

1. Safety Precautions

This device should only be used by physicians conversant with ultrasound operation and fully qualified and certified medical personnel. For the operation of **Ultrasound System**, please refer to the **Operation Manual** for the system. When performing biopsy operation, be sure to put a sterilized transducer cover on the transducer and use a biopsy bracket/adapter specific for this transducer.

In using this device, please check for the **Operation Manual for Biopsy Bracket/Adapter** and the **Operation Manual for Ultrasound System**.

WARNING

- **Prevent blood, body fluid, etc. from directly adhering to the transducer. Adhesion of them may cause infection.**
 - If blood and body fluid are likely to adhere to the transducer, be sure to use a transducer cover.
 - Wear sterilized protective gloves before using the transducer.
 - Because the transducer cannot be sterilized, be sure to use a sterilized transducer cover.
 - Use of transducer covers coated with silicone oil is prohibited.
 - For patients with hypersensitivity to natural rubber, use transducer covers, etc. free of natural rubber content. Some covers, etc. use components with natural rubber origin. Natural rubber may rarely cause allergic symptoms such as itching, redness, rash, swelling, fever, breathing difficulties, hypotension, and shock. If any of these symptoms occur, discontinue use immediately and take appropriate measures.
 - Transducer covers should be replaced after each inspection.
- **Use sterile ultrasound gel when using to invasive procedures.**
- **Use sterile single-use gel packets when infection is a concern.**
- **Do not allow fluids containing organic solvents to adhere to the transducer (excluding, however, the cleaners and disinfectants described in this manual).**

Doing so may damage it. There is also a risk of electric shock.
- **Do not make a strong impact on the transducer, push it to a hard thing forcibly, or drop it. Also do not forcibly bend, pull, or twist its cable.**

Doing so may cause an electric shock.
- **Do not pour a liquid on its connector.**

Doing so may cause an electric shock, a shortcircuit, a fire, or a breakdown.
- **Do not use the transducer when it is broken or damaged.**

Doing so may cause an electric shock or injury.

 - Before and after an examination, check that the transducer has no abnormality, such as a scratch and a crack.

- **Do not disassemble, repair, or modify the transducer.**

Doing so may cause an electric shock.

- Repair works require special knowledge and well-trained skills. If any repair is needed, please contact our service representative.

2. Caring for Transducer

Before Use

- (1) Inspect prior to use and confirm device to be free of any abnormalities.
- (2) Clean and disinfect transducer.

After use

- (1) Remove the transducer with the power turned off according to the operation procedures of Ultrasound System.
- (2) When a transducer cover was used, remove it from the transducer and dispose it.
- (3) Wipe the transducer clean of the ultrasound gel or stains with a soft cloth dipped in hot water (40 °C or less) and air-dry it.
- (4) Perform after-use inspection and check that the transducer has no abnormality.
- (5) Clean / disinfect the transducer.
- (6) Keep the transducer in a clean place.

<When carrying a transducer>

Be sure to disinfect it and put it in its storage case.

Precautions for Cleaning & Disinfection

- **Do not use a hard brush for cleaning or disinfecting the transducer.**

Doing so may damage it.
- **Do not immerse the transducer in a disinfection solution longer than a specified time.**

The performance of the transducer may deteriorate.
- **Do not use undesignated chemicals (for disinfection and cleaning).**

The performance of the transducer may deteriorate.
- **Be sure to use protective gloves and clean and disinfect the transducer to prevent infection.**
- **Be sure to comply with transducer's usage environment and storage environment conditions.**

The performance of the transducer may deteriorate.

- When returning the transducer to our service representative, be sure to disinfect it to prevent infection.
- For the range and time for immersing the transducer when cleaning and disinfecting it with a chemical solution, check the table shown on the back side.
- For the effects and procedures of cleaning and disinfection, please check for the explanatory leaflet of the chemical solution.
- The conditions described in the table on the reverse side of this sheet are an example of the cleaning and disinfection conditions. Clean and disinfect under appropriate conditions according to the level of contamination.

