
Cleaning and Disinfecting FUJIFILM SonoSite Products

User Guide

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Value from Innovation

SonoSite

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CHAPTER 1

Introduction

About this guide

This guide contains instructions for cleaning and disinfecting SonoSite systems, transducers, and accessories. Each system is presented in its own chapter, with cleaning and disinfecting instructions designed specifically for that system.

If your FUJIFILM SonoSite system is not listed here, refer to the system user guide, or contact FUJIFILM SonoSite for cleaning instructions.

Conventions

The document follows these conventions:

- ▶ A **WARNING** describes precautions necessary to prevent injury or loss of life.
- ▶ A **Caution** describes precautions necessary to protect the products.
- ▶ A **Note** provides supplemental information.
- ▶ Numbered and lettered steps must be performed in a specific order.
- ▶ Bulleted lists present information in list format but do not imply a sequence.

For labeling symbols used, see the corresponding ultrasound system user guide.

Technical support

To order sheaths, bite guards, tip covers, and other supplies, see www.civco.com.

For more information or for technical support, contact FUJIFILM SonoSite as follows.

Phone (U.S. or Canada)	877-657-8118
Phone (Outside U.S. or Canada)	425-951-1330, or call your local representative
Fax	425-951-6700
E-mail	service@sonosite.com
Web	www.sonosite.com
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This chapter contains instructions for cleaning and disinfecting the iViz ultrasound system, transducers, and accessories. Use the FUJIFILM SonoSite recommendations when cleaning and disinfecting your ultrasound system, transducer, and accessories. Use the cleaning recommendations in the accessory manufacturer’s instructions when cleaning or disinfecting your accessories.

The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.

See www.sonosite.com/transducers for images of transducers.

Also included is a listing of disinfectants that SonoSite has tested and deemed compatible with the iViz system, transducers, and accessories. This information is presented in the following tables.

- ▶ **Table 2-5, “Cleaners and disinfectants compatible with the iViz system and transducers”** on page 15 shows compatibility between disinfectants, the system, and transducers.

- ▶ **Table 2-6, “Cleaners and disinfectants compatible with iViz accessories”** on page 18 shows compatibility between disinfectants and accessories.
- ▶ **Table 2-7, “High-level disinfectants compatible with iViz transducers”** on page 18 shows compatibility between high-level disinfectants and transducers.

Note

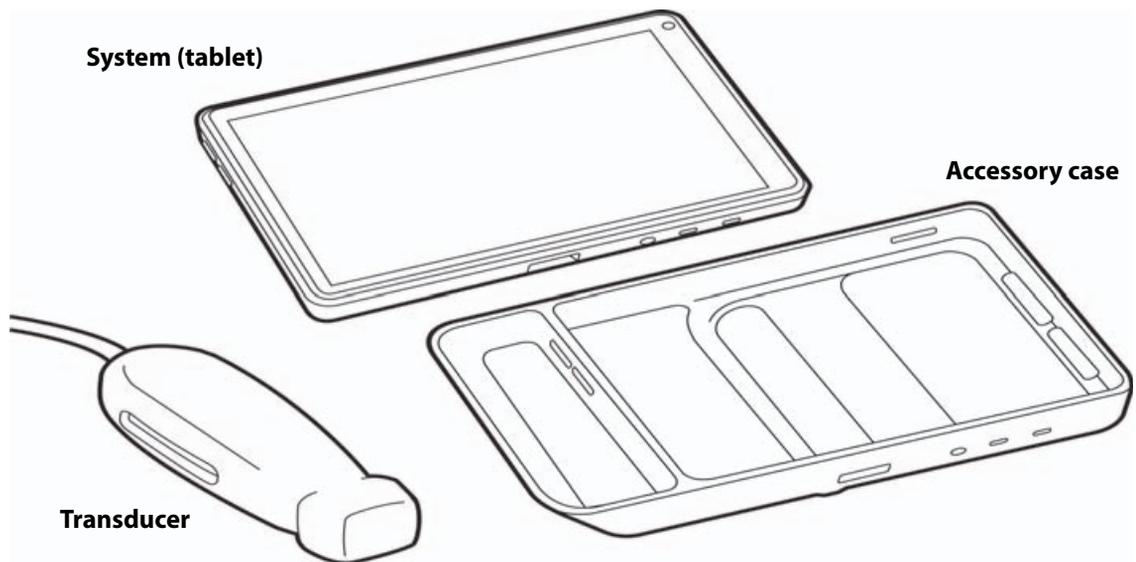
The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.

WARNING

- ▶ Ensure that cleaning and disinfecting solutions and wipes are not expired.
- ▶ Some cleaners and disinfectants can cause an allergic reaction to some individuals.

Cleaning and disinfecting

The iViz ultrasound system consists of the system (tablet), accessory case, and transducer.



This section includes instructions for cleaning and disinfecting the iViz ultrasound system. The system must be cleaned and disinfected after each exam. It is important to follow this cleaning and disinfection process without shortening or skipping steps. Only use cleaners and disinfectants approved by FUJIFILM SonoSite on the iViz system. Be sure to observe the solution strength and duration requirements detailed in the cleaning and disinfection procedures.

Included in this section are instructions for two levels of cleaning and disinfection for both the transducer and the system. The level of cleaning and disinfection required depends on the type of tissue the system comes into contact with during an exam. For more information, see **“Cleaning and disinfecting the system and protective case”** on page 5.

The materials used in the iViz system are designed and tested to work with the cleaners and disinfectants listed in this chapter. The iViz system will not be damaged if cleaned according to the approved instructions and with the approved cleaners and disinfectants. Before using a disinfectant, confirm that it is appropriate for your facility’s use. Verify expiration dates, concentration, and efficacy of chemicals (for example, a chemical strip test).

When preparing, using, and disposing of chemicals, be sure to follow manufacturer recommendations and local regulations.

WARNING

Residual chemicals from some disinfectants can cause an allergic reaction in some individuals.

Caution

- ▶ Follow the manufacturer’s cleaning label instructions for solution strengths and disinfectant contact duration.
- ▶ Check the expiration date on all cleaning and disinfection solutions and wipes. Do not use chemicals or wipes that have expired.
- ▶ Do not allow cleaning solution or disinfectant into the battery compartment, system controls, or transducer connector.
- ▶ Do not use strong solvents, such as thinner or benzene, or abrasive cleansers since these will damage the exterior surfaces. Use only FUJIFILM SonoSite recommended cleaners or disinfectants.
- ▶ Use only a soft cloth lightly dampened in a mild soap or compatible cleaning solution to remove any disinfectant on metal surfaces.

Cleaning and disinfecting the system and protective case

The following procedures can be used to clean and disinfect the system and protective case.

Caution

Do not immerse the system or the protective case in any liquid.

To clean the system and protective case

- 1 Make sure the system is turned off.
- 2 Disconnect the transducer.

- 3 Remove the system from the protective case.
- 4 Using a soft, damp cloth (dampened with cleaner or disinfectant) or a premoistened disinfectant wipe, clean any particulate matter or bodily fluids from all system and protective case surfaces.
 - ▶ Be sure to use only cleaners listed in **Table 2-4, “Compatible cleaners and disinfectants”** on page 11.
 - ▶ Wipe from clean areas to the soiled areas to avoid cross-contamination.

WARNING

Wear the appropriate personal protective equipment (PPE), such as eyewear and gloves, recommended by the chemical manufacturer.

Cautions

- ▶ Do not spray cleaners or disinfectants directly on the system surfaces. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- ▶ Do not allow moisture to get on the transducer connector or into the connector ports on the system.
- ▶ Do not scratch the display screen.

- 5 Verify that all gel, particulate matter, and bodily fluids have been removed.

Note

Repeat steps 4-5 with new cleaning materials, if necessary.

To disinfect the system and protective case

- 1 Wipe all surfaces with a premoistened wipe or a cloth moistened with a compatible disinfectant listed in **Table 2-4, “Compatible cleaners and disinfectants”** on page 11.
 - ▶ Apply the disinfectant solution to the cloth rather than applying it directly to surfaces.
 - ▶ Follow the chemical manufacturer’s requirements for wet contact time.

Caution

Use only FUJIFILM SonoSite recommended disinfectants. Using a non-recommended disinfect solution or incorrect solution strength can damage or discolor the transducer and void the transducer warranty.

- 2 Allow the system to air dry following the chemical manufacturer’s requirements for wet contact time.

Cleaning and disinfecting the transducer

Cleaning and disinfecting the transducer requires that you chose the proper cleaning and disinfecting level.

Determining the required cleaning and disinfection level

Before cleaning, visually inspect the ultrasound system to determine that it is free of any unacceptable deterioration, such as corrosion, discoloration, pitting, or cracked seals. If damage is evident, discontinue use, and contact FUJIFILM SonoSite or your local representative.

Spaulding classifications are a tool to help reduce cross-contamination and infection by specifying the level of cleaning and disinfecting required for your medical equipment. The Spaulding classification is based on the type of device, its usage, and the risk of infection. Based on these criteria, the iViz ultrasound system is classified as either non-critical or semi-critical, depending on how it is used.

Each Spaulding classification mandates a specific level of cleaning and disinfection of the equipment before it can be used in the next exam. Use the following guide to determine the level of cleaning and disinfection for the iViz ultrasound system according to the appropriate Spaulding classification.

Table 2-1: Cleaning and disinfection guidelines

If any part of the system came into contact with...	Then disinfect to the following level	
Broken skin, mucosal membranes, blood, and/or bodily fluids (semi-critical)		Option A Go to “High-level disinfection (semi-critical)” on page 8
Unbroken skin, no blood or bodily fluids (non-critical)		Option B Go to “Intermediate-level disinfection (non-critical)” on page 11

Option **A** High-level disinfection (semi-critical)

Clean and disinfect the transducer immediately after use.

Be sure to follow the manufacturer's instructions when using cleaners and disinfectants.

Refer to **Table 2-2, “Compatible cleaners and disinfectants”** on page 8 for a list of cleaners and disinfectants recommended for use with the transducer.

Table 2-2: Compatible cleaners and disinfectants

Product	L38v transducer	P21v transducer
Sani-Cloth AF3 (grey top)	✓	✓
Sani-Cloth Bleach Wipes (yellow top)	✓	✓
Sani-Cloth Plus (red top)	✓	✓
Sani-Cloth HB (green top)	✓	✓
T-Spray II (PI-Spray II)	✓	✓

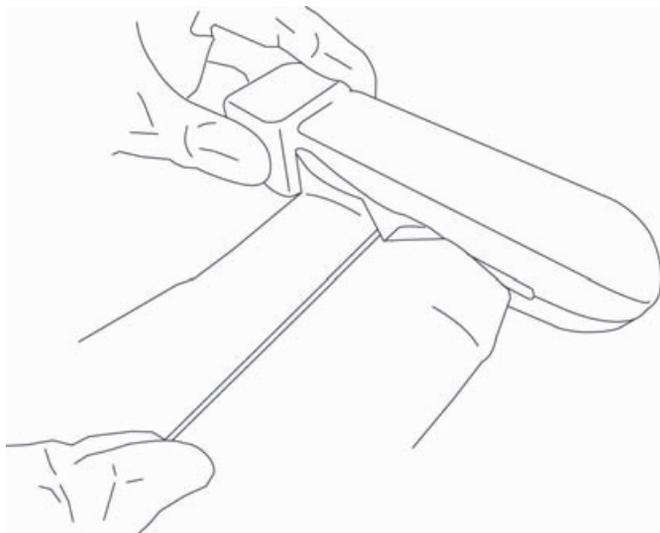
Cleaning and disinfecting the transducer

Use the following procedures to clean and disinfect the transducer.

To clean the transducer

- 1 Clean the transducer cord using either a cloth dampened with cleaner or disinfectant or a premoistened disinfectant wipe. Start at the connector and wipe toward the scan head. Do not get any water or cleaner on the connector.
- 2 Clean all transducer surfaces using either a soft, damp, soapy cloth or disinfectant wipe. Be sure to remove any gels or particulate matter.

- 3 Clean the transducer cooling slot using a thin, disposable instrument, such as a swab, to push a soft cloth lightly dampened with a cleaning solution or premoistened wipe through the slot.



- a Pull the cloth back and forth from one side of the slot to the other.
- b Pull the cloth up and down from the transducer connector to the transducer head.
- c Remove the cloth from the slot.
- d Dispose of the cloth and the instrument used to insert the cloth.
- e Verify that all gel, particulate matter, and bodily fluids have been removed.

Note | Repeat Step 3 with new cleaning materials, if necessary.

To high-level disinfect the transducer

- 1 Mix the disinfectant solution following disinfectant label instructions for solution strengths and disinfectant contact duration.

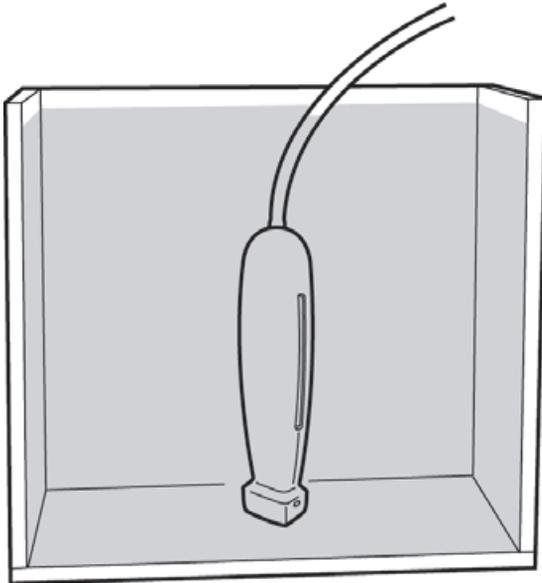
Be sure to use a compatible disinfectant as listed in [Table 2-7, “High-level disinfectants compatible with iViz transducers”](#) on page 18.

Caution | Use only FUJIFILM SonoSite recommended disinfectants. Using a non-recommended disinfection solution, incorrect solution strength, or immersing a transducer deeper or for a longer period of time than recommended can damage or discolor the transducer and void the transducer warranty.

2 Immerse the transducer and about two inches of the cable in the disinfectant solution.

Caution | Do not immerse the transducer connector in any liquid.

Use this diagram as a reference and then follow the instructions on the disinfectant label for the duration of the transducer immersion.



3 Using the instructions on the disinfectant label, rinse to the point of the previous immersion, and then air dry or towel dry with a clean, non-linting cloth.

4 Examine the transducer and cord for damage, such as cracks or splitting where fluid can enter.

If damage is evident, discontinue use of the transducer and contact FUJIFILM SonoSite or your local representative

Table 2-3: Approved high-level disinfectants and soak times

Disinfectant	Temperature	Duration
Cidex	25° C (77° F)	45 minutes
Cidex OPA	20° C (68° F)	12 minutes

Cleaning and disinfecting the transducer requires that you chose the proper cleaning and disinfecting level.

Option **B** Intermediate-level disinfection (non-critical)

Clean and disinfect the system and protective case immediately after use. Be sure to follow the manufacturer's instructions when using cleaners and disinfectants. See **“Cleaning and disinfecting the system and protective case”** on page 5.

For non-critical disinfection, clean the transducer as described in **“To clean the transducer”** on page 11, and then disinfect it as described in **“To disinfect the transducer”** on page 12.

If the transducer has come into contact with broken skin, mucosal membranes, or blood, you must then do a high-level disinfection; see **“High-level disinfection (semi-critical)”** on page 8.

The materials listed in **Table 2-4, “Compatible cleaners and disinfectants”** on page 11 are chemically compatible with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

Table 2-4: Compatible cleaners and disinfectants

Product	System	Protective case	Carry case	L38v	P21v
Sani-Cloth AF3 (grey top)	✓	✓	✓	✓	✓
Sani-Cloth Bleach Wipes (yellow top)	✓	✓		✓	✓
Sani-Cloth Plus (red top)	✓	✓	✓	✓	✓
Sani-Cloth HB (green top)	✓			✓	✓
Super Sani-Cloth (purple top)	✓		✓		
T-Spray II (PI-Spray II)	✓	✓	✓	✓	✓

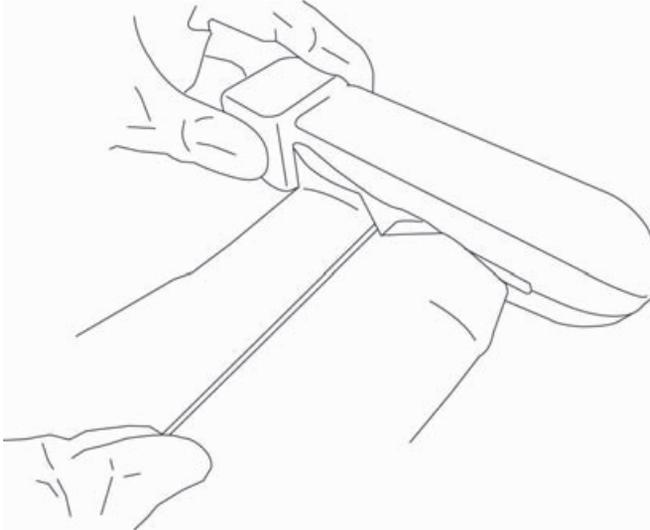
Note

Proper cleaning of the slot is important because good airflow through the slot improves cooling of the transducer electronics and extends the life of the equipment.

To clean the transducer

- 1 Clean the transducer cord using either a soft, damp, soapy cloth or a premoistened wipe. Start at the connector and wipe toward the scan head. Do not get any water or cleaner on the connector.

- 2 Clean all transducer surfaces using either a soft cloth dampened with cleaner or disinfectant or a premoistened wipe. Be sure to remove any gels or particulate matter.
- 3 Clean the transducer cooling slot using a thin, disposable instrument, such as a swab, to push a soft cloth lightly dampened with a cleaning solution or a premoistened wipe through the slot.



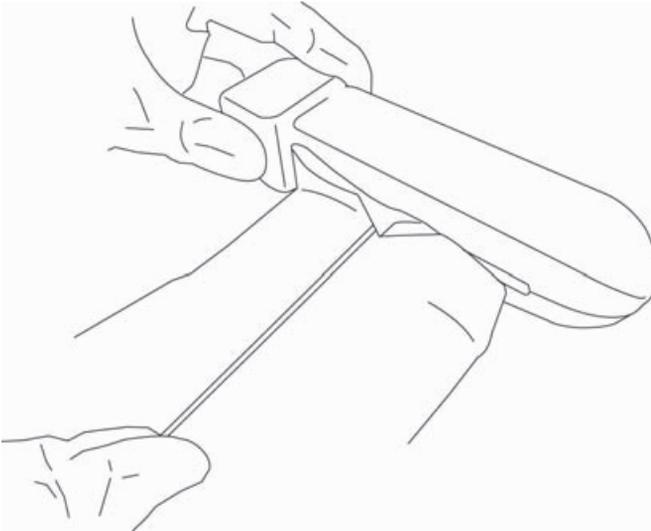
- a Pull the cloth back and forth from one side of the slot to the other.
- b Pull the cloth up and down from the transducer connector to the transducer head.
- c Remove the cloth from the slot.
- d Dispose of the cloth and the instrument used to insert the cloth.
- e Verify that all gel, particulate matter, and bodily fluids have been removed.

Note

Repeat Step 3 with new cleaning materials, if necessary.

To disinfect the transducer

- 1 Disinfect the transducer cord and body by wiping with a cloth moistened with a compatible disinfectant or premoistened disinfectant wipe. Do not get any disinfectant on the connector.
- 2 Disinfect the cooling slot by using a thin instrument, such as a swab, to push a disinfectant wipe into the slot



- a** Pull the wipe back and forth from one side of the slot to the other.
 - b** Pull the wipe up and down from the transducer connector to the transducer head.
 - c** Remove the disinfecting wipe from the slot.
 - d** Air dry.
- 3** Examine the transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, do not use the transducer and contact FUJIFILM SonoSite or your local representative.

Cleaning the iViz carry case

To clean the iViz carry case, use mild soap and water, and wash it by hand or machine. You can also use one of the cleaners listed in [Table 2-4, “Compatible cleaners and disinfectants”](#) on page 11 to clean it.

Using other chemicals may cause discoloration.

Storing

Clean and disinfect the iViz ultrasound system prior to storing it.

Store the system in a clean place with good airflow. Disconnect the transducer from the system, and hang it vertically.

