK	OK	OK	OK	OK	OK*6	OK	–
PLT-1204MV, PVT-375MV PVT-382MV/675MV/675MVL	Type D: OK			–	OK	OK	OK	OK	OK	OK	OK	OK	OK		OK		OK			OK	–	OK	OK	OK	OK	–	–
PVT-681MV	Type D: OK			–	–	OK	OK	OK	OK	OK	OK	OK	OK		OK		–			–	–	OK	OK	OK	OK	–	–

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 and the connector handle may become difficult to turn. These are not abnormalities.

*3: When multiple model names are referred to, they are abbreviated. For example, "PLT-604AT and PLT-704AT" is abbreviated as "PLT-604AT/704AT". For the transducers supported by each diagnostic ultrasound system, refer to the operation manual supplied with the diagnostic ultrasound system. Note that some of the listed models may not be available in some regions.

*4: The mouthpieces supplied with the TEE transducer can be sterilized by autoclaving (temperature: 134°C, holding time: 18 min). Confirm that "AUTOCLAVABLE" is indicated on the mouthpiece.

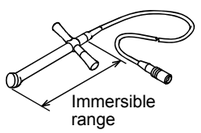
*5: If a waterproof cover is placed over the transducer connector, the entire transducer can be immersed in water, cleaning solution, or disinfectant.

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

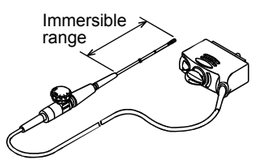
*7: High-Level Disinfection is also required.

*8: The biopsy adaptors, needle stopper, and depth gauge supplied with the transducer can be also sterilized by autoclaving (temperature: 134°C (273.2°F), holding time: 18 min).

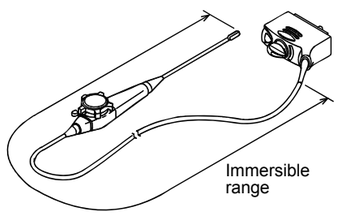
● Type A (PC-20M etc.)



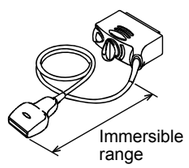
● Type B (PET-508MA etc.)



● Type C (PET-510MB etc.)



● Type D (PLT-704AT etc.)



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

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