Cleaning transducers

Immerse the cleaned transducer in the cleaning agent specified in the table below, or wipe the transducer with gauze or sheets soaked with the cleaning agent, then washing off the chemical with sterile water.

Chemical type	Trade name	Usage and time for immersing
Enzyme	CIDEZYME® (ENZOL®)	Diluted 125 times for use, 1 minute immersion Temperature: Room temperature
	MetriZyme™	Diluted 130 times for use, 5 minute immersion Temperature: Room temperature
Benzalkonium chloride	Protex™ Disinfectant Wipes	Wipe with impregnated soft cloth Temperature: Room temperature
	Protex™ ULTRA Disinfectant Wipes	
	Super Sani-Cloth®	
	Sani-Cloth® HB	
	Sani-Cloth® Plus	
	Protex™ Disinfectant Spray	Wipe with impregnated gauze Temperature: Room temperature
	PI-Spray	
	Clinell® Universal Spray	
	ANIOS'CLEAN EXCEL D	Diluted 200 times for use, 15 minute immersion Temperature: Room temperature
	ANIOSYME X3	Diluted 200 times for use, 5 minute immersion Temperature: Room temperature
	10 w/v% Osvan®	Diluted 100 times for use, 10 minute immersion Temperature: Room temperature
	10 w/v% DIAMITOL®	
Chlorhexidine Gluconate	5 w/v% Hibitane™	Diluted 50 times for use, 10 minute immersion, or diluted 10 times for wiping with impregnated gauze Temperature: Room temperature

Chemical type	Trade name	Usage and time for immersing
potassium peroxymonosulfate	Antec Virkon® S	Diluted 1000 times for use, 5 minute immersion Temperature: Room temperature
	RUBYSTA®	Wipe with impregnated soft cloth Temperature: Room temperature
Ethyl alcohol	80 vol% Ethyl alcohol	Wipe with impregnated gauze Temperature: Room temperature
	Hypoethanol (Sodium thiosulfate ethanol solution)	
Isopropyl alcohol	70 vol% Isopropyl alcohol	Wipe with impregnated gauze Temperature: Room temperature
Sodium hypochlorite	Milton®	Diluted 80 times for use, 60 minute immersion, or diluted 10 times for wiping with impregnated gauze Temperature: Room temperature
	Sani-Cloth® Bleach	Wipe with impregnated soft cloth Temperature: Room temperature
Povidone iodine	10 w/v% BETADINE®	Diluted 100 times for wiping with impregnated gauze Temperature: Room temperature
Chlorine dioxide	Tristel Duo™ ULT (Tristel Solutions Limited)	Wipe with impregnated soft cloth Temperature: Room temperature
Sodium percarbonate	Rely+On™ PeraSafe	Diluted 62 times for use, 60 minute immersion Temperature: Room temperature
	gigasept® Pearls	Diluted 50 times for use, 30 minute immersion Temperature: Room temperature

Disinfecting transducers (immersion)

Immerse the cleaned transducer in the disinfectant solution specified in the table below, then washing off the disinfectant with sterile water.