Transporting

When transporting the iViz ultrasound system, you must take precautions to protect the equipment from damage and avoid cross-contamination.

Clean and disinfect the system by following the instructions in **“Cleaning and disinfecting the system and protective case”** on page 5.

Be sure to transport the system in a container approved by your facility.

Disposing of the system

If the iViz ultrasound system shows damage or deterioration, such as corrosion, discoloration, pitting, or cracking, do not dispose of it. Contact FUJIFILM SonoSite or your local representative.

WARNING

The battery inside this unit may explode if exposed to very high temperatures. Do not destroy this unit by incinerating or burning. Return the unit to FUJIFILM SonoSite or your local representative for disposal.

Compatible cleaners and disinfectants (system and transducers)

Table 2-5: Cleaners and disinfectants compatible with the iViz system and transducers

Disinfectants	iViz system	Protective case	L38v	P21v
Airkem A-33			✓	✓
Aniosyme DD1- 5%			✓	✓
Anioxide 1000			✓	✓
Asepti Wipe II			✓	✓
Baxedin Pre-Op			✓	✓
Caviwipes			✓	✓
Cidalkan			✓	✓
Cidalkan Lingettes		✓	✓	✓
Clinell Universal Sanitising Wipes	✓		✓	✓
Control III		✓		
Coverage Germicidal Surface Wipes		✓	✓	✓
Coverage Plus Germicidal Surface Wipes		✓	✓	✓
Coverage Spray TB		✓		
DisCide Ultra Disinfecting Towlettes		✓		
Dispatch Wipes		✓		

Table 2-5: Cleaners and disinfectants compatible with the iViz system and transducers

Disinfectants	iViz system	Protective case	L38v	P21v
Dynacide PA		✓	✓	✓
Echo Clean lingettes		✓	✓	✓
End Bac II		✓	✓	✓
Endospirine		✓	✓	✓
Gluco Chlor Wipes		✓	✓	✓
Hydrogen Peroxide 3%		✓	✓	✓
Incidin Plus 1%		✓	✓	✓
Incidin Plus 3%		✓	✓	✓
Korsolex Extra		✓	✓	✓
Madacide-1			✓	✓
Medzyme		✓	✓	✓
MetriSponge			✓	✓
Percept RTU Wipes			✓	✓
Protex Spray		✓		
Protex Wipes		✓		
Sani-Cloth AF3	✓	✓	✓	✓
Sani-Cloth Bleach Wipes	✓	✓	✓	✓

Table 2-5: Cleaners and disinfectants compatible with the iViz system and transducers

Disinfectants	iViz system	Protective case	L38v	P21v
Sani-Cloth HB	✓		✓	✓
Sani-Cloth Plus	✓	✓	✓	✓
Staphene			✓	✓
Steranios 2%			✓	✓
Super Sanicloth	✓			
Trigene Advance Wipes			✓	✓
Tristel Solo			✓	✓
Tristel Wipes	✓			
T-Spray			✓	✓
T-Spray II	✓		✓	✓
Virex TB			✓	✓
Wet Task Wipes		✓	✓	✓
Wex-Cide			✓	✓
Wet Wipe Disinfection			✓	✓
Wipes Plus Disinfecting Wipes			✓	✓

Compatible cleaners and disinfectants (accessories)

Table 2-6: Cleaners and disinfectants compatible with iViz accessories

Disinfectants	iViz carry case
Sani-Cloth AF3	✓
Sani-Cloth HB	✓
Sani-Cloth Plus	✓
Super Sanicloth	✓
Tristel Wipes	✓
T-Spray II	✓

Compatible high-level disinfectants compatible (transducers)

Table 2-7: High-level disinfectants compatible with iViz transducers

High-level Disinfectants	L38v	P21v
Cidex	✓	✓
Cidex Plus	✓	✓
Cidex OPA	✓	✓
Metricide OPA Plus	✓	✓

CHAPTER 3

Cleaning and disinfecting the X-Porte ultrasound system

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This chapter contains instructions for cleaning and disinfecting the X-Porte ultrasound system, transducers, and accessories. Use the FUJIFILM SonoSite recommendations when cleaning or disinfecting your ultrasound system, transducer, and accessories. Use the cleaning recommendations in the component manufacturer’s instructions when cleaning or disinfecting your components.

The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.

See www.sonosite.com/transducers for images of transducers.

Also included is a listing of disinfectants that SonoSite has tested and deemed compatible with the X-Porte system, transducers, and accessories. This information is presented in the following tables.

- ▶ **Table 3-2, “Cleaners and disinfectants compatible with X-Porte system and transducers”** on page 31 shows compatibility between disinfectants, the system, and transducers.
- ▶ **Table 3-3, “Cleaners and disinfectants compatible with X-Porte system accessories”** on page 36 shows compatibility between disinfectants and accessories.

- ▶ **Table 3-4, “High-level disinfectants compatible with X-Porte transducers”** on page 40 shows compatibility between high-level disinfectants and transducers.

Note

- ▶ The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.
- ▶ For cleaning the TEE_{Exp} transducer, refer to the cleaning and disinfection instructions in the *TEE_{Exp} User Guide*.

Before getting started

- ▶ Follow the disinfectant manufacturer’s recommendations regarding appropriate personal protective equipment (PPE), such as protective eyewear and gloves.
- ▶ Inspect the system and transducer to determine that they are free of any unacceptable deterioration, such as corrosion, discoloration, pitting, or cracked seals. If damage is evident, discontinue use, and contact FUJIFILM SonoSite or your local representative.
- ▶ Confirm that cleaning and disinfecting materials are appropriate for your facility’s use. FUJIFILM SonoSite tests cleaners and disinfectants for use with the FUJIFILM SonoSite systems and transducers.
- ▶ Disinfectants and cleaning methods listed in this chapter are recommended by FUJIFILM SonoSite for material compatibility with the products.
- ▶ Ensure that the disinfectant type and the solution strength and duration are appropriate for the equipment and application.
- ▶ Follow manufacturer recommendations and local regulations, when preparing, using and disposing of chemicals.

WARNING

- ▶ Ensure that cleaning and disinfecting solutions and wipes are not expired.
- ▶ Some cleaners and disinfectants can cause an allergic reaction to some individuals.

Caution

- ▶ Do not allow cleaning solution or disinfectant into the system connectors, or transducer connector.
- ▶ Do not use strong solvents such as thinner or benzene, or abrasive cleansers, since these will damage the exterior surfaces. Use only FUJIFILM SonoSite recommended cleaners or disinfectants.

Cleaning and disinfecting

Determining the required cleaning and disinfecting level

WARNING

The cleaning instructions contained in this chapter are based on requirements mandated by the American Food and Drug Administration (FDA). Failure to follow these instructions may result in cross contamination and patient infection.

The level of cleaning and disinfecting required for the system is dictated by the type of tissue it contacts during use. Use **Table 3-1, “Choosing a cleaning and disinfecting method”** on page 21 to determine the level of cleaning and disinfecting required.

Table 3-1: Choosing a cleaning and disinfecting method

Did any part of the system or transducer come in contact with broken skin, blood, mucosal membranes, or bodily fluids?	
YES	Came in contact with broken skin, blood, mucosal membranes, or bodily fluids. 
OR	
NO	Did not come in contact with broken skin, blood, or bodily fluids. 
Option A Go to “Clean and disinfect system and transducer to a high level (semi-critical uses)” on page 22.	
Option B Go to “Clean and disinfect system and transducer to a low level (non-critical uses)” on page 26.	

Spaulding classifications

Spaulding classifications (non-critical, semi-critical) determine the approach for cleaning and disinfecting medical equipment based on the device, the way it has been used, and the risk of infection. The system and transducers are designed for use within the Spaulding classifications of non-critical and semi-critical uses.

Option **A** Clean and disinfect system and transducer to a high level (semi-critical uses)

Use this procedure to clean and high-level disinfect the ultrasound system and transducer **whenever it has come into contact with blood, broken skin, mucosal membranes, or bodily fluids.**

Follow the manufacturer's instructions when using cleaners and disinfectants. The cleaners and disinfectants listed in the procedure are chemically compatible with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

WARNING

- ▶ To avoid electrical shock, before cleaning, disconnect the system from the power supply.
- ▶ Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as eyewear and gloves.

Cautions

- ▶ Do not skip any steps or abbreviate the cleaning and disinfecting process in any way.
- ▶ Do not spray cleaners or disinfectants directly on the system surfaces or on system and transducer connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- ▶ Do not attempt to disinfect a transducer or transducer cable using a method or chemical that is not included here. This can damage the transducer and void the warranty.
- ▶ Use only FUJIFILM SonoSite recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage the System and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.

Note

You must clean and disinfect both the ultrasound system and the transducer after each use, but only the transducer can be disinfected to a high level.

Cleaning and disinfecting the system and transducer (semi-critical)

To clean and disinfect the system and transducer

- 1 Turn off** the system by pressing the **Power button**.
- 2 Unplug** the power cord from the outlet.
- 3 Remove** the disposable transducer sheath, if applicable.

4 Disconnect the transducer from the system. Temporarily place it where it will not cross-contaminate clean equipment or surfaces while you clean the ultrasound console.

5 Clean the exterior surfaces of the **ULTRASOUND SYSTEM** to remove any debris or bodily fluids. Use the following procedure:

a Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 3-2, “Cleaners and disinfectants compatible with X-Porte system and transducers”** on page 31.

b Remove all gel, debris, and bodily fluids from the system.

c With a new wipe, clean the system, including the display, by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.

d Observe the minimum wet contact time recommended by the manufacturer. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.

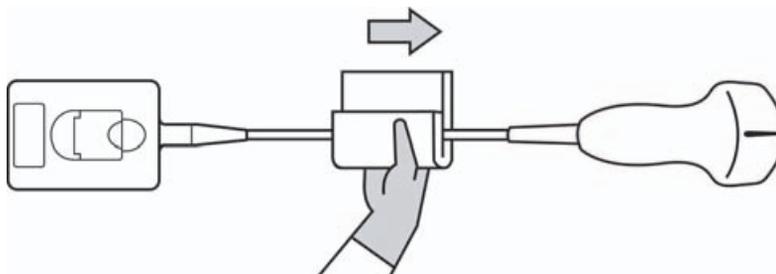
e Allow the ultrasound console to air dry in a clean, well-ventilated space.

6 Clean the **TRANSDUCER CABLE AND BODY** to remove any debris or bodily fluids. Use the following procedure:

a Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 3-2, “Cleaners and disinfectants compatible with X-Porte system and transducers”** on page 31.

b Remove all gel, debris, and bodily fluids from the transducer.

c With a new wipe, clean the cable and transducer, starting from the cable, wiping toward the scanhead. This method helps to avoid cross-contamination.



Caution

Do not allow moisture near the electronic components of the connector.

d Observe the minimum wet contact time recommended by the manufacturer. Monitor the transducer for wet appearance. Re-apply with a new wipe if no longer wet.

7 Verify that all gel, debris, and bodily fluids have been removed from the system and transducer. If necessary, repeat steps 5 & 6 with a new wipe.

WARNING

Failure to remove all gel, debris, and bodily fluid could leave contaminants on the probe.

8 Prepare the disinfectant for use.

- a** Choose a high-level disinfectant from **Table 3-4, “High-level disinfectants compatible with X-Porte transducers”** on page 40.
- b** Check the expiration date on the bottle to ensure the disinfectant has not expired.
- c** Mix or check that the disinfection chemicals have the concentration recommended by the manufacturer (for example, a chemical strip test).
- d** Check that the temperature of the disinfectant is within the manufacturer’s recommended limits.

9 Perform a high-level disinfection of the transducer. Use the following procedure:

- a** Immerse the transducer in a high-level disinfectant solution. See the chemical manufacturer’s recommendations for soak time.

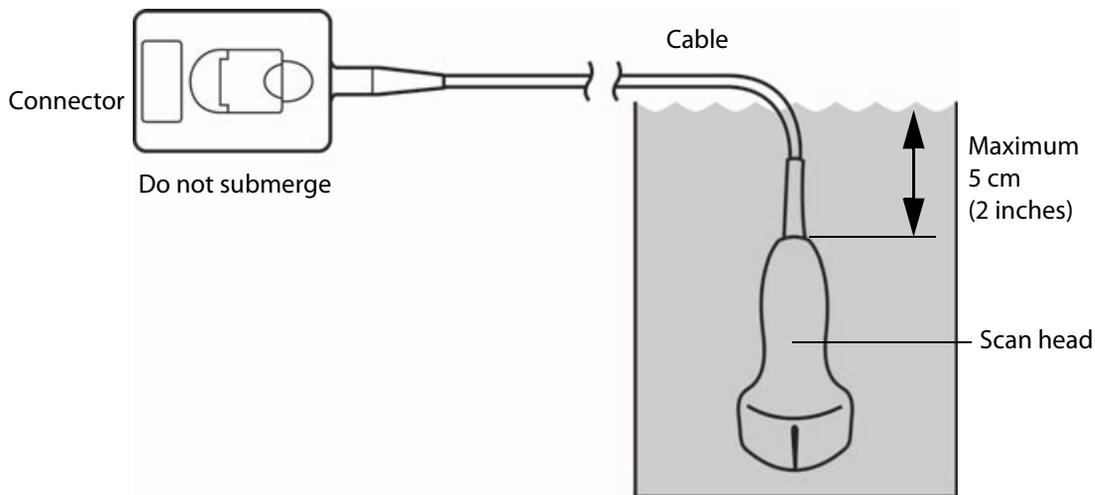
WARNING

High-level disinfectants can cause harm to the patient if not completely removed from the transducer. Follow the manufacturer’s rinse instructions to remove chemical residue.

Cautions

- ▶ Do not soak the transducer longer than recommended by the chemical manufacturer.
- ▶ Do not immerse the transducer connector in any disinfectant solution.
- ▶ Use only FUJIFILM SonoSite recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage or discolor the transducer and void the warranty.

- b** Ensure that the connector and most of the cable remain out of the fluid. You may submerge 2 inches (5 cm) of the cable proximal to the transducer scanhead.



10 Rinse the transducer **3 separate times** using the following procedure:

- a** Rinse the transducer in clean, running water according to the disinfectant manufacturer's instructions (at least 1 minute).
- b** Ensure that the connector and at least 12-18 inches (31-46 cm) of the cable from the connector remain out of the fluid.
- c** Replace the rinse water before beginning the next rinse.

11 Dry the transducer with a sterile, lint-free cloth.

12 Dispose of the disinfectant according to the manufacturer's guidelines.

13 Examine the transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, discontinue use of the transducer, and contact FUJIFILM SonoSite or your local representative.

Option **B** Clean and disinfect system and transducer to a low level (non-critical uses)

Use the following procedure to clean and disinfect the ultrasound system and transducer **if it has not come into contact with blood, broken skin, mucosal membranes, or bodily fluids.**

WARNING

If the system or transducer has come into contact with any of the following, use the high-level cleaning and disinfection procedure. See Option A, “**Clean and disinfect system and transducer to a high level (semi-critical uses)**” on page 22:

- ▶ Blood
- ▶ Broken skin
- ▶ Mucosal membranes
- ▶ Bodily fluids

Follow the manufacturer's instructions when using cleaners and disinfectants. The materials listed in the table below are chemically compatible with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

WARNING

- ▶ To avoid electrical shock, before cleaning, disconnect the system from the power supply.
- ▶ Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as eyewear and gloves.

Caution

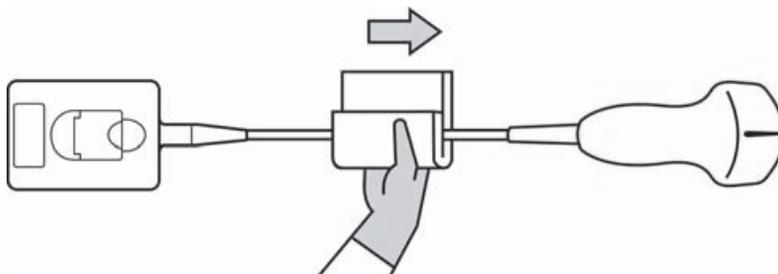
- ▶ Do not spray cleaners or disinfectants directly on the system surfaces or on system and transducer connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- ▶ Use only FUJIFILM SonoSite-recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage the System and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.
- ▶ Do not attempt to disinfect a transducer or transducer cable using a method or chemical that is not included here. Doing so can damage the transducer and void the warranty.

Cleaning and disinfecting the system and transducer (non-critical)

To clean and disinfect the system and transducer

- 1 **Turn off** the system by pressing the **Power button**.
- 2 **Unplug** the power cord from the outlet.

- 3 Remove the transducer sheath, if applicable.
- 4 **Disconnect** the transducer from the system. Temporarily place it where it will not cross-contaminate clean equipment or surfaces while you clean the ultrasound console.
- 5 **Clean** the exterior surfaces of the **ULTRASOUND SYSTEM** to remove any debris or bodily fluids. Use the following procedure:
 - a Use either a premoistened wipe or a soft cloth dampened with cleaner and disinfectant. Choose a cleaner from **Table 3-2, “Cleaners and disinfectants compatible with X-Porte system and transducers”** on page 31.
 - b Remove all gel, debris, and bodily fluids from the system.
 - c With a new wipe, clean the system, including the display, by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.
 - d Observe the minimum wet contact time recommended by the manufacturer. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.
- 6 **Clean** the **TRANSDUCER CABLE AND BODY** to remove any debris or bodily fluids. Use the following procedure:
 - a Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 3-2, “Cleaners and disinfectants compatible with X-Porte system and transducers”** on page 31.
 - b Remove all gel, debris, and bodily fluids from the transducer.
 - c With a new wipe, clean the cable and transducer, starting from the cable, wiping toward the scanhead. This method helps to avoid cross-contamination.



Caution | Do not allow moisture near the electronic components of the connector.

- d Observe the required wet contact time. Monitor the transducer for wet appearance. Re-apply with a new wipe if no longer wet.
- 7 **Verify** that all gel, debris, and bodily fluids have been removed from the system and transducer. If necessary, repeat steps 5 and 6 with a new wipe.

- 8 Allow** the ultrasound system, including the console and transducer, to air dry in a clean, well-ventilated space.
- 9 Examine** the system, transducer and cable for damage, such as cracks or splitting where fluid can enter.
If damage is evident, do not use. Instead, contact FUJIFILM SonoSite or your local representative.

Storing the transducer

To store the transducer

- 1** Make sure the transducer has been cleaned and disinfected as detailed in this chapter.
- 2** Store the transducer so that it hangs freely and vertically, and observe the following precautions:
 - ▶ Store the transducer away from any contaminated transducers.
 - ▶ Store the transducer in an environment that is safe and has good airflow. Do not store the transducer in closed containers or where condensation may occur.
 - ▶ Avoid direct sunlight and exposure to x-rays. Recommended storage temperature range is between 0° C (32° F) and +45° C (113° F).
 - ▶ If using a wall-mounted rack for storage, ensure that:
 - ▶ It is securely mounted.
 - ▶ The storage slots do not mar the transducer or cause damage to the cable.
 - ▶ The rack is sized and positioned to prevent the transducer from inadvertently falling.
 - ▶ Make sure the connector is supported and secure.

Transporting the transducer

When transporting the transducer, you must take precautions to protect the transducer from damage and avoid cross-contamination. Be sure to use a container approved by your organization.

To transport a soiled transducer for cleaning

A soiled transducer is one that has been contaminated and must be cleaned before using it in an exam.

- 1 Place the transducer in a clean, approved container.

WARNING

To prevent cross-contamination or unprotected exposure of personnel to biological material, containers used to transport contaminated transducers should carry an ISO biohazard label similar to the following:



Caution

Ensure the transducer is dry before placing it in a closed container. Condensation from a damp transducer can damage the connector.

- 2 Transport the transducer in the container to the point of processing. Do not open the container until the transducer is ready to be cleaned.

Caution

Do not leave the transducer in a sealed container for long periods of time.

To transport a clean transducer

A clean transducer is one that has completed the cleaning and disinfection process, has been stored properly, and is ready to be used in an examination.

- 1 Place the transducer in a clean, approved container. To identify the transducer as clean, containers used to transport clean transducers should carry a cleanliness verification sticker or certificate.
- 2 Transport the transducer in the container to the point of use. Do not open the container until the transducer is ready to be used.

To ship a transducer

WARNING

Whenever possible, avoid shipping a contaminated transducer. Before shipping, ensure the transducer has been cleaned and disinfected using the steps detailed in this chapter or according to special instructions received from FUJIFILM SonoSite. If you are returning the transducer to FUJIFILM SonoSite, document the disinfection on a "Declaration of Cleanliness," and attach it to the packing list.

- 1 Place the transducer in the shipping container and seal it. Do not allow any part of the transducer to protrude from the container.
- 2 Ship the transducer using the following precautions:
 - ▶ Clearly label the container as fragile.
 - ▶ Do not stack items on top of the shipping container.

- ▶ Do not exceed the shipping temperature range: -35°C (-31°F) to $+65^{\circ}\text{C}$ (149°F).
- ▶ Do not open the shipping container until it reaches its final destination.
- ▶ After arrival, the transducer must be cleaned and disinfected before it can be used in an exam.

Compatible cleaners and disinfectants (system and transducers)

Table 3-2: Cleaners and disinfectants compatible with X-Porte system and transducers

Disinfectants	X-Porte System	X-Porte Docking Stand	C11xp	C35xp	C60xp	D2xp	HFL38xp	HFL50xp	HSL25xp	ICTxp	L25xp	L38xp	P10xp	P21xp
Airkem A-33	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Alcohol-Ethanol					✓		✓	✓	✓	✓	✓	✓	✓	✓
Anios Wipes	✓	✓			✓		✓	✓		✓				
Aniosyme DD1- 5%	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
Anioxide 1000	✓	✓												
Asepti HB	✓	✓	✓		✓		✓	✓	✓	✓	✓	✓	✓	✓
Asepti Wipe II	✓	✓												
Baxedin Pre-Op			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Carpe Diem TB Wipes					✓		✓	✓		✓				
Caviwipes		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Cidalkan Lingettes	✓	✓												
Clinell Universal Sanitising Wipes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Clorox Germicidal Wipes		✓	✓		✓		✓	✓	✓	✓	✓	✓	✓	✓
Clorox Hydrogen Peroxide Wipes		✓												

Table 3-2: Cleaners and disinfectants compatible with X-Porte system and transducers

Disinfectants	X-Porte System	X-Porte Docking Stand	C11xp	C35xp	C60xp	D2xp	HFL38xp	HFL50xp	HSL25xp	ICTxp	L25xp	L38xp	P10xp	P21xp
Control III	✓	✓												
Coverage Germicidal Surface Wipes		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Coverage Plus Germicidal Surface Wipes				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Coverage Spray									✓		✓	✓	✓	✓
Coverage Spray TB		✓			✓		✓	✓	✓	✓		✓	✓	✓
Dispatch Wipes						✓								
Dynacide PA	✓	✓	✓	✓		✓			✓		✓	✓	✓	✓
Echo Clean lingettes					✓		✓	✓		✓				
End Bac II					✓		✓	✓		✓				
Endosporine	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Envirocide		✓							✓		✓	✓	✓	✓
Gluco Chlor Wipes			✓		✓		✓	✓	✓	✓	✓	✓	✓	✓
Hydrogen Peroxide 3%	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Incidin Plus 1%	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Incidin Plus 3%	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Table 3-2: Cleaners and disinfectants compatible with X-Porte system and transducers

Disinfectants	X-Porte System	X-Porte Docking Stand	C11xp	C35xp	C60xp	D2xp	HFL38xp	HFL50xp	HSL25xp	ICTxp	L25xp	L38xp	P10xp	P21xp
Madacide-1				✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
Medzyme	✓	✓		✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
MetriSponge			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
MetriZyme	✓	✓												
Mikrobac Forte 2%	✓	✓		✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
Mikrobac Tissues			✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
Mikrozid Sensitive Wipes									✓			✓	✓	✓
Oxivir TB Wipes					✓		✓	✓		✓				
Percept RTU Wipes			✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
PI-Spray					✓		✓	✓	✓	✓	✓	✓	✓	✓
PI-Spray II		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Protex Spray	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
Protex Wipes	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
Rely+On Perasafe	✓	✓		✓										
Reynard Surface Disinfection Wipes									✓			✓	✓	✓
Reynard Neutral Detergent Wipes									✓			✓	✓	✓

Table 3-2: Cleaners and disinfectants compatible with X-Porte system and transducers

Disinfectants	X-Porte System	X-Porte Docking Stand	C11xp	C35xp	C60xp	D2xp	HFL38xp	HFL50xp	HSL25xp	ICTxp	L25xp	L38xp	P10xp	P21xp
Sani-Cloth AF	✓	✓			✓		✓	✓		✓				
Sani-Cloth AF3	✓	✓	✓		✓		✓	✓	✓	✓	✓	✓	✓	✓
Sani-Cloth Bleach Wipes		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sani-Cloth HB	✓	✓		✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
Sani-Cloth Plus		✓			✓		✓	✓		✓	✓	✓	✓	✓
Simple Chlor	✓													
SONO Ultrasound Wipes									✓			✓	✓	✓
Staphene					✓		✓	✓		✓				
Steranios 2%	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Steranios 20%	✓	✓												
Trigene Advance Wipes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tristel Solo		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tuffie 5 Wipes									✓			✓	✓	✓
Virex II 256		✓	✓		✓		✓	✓	✓	✓	✓	✓	✓	✓
Virex TB		✓			✓		✓	✓	✓	✓	✓	✓	✓	✓
Virox 5 RTU Wipes	✓	✓	✓	✓		✓			✓		✓	✓	✓	✓

Table 3-2: Cleaners and disinfectants compatible with X-Porte system and transducers

Disinfectants	X-Porte System	X-Porte Docking Stand	C11xp	C35xp	C60xp	D2xp	HFL38xp	HFL50xp	HSL25xp	ICTxp	L25xp	L38xp	P10xp	P21xp
Wet Task Wipes	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Wex-Cide	✓	✓												
Wipes Plus Disinfecting Wipes			✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Wood Wyant Ultra Wipes	✓	✓												

Compatible cleaners and disinfectants (system accessories)

Table 3-3: Cleaners and disinfectants compatible with X-Porte system accessories

Disinfectants	X-Porte TTC	PowerPark Docking Station	ACDC Power Supply	Digital Video Cable	ECG Cable	Footswitch
Accel TB Wipes		✓				
Airkem A-33	✓	✓	✓	✓		
Alcohol-Ethanol	✓					
Alcohol - Isopropyl	✓				✓	✓
Anios Wipes	✓	✓	✓	✓		
Aniosyme DD1- 5%		✓	✓	✓		
Anioxide 1000		✓	✓	✓		
Asepti HB	✓	✓	✓	✓	✓	
Asepti Steryl			✓	✓		
Asepti Wipe II	✓	✓	✓	✓		
Baxedin Pre-Op	✓	✓		✓		
Carpe Diem TB Wipes	✓			✓		
Caviwipes	✓	✓	✓	✓	✓	
Cidalkan	✓		✓	✓		

Table 3-3: Cleaners and disinfectants compatible with X-Porte system accessories

Disinfectants	X-Porte TTC	PowerPark Docking Station	ACDC Power Supply	Digital Video Cable	ECG Cable	Footswitch
Cidalkan Lingettes	✓		✓	✓		
Clinell Universal Sanitising Wipes	✓	✓	✓	✓		
Clorox Germicidal Wipes	✓		✓	✓		
Clorox Hydrogen Peroxide Wipes	✓	✓	✓	✓		
Control III	✓	✓	✓	✓		
Coverage Germicidal Surface Wipes	✓					
Coverage Plus Germicidal Surface Wipes	✓	✓	✓	✓		
Coverage Spray	✓		✓	✓		
Coverage Spray TB				✓		
DisCide Ultra Disinfecting Towlettes	✓		✓	✓		
Dynacide PA	✓	✓	✓	✓		
Echo Clean lingettes	✓	✓	✓	✓	✓	
End Bac II	✓		✓	✓		
Endosporeine		✓	✓	✓		

Table 3-3: Cleaners and disinfectants compatible with X-Porte system accessories

Disinfectants	X-Porte TTC	PowerPark Docking Station	ACDC Power Supply	Digital Video Cable	ECG Cable	Footswitch
Envirocide	✓	✓	✓	✓		
Gluco Chlor Wipes	✓		✓	✓		
Hydrogen Peroxide 3%	✓	✓	✓	✓	✓	
Incidin Plus 1%	✓	✓	✓	✓		
Incidin Plus 3%	✓	✓	✓	✓		
Medzyme	✓	✓	✓	✓		
Mikrobac Forte 2%	✓	✓				
Mikrobac Tissues	✓	✓	✓	✓		
Mikrozid Tucher		✓		✓		
Oxivir TB Wipes				✓		
Percept RTU Wipes		✓	✓	✓	✓	
PI-Spray			✓	✓		
PI-Spray II	✓	✓	✓			
Protex Spray		✓		✓		
Protex Wipes		✓		✓		

Table 3-3: Cleaners and disinfectants compatible with X-Porte system accessories

Disinfectants	X-Porte TTC	PowerPark Docking Station	ACDC Power Supply	Digital Video Cable	ECG Cable	Footswitch
Rely+On Perasafe	✓	✓	✓	✓		
Sani-Cloth AF	✓	✓		✓		
Sani-Cloth AF3	✓	✓		✓		
Sani-Cloth Bleach Wipes	✓		✓	✓		
Sani-Cloth HB	✓	✓	✓	✓	✓	
Sani-Cloth Plus	✓	✓	✓	✓	✓	
Simple Chlor	✓				✓	
Staphene	✓		✓			
Steranios 2%		✓	✓	✓	✓	
Steranios 20%		✓	✓	✓		
Super Sani-Cloth	✓		✓		✓	
Trigene Advance Wipes	✓		✓			
Tristel Solo	✓	✓	✓	✓		
Tristel Wipes	✓		✓			
Virex II 256	✓				✓	

Table 3-3: Cleaners and disinfectants compatible with X-Porte system accessories

Disinfectants	X-Porte TTC	PowerPark Docking Station	ACDC Power Supply	Digital Video Cable	ECG Cable	Footswitch
Virex TB	✓		✓			
Virox 5 RTU Wipes	✓	✓		✓	✓	
Wet Task Wipes	✓		✓			
Wex-Cide	✓	✓	✓			
Wipes Plus Disinfecting Wipes	✓	✓	✓	✓		
Wood Wyant Ultra Wipes	✓			✓		

Compatible high-level disinfectants (transducers)

Table 3-4: High-level disinfectants compatible with X-Porte transducers

High-level Disinfectants	C11xp	C60xp	HFL38xp	HFL50xp	HSL25xp	ICTxp	L25xp	L38xp	P10xp	P21xp
Cidex	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Cidex OPA	✓	✓	✓	✓	✓		✓	✓	✓	✓
Cidex Plus	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Metricide OPA Plus	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Nanosonics Trophon EPR	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

CHAPTER 4

Cleaning and disinfecting the Edge ultrasound system

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This chapter contains instructions for cleaning and disinfecting the Edge ultrasound system, transducers, and accessories. Use the FUJIFILM SonoSite recommendations when cleaning or disinfecting your ultrasound system, transducer, and accessories. Use the cleaning recommendations in the component manufacturer’s instructions when cleaning or disinfecting your components.

The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.

See www.sonosite.com/transducers for images of transducers.

Also included is a listing of disinfectants that SonoSite has tested and deemed compatible with the Edge system, transducers, and accessories. This information is presented in the following tables.

- ▶ **Table 4-2, “Cleaners and disinfectants compatible with Edge system and transducers”** on page 52 shows compatibility between disinfectants, the system, and transducers.
- ▶ **Table 4-3, “Cleaners and disinfectants compatible with Edge system accessories”** on page 56 shows compatibility between disinfectants and accessories.

- ▶ **Table 4-4, “High-level disinfectants compatible with Edge transducers”** on page 61 shows compatibility between high-level disinfectants and transducers.

Note

- ▶ The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.
- ▶ For cleaning the TEEEx transducer, refer to the cleaning and disinfection instructions in the *TEEEx User Guide*.

Before getting started

- ▶ Follow the disinfectant manufacturer’s recommendations regarding appropriate personal protective equipment (PPE), such as protective eyewear and gloves.
- ▶ Inspect the system and transducer to determine that they are free of any unacceptable deterioration, such as corrosion, discoloration, pitting, or cracked seals. If damage is evident, discontinue use, and contact FUJIFILM SonoSite or your local representative.
- ▶ Confirm that cleaning and disinfecting materials are appropriate for your facility’s use. FUJIFILM SonoSite tests cleaners and disinfectants for use with the FUJIFILM SonoSite systems and transducers.
- ▶ Disinfectants and cleaning methods listed in this chapter are recommended by FUJIFILM SonoSite for material compatibility with the products.
- ▶ Ensure that the disinfectant type and the solution strength and duration are appropriate for the equipment and application.
- ▶ Follow manufacturer recommendations and local regulations, when preparing, using and disposing of chemicals.

WARNING

- ▶ Ensure that cleaning and disinfecting solutions and wipes are not expired.
- ▶ Some cleaners and disinfectants can cause an allergic reaction to some individuals.

Caution

- ▶ Do not allow cleaning solution or disinfectant into the system connectors, or transducer connector.
- ▶ Do not use strong solvents such as thinner or benzene, or abrasive cleansers, since these will damage the exterior surfaces. Use only FUJIFILM SonoSite recommended cleaners or disinfectants.

Cleaning and disinfecting

Determining the required cleaning and disinfecting level

WARNING

The cleaning instructions contained in this chapter are based on requirements mandated by the American Food and Drug Administration (FDA). Failure to follow these instructions may result in cross contamination and patient infection.

The level of cleaning and disinfecting required for the system is dictated by the type of tissue it contacts during use. Use **Table 4-1, “Choosing a cleaning and disinfecting method”** to determine the level of cleaning and disinfecting required.

Table 4-1: Choosing a cleaning and disinfecting method

Did any part of the system or transducer come in contact with broken skin, blood, mucosal membranes, or bodily fluids?	
YES	Came in contact with broken skin, blood, mucosal membranes, or bodily fluids. 
OR	
NO	Did not come in contact with broken skin, blood, or bodily fluids. 
Option A Go to “Clean and disinfect system and transducer to a high level (semi-critical uses)” on page 44.	
Option B Go to “Clean and disinfect system and transducer to a low level (non-critical uses)” on page 48.	

Spaulding classifications

Spaulding classifications (non-critical, semi-critical) determine the approach for cleaning and disinfecting medical equipment based on the device, the way it has been used, and the risk of infection. The system and transducers are designed for use within the Spaulding classifications of non-critical and semi-critical uses.

Option **A** Clean and disinfect system and transducer to a high level (semi-critical uses)

Use this procedure to clean and high-level disinfect the ultrasound system and transducer **whenever it has come into contact with blood, broken skin, mucosal membranes, or bodily fluids.**

Follow the manufacturer's instructions when using cleaners and disinfectants. The cleaners and disinfectants listed in the procedure are chemically compatible with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

WARNING

- ▶ To avoid electrical shock, before cleaning, disconnect the system from the power supply.
- ▶ Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as eyewear and gloves.

Caution

- ▶ Do not skip any steps or abbreviate the cleaning and disinfecting process in any way.
- ▶ Do not spray cleaners or disinfectants directly on the system surfaces or on system and transducer connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- ▶ Do not attempt to disinfect a transducer or transducer cable using a method or chemical that is not included here. This can damage the transducer and void the warranty.
- ▶ Use only FUJIFILM SonoSite recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage the System and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.

Note

- ▶ You must clean and disinfect both the ultrasound system and the transducer after each use, but only the transducer can be disinfected to a high level.
- ▶ For the purposes of cleaning and disinfecting, the battery should be considered as part of the ultrasound system, and not an accessory.

Cleaning and disinfecting the system and transducer (semi-critical)

To clean and disinfect the system and transducer

- 1 Turn off** the system by pressing the **Power button**.
- 2 Unplug** the power cord from the outlet.
- 3** Remove the disposable transducer sheath, if applicable.

4 Disconnect the transducer from the system. Temporarily place it where it will not cross-contaminate clean equipment or surfaces while you clean the ultrasound console.

5 Clean the exterior surfaces of the **ULTRASOUND SYSTEM** to remove any debris or bodily fluids. Use the following procedure:

a Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 4-2, "Cleaners and disinfectants compatible with Edge system and transducers"** on page 52.

b Remove all gel, debris, and bodily fluids from the system.

c With a new wipe, clean the system, including the display, by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.

d Observe the minimum wet contact time recommended by the manufacturer. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.

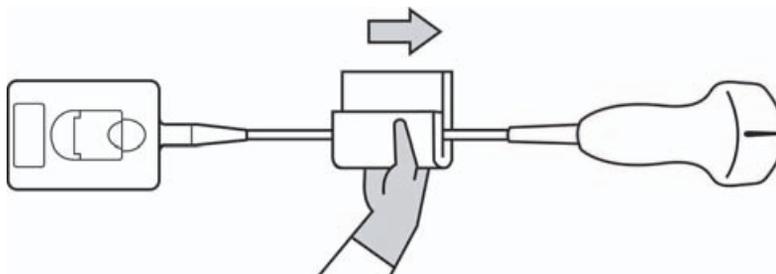
e Allow the ultrasound console to air dry in a clean, well-ventilated space.

6 Clean the **TRANSDUCER CABLE AND BODY** to remove any debris or bodily fluids. Use the following procedure:

a Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 4-2, "Cleaners and disinfectants compatible with Edge system and transducers"** on page 52.

b Remove all gel, debris, and bodily fluids from the transducer.

c With a new wipe, clean the cable and transducer, starting from the cable, wiping toward the scanhead. This method helps to avoid cross-contamination.



Caution

Do not allow moisture near the electronic components of the connector.

d Observe the minimum wet contact time recommended by the manufacturer. Monitor the transducer for wet appearance. Re-apply with a new wipe if no longer wet.

7 Verify that all gel, debris, and bodily fluids have been removed from the system and transducer. If necessary, repeat steps 5 & 6 with a new wipe.

WARNING

Failure to remove all gel, debris, and bodily fluid could leave contaminants on the probe.

8 Examine the system, transducer, and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, discontinue use, and contact FUJIFILM SonoSite or your local representative.

9 Prepare the disinfectant for use.

- a** Choose a high-level disinfectant from **Table 4-4, “High-level disinfectants compatible with Edge transducers”** on page 61.
- b** Check the expiration date on the bottle to ensure the disinfectant has not expired.
- c** Mix or check that the disinfection chemicals have the concentration recommended by the manufacturer (for example, a chemical strip test).
- d** Check that the temperature of the disinfectant is within the manufacturer’s recommended limits.

10 Perform a high-level disinfection of the transducer. Use the following procedure:

- a** Immerse the transducer in a high-level disinfectant solution. See the chemical manufacturer’s recommendations for soak time.

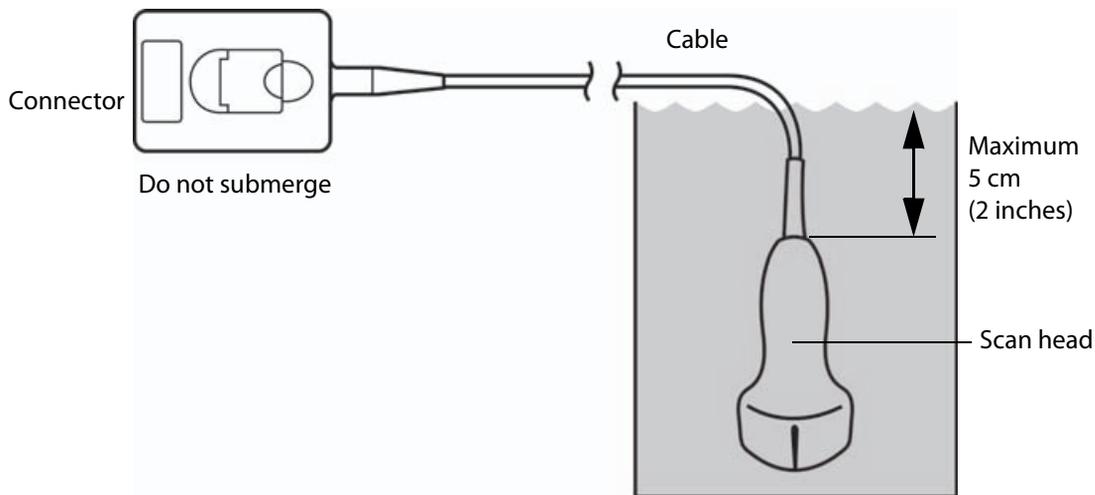
WARNING

High-level disinfectants can cause harm to the patient if not completely removed from the transducer. Follow the manufacturer’s rinse instructions to remove chemical residue.