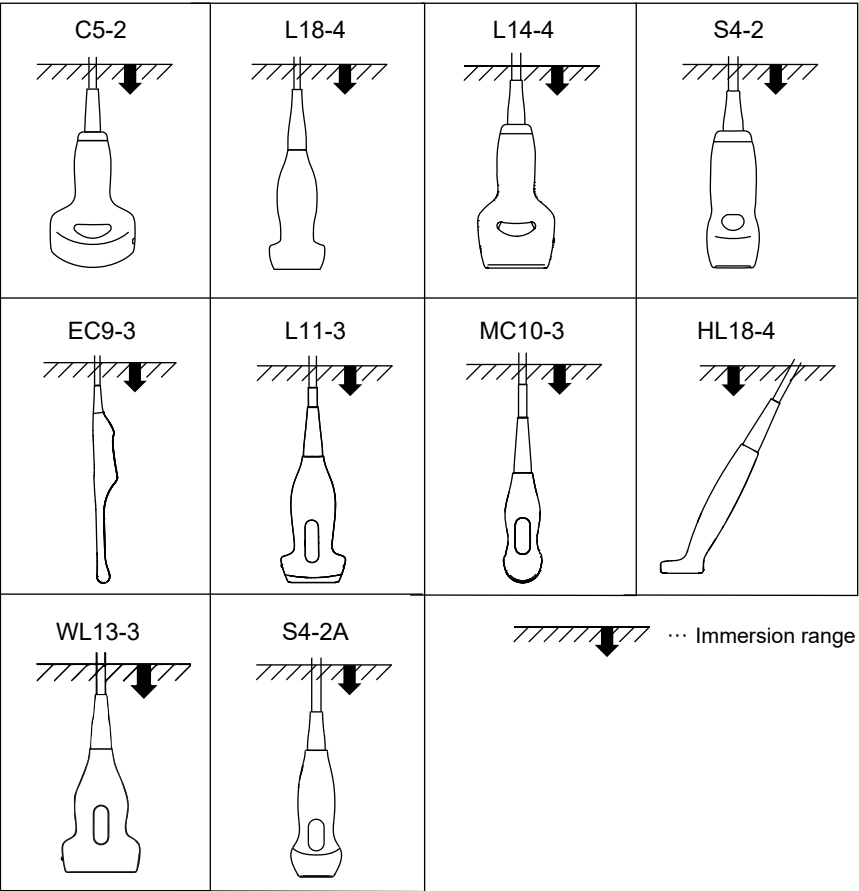
Chemical type	Trade name	Usage and time for immersing
Ortho-phthalaldehyde	CIDEX® OPA (0.55%)	Use undiluted, 12 minute immersion Temperature: Room temperature
Glutaraldehyde	Glutohyde® plus (3.5%)	Use undiluted, 60 minute immersion Temperature: Room temperature
	STERIHYTE® (2%)	Use undiluted, 60 minute immersion Temperature: Room temperature
	MetriCide™ Plus 30	Use undiluted, 90 minute immersion Temperature: Room temperature
Succindialdehyde	gigasept® FF new	Diluted 17 times for use, 60 minute immersion Temperature: Room temperature

Disinfecting transducers (trophon® EPR/trophon® 2)

Be sure to refer to the instruction manual provided by the manufacturer, Nanosonics Ltd.

Chemical type	Trade name	Usage and time for immersing
Hydrogen peroxide	trophon® EPR	Follow the manufacturer's operation manual.
	trophon® 2	Follow the manufacturer's operation manual.

Acceptable range for immersing the transducer



US
Konica Minolta Healthcare Americas, Inc.
411 Newark-Pompton Turnpike, Wayne, NJ 07470,
U.S.A.
TEL. 973-633-1500

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EC	REP
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Konica Minolta Business Solutions Europe GmbH
Capellalaan 65,2132 JL, Hoofddorp,
The Netherlands
TEL. +31-20-658-4100

IN
Konica Minolta Healthcare India Private Ltd.
Office No 1121, 2nd Floor, Building No 11,
Solitaire Corporate Park, Chakala, Andheri East,
Mumbai 400093 India
TEL. +91-22-61916900

CA
Konica Minolta Business Solutions (Canada) Ltd.
5875 Explorer Drive, Mississauga,
Ontario, L4W 0E1, Canada
TEL. 905-890-6600

CN
KONICA MINOLTA MEDICAL TECHNOLOGY (SHANGHAI) CO.,LTD.
Room1602, Tower B, Hongwell International Plaza,
1602 West Zhongshan Road, Xuhui District,
Shanghai 200235 China
TEL. 021-6422-2626