Cautions

- ▶ Do not soak the transducer longer than recommended by the chemical manufacturer.
- ▶ Do not immerse the transducer connector in any disinfectant solution.
- ▶ Use only FUJIFILM SonoSite recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage or discolor the transducer and void the warranty.

- b** Ensure that the connector and most of the cable remain out of the fluid. You may submerge 2 inches (5 cm) of the cable proximal to the transducer scanhead.



11 Rinse the transducer **3 separate times** using the following procedure:

- a** Rinse the transducer in clean, running water according to the disinfectant manufacturer's instructions (at least 1 minute).
- b** Ensure that the connector and at least 12-18 inches (31-46 cm) of the cable from the connector remain dry.
- c** Repeat this step until the transducer has been rinsed 3 separate times.

12 Dry the transducer with a sterile, lint-free cloth.

13 Dispose of the disinfectant according to the manufacturer's guidelines.

14 Examine the transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, discontinue use of the transducer, and contact FUJIFILM SonoSite or your local representative.

Option **B** Clean and disinfect system and transducer to a low level (non-critical uses)

Use the following procedure to clean and disinfect the ultrasound system and transducer **if it has not come into contact with blood, broken skin, mucosal membranes, or bodily fluids.**

WARNING

If the system or transducer has come into contact with any of the following, use the high-level cleaning and disinfection procedure. See Option A, “**Clean and disinfect system and transducer to a high level (semi-critical uses)**” on page 44:

- ▶ Blood
- ▶ Broken skin
- ▶ Mucosal membranes
- ▶ Bodily fluids

Follow the manufacturer's instructions when using cleaners and disinfectants. The materials listed in the table below are chemically compatible with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

WARNING

- ▶ To avoid electrical shock, before cleaning, disconnect the system from the power supply.
- ▶ Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as eyewear and gloves.

Caution

- ▶ Do not spray cleaners or disinfectants directly on the system surfaces or on system and transducer connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- ▶ Use only FUJIFILM SonoSite-recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage the System and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.
- ▶ Do not attempt to disinfect a transducer or transducer cable using a method or chemical that is not included here. Doing so can damage the transducer and void the warranty.

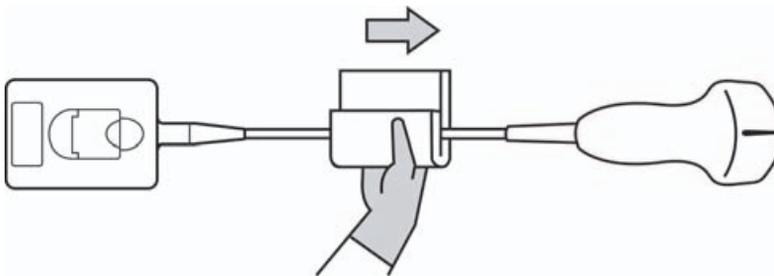
Note

For the purposes of cleaning and disinfecting, the battery should be considered as part of the ultrasound system, and not an accessory.

Cleaning and disinfecting the system and transducer (non-critical)

To clean and disinfect the system and transducer

- 1 **Turn off** the system by pressing the **Power button**.
- 2 **Unplug** the power cord from the outlet.
- 3 Remove the transducer sheath, if applicable.
- 4 **Disconnect** the transducer from the system. Temporarily place it where it will not cross-contaminate clean equipment or surfaces while you clean the ultrasound console.
- 5 **Clean** the exterior surfaces of the **ULTRASOUND SYSTEM** to remove any debris or bodily fluids. Use the following procedure:
 - a Use either a premoistened wipe or a soft cloth dampened with cleaner and disinfectant. Choose a cleaner from **Table 4-2, "Cleaners and disinfectants compatible with Edge system and transducers"** on page 52.
 - b Remove all gel, debris, and bodily fluids from the system.
 - c With a new wipe, clean the system, including the display, by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.
 - d Observe the minimum wet contact time recommended by the manufacturer. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.
- 6 **Clean** the **TRANSDUCER CABLE AND BODY** to remove any debris or bodily fluids. Use the following procedure:
 - a Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 4-2, "Cleaners and disinfectants compatible with Edge system and transducers"** on page 52.
 - b Remove all gel, debris, and bodily fluids from the transducer.
 - c With a new wipe, clean the cable and transducer, starting from the cable, wiping toward the scanhead. This method helps to avoid cross-contamination.



Caution | Do not allow moisture near the electronic components of the connector.

- d** Observe the required wet contact time. Monitor the transducer for wet appearance. Re-apply with a new wipe if no longer wet.
- 7 Verify** that all gel, debris, and bodily fluids have been removed from the system and transducer. If necessary, repeat steps 5 and 6 with a new wipe.
 - 8 Allow** the ultrasound system, including the console and transducer, to air dry in a clean, well-ventilated space.
 - 9 Examine** the system, transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, do not use. Instead, contact FUJIFILM SonoSite or your local representative.

Storing the transducer

To store the transducer

- 1** Make sure the transducer has been cleaned and disinfected as detailed in this chapter.
- 2** Store the transducer so that it hangs freely and vertically, and observe the following precautions:
 - ▶ Store the transducer away from any contaminated transducers.
 - ▶ Store the transducer in an environment that is safe and has good airflow. Do not store the transducer in closed containers or where condensation may occur.
 - ▶ Avoid direct sunlight and exposure to x-rays. Recommended storage temperature range is between 0° C (32° F) and +45° C (113° F).
 - ▶ If using a wall-mounted rack for storage, ensure that:
 - ▶ It is securely mounted.
 - ▶ The storage slots do not mar the transducer or cause damage to the cable.
 - ▶ The rack is sized and positioned to prevent the transducer from inadvertently falling.
 - ▶ Make sure the connector is supported and secure.

Transporting the transducer

When transporting the transducer, you must take precautions to protect the transducer from damage and avoid cross-contamination. Be sure to use a container approved by your organization.

To transport a soiled transducer for cleaning

A soiled transducer is one that has been contaminated and must be cleaned before using it in an exam.

- 1 Place the transducer in a clean, approved container.

WARNING

To prevent cross-contamination or unprotected exposure of personnel to biological material, containers used to transport contaminated transducers should carry an ISO biohazard label similar to the following:



Caution

Ensure the transducer is dry before placing it in a closed container. Condensation from a damp transducer can damage the connector.

- 2 Transport the transducer in the container to the point of processing. Do not open the container until the transducer is ready to be cleaned.

Caution

Do not leave the transducer in a sealed container for long periods of time.

To transport a clean transducer

A clean transducer is one that has completed the cleaning and disinfection process, has been stored properly, and is ready to be used in an examination.

- 1 Place the transducer in a clean, approved container. To identify the transducer as clean, containers used to transport clean transducers should carry a cleanliness verification sticker or certificate.
- 2 Transport the transducer in the container to the point of use. Do not open the container until the transducer is ready to be used.

To ship a transducer

WARNING

Whenever possible, avoid shipping a contaminated transducer. Before shipping, ensure the transducer has been cleaned and disinfected using the steps detailed in this chapter or according to special instructions received from FUJIFILM SonoSite. If you are returning the transducer to FUJIFILM SonoSite, document the disinfection on a "Declaration of Cleanliness," and attach it to the packing list.

- 1 Place the transducer in the shipping container and seal it. Do not allow any part of the transducer to protrude from the container.
- 2 Ship the transducer using the following precautions:
 - ▶ Clearly label the container as fragile.
 - ▶ Do not stack items on top of the shipping container.

- ▶ Do not exceed the shipping temperature range: -35° C (-31° F) to +65° C (149° F).
- ▶ Do not open the shipping container until it reaches its final destination.
- ▶ After arrival, the transducer must be cleaned and disinfected before it can be used in an exam.

Compatible cleaners and disinfectants (system and transducers)

Table 4-2: Cleaners and disinfectants compatible with Edge system and transducers

Disinfectants	Edge System	Edge Stand	C11x	C60x	C60xi	C8x	HFL38x	HFL50x	ICTx	L25x	L38x	L38xi	L52x	P10x	P11x	P21x	SLAX
Accel Intervention Wipes	✓												✓				
Accel Prevention Wipes	✓																
Accel TB Wipes	✓	✓															
Airkem A-33	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Alcohol-Ethanol	✓	✓			✓			✓		✓			✓				
Anios Wipes	✓	✓						✓					✓				
Aniosyme DD1-5%	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Anioxide 1000	✓	✓															
Asepti HB	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Asepti Wipe II	✓	✓															
Baxedin Pre-Op	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Carpe Diem TB Wipes								✓									
Caviwipes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Table 4-2: Cleaners and disinfectants compatible with Edge system and transducers

Disinfectants	Edge System	Edge Stand	C11x	C60x	C60xi	C8x	HFL38x	HFL50x	ICTx	L25x	L38x	L38xi	L52x	P10x	P11x	P21x	SLAX
Cidalkan	✓														✓		
Cidalkan Lingettes	✓	✓													✓		
Clinell Universal Sanitising Wipes	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓		✓	✓	✓	✓
Clorox Germicidal Wipes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓
Clorox Hydrogen Peroxide Wipes	✓	✓															
Control III	✓	✓													✓		
Coverage Germicidal Surface Wipes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Coverage Plus Germicidal Surface Wipes	✓			✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Coverage Spray	✓	✓			✓												
Coverage Spray TB				✓	✓	✓	✓	✓	✓		✓	✓		✓	✓	✓	✓
DisCide Ultra Disinfecting Towlettes	✓														✓		
Dynacide PA	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓
Echo Clean lingettes	✓						✓						✓				
End Bac II	✓							✓					✓				
Endosporine	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓

Table 4-2: Cleaners and disinfectants compatible with Edge system and transducers

Disinfectants	Edge System	Edge Stand	C11x	C60x	C60xi	C8x	HFL38x	HFL50x	ICTx	L25x	L38x	L38xi	L52x	P10x	P11x	P21x	SLAX
Envirocide	✓	✓															
Gluco Chlor Wipes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Hydrogen Peroxide 3%	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Incidin Plus 1%	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Incidin Plus 3%	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Madacide-1	✓			✓	✓	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓
Medzyme	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
MetriSponge			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Metrizyme															✓		
Mikrobac Forte 2%	✓	✓		✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Mikrobac Tissues	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mikrozid Sensitive Wipes	✓																
Oxivir TB Wipes								✓									
Percept RTU Wipes		✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
PI-Spray		✓		✓	✓		✓	✓	✓		✓	✓	✓	✓		✓	✓
PI-Spray II	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Protex Spray	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Protex Wipes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Table 4-2: Cleaners and disinfectants compatible with Edge system and transducers

Disinfectants	Edge System	Edge Stand	C11x	C60x	C60xi	C8x	HFL38x	HFL50x	ICTx	L25x	L38x	L38xi	L52x	P10x	P11x	P21x	SLAx
Rely+On Perasafe		✓											✓		✓		
Reynard Neutral Detergent Wipes	✓				✓												
Reynard Surface Disinfection Wipes	✓				✓												
Sani-Cloth AF	✓	✓						✓					✓				
Sani-Cloth AF3		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓
Sani-Cloth Bleach Wipes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sani-Cloth HB	✓			✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Sani-Cloth Plus	✓	✓						✓					✓				
Simple Chlor															✓		
SONO Ultrasound Wipes	✓				✓												
Staphene								✓					✓				
Steranios 2%	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Steranios 20%	✓	✓															
Super Sanicloth	✓														✓		
Trigene Advance Wipes	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tristel Solo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tristel Wipes															✓		

Table 4-2: Cleaners and disinfectants compatible with Edge system and transducers

Disinfectants	Edge System	Edge Stand	C11x	C60x	C60xi	C8x	HFL38x	HFL50x	ICTx	L25x	L38x	L38xi	L52x	P10x	P11x	P21x	SLAX
Tuffie 5 Wipes	✓				✓												
Virex II 256	✓	✓	✓		✓			✓		✓			✓		✓		
Virex TB	✓	✓			✓			✓					✓				
Virox 5 RTU Wipes	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓
Wet Task Wipes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Wex-Cide	✓	✓													✓		
Wipes Plus Disinfecting Wipes	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Wood Wyant Ultra Wipes	✓	✓													✓		

Compatible cleaners and disinfectants (system accessories)

Table 4-3: Cleaners and disinfectants compatible with Edge system accessories

Disinfectants	Edge TTC	Footswitch	Power Supply	PowerPack	PowerPark	Mini-Dock	ECG Cable
Accel Intervention Wipes	✓						
Accel Prevention Wipes					✓		
Accel TB Wipes	✓						
Airkem A-33	✓		✓	✓	✓	✓	

Table 4-3: Cleaners and disinfectants compatible with Edge system accessories

Disinfectants	Edge TTC	Footswitch	Power Supply	PowerPack	PowerPark	Mini-Dock	ECG Cable
Alcohol-Ethanol	✓						
Alcohol - Isopropyl	✓	✓					✓
Anios Wipes	✓		✓	✓	✓	✓	
Aniosyme DD1- 5%	✓		✓	✓	✓	✓	
Anioxide 1000	✓		✓	✓	✓	✓	
Asepti HB	✓		✓	✓	✓	✓	✓
Asepti Steryl	✓		✓	✓		✓	
Asepti Wipe II	✓			✓	✓	✓	
Baxedin Pre-Op	✓		✓	✓	✓	✓	
Carpe Diem TB Wipes				✓			
Caviwipes	✓		✓	✓	✓	✓	✓
Cidalkan	✓		✓	✓		✓	
Cidalkan Lingettes	✓		✓	✓		✓	
Clinell Universal Sanitising Wipes	✓		✓	✓	✓	✓	
Clorox Germicidal Wipes			✓	✓		✓	
Clorox Hydrogen Peroxide Wipes	✓		✓	✓	✓	✓	

Table 4-3: Cleaners and disinfectants compatible with Edge system accessories

Disinfectants	Edge TTC	Footswitch	Power Supply	PowerPack	PowerPark	Mini-Dock	ECG Cable
Control III	✓		✓	✓	✓	✓	
Coverage Germicidal Surface Wipes	✓		✓				
Coverage Plus Germicidal Surface Wipes	✓		✓	✓	✓	✓	
Coverage Spray	✓			✓	✓	✓	
Coverage Spray TB	✓		✓	✓	✓	✓	
DisCide Ultra Disinfecting Towlettes	✓		✓	✓	✓	✓	
Dynacide PA	✓			✓	✓	✓	
Echo Clean lingettes	✓		✓	✓	✓	✓	
End Bac II	✓		✓	✓	✓	✓	
Endosporine	✓		✓	✓	✓	✓	
Envirocide	✓		✓	✓	✓	✓	
Glucoclor Wipes			✓	✓	✓	✓	
Hydrogen Peroxide 3%	✓		✓	✓	✓	✓	✓
Incidin Plus 1%	✓		✓	✓	✓	✓	
Incidin Plus 3%	✓		✓	✓	✓	✓	
Medzyme	✓		✓	✓	✓	✓	

Table 4-3: Cleaners and disinfectants compatible with Edge system accessories

Disinfectants	Edge TTC	Footswitch	Power Supply	PowerPack	PowerPark	Mini-Dock	ECG Cable
Mikrobac Forte 2%	✓				✓		
Mikrobac Tissues	✓		✓	✓	✓	✓	
Mikrozyd Tucher			✓	✓	✓		
Oxivir TB Wipes	✓			✓	✓	✓	
Percept RTU Wipes			✓	✓	✓	✓	
PI-Spray	✓		✓	✓		✓	
PI-Spray II	✓		✓	✓	✓	✓	
Protex Spray	✓			✓	✓		
Protex Wipes	✓			✓	✓		
Rely+On Perasafe	✓		✓	✓	✓	✓	
Sani-Cloth AF	✓			✓	✓		
Sani-Cloth AF3				✓	✓		
Sani-Cloth Bleach Wipes	✓		✓	✓	✓	✓	
Sani-Cloth HB	✓		✓	✓	✓	✓	✓
Sani-Cloth Plus	✓		✓	✓	✓	✓	✓
Simple Chlor	✓						
Staphene	✓		✓				

Table 4-3: Cleaners and disinfectants compatible with Edge system accessories

Disinfectants	Edge TTC	Footswitch	Power Supply	PowerPack	PowerPark	Mini-Dock	ECG Cable
Steranios 2%	✓		✓	✓	✓	✓	✓
Steranios 20%	✓		✓	✓	✓	✓	
Super Sani-Cloth	✓		✓			✓	✓
Trigene Advance Wipes	✓		✓			✓	
Tristel Solo	✓		✓	✓	✓	✓	
Tristel Wipes	✓		✓			✓	
Virex II 256	✓						✓
Virex TB			✓	✓	✓	✓	
Virox 5 RTU Wipes	✓						✓
Wet Task Wipes	✓		✓	✓	✓	✓	
Wex-Cide	✓			✓	✓	✓	
Wipes Plus Disinfecting Wipes			✓	✓	✓	✓	
Wood Wyant Ultra Wipes	✓					✓	

Compatible high-level disinfectants (transducers)

Table 4-4: High-level disinfectants compatible with Edge transducers

High-level Disinfectants	C11x	C60x	C60xi	C8x	HFL38x	HFL50x	ICTx	L25x	L38x	L38xi	L52x	P10x	P11x	P21x	SLAx
Cidex	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓		✓	
Cidex OPA	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		✓	
Metricide OPA Plus	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	
Nanosonics Trophon EPR	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓		✓	✓
Revital-Ox Resert HLD													✓		✓
Cidex Plus	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

CHAPTER 5

Cleaning and disinfecting the SonoSite Edge II ultrasound system

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This chapter contains instructions for cleaning and disinfecting the SonoSite Edge II ultrasound system, transducers, and accessories. Use the FUJIFILM SonoSite recommendations when cleaning or disinfecting your ultrasound system, transducer, and accessories. Use the cleaning recommendations in the component manufacturer's instructions when cleaning or disinfecting your components.

The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.

See www.sonosite.com/transducers for images of transducers.

Also included is a listing of disinfectants that FUJIFILM SonoSite has tested and deemed compatible with the SonoSite Edge II system, transducers, and accessories. This information is presented in the following tables.

- ▶ **Table 5-2, “Cleaners and disinfectants compatible with SonoSite Edge II system and transducers”** on page 74 shows compatibility between disinfectants, the system, and transducers.
- ▶ **Table 5-3, “Cleaners and disinfectants compatible with SonoSite Edge II system accessories”** on page 79 shows compatibility between disinfectants and accessories.

- ▶ **Table 5-4, “High-level disinfectants compatible with SonoSite Edge II transducers”** on page 82 shows compatibility between high-level disinfectants and transducers.

Note

- ▶ The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.
- ▶ For cleaning the TEExi transducer, refer to the cleaning and disinfection instructions in the *TEExi User Guide*.

Before getting started

- ▶ Follow the disinfectant manufacturer’s recommendations regarding appropriate personal protective equipment (PPE), such as protective eyewear and gloves.
- ▶ Inspect the system and transducer to determine that they are free of any unacceptable deterioration, such as corrosion, discoloration, pitting, or cracked seals. If damage is evident, discontinue use, and contact FUJIFILM SonoSite or your local representative.
- ▶ Confirm that cleaning and disinfecting materials are appropriate for your facility’s use. FUJIFILM SonoSite tests cleaners and disinfectants for use with the FUJIFILM SonoSite systems and transducers.
- ▶ Disinfectants and cleaning methods listed in this chapter are recommended by FUJIFILM SonoSite for material compatibility with the products.
- ▶ Ensure that the disinfectant type and the solution strength and duration are appropriate for the equipment and application.
- ▶ Follow manufacturer recommendations and local regulations, when preparing, using and disposing of chemicals.

WARNINGS

- ▶ Ensure that cleaning and disinfecting solutions and wipes are not expired.
- ▶ Some cleaners and disinfectants can cause an allergic reaction to some individuals.

Caution

- ▶ Do not allow cleaning solution or disinfectant into the system connectors, or transducer connector.
- ▶ Do not use strong solvents such as thinner or benzene, or abrasive cleansers, since these will damage the exterior surfaces. Use only FUJIFILM SonoSite recommended cleaners or disinfectants.

Cleaning and disinfecting

Determining the required cleaning and disinfecting level

WARNING

The cleaning instructions contained in this chapter are based on requirements mandated by the American Food and Drug Administration (FDA). Failure to follow these instructions may result in cross contamination and patient infection.

The level of cleaning and disinfecting required for the system is dictated by the type of tissue it contacts during use. Use **Table 5-1, “Choosing a cleaning and disinfecting method”** to determine the level of cleaning and disinfecting required.

Table 5-1: Choosing a cleaning and disinfecting method

Did any part of the system or transducer come in contact with broken skin, blood, mucosal membranes, or bodily fluids?	
YES	Came in contact with broken skin, blood, mucosal membranes, or bodily fluids. 
OR	
NO	Did not come in contact with broken skin, blood, or bodily fluids. 
Option A Go to “Clean and disinfect system and transducer to a high level (semi-critical uses)” on page 66.	
Option B Go to “Clean and disinfect system and transducer to a low level (non-critical uses)” on page 70.	

Spaulding classifications

Spaulding classifications (non-critical, semi-critical) determine the approach for cleaning and disinfecting medical equipment based on the device, the way it has been used, and the risk of infection. The system and transducers are designed for use within the Spaulding classifications of non-critical and semi-critical uses.

Option **A** Clean and disinfect system and transducer to a high level (semi-critical uses)

Use this procedure to clean and high-level disinfect the ultrasound system and transducer **whenever it has come into contact with blood, broken skin, mucosal membranes, or bodily fluids.**

Follow the manufacturer's instructions when using cleaners and disinfectants. The cleaners and disinfectants listed in the procedure are chemically compatible with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

WARNING

- ▶ To avoid electrical shock, before cleaning, disconnect the system from the power supply.
- ▶ Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as eyewear and gloves.

Caution

- ▶ Do not skip any steps or abbreviate the cleaning and disinfecting process in any way.
- ▶ Do not spray cleaners or disinfectants directly on the system surfaces or on system and transducer connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- ▶ Do not attempt to disinfect a transducer or transducer cable using a method or chemical that is not included here. This can damage the transducer and void the warranty.
- ▶ Use only FUJIFILM SonoSite recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage the System and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.

Note

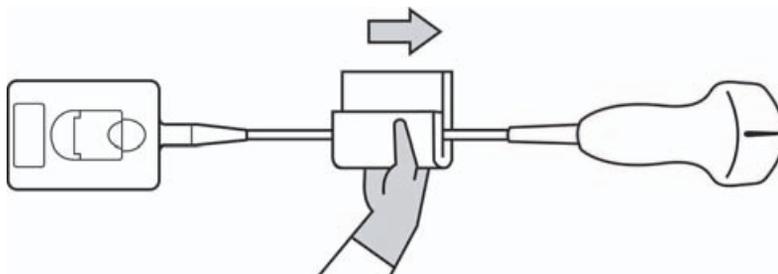
- ▶ You must clean and disinfect both the ultrasound system and the transducer after each use, but only the transducer can be disinfecting to a high level.
- ▶ For the purposes of cleaning and disinfecting, the battery should be considered as part of the ultrasound system, and not an accessory.

Cleaning and disinfecting the system and transducer (semi-critical)

To clean and disinfect the system and transducer

- 1 Turn off** the system by pressing the **Power button**.
- 2 Unplug** the power cord from the outlet.
- 3** Remove the disposable transducer sheath, if applicable.

- 4 Disconnect** the transducer from the system. Temporarily place it where it will not cross-contaminate clean equipment or surfaces while you clean the ultrasound console.
- 5 Clean** the exterior surfaces of the **ULTRASOUND SYSTEM** to remove any debris or bodily fluids. Use the following procedure:
- a** Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 5-2, “Cleaners and disinfectants compatible with SonoSite Edge II system and transducers”** on page 74.
 - b** Remove all gel, debris, and bodily fluids from the system.
 - c** With a new wipe, clean the system, including the display, by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.
 - d** Observe the minimum wet contact time recommended by the manufacturer. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.
 - e** Allow the ultrasound console to air dry in a clean, well-ventilated space.
- 6 Clean** the **TRANSDUCER CABLE AND BODY** to remove any debris or bodily fluids. Use the following procedure:
- a** Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 5-2, “Cleaners and disinfectants compatible with SonoSite Edge II system and transducers”** on page 74.
 - b** Remove all gel, debris, and bodily fluids from the transducer.
 - c** With a new wipe, clean the cable and transducer, starting from the cable, wiping toward the scanhead. This method helps to avoid cross-contamination.



Caution

Do not allow moisture near the electronic components of the connector.

- d** Observe the minimum wet contact time recommended by the manufacturer. Monitor the transducer for wet appearance. Re-apply with a new wipe if no longer wet.

7 Verify that all gel, debris, and bodily fluids have been removed from the system and transducer. If necessary, repeat steps 5 & 6 with a new wipe.

WARNING

Failure to remove all gel, debris, and bodily fluid could leave contaminants on the probe.

8 Examine the system, transducer, and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, discontinue use, and contact FUJIFILM SonoSite or your local representative.

9 Prepare the disinfectant for use.

- a** Choose a high-level disinfectant from **Table 5-4, “High-level disinfectants compatible with SonoSite Edge II transducers”** on page 82.
- b** Check the expiration date on the bottle to ensure the disinfectant has not expired.
- c** Mix or check that the disinfection chemicals have the concentration recommended by the manufacturer (for example, a chemical strip test).
- d** Check that the temperature of the disinfectant is within the manufacturer’s recommended limits.

10 Perform a high-level disinfection of the transducer. Use the following procedure:

- a** Immerse the transducer in a high-level disinfectant solution. See the chemical manufacturer’s recommendations for soak time.

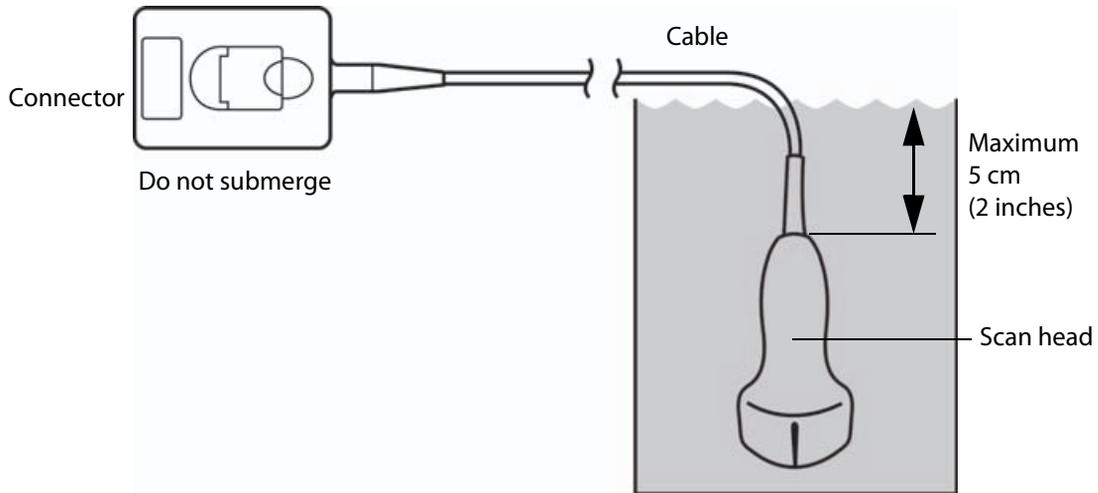
WARNING

High-level disinfectants can cause harm to the patient if not completely removed from the transducer. Follow the manufacturer’s rinse instructions to remove chemical residue.

Cautions

- ▶ Do not soak the transducer longer than recommended by the chemical manufacturer.
- ▶ Do not immerse the transducer connector in any disinfectant solution.
- ▶ Use only FUJIFILM SonoSite recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage or discolor the transducer and void the warranty.

- b** Ensure that the connector and most of the cable remain out of the fluid. You may submerge 2 inches (5 cm) of the cable proximal to the transducer scanhead.



11 Rinse the transducer **3 separate times** using the following procedure:

- a** Rinse the transducer in clean, running water according to the disinfectant manufacturer's instructions (at least 1 minute).
- b** Ensure that the connector and at least 12-18 inches (31-46 cm) of the cable from the connector remain dry.
- c** Repeat this step until the transducer has been rinsed 3 separate times.

12 Dry the transducer with a sterile, lint-free cloth.

13 Dispose of the disinfectant according to the manufacturer's guidelines.

14 Examine the transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, discontinue use of the transducer, and contact FUJIFILM SonoSite or your local representative.

Option **B** Clean and disinfect system and transducer to a low level (non-critical uses)

Use the following procedure to clean and disinfect the ultrasound system and transducer **if it has not come into contact with blood, broken skin, mucosal membranes, or bodily fluids.**

WARNING

If the system or transducer has come into contact with any of the following, use the high-level cleaning and disinfection procedure. See Option A, **“Clean and disinfect system and transducer to a high level (semi-critical uses)”** on page 66:

- ▶ Blood
- ▶ Broken skin
- ▶ Mucosal membranes
- ▶ Bodily fluids

Follow the manufacturer's instructions when using cleaners and disinfectants. The materials listed in the table below are chemically compatible with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

WARNINGS

- ▶ To avoid electrical shock, before cleaning, disconnect the system from the power supply.
- ▶ Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as eyewear and gloves.

Caution

- ▶ Do not spray cleaners or disinfectants directly on the system surfaces or on system and transducer connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- ▶ Use only FUJIFILM SonoSite-recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage the System and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.
- ▶ Do not attempt to disinfect a transducer or transducer cable using a method or chemical that is not included here. Doing so can damage the transducer and void the warranty.

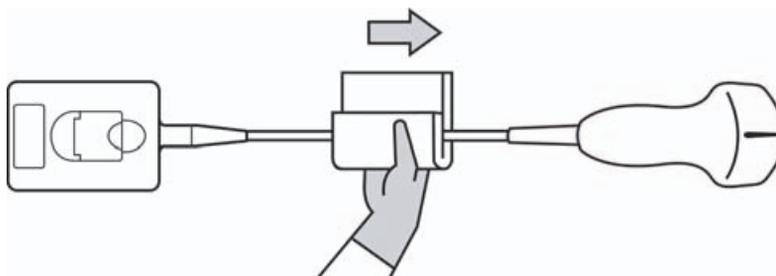
Note

For the purposes of cleaning and disinfecting, the battery should be considered as part of the ultrasound system, and not an accessory.

Cleaning and disinfecting the system and transducer (non-critical)

To clean and disinfect the system and transducer

- 1 **Turn off** the system by pressing the **Power button**.
- 2 **Unplug** the power cord from the outlet.
- 3 Remove the transducer sheath, if applicable.
- 4 **Disconnect** the transducer from the system. Temporarily place it where it will not cross-contaminate clean equipment or surfaces while you clean the ultrasound console.
- 5 **Clean** the exterior surfaces of the **ULTRASOUND SYSTEM** to remove any debris or bodily fluids. Use the following procedure:
 - a Use either a premoistened wipe or a soft cloth dampened with cleaner and disinfectant. Choose a cleaner from **Table 5-2, “Cleaners and disinfectants compatible with SonoSite Edge II system and transducers”** on page 74.
 - b Remove all gel, debris, and bodily fluids from the system.
 - c With a new wipe, clean the system, including the display, by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.
 - d Observe the minimum wet contact time recommended by the manufacturer. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.
- 6 **Clean** the **TRANSDUCER CABLE AND BODY** to remove any debris or bodily fluids. Use the following procedure:
 - a Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 5-2, “Cleaners and disinfectants compatible with SonoSite Edge II system and transducers”** on page 74.
 - b Remove all gel, debris, and bodily fluids from the transducer.
 - c With a new wipe, clean the cable and transducer, starting from the cable, wiping toward the scanhead. This method helps to avoid cross-contamination.



Caution

Do not allow moisture near the electronic components of the connector.

- d** Observe the required wet contact time. Monitor the transducer for wet appearance. Re-apply with a new wipe if no longer wet.
- 7 Verify** that all gel, debris, and bodily fluids have been removed from the system and transducer. If necessary, repeat steps 5 and 6 with a new wipe.
- 8 Allow** the ultrasound system, including the console and transducer, to air dry in a clean, well-ventilated space.
- 9 Examine** the system, transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, do not use the transducer. Instead, contact FUJIFILM SonoSite or your local representative.

Storing the transducer

To store the transducer

- 1** Make sure the transducer has been cleaned and disinfected as detailed in this chapter.
- 2** Store the transducer so that it hangs freely and vertically, and observe the following precautions:
 - ▶ Store the transducer away from any contaminated transducers.
 - ▶ Store the transducer in an environment that is safe and has good airflow. Do not store the transducer in closed containers or where condensation may occur.
 - ▶ Avoid direct sunlight and exposure to x-rays. Recommended storage temperature range is between 0° C (32° F) and +45° C (113° F).
 - ▶ If using a wall-mounted rack for storage, ensure that:
 - ▶ It is securely mounted.
 - ▶ The storage slots do not mar the transducer or cause damage to the cable.
 - ▶ The rack is sized and positioned to prevent the transducer from inadvertently falling.
 - ▶ Make sure the connector is supported and secure.

Transporting the transducer

When transporting the transducer, you must take precautions to protect the transducer from damage and avoid cross-contamination. Be sure to use a container approved by your organization.

To transport a soiled transducer for cleaning

A soiled transducer is one that has been contaminated and must be cleaned before using it in an exam.

- 1 Place the transducer in a clean, approved container.

WARNING

To prevent cross-contamination or unprotected exposure of personnel to biological material, containers used to transport contaminated transducers should carry an ISO biohazard label similar to the following:



Caution

Ensure the transducer is dry before placing it in a closed container. Condensation from a damp transducer can damage the connector.

- 2 Transport the transducer in the container to the point of processing. Do not open the container until the transducer is ready to be cleaned.

Caution

Do not leave the transducer in a sealed container for long periods of time.

To transport a clean transducer

A clean transducer is one that has completed the cleaning and disinfection process, has been stored properly, and is ready to be used in an examination.

- 1 Place the transducer in a clean, approved container. To identify the transducer as clean, containers used to transport clean transducers should carry a cleanliness verification sticker or certificate.
- 2 Transport the transducer in the container to the point of use. Do not open the container until the transducer is ready to be used.

To ship a transducer

WARNING

Whenever possible, avoid shipping a contaminated transducer. Before shipping, ensure the transducer has been cleaned and disinfected using the steps detailed in this chapter or according to special instructions received from FUJIFILM SonoSite. If you are returning the transducer to FUJIFILM SonoSite, document the disinfection on a "Declaration of Cleanliness," and attach it to the packing list.

- 1 Place the transducer in the shipping container and seal it. Do not allow any part of the transducer to protrude from the container.
- 2 Ship the transducer using the following precautions:

- ▶ Clearly label the container as fragile.
- ▶ Do not stack items on top of the shipping container.
- ▶ Do not exceed the shipping temperature range: -35° C (-31° F) to +65° C (149° F).
- ▶ Do not open the shipping container until it reaches its final destination.
- ▶ After arrival, the transducer must be cleaned and disinfected before it can be used in an exam.

Compatible cleaners and disinfectants (system and transducers)

Table 5-2: Cleaners and disinfectants compatible with SonoSite Edge II system and transducers

Disinfectants	SonoSite Edge II System	SonoSite Edge II Stand	C11x	rC60xi	HFL38xi	HFL50x	HSL25x	ICTx	L25x	L38xi	L52x	P10x	P11x	rP19x
Accel Intervention Wipes											✓			
Airkem A-33			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Alcohol-Ethanol		✓		✓	✓	✓	✓		✓		✓			✓
Anios Wipes						✓		✓			✓			
Aniosyme DD1- 5%			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Asepti HB		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Asepti Steryl	✓													
Asepti Wipe II	✓	✓												
Baxedin Pre-Op			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Carpe Diem TB Wipes						✓								
Caviwipes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Table 5-2: Cleaners and disinfectants compatible with SonoSite Edge II system and transducers

Disinfectants	SonoSite Edge II System	SonoSite Edge II Stand	C11x	rC60xi	HFL38xi	HFL50x	HSL25x	ICTx	L25x	L38xi	L52x	P10x	P11x	rP19x
Cidalkan	✓												✓	
Cidalkan Lingettes	✓												✓	
Clinell Universal Sanitising Wipes			✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓
Clorox Germicidal Wipes			✓	✓	✓	✓	✓	✓	✓	✓		✓		✓
Clorox Hydrogen Peroxide Wipes	✓	✓												
Control III	✓												✓	
Coverage Germicidal Surface Wipes	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Coverage Plus Germicidal Surface Wipes	✓			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Coverage Spray				✓	✓		✓							✓
Coverage Spray TB				✓	✓	✓	✓	✓		✓		✓		✓
DisCide Ultra Disinfecting Towlettes	✓												✓	
Dynacide PA		✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓
Echo Clean lingettes	✓					✓					✓			
End Bac II	✓					✓					✓			
Endosporine	✓		✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓

Table 5-2: Cleaners and disinfectants compatible with SonoSite Edge II system and transducers

Disinfectants	SonoSite Edge II System	SonoSite Edge II Stand	C11x	rC60xi	HFL38xi	HFL50x	HSL25x	ICTx	L25x	L38xi	L52x	P10x	P11x	rP19x
Envirocide	✓	✓		✓	✓		✓							✓
Gluco Chlor Wipes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓
Hydrogen Peroxide 3%	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Incidin Plus 1%			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Incidin Plus 3%			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Madacide-1				✓	✓	✓	✓	✓		✓	✓	✓		✓
Medzyme			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
MetriSponge			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓
MetriZyme													✓	
Mikrobac Forte 2%				✓	✓	✓	✓	✓		✓	✓	✓	✓	✓
Mikrobac Tissues			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mikrozid Sensitive Wipes					✓		✓							✓
Oxivir TB Wipes						✓								
Percept RTU Wipes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓
PI-Spray					✓	✓	✓	✓		✓	✓	✓		✓
PI-Spray II	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Table 5-2: Cleaners and disinfectants compatible with SonoSite Edge II system and transducers

Disinfectants	SonoSite Edge II System	SonoSite Edge II Stand	C11x	rC60xi	HFL38xi	HFL50x	HSL25x	ICTx	L25x	L38xi	L52x	P10x	P11x	rP19x
Protex Spray	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓
Protex Wipes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Rely+On Perasafe	✓	✓									✓		✓	
Reynard Neutral Detergent Wipes				✓	✓		✓							✓
Reynard Surface Disinfection Wipes				✓	✓		✓							✓
Sani-Cloth AF		✓				✓					✓			
Sani-Cloth AF3	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓
Sani-Cloth Bleach Wipes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sani-Cloth HB	✓			✓	✓	✓	✓	✓		✓	✓	✓	✓	✓
Sani-Cloth Plus	✓	✓				✓					✓			
Simple Chlor													✓	
SONO Ultrasound Wipes				✓	✓		✓							✓
Staphene						✓					✓			
Steranios 2%			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Super Sanicloth	✓												✓	

Table 5-2: Cleaners and disinfectants compatible with SonoSite Edge II system and transducers

Disinfectants	SonoSite Edge II System	SonoSite Edge II Stand	C11x	rC60xi	HFL38xi	HFL50x	HSL25x	ICTx	L25x	L38xi	L52x	P10x	P11x	rP19x
Trigene Advance Wipes	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tristel Solo	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tristel Wipes	✓												✓	
T-Spray				✓										
T-Spray II				✓										
Tuffie 5 Wipes				✓	✓		✓							✓
Virex II 256	✓	✓	✓	✓	✓	✓	✓		✓		✓		✓	✓
Virex TB				✓	✓	✓	✓				✓			✓
Virox 5 RTU Wipes	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
Wet Task Wipes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓
Wex-Cide													✓	
Wipes Plus Disinfecting Wipes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓
Wood Wyant Ultra Wipes													✓	

Compatible cleaners and disinfectants (system accessories)

Table 5-3: Cleaners and disinfectants compatible with SonoSite Edge II system accessories

Disinfectants	PowerPack	PowerPark	TTC	ECG Cable
Accel Intervention Wipes			✓	
Accel TB Wipes		✓		
Airkem A-33	✓	✓		
Alcohol-Ethanol			✓	
Alcohol - Isopropyl				✓
Anios Wipes	✓	✓		
Aniosyme DD1- 5%	✓	✓		
Anioxide 1000	✓	✓		
Asepti HB	✓	✓	✓	✓
Asepti Steryl	✓			
Asepti Wipe II	✓	✓		
Baxedin Pre-Op	✓			
Carpe Diem TB Wipes	✓			
Caviwipes	✓	✓	✓	✓
Cidalkan	✓		✓	
Cidalkan Lingettes			✓	
Clinell Universal Sanitising Wipes	✓	✓		
Clorox Germicidal Wipes	✓			
Clorox Hydrogen Peroxide Wipes	✓	✓	✓	
Control III	✓	✓		

Table 5-3: Cleaners and disinfectants compatible with SonoSite Edge II system accessories

Disinfectants	PowerPack	PowerPark	TTC	ECG Cable
Coverage Spray	✓			
Coverage Spray TB	✓		✓	
DisCide Ultra Disinfecting Towlettes	✓		✓	
Dynacide PA	✓	✓	✓	
Echo Clean lingettes	✓	✓	✓	✓
End Bac II	✓		✓	
Endosporine	✓	✓	✓	
Envirocide	✓	✓	✓	
Gluco Chlor Wipes	✓			
Hydrogen Peroxide 3%	✓	✓	✓	✓
Incidin Plus 1%	✓	✓		
Incidin Plus 3%	✓	✓		
Medzyme	✓	✓		
Mikrobac Forte 2%	✓	✓		
Mikrobac Tissues	✓	✓		
Oxivir TB Wipes	✓		✓	
Percept RTU Wipes	✓	✓		
PI-Spray	✓			
PI-Spray II	✓	✓	✓	
Protex Spray	✓	✓	✓	

Table 5-3: Cleaners and disinfectants compatible with SonoSite Edge II system accessories

Disinfectants	PowerPack	PowerPark	TTC	ECG Cable
Protex Wipes	✓	✓	✓	
Rely+On Perasafe	✓	✓	✓	
Sani-Cloth AF	✓	✓		
Sani-Cloth AF3	✓	✓	✓	
Sani-Cloth Bleach Wipes	✓			
Sani-Cloth HB	✓		✓	✓
Sani-Cloth Plus		✓	✓	✓
Staphene	✓		✓	
Steranios 2%	✓	✓	✓	
Steranios 20%	✓	✓		
Super Sani-Cloth			✓	
Trigene Advance Wipes			✓	
Tristel Solo	✓	✓	✓	
Tristel Wipes			✓	
Virex II 256	✓		✓	✓
Virex TB	✓			
Virox 5 RTU Wipes	✓	✓	✓	✓
Wet Task Wipes	✓			
Wex-Cide	✓	✓	✓	
Wipes Plus Disinfecting Wipes	✓	✓		

Compatible high-level disinfectants (transducers)

Table 5-4: High-level disinfectants compatible with SonoSite Edge II transducers

High-level Disinfectants	C11x	rC60xi	HFL38xi	HFL50x	HSL25x	ICTx	L25x	L38xi	L52x	P10x	P11x	rP19x
Cidex	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Cidex OPA	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓
Metricide OPA Plus	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Nanosonics Trophon EPR	✓	✓	✓	✓	✓	✓	✓	✓		✓		✓
Cidex Plus	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

CHAPTER 6

Cleaning and disinfecting the S Series ultrasound system

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This chapter contains instructions for cleaning and disinfecting the S Series ultrasound system, transducers and accessories. Use the FUJIFILM SonoSite recommendations when cleaning or disinfecting your ultrasound system, transducer, and accessories. Use the cleaning recommendations in the component manufacturer’s instructions when cleaning or disinfecting your components.

The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.

See www.sonosite.com/transducers for images of transducers.

Also included is a listing of disinfectants that SonoSite has tested and deemed compatible with the S Series system, transducers, and accessories. This information is presented in the following tables.

- ▶ **Table 6-2, “Cleaners and disinfectants compatible with S Series system and transducers”** on page 94 shows compatibility between disinfectants, the system, and transducers.
- ▶ **Table 6-3, “Cleaners and disinfectants compatible with S Series system accessories”** on page 98 shows compatibility between disinfectants and accessories.

- ▶ **Table 6-4, “High-level disinfectants compatible with S Series transducers”** on page 102 shows compatibility between high-level disinfectants and transducers.

Note

- ▶ The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.
- ▶ For cleaning the TEE_{Ex} transducer, refer to the cleaning and disinfection instructions in the *TEE_{Ex} User Guide*.
- ▶ For cleaning the TEE_{Xi} transducer, refer to the cleaning and disinfection instructions in the *TEE_{Xi} User Guide*.

Before getting started

- ▶ Follow the disinfectant manufacturer’s recommendations regarding appropriate personal protective equipment (PPE), such as protective eyewear and gloves.
- ▶ Inspect the system and transducer to determine that they are free of any unacceptable deterioration, such as corrosion, discoloration, pitting, or cracked seals. If damage is evident, discontinue use, and contact FUJIFILM SonoSite or your local representative.
- ▶ Confirm that cleaning and disinfecting materials are appropriate for your facility’s use. FUJIFILM SonoSite tests cleaners and disinfectants for use with the FUJIFILM SonoSite systems and transducers.
- ▶ Disinfectants and cleaning methods listed in this chapter are recommended by FUJIFILM SonoSite for material compatibility with the products.
- ▶ Ensure that the disinfectant type and the solution strength and duration are appropriate for the equipment and application.
- ▶ Follow manufacturer recommendations and local regulations, when preparing, using and disposing of chemicals.

WARNING

- ▶ Ensure that cleaning and disinfecting solutions and wipes are not expired.
- ▶ Some cleaners and disinfectants can cause an allergic reaction to some individuals.

Caution

- ▶ Do not allow cleaning solution or disinfectant into the system connectors, or transducer connector.
- ▶ Do not use strong solvents such as thinner or benzene, or abrasive cleansers, since these will damage the exterior surfaces. Use only FUJIFILM SonoSite recommended cleaners or disinfectants.

Cleaning and disinfecting

Determining the required cleaning and disinfecting level

WARNING

The cleaning instructions contained in this chapter are based on requirements mandated by the American Food and Drug Administration (FDA). Failure to follow these instructions may result in cross contamination and patient infection.

The level of cleaning and disinfecting required for the system is dictated by the type of tissue it contacts during use. Use **Table 6-1, “Choosing a cleaning and disinfecting method”** on page 85 to determine the level of cleaning and disinfecting required.

Table 6-1: Choosing a cleaning and disinfecting method

Did any part of the system or transducer come in contact with broken skin, blood, mucosal membranes, or bodily fluids?	
YES	Came in contact with broken skin, blood, mucosal membranes, or bodily fluids. 
OR	
NO	Did not come in contact with broken skin, blood, or bodily fluids. 
Option A Go to “Clean and disinfect system and transducer to a high level (semi-critical uses)” on page 86.	
Option B Go to “Clean and disinfect system and transducer to a low level (non-critical uses)” on page 90.	

Spaulding classifications

Spaulding classifications (non-critical, semi-critical) determine the approach for cleaning and disinfecting medical equipment based on the device, the way it has been used, and the risk of infection. The system and transducers are designed for use within the Spaulding classifications of non-critical and semi-critical uses.

Option **A** Clean and disinfect system and transducer to a high level (semi-critical uses)

Use this procedure to clean and high-level disinfect the ultrasound system and transducer **whenever it has come into contact with blood, broken skin, mucosal membranes, or bodily fluids.**

Follow the manufacturer's instructions when using cleaners and disinfectants. The cleaners and disinfectants listed in the procedure are chemically compatible with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

WARNING

- ▶ To avoid electrical shock, before cleaning, disconnect the system from the power supply.
- ▶ Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as eyewear and gloves.

Caution

- ▶ Do not skip any steps or abbreviate the cleaning and disinfecting process in any way.
- ▶ Do not spray cleaners or disinfectants directly on the system surfaces or on system and transducer connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- ▶ Do not attempt to disinfect a transducer or transducer cable using a method or chemical that is not included here. This can damage the transducer and void the warranty.
- ▶ Use only FUJIFILM SonoSite recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage the System and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.

Note

- ▶ You must clean and disinfect both the ultrasound system and the transducer after each use, but only the transducer can be disinfected to a high level.
- ▶ For the purposes of cleaning and disinfecting, the battery should be considered as part of the ultrasound system, and not an accessory.

Cleaning and disinfecting the system and transducer (semi-critical)

To clean and disinfect the system and transducer

- 1 Turn off** the system by pressing the **Power button**.
- 2 Unplug** the power cord from the outlet.
- 3** Remove the disposable transducer sheath, if applicable.

4 Disconnect the transducer from the system. Temporarily place it where it will not cross-contaminate clean equipment or surfaces while you clean the ultrasound console.

5 Clean the exterior surfaces of the **ULTRASOUND SYSTEM** to remove any debris or bodily fluids. Use the following procedure:

a Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 6-2, “Cleaners and disinfectants compatible with S Series system and transducers”** on page 94.

b Remove all gel, debris, and bodily fluids from the system.

c With a new wipe, clean the system, including the display, by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.

d Observe the minimum wet contact time recommended by the manufacturer. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.

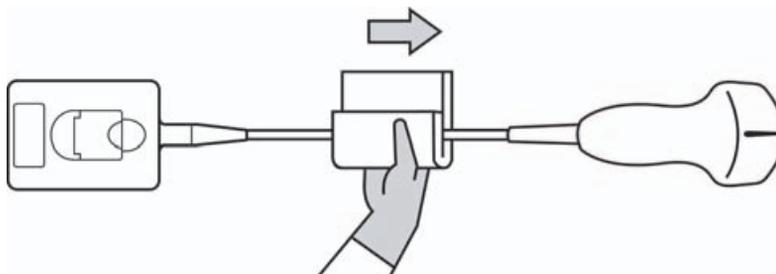
e Allow the ultrasound console to air dry in a clean, well-ventilated space.

6 Clean the **TRANSDUCER CABLE AND BODY** to remove any debris or bodily fluids. Use the following procedure:

a Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 6-2, “Cleaners and disinfectants compatible with S Series system and transducers”** on page 94.

b Remove all gel, debris, and bodily fluids from the transducer.

c With a new wipe, clean the cable and transducer, starting from the cable, wiping toward the scanhead. This method helps to avoid cross-contamination.



Caution

Do not allow moisture near the electronic components of the connector.

d Observe the minimum wet contact time recommended by the manufacturer. Monitor the transducer for wet appearance. Re-apply with a new wipe if no longer wet.

7 Verify that all gel, debris, and bodily fluids have been removed from the system and transducer. If necessary, repeat steps 5 & 6 with a new wipe.

WARNING

Failure to remove all gel, debris, and bodily fluid could leave contaminants on the probe.

8 Prepare the disinfectant for use.

- a** Choose a high-level disinfectant from **Table 6-4, “High-level disinfectants compatible with S Series transducers”** on page 102.
- b** Check the expiration date on the bottle to ensure the disinfectant has not expired.
- c** Mix or check that the disinfection chemicals have the concentration recommended by the manufacturer (for example, a chemical strip test).
- d** Check that the temperature of the disinfectant is within the manufacturer’s recommended limits.

9 Perform a high-level disinfection of the transducer. Use the following procedure:

- a** Immerse the transducer in a high-level disinfectant solution. See the chemical manufacturer’s recommendations for soak time.

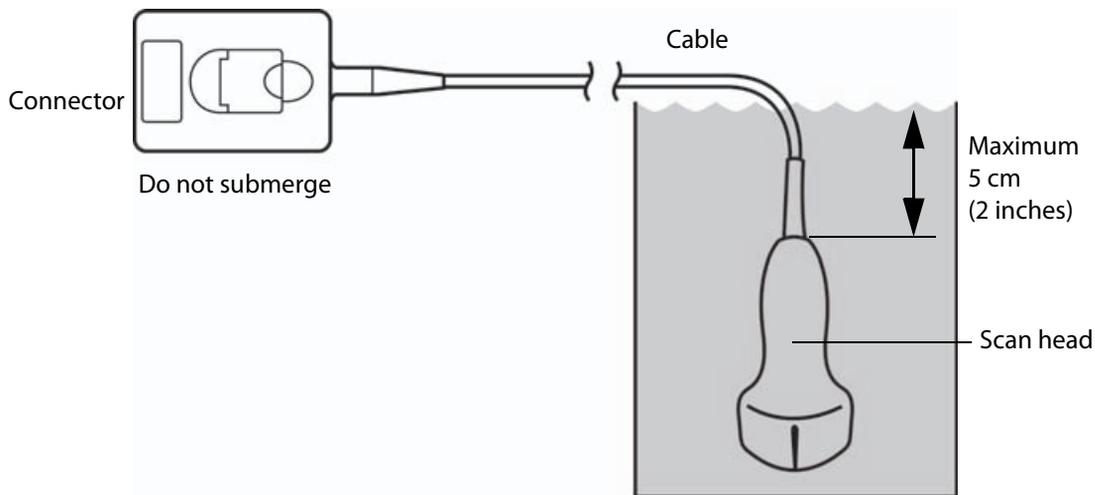
WARNING

High-level disinfectants can cause harm to the patient if not completely removed from the transducer. Follow the manufacturer’s rinse instructions to remove chemical residue.

Cautions

- ▶ Do not soak the transducer longer than recommended by the chemical manufacturer.
- ▶ Do not immerse the transducer connector in any disinfectant solution.
- ▶ Use only FUJIFILM SonoSite recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage or discolor the transducer and void the warranty.

- b** Ensure that the connector and most of the cable remain out of the fluid. You may submerge 2 inches (5 cm) of the cable proximal to the transducer scanhead.



10 Rinse the transducer **3 separate times** using the following procedure:

- a** Rinse the transducer in clean, running water according to the disinfectant manufacturer's instructions (at least 1 minute).
- b** Ensure that the connector and at least 12-18 inches (31-46 cm) of the cable from the connector remain dry.
- c** Repeat this step until the transducer has been rinsed 3 separate times.

11 Dry the transducer with a sterile, lint-free cloth.

12 Dispose of the disinfectant according to the manufacturer's guidelines.

13 Examine the transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, discontinue use of the transducer, and contact FUJIFILM SonoSite or your local representative.

Option **B** Clean and disinfect system and transducer to a low level (non-critical uses)

Use the following procedure to clean and disinfect the ultrasound system and transducer **if it has not come into contact with blood, broken skin, mucosal membranes, or bodily fluids.**

WARNING

If the system or transducer has come into contact with any of the following, use the high-level cleaning and disinfection procedure. See Option A, “**Clean and disinfect system and transducer to a high level (semi-critical uses)**” on page 86:

- ▶ Blood
- ▶ Broken skin
- ▶ Mucosal membranes
- ▶ Bodily fluids

Follow the manufacturer's instructions when using cleaners and disinfectants. The materials listed in the table below are chemically compatible with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

WARNING

- ▶ To avoid electrical shock, before cleaning, disconnect the system from the power supply.
- ▶ Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as eyewear and gloves.

Caution

- ▶ Do not spray cleaners or disinfectants directly on the system surfaces or on system and transducer connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- ▶ Use only FUJIFILM SonoSite-recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage the System and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.
- ▶ Do not attempt to disinfect a transducer or transducer cable using a method or chemical that is not included here. Doing so can damage the transducer and void the warranty.

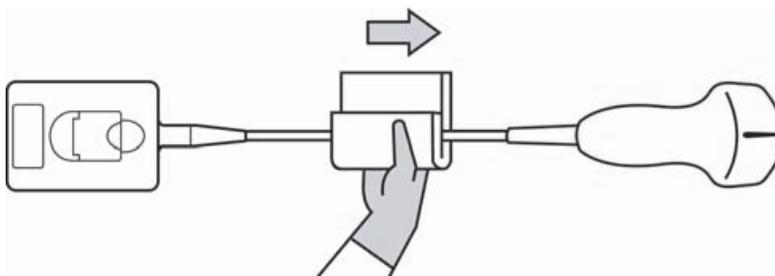
Note

For the purposes of cleaning and disinfecting, the battery should be considered as part of the ultrasound system, and not an accessory.

Cleaning and disinfecting the system and transducer (non-critical)

To clean and disinfect the system and transducer

- 1 Turn off** the system by pressing the **Power button**.
- 2 Unplug** the power cord from the outlet.
- 3** Remove the transducer sheath, if applicable.
- 4 Disconnect** the transducer from the system. Temporarily place it where it will not cross-contaminate clean equipment or surfaces while you clean the ultrasound console.
- 5 Clean** the exterior surfaces of the **ULTRASOUND SYSTEM** to remove any debris or bodily fluids. Use the following procedure:
 - Use either a premoistened wipe or a soft cloth dampened with cleaner and disinfectant. Choose a cleaner from **Table 6-2, “Cleaners and disinfectants compatible with S Series system and transducers”** on page 94.
 - Remove all gel, debris, and bodily fluids from the system.
 - With a new wipe, clean the system, including the display, by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.
 - Observe the minimum wet contact time recommended by the manufacturer. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.
- 6 Clean** the **TRANSDUCER CABLE AND BODY** to remove any debris or bodily fluids. Use the following procedure:
 - Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 6-2, “Cleaners and disinfectants compatible with S Series system and transducers”** on page 94.
 - Remove all gel, debris, and bodily fluids from the transducer.
 - With a new wipe, clean the cable and transducer, starting from the cable, wiping toward the scanhead. This method helps to avoid cross-contamination.



Caution

Do not allow moisture near the electronic components of the connector.

d Observe the minimum wet contact time. Monitor the transducer for wet appearance. Re-apply with a new wipe if no longer wet.

- 7 Verify** that all gel, debris, and bodily fluids have been removed from the system and transducer. If necessary, repeat steps 5 and 6 with a new wipe.
- 8 Allow** the ultrasound system, including the console and transducer, to air dry in a clean, well-ventilated space.
- 9 Examine** the system, transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, do not use. Instead, contact FUJIFILM SonoSite or your local representative.

Storing the transducer

To store the transducer

- 1** Make sure the transducer has been cleaned and disinfected as detailed in this chapter.
- 2** Store the transducer so that it hangs freely and vertically, and observe the following precautions:
 - ▶ Store the transducer away from any contaminated transducers.
 - ▶ Store the transducer in an environment that is safe and has good airflow. Do not store the transducer in closed containers or where condensation may occur.
 - ▶ Avoid direct sunlight and exposure to x-rays. Recommended storage temperature range is between 0° C (32° F) and +45° C (113° F).
 - ▶ If using a wall-mounted rack for storage, ensure that:
 - ▶ It is securely mounted.
 - ▶ The storage slots do not mar the transducer or cause damage to the cable.
 - ▶ The rack is sized and positioned to prevent the transducer from inadvertently falling.
 - ▶ Make sure the connector is supported and secure.

Transporting the transducer

When transporting the transducer, you must take precautions to protect the transducer from damage and avoid cross-contamination. Be sure to use a container approved by your organization.

To transport a soiled transducer for cleaning

A soiled transducer is one that has been contaminated and must be cleaned before using it in an exam.

- 1 Place the transducer in a clean, approved container.

WARNING

To prevent cross-contamination or unprotected exposure of personnel to biological material, containers used to transport contaminated transducers should carry an ISO biohazard label similar to the following:



Caution

Ensure the transducer is dry before placing it in a closed container. Condensation from a damp transducer can damage the connector.

- 2 Transport the transducer in the container to the point of processing. Do not open the container until the transducer is ready to be cleaned.

Caution

Do not leave the transducer in a sealed container for long periods of time.

To transport a clean transducer

A clean transducer is one that has completed the cleaning and disinfection process, has been stored properly, and is ready to be used in an examination.

- 1 Place the transducer in a clean, approved container. To identify the transducer as clean, containers used to transport clean transducers should carry a cleanliness verification sticker or certificate.
- 2 Transport the transducer in the container to the point of use. Do not open the container until the transducer is ready to be used.

To ship a transducer

WARNING

Whenever possible, avoid shipping a contaminated transducer. Before shipping, ensure the transducer has been cleaned and disinfected using the steps detailed in this chapter or according to special instructions received from FUJIFILM SonoSite. If you are returning the transducer to FUJIFILM SonoSite, document the disinfection on a "Declaration of Cleanliness," and attach it to the packing list.

- 1 Place the transducer in the shipping container and seal it. Do not allow any part of the transducer to protrude from the container.
- 2 Ship the transducer using the following precautions:
 - ▶ Clearly label the container as fragile.
 - ▶ Do not stack items on top of the shipping container.

- ▶ Do not exceed the shipping temperature range: -35° C (-31° F) to +65° C (149° F).
- ▶ Do not open the shipping container until it reaches its final destination.
- ▶ After arrival, the transducer must be cleaned and disinfected before it can be used in an exam.

Compatible cleaners and disinfectants (system and transducers)

Table 6-2: Cleaners and disinfectants compatible with S Series system and transducers

Disinfectants	S-Series System	V-Universal Stand	C8x	C11x	C60x	C60xi	HFL38x	HFL50x	ICTx	L25x	L38x	L38xi	L52x	P10x	P11x	P21x	SLAx
Accel Intervention Wipes													✓				
Accel TB Wipes	✓																
Airkem A-33	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Alcohol-Ethanol	✓	✓				✓		✓		✓			✓				
Anios Wipes		✓						✓					✓				
Aniosyme DD1-5%	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Asepti HB	✓			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Asepti Wipe II	✓																
Bacoban WB	✓																
Baxedin Pre-Op	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Carpe Diem TB Wipes								✓									
Caviwipes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Table 6-2: Cleaners and disinfectants compatible with S Series system and transducers

Disinfectants	S-Series System	V-Universal Stand	C8x	C11x	C60x	C60xi	HFL38x	HFL50x	ICTx	L25x	L38x	L38xi	L52x	P10x	P11x	P21x	SLAX
Cidalkan															✓		
Cidalkan Lingettes		✓													✓		
Cleanisept Wipes	✓																
Clinell Universal Sanitising Wipes		✓		✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓
Clorox Germicidal Wipes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓		✓	✓
Clorox Hydrogen Peroxide Wipes	✓	✓															
Control III	✓	✓													✓		
Coverage Germicidal Surface Wipes		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Coverage Plus Germicidal Surface Wipes			✓		✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Coverage Spray		✓				✓											
Coverage Spray TB			✓		✓	✓	✓	✓	✓		✓	✓		✓		✓	✓
DisCide Ultra Disinfecting Towlettes	✓														✓		
Dynacide PA	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓
Echo Clean lingettes	✓							✓					✓				

Table 6-2: Cleaners and disinfectants compatible with S Series system and transducers

Disinfectants	S-Series System	V-Universal Stand	C8x	C11x	C60x	C60xi	HFL38x	HFL50x	ICTx	L25x	L38x	L38xi	L52x	P10x	P11x	P21x	SLAX
End Bac II								✓					✓				
Endosporine		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓
Envirocide	✓	✓				✓											
Gluko Chlor Wipes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Hydrogen Peroxide 3%	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Incidin Plus 1%	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Incidin Plus 3%		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Madacide-1	✓		✓		✓	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓
Medzyme	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
MetriSponge			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
MetriZyme															✓		
Mikrobac Forte 2%		✓	✓		✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Mikrobac Tissues	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Oxivir TB Wipes								✓									
Percept RTU Wipes	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
PI-Spray		✓			✓	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓
PI-Spray II	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Table 6-2: Cleaners and disinfectants compatible with S Series system and transducers

Disinfectants	S-Series System	V-Universal Stand	C8x	C11x	C60x	C60xi	HFL38x	HFL50x	ICTx	L25x	L38x	L38xi	L52x	P10x	P11x	P21x	SLAX
Protex Spray	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Protex Wipes		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Rely+On Perasafe													✓		✓		
Sani-Cloth AF	✓	✓						✓					✓				
Sani-Cloth AF3	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓
Sani-Cloth Bleach Wipes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sani-Cloth HB	✓		✓		✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Sani-Cloth Plus	✓							✓									
Simple Chlor	✓														✓		
Staphene								✓					✓				
Steranios 2%	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Steranios 20%	✓	✓															
Super Sanicloth															✓		
Trigene Advance Wipes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tristel Solo	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tristel Wipes	✓														✓		
Virex II 256				✓		✓		✓		✓			✓		✓		

Table 6-2: Cleaners and disinfectants compatible with S Series system and transducers

Disinfectants	S-Series System	V-Universal Stand	C8x	C11x	C60x	C60xi	HFL38x	HFL50x	ICTx	L25x	L38x	L38xi	L52x	P10x	P11x	P21x	SLAX
Virex TB		✓				✓		✓					✓				
Virox 5 RTU Wipes	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓
Wet Task Wipes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Wex-Cide	✓	✓													✓		
Wipes Plus Disinfecting Wipes	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Wood Wyant Ultra Wipes	✓	✓													✓		

Compatible cleaners and disinfectants (system accessories)

Table 6-3: Cleaners and disinfectants compatible with S Series system accessories

Disinfectants	Power Supply	PowerPack	PowerPark	S Series TTC	ECG Cable
Accel Intervention Wipes				✓	
Accel TB Wipes			✓	✓	
Airkem A-33		✓	✓	✓	
Alcohol-Ethanol				✓	
Alcohol - Isopropyl		✓		✓	✓
Anios Wipes		✓	✓	✓	

Table 6-3: Cleaners and disinfectants compatible with S Series system accessories

Disinfectants	Power Supply	PowerPack	PowerPark	S Series TTC	ECG Cable
Aniosyme DD1- 5%		✓	✓	✓	✓
Anioxide 1000		✓	✓	✓	
Asepti HB		✓	✓	✓	✓
Asepti Steryl		✓			
Asepti Wipe II		✓	✓	✓	✓
Baxedin Pre-Op		✓		✓	
Carpe Diem TB Wipes		✓		✓	
Caviwipes		✓	✓	✓	✓
Cidalkan		✓		✓	
Clinell Universal Sanitising Wipes		✓	✓	✓	
Clorox Germicidal Wipes		✓			
Clorox Hydrogen Peroxide Wipes		✓	✓	✓	
Control III		✓	✓	✓	
Coverage Germicidal Surface Wipes		✓		✓	
Coverage Plus Germicidal Surface Wipes		✓		✓	
Coverage Spray		✓		✓	

Table 6-3: Cleaners and disinfectants compatible with S Series system accessories

Disinfectants	Power Supply	PowerPack	PowerPark	S Series TTC	ECG Cable
Coverage Spray TB		✓		✓	
DisCide Ultra Disinfecting Towlettes		✓		✓	
Dynacide PA		✓	✓	✓	
Echo Clean lingettes		✓	✓	✓	✓
End Bac II		✓		✓	
Endosporine		✓	✓	✓	
Envirocide		✓	✓	✓	
Gluco Chlor Wipes				✓	
Hydrogen Peroxide 3%		✓	✓	✓	✓
Incidin Plus 1%		✓	✓	✓	
Incidin Plus 3%		✓	✓	✓	
Medzyme		✓	✓	✓	
MetriZyme				✓	
Mikrobac Forte 2%		✓	✓	✓	
Mikrobac Tissues		✓	✓	✓	
Oxivir TB Wipes		✓		✓	
Percept RTU Wipes		✓	✓		

Table 6-3: Cleaners and disinfectants compatible with S Series system accessories

Disinfectants	Power Supply	PowerPack	PowerPark	S Series TTC	ECG Cable
PI-Spray		✓			
PI-Spray II		✓	✓	✓	
Protex Spray		✓	✓	✓	
Protex Wipes		✓	✓	✓	
Rely+On Perasafe		✓	✓	✓	
Sani-Cloth AF		✓	✓	✓	
Sani-Cloth AF3			✓	✓	
Sani-Cloth Bleach Wipes		✓			
Sani-Cloth HB		✓		✓	✓
Sani-Cloth Plus		✓	✓	✓	✓
Simple Chlor		✓	✓	✓	✓
Staphene		✓		✓	
Steranios 2%		✓	✓	✓	✓
Steranios 20%		✓	✓	✓	
Super Sani-Cloth		✓	✓		✓
Trigene Advance Wipes		✓		✓	
Tristel Solo		✓	✓	✓	

Table 6-3: Cleaners and disinfectants compatible with S Series system accessories

Disinfectants	Power Supply	PowerPack	PowerPark	S Series TTC	ECG Cable
Tristel Wipes		✓		✓	
Virex II 256		✓		✓	✓
Virex TB		✓			
Virox 5 RTU Wipes		✓	✓	✓	✓
Wet Task Wipes		✓		✓	
Wet Wipe Disinfection					
Wex-Cide		✓	✓	✓	
Wipes Plus Disinfecting Wipes		✓	✓	✓	
Wood Wyant Ultra Wipes				✓	

Compatible high-level disinfectants (transducers)

Table 6-4: High-level disinfectants compatible with S Series transducers

High-level Disinfectants	C11x	C60x	C60xi	C8x	HFL38x	HFL50x	ICTx	L25x	L38x	L38xi	P10x	P11x	P21x	SLAx
Cidex	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Cidex OPA	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	
Metricide OPA Plus	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Nanosonics Trophon EPR	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓

Table 6-4: High-level disinfectants compatible with S Series transducers

High-level Disinfectants	C11x	C60x	C60xi	C8x	HFL38x	HFL50x	ICTx	L25x	L38x	L38xi	P10x	P11x	P21x	SLAx
Revital-Ox Resert HLD														✓
Cidex Plus	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

CHAPTER 7

Cleaning and disinfecting the SonoSite SII Series ultrasound system

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This chapter contains instructions for cleaning and disinfecting the SonoSite SII Series ultrasound system, transducers and accessories. Use the FUJIFILM SonoSite recommendations when cleaning or disinfecting your ultrasound system, transducer, and accessories. Use the cleaning recommendations in the component manufacturer's instructions when cleaning or disinfecting your components.

The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.

See www.sonosite.com/transducers for images of transducers.

Also included is a listing of disinfectants that SonoSite has tested and deemed compatible with the SonoSite SII Series system, transducers, and accessories. This information is presented in the following tables.

- ▶ **Table 7-2, “Cleaners and disinfectants compatible with SonoSite SII system and transducers”** on page 116 shows compatibility between disinfectants, the system, and transducers.
- ▶ **Table 7-3, “Cleaners and disinfectants compatible with SonoSite SII system accessories”** on page 121 shows compatibility between disinfectants and accessories.

- ▶ **Table 7-4, “High-level disinfectants compatible with SonoSite SII transducers”** on page 125 shows compatibility between high-level disinfectants and transducers.

Note

The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.

Before getting started

- ▶ Follow the disinfectant manufacturer’s recommendations regarding appropriate personal protective equipment (PPE), such as protective eyewear and gloves.
- ▶ Inspect the system and transducer to determine that they are free of any unacceptable deterioration, such as corrosion, discoloration, pitting, or cracked seals. If damage is evident, discontinue use, and contact FUJIFILM SonoSite or your local representative.
- ▶ Confirm that cleaning and disinfecting materials are appropriate for your facility’s use. FUJIFILM SonoSite tests cleaners and disinfectants for use with the FUJIFILM SonoSite systems and transducers.
- ▶ Disinfectants and cleaning methods listed in this chapter are recommended by FUJIFILM SonoSite for material compatibility with the products.
- ▶ Ensure that the disinfectant type and the solution strength and duration are appropriate for the equipment and application.
- ▶ Follow manufacturer recommendations and local regulations, when preparing, using and disposing of chemicals.

WARNING

- ▶ Ensure that cleaning and disinfecting solutions and wipes are not expired.
- ▶ Some cleaners and disinfectants can cause an allergic reaction to some individuals.

Caution

- ▶ Do not allow cleaning solution or disinfectant into the system connectors, or transducer connector.
- ▶ Do not use strong solvents such as thinner or benzene, or abrasive cleansers, since these will damage the exterior surfaces. Use only FUJIFILM SonoSite recommended cleaners or disinfectants.

Cleaning and disinfecting

Determining the required cleaning and disinfecting level

WARNING

The cleaning instructions contained in this chapter are based on requirements mandated by the American Food and Drug Administration (FDA). Failure to follow these instructions may result in cross contamination and patient infection.

The level of cleaning and disinfecting required for the system is dictated by the type of tissue it contacts during use. Use **Table 7-1, “Choosing a cleaning and disinfecting method”** to determine the level of cleaning and disinfecting required.

Table 7-1: Choosing a cleaning and disinfecting method

Did any part of the system or transducer come in contact with broken skin, blood, mucosal membranes, or bodily fluids?	
YES	Came in contact with broken skin, blood, mucosal membranes, or bodily fluids. 
OR	
NO	Did not come in contact with broken skin, blood, or bodily fluids. 
Option A Go to “Clean and disinfect system and transducer to a high level (semi-critical uses)” on page 108.	
Option B Go to “Clean and disinfect system and transducer to a low level (non-critical uses)” on page 112.	

Spaulding classifications

Spaulding classifications (non-critical, semi-critical) determine the approach for cleaning and disinfecting medical equipment based on the device, the way it has been used, and the risk of infection. The system and transducers are designed for use within the Spaulding classifications of non-critical and semi-critical uses.

Option **A** Clean and disinfect system and transducer to a high level (semi-critical uses)

Use this procedure to clean and high-level disinfect the ultrasound system and transducer **whenever it has come into contact with blood, broken skin, mucosal membranes, or bodily fluids.**

Follow the manufacturer's instructions when using cleaners and disinfectants. The cleaners and disinfectants listed in the procedure are chemically compatible with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

WARNING

- ▶ To avoid electrical shock, before cleaning, disconnect the system from the power supply.
- ▶ Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as eyewear and gloves.

Caution

- ▶ Do not skip any steps or abbreviate the cleaning and disinfecting process in any way.
- ▶ Do not spray cleaners or disinfectants directly on the system surfaces or on system and transducer connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- ▶ Do not attempt to disinfect a transducer or transducer cable using a method or chemical that is not included here. This can damage the transducer and void the warranty.
- ▶ Use only FUJIFILM SonoSite recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage the System and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.

Note

- ▶ You must clean and disinfect both the ultrasound system and the transducer after each use, but only the transducer can be disinfecting to a high level.
- ▶ For the purposes of cleaning and disinfecting, the battery should be considered as part of the ultrasound system, and not an accessory.

Cleaning and disinfecting the system and transducer (semi-critical)

To clean and disinfect the system and transducer

- 1 Turn off** the system by pressing the **Power button**.
- 2 Unplug** the power cord from the outlet.
- 3** Remove the disposable transducer sheath, if applicable.

4 Disconnect the transducer from the system. Temporarily place it where it will not cross-contaminate clean equipment or surfaces while you clean the ultrasound console.

5 Clean the exterior surfaces of the **ULTRASOUND SYSTEM** to remove any debris or bodily fluids. Use the following procedure:

a Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 7-2, “Cleaners and disinfectants compatible with SonoSite SII system and transducers”** on page 116.

b Remove all gel, debris, and bodily fluids from the system.

c With a new wipe, clean the system, including the display, by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.

d Observe the minimum wet contact time recommended by the manufacturer. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.

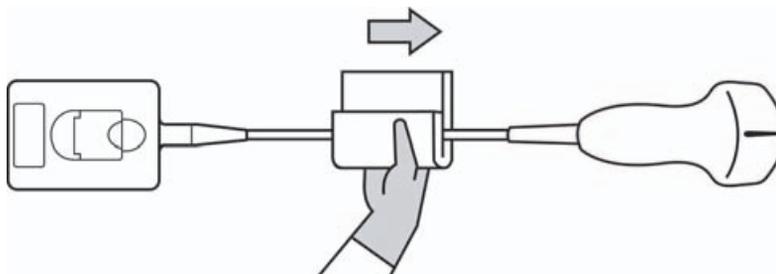
e Allow the ultrasound console to air dry in a clean, well-ventilated space.

6 Clean the **TRANSDUCER CABLE AND BODY** to remove any debris or bodily fluids. Use the following procedure:

a Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 7-2, “Cleaners and disinfectants compatible with SonoSite SII system and transducers”** on page 116.

b Remove all gel, debris, and bodily fluids from the transducer.

c With a new wipe, clean the cable and transducer, starting from the cable, wiping toward the scanhead. This method helps to avoid cross-contamination.



Caution

Do not allow moisture near the electronic components of the connector.

d Observe the minimum wet contact time recommended by the manufacturer. Monitor the transducer for wet appearance. Re-apply with a new wipe if no longer wet.

7 Verify that all gel, debris, and bodily fluids have been removed from the system and transducer. If necessary, repeat steps 5 & 6 with a new wipe.

WARNING

Failure to remove all gel, debris, and bodily fluid could leave contaminants on the probe.

8 Examine the system, transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, do not use. Instead, contact FUJIFILM SonoSite or your local representative.

9 Prepare the disinfectant for use.

- a** Choose a high-level disinfectant from **Table 7-4, “High-level disinfectants compatible with SonoSite SII transducers”** on page 125.
- b** Check the expiration date on the bottle to ensure the disinfectant has not expired.
- c** Mix or check that the disinfection chemicals have the concentration recommended by the manufacturer (for example, a chemical strip test).
- d** Check that the temperature of the disinfectant is within the manufacturer’s recommended limits.

10 Perform a high-level disinfection of the transducer. Use the following procedure:

- a** Immerse the transducer in a high-level disinfectant solution. See the chemical manufacturer’s recommendations for soak time.

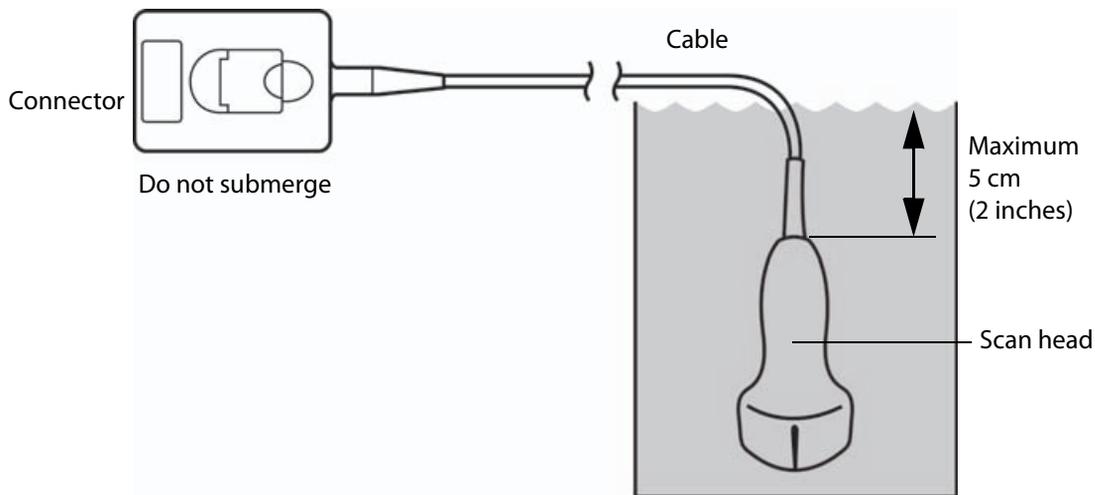
WARNING

High-level disinfectants can cause harm to the patient if not completely removed from the transducer. Follow the manufacturer’s rinse instructions to remove chemical residue.

Cautions

- ▶ Do not soak the transducer longer than recommended by the chemical manufacturer.
- ▶ Do not immerse the transducer connector in any disinfectant solution.
- ▶ Use only FUJIFILM SonoSite recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage or discolor the transducer and void the warranty.

- b** Ensure that the connector and most of the cable remain out of the fluid. You may submerge 2 inches (5 cm) of the cable proximal to the transducer scanhead.



11 Rinse the transducer **3 separate times** using the following procedure:

- a** Rinse the transducer in clean, running water according to the disinfectant manufacturer's instructions (at least 1 minute).
- b** Ensure that the connector and at least 12-18 inches (31-46 cm) of the cable from the connector remain dry.
- c** Repeat this step until the transducer has been rinsed 3 separate times.

12 Dry the transducer with a sterile, lint-free cloth.

13 Dispose of the disinfectant according to the manufacturer's guidelines.

14 Examine the transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, discontinue use of the transducer, and contact FUJIFILM SonoSite or your local representative.

Option **B** Clean and disinfect system and transducer to a low level (non-critical uses)

Use the following procedure to clean and disinfect the ultrasound system and transducer **if it has not come into contact with blood, broken skin, mucosal membranes, or bodily fluids.**

WARNING

If the system or transducer has come into contact with any of the following, use the high-level cleaning and disinfection procedure. See Option A, “**Clean and disinfect system and transducer to a high level (semi-critical uses)**” on page 108:

- ▶ Blood
- ▶ Broken skin
- ▶ Mucosal membranes
- ▶ Bodily fluids

Follow the manufacturer's instructions when using cleaners and disinfectants. The materials listed in the table below are chemically compatible with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

WARNING

- ▶ To avoid electrical shock, before cleaning, disconnect the system from the power supply.
- ▶ Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as eyewear and gloves.

Caution

- ▶ Do not spray cleaners or disinfectants directly on the system surfaces or on system and transducer connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- ▶ Use only FUJIFILM SonoSite-recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage the System and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.
- ▶ Do not attempt to disinfect a transducer or transducer cable using a method or chemical that is not included here. Doing so can damage the transducer and void the warranty.

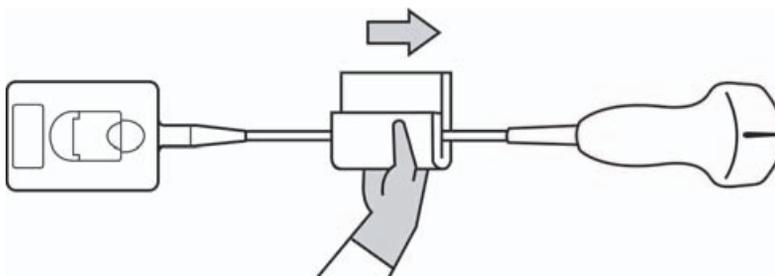
Note

For the purposes of cleaning and disinfecting, the battery should be considered as part of the ultrasound system, and not an accessory.

Cleaning and disinfecting the system and transducer (non-critical)

To clean and disinfect the system and transducer

- 1 **Turn off** the system by pressing the **Power button**.
- 2 **Unplug** the power cord from the outlet.
- 3 Remove the transducer sheath, if applicable.
- 4 **Disconnect** the transducer from the system. Temporarily place it where it will not cross-contaminate clean equipment or surfaces while you clean the ultrasound console.
- 5 **Clean** the exterior surfaces of the **ULTRASOUND SYSTEM** to remove any debris or bodily fluids. Use the following procedure:
 - a Use either a premoistened wipe or a soft cloth dampened with cleaner and disinfectant. Choose a cleaner from **Table 7-2, “Cleaners and disinfectants compatible with SonoSite SII system and transducers”** on page 116.
 - b Remove all gel, debris, and bodily fluids from the system.
 - c With a new wipe, clean the system, including the display, by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.
 - d Observe the minimum wet contact time recommended by the manufacturer. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.
- 6 **Clean** the **TRANSDUCER CABLE AND BODY** to remove any debris or bodily fluids. Use the following procedure:
 - a Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 7-2, “Cleaners and disinfectants compatible with SonoSite SII system and transducers”** on page 116.
 - b Remove all gel, debris, and bodily fluids from the transducer.
 - c With a new wipe, clean the cable and transducer, starting from the cable, wiping toward the scanhead. This method helps to avoid cross-contamination.



Caution

Do not allow moisture near the electronic components of the connector.

- d** Observe the minimum wet contact time. Monitor the transducer for wet appearance. Re-apply with a new wipe if no longer wet.
- 7 Verify** that all gel, debris, and bodily fluids have been removed from the system and transducer. If necessary, repeat steps 5 and 6 with a new wipe.
 - 8 Allow** the ultrasound system, including the console and transducer, to air dry in a clean, well-ventilated space.
 - 9 Examine** the system, transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, do not use. Instead, contact FUJIFILM SonoSite or your local representative.

Storing the transducer

To store the transducer

- 1 Make sure the transducer has been cleaned and disinfected as detailed in this chapter.
- 2 Store the transducer so that it hangs freely and vertically, and observe the following precautions:
 - ▶ Store the transducer away from any contaminated transducers.
 - ▶ Store the transducer in an environment that is safe and has good airflow. Do not store the transducer in closed containers or where condensation may occur.
 - ▶ Avoid direct sunlight and exposure to x-rays. Recommended storage temperature range is between 0° C (32° F) and +45° C (113° F).
 - ▶ If using a wall-mounted rack for storage, ensure that:
 - ▶ It is securely mounted.
 - ▶ The storage slots do not mar the transducer or cause damage to the cable.
 - ▶ The rack is sized and positioned to prevent the transducer from inadvertently falling.
 - ▶ Make sure the connector is supported and secure.

Transporting the transducer

When transporting the transducer, you must take precautions to protect the transducer from damage and avoid cross-contamination. Be sure to use a container approved by your organization.

To transport a soiled transducer for cleaning

A soiled transducer is one that has been contaminated and must be cleaned before using it in an exam.

- 1 Place the transducer in a clean, approved container.

WARNING

To prevent cross-contamination or unprotected exposure of personnel to biological material, containers used to transport contaminated transducers should carry an ISO biohazard label similar to the following:



Caution

Ensure the transducer is dry before placing it in a closed container. Condensation from a damp transducer can damage the connector.

- 2 Transport the transducer in the container to the point of processing. Do not open the container until the transducer is ready to be cleaned.

Caution

Do not leave the transducer in a sealed container for long periods of time.

To transport a clean transducer

A clean transducer is one that has completed the cleaning and disinfection process, has been stored properly, and is ready to be used in an examination.

- 1 Place the transducer in a clean, approved container. To identify the transducer as clean, containers used to transport clean transducers should carry a cleanliness verification sticker or certificate.
- 2 Transport the transducer in the container to the point of use. Do not open the container until the transducer is ready to be used.

To ship a transducer

WARNING

Whenever possible, avoid shipping a contaminated transducer. Before shipping, ensure the transducer has been cleaned and disinfected using the steps detailed in this chapter or according to special instructions received from FUJIFILM SonoSite. If you are returning the transducer to FUJIFILM SonoSite, document the disinfection on a "Declaration of Cleanliness," and attach it to the packing list.

- 1 Place the transducer in the shipping container and seal it. Do not allow any part of the transducer to protrude from the container.
- 2 Ship the transducer using the following precautions:
 - ▶ Clearly label the container as fragile.
 - ▶ Do not stack items on top of the shipping container.

- ▶ Do not exceed the shipping temperature range: -35° C (-31° F) to +65° C (149° F).
- ▶ Do not open the shipping container until it reaches its final destination.
- ▶ After arrival, the transducer must be cleaned and disinfected before it can be used in an exam.

Compatible cleaners and disinfectants (system and transducers)

Table 7-2: Cleaners and disinfectants compatible with SonoSite SII system and transducers

Disinfectants	SonoSite SII System	SonoSite SII Stand	C11x	HFL38xi	HFL50x	HSL25x	ICTx	L25x	L38xi	L52x	P10x	P11x	rC60xi	rP19x
Accel Intervention Wipes										✓				
Accel TB Wipes	✓	✓					✓							
Airkem A-33			✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Alcohol-Ethanol		✓		✓	✓	✓	✓	✓		✓			✓	✓
Alcohol-Isopropanol		✓												
Anios Wipes					✓		✓			✓				
Aniosyme DD1- 5%	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Asepti HB	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Asepti Wipe II	✓	✓												
Baxedin Pre-Op			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Carpe Diem TB Wipes					✓									
Caviwipes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Table 7-2: Cleaners and disinfectants compatible with SonoSite SII system and transducers

Disinfectants	SonoSite SII System	SonoSite SII Stand	C11x	HFL38xi	HFL50x	HSL25x	ICTx	L25x	L38xi	L52x	P10x	P11x	rC60xi	rP19x
Cidalkan	✓											✓		
Cidalkan Lingettes		✓										✓		
Clinell Universal Sanitising Wipes			✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓
Clorox Germicidal Wipes			✓	✓	✓	✓	✓	✓	✓		✓		✓	✓
Clorox Hydrogen Peroxide Wipes		✓												
Control III												✓		
Coverage Germicidal Surface Wipes	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Coverage Plus Germicidal Surface Wipes	✓			✓	✓	✓	✓		✓	✓	✓	✓	✓	✓
Coverage Spray				✓		✓							✓	✓
Coverage Spray TB				✓	✓	✓	✓		✓		✓		✓	✓
DisCide Ultra Disinfecting Towelettes												✓		
Dynacide PA		✓	✓	✓		✓		✓	✓		✓	✓	✓	✓
Echo Clean lingettes	✓				✓		✓			✓				
End Bac II					✓					✓				

Table 7-2: Cleaners and disinfectants compatible with SonoSite SII system and transducers

Disinfectants	SonoSite SII System	SonoSite SII Stand	C11x	HFL38xi	HFL50x	HSL25x	ICTx	L25x	L38xi	L52x	P10x	P11x	rC60xi	rP19x
Endosporine	✓		✓	✓	✓	✓		✓	✓		✓	✓	✓	✓
Envirocide	✓	✓		✓		✓	✓						✓	✓
Gluko Chlor Wipes			✓	✓	✓	✓		✓	✓	✓	✓		✓	✓
Hydrogen Peroxide 3%	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Incidin Plus 1%			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Incidin Plus 3%	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Madacide-1				✓	✓	✓	✓		✓	✓	✓		✓	✓
Medzyme	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Meliseptol Wipes Sensitive	✓													
MetriSponge			✓	✓	✓	✓		✓	✓	✓	✓		✓	✓
MetriZyme												✓		
Mikrobac Forte 2%				✓	✓	✓	✓		✓	✓	✓	✓	✓	✓
Mikrobac Tissues	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mikrozid Sensitive Wipes	✓			✓		✓	✓							✓
Oxivir TB Wipes	✓				✓									
Percept RTU Wipes			✓	✓	✓	✓		✓	✓	✓	✓		✓	✓

Table 7-2: Cleaners and disinfectants compatible with SonoSite SII system and transducers

Disinfectants	SonoSite SII System	SonoSite SII Stand	C11x	HFL38xi	HFL50x	HSL25x	ICTx	L25x	L38xi	L52x	P10x	P11x	rC60xi	rP19x
PI-Spray				✓	✓	✓	✓		✓	✓	✓		✓	✓
PI-Spray II	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Protex Spray	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Protex Wipes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Rely+On Perasafe	✓						✓			✓				
Reynard Neutral Detergent Wipes				✓		✓								✓
Reynard Surface Disinfection Wipes	✓			✓		✓								✓
Sani-Cloth AF		✓			✓					✓				
Sani-Cloth AF3	✓	✓	✓	✓	✓	✓		✓	✓		✓	✓	✓	✓
Sani-Cloth Active Wipes	✓													
Sani-Cloth Bleach Wipes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sani-Cloth HB	✓			✓	✓	✓	✓		✓	✓	✓	✓	✓	✓
Sani-Cloth Plus	✓	✓			✓		✓			✓				
Simple Chlor												✓		
SONO Ultrasound Wipes	✓			✓		✓								✓
Staphene					✓					✓				

Table 7-2: Cleaners and disinfectants compatible with SonoSite SII system and transducers

Disinfectants	SonoSite SII System	SonoSite SII Stand	C11x	HFL38xi	HFL50x	HSL25x	ICTx	L25x	L38xi	L52x	P10x	P11x	rC60xi	rP19x
Steranios 2%			✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Steranios 20%							✓							
Super Sanicloth	✓											✓		
Trigene Advance Wipes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tristel Solo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tristel Wipes												✓		
Tuffie 5 Wipes	✓			✓		✓								✓
Virex II 256		✓	✓	✓	✓	✓		✓		✓		✓	✓	✓
Virex TB				✓	✓	✓				✓			✓	✓
Virox 5 RTU Wipes	✓	✓	✓	✓		✓		✓	✓	✓	✓	✓	✓	✓
Wet Task Wipes			✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Wex-Cide	✓						✓					✓		
Wipes Plus Disinfecting Wipes	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Wood Wyant Ultra Wipes												✓		

Compatible cleaners and disinfectants (system accessories)

Table 7-3: Cleaners and disinfectants compatible with SonoSite SII system accessories

Disinfectants	Power Supply	PowerPark	PowerPack	ECG Cable
Accel Prevention Wipes		✓		
Airkem A-33	✓		✓	
Alcohol - Isopropyl				✓
Anios Wipes	✓		✓	
Anioxy Twin		✓		
Aniosyme DD1- 5%	✓		✓	
Anioxide 1000	✓		✓	
Asepti HB	✓		✓	✓
Asepti Steryl	✓		✓	
Asepti Wipe II	✓		✓	
Bacoban		✓		
Bacoban WB		✓		
Baxedin Pre-Op		✓	✓	
Carpe Diem TB Wipes			✓	
Caviwipes	✓		✓	✓
Cidalkan	✓		✓	

Table 7-3: Cleaners and disinfectants compatible with SonoSite SII system accessories

Disinfectants	Power Supply	PowerPark	PowerPack	ECG Cable
Cidalkan Lingettes	✓	✓		
Cleanisept Wipes		✓		
Clinell Universal Sanitising Wipes	✓		✓	
Clorox Germicidal Wipes	✓	✓	✓	
Clorox Hydrogen Peroxide Wipes			✓	
Control III	✓		✓	
Coverage Germicidal Surface Wipes	✓	✓		
Coverage Plus Germicidal Surface Wipes	✓			
Coverage Spray			✓	
Coverage Spray TB			✓	
DisCide Ultra Disinfecting Towlettes	✓		✓	
Dispatch Wipes		✓		
Dynacide PA	✓		✓	
Echo Clean lingettes	✓		✓	✓
End Bac II	✓		✓	
Endosporine	✓		✓	

Table 7-3: Cleaners and disinfectants compatible with SonoSite SII system accessories

Disinfectants	Power Supply	PowerPark	PowerPack	ECG Cable
Envirocide	✓		✓	
Gluko Chlor Wipes	✓		✓	
Hydrogen Peroxide 3%	✓		✓	✓
Incidin Plus 1%	✓		✓	
Incidin Plus 3%	✓		✓	
Kodan Tucher		✓		
Korsolex Extra		✓		
Medzyme	✓		✓	
Metrisponge		✓		
Metrizyme		✓		
Mikrobac Forte 2%			✓	
Mikrobac Tissues			✓	
Mikrozid Tucher		✓		
Oxivir TB Wipes		✓	✓	
Percept RTU Wipes	✓		✓	
PI-Spray	✓		✓	
PI-Spray II	✓		✓	

Table 7-3: Cleaners and disinfectants compatible with SonoSite SII system accessories

Disinfectants	Power Supply	PowerPark	PowerPack	ECG Cable
Protex Spray			✓	
Protex Wipes			✓	
Rely+On Perasafe			✓	
Sani-Cloth AF			✓	
Sani-Cloth AF3		✓	✓	
Sani-Cloth Bleach Wipes	✓		✓	
Sani-Cloth HB	✓		✓	✓
Sani-Cloth Plus	✓		✓	✓
Sekusept		✓		
Simple Chlor		✓		✓
Staphene	✓		✓	
Steranios 2%	✓		✓	✓
Steranios 20%	✓		✓	
Super Sani-Cloth	✓			✓
Trigene Advance Wipes	✓	✓		
Tristel Duo		✓		
Tristel Solo	✓		✓	

Table 7-3: Cleaners and disinfectants compatible with SonoSite SII system accessories

Disinfectants	Power Supply	PowerPark	PowerPack	ECG Cable
Tristel Wipes	✓			
Virex II 256		✓	✓	✓
Virex TB	✓		✓	
Virox 5 RTU Wipes			✓	✓
Wet Task Wipes	✓	✓	✓	
Wet Wipe Disinfection		✓		
Wex-Cide			✓	
Wipes Plus Disinfecting Wipes	✓		✓	

Compatible high-level disinfectants (transducers)

Table 7-4: High-level disinfectants compatible with SonoSite SII transducers

High-level Disinfectants	C11x	HFL38xi	HFL50x	HSL25x	ICTx	L25x	L38xi	L52x	P10x	P11x	rC60xi	rP19x
Cidex	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Cidex OPA	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Metricide OPA Plus	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Nanosonics Trophon EPR	✓	✓	✓	✓	✓	✓	✓		✓		✓	✓
Cidex Plus	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

CHAPTER 8

Cleaning and disinfecting the FC1 ultrasound system

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This chapter contains instructions for cleaning and disinfecting the FC1 ultrasound system, transducers and accessories. Use the FUJIFILM SonoSite recommendations when cleaning or disinfecting your ultrasound system, transducer, and accessories. Use the cleaning recommendations in the component manufacturer’s instructions when cleaning or disinfecting your components.

The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.

See www.sonosite.com/transducers for images of transducers.

Also included is a listing of disinfectants that SonoSite has tested and deemed compatible with the FC1 system, transducers, and accessories. This information is presented in the following tables.

- ▶ **Table 8-2, “Cleaners and disinfectants compatible with FC1 system and transducers”** on page 138 shows compatibility between disinfectants, the system, and transducers.
- ▶ **Table 8-3, “Cleaners and disinfectants compatible with FC1 system accessories”** on page 142 shows compatibility between disinfectants and accessories.

- ▶ **Table 8-4, “High-level disinfectants compatible with FC1 transducers”** on page 146 shows compatibility between high-level disinfectants and transducers.

Note

The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.

Before getting started

- ▶ Follow the disinfectant manufacturer’s recommendations regarding appropriate personal protective equipment (PPE), such as protective eyewear and gloves.
- ▶ Inspect the system and transducer to determine that they are free of any unacceptable deterioration, such as corrosion, discoloration, pitting, or cracked seals. If damage is evident, discontinue use, and contact FUJIFILM SonoSite or your local representative.
- ▶ Confirm that cleaning and disinfecting materials are appropriate for your facility’s use. FUJIFILM SonoSite tests cleaners and disinfectants for use with the FUJIFILM SonoSite systems and transducers.
- ▶ Disinfectants and cleaning methods listed in this chapter are recommended by FUJIFILM SonoSite for material compatibility with the products.
- ▶ Ensure that the disinfectant type and the solution strength and duration are appropriate for the equipment and application.
- ▶ Follow manufacturer recommendations and local regulations, when preparing, using and disposing of chemicals.

WARNING

- ▶ Ensure that cleaning and disinfecting solutions and wipes are not expired.
- ▶ Some cleaners and disinfectants can cause an allergic reaction to some individuals.

Caution

- ▶ Do not allow cleaning solution or disinfectant into the system connectors, or transducer connector.
- ▶ Do not use strong solvents such as thinner or benzene, or abrasive cleansers, since these will damage the exterior surfaces. Use only FUJIFILM SonoSite recommended cleaners or disinfectants.

Cleaning and disinfecting

Determining the required cleaning and disinfecting level

WARNING

The cleaning instructions contained in this chapter are based on requirements mandated by the American Food and Drug Administration (FDA). Failure to follow these instructions may result in cross contamination and patient infection.

The level of cleaning and disinfecting required for the system is dictated by the type of tissue it contacts during use. Use **Table 8-1, “Choosing a cleaning and disinfecting method”** on page 129 to determine the level of cleaning and disinfecting required.

Table 8-1: Choosing a cleaning and disinfecting method

Did any part of the system or transducer come in contact with broken skin, blood, mucosal membranes, or bodily fluids?	
YES	Came in contact with broken skin, blood, mucosal membranes, or bodily fluids. 
OR	
NO	Did not come in contact with broken skin, blood, or bodily fluids. 
Option A Go to “Clean and disinfect system and transducer to a high level (semi-critical uses)” on page 130.	
Option B Go to “Clean and disinfect system and transducer to a low level (non-critical uses)” on page 134.	

Spaulding classifications

Spaulding classifications (non-critical, semi-critical) determine the approach for cleaning and disinfecting medical equipment based on the device, the way it has been used, and the risk of infection. The system and transducers are designed for use within the Spaulding classifications of non-critical and semi-critical uses.

Option **A** Clean and disinfect system and transducer to a high level (semi-critical uses)

Use this procedure to clean and high-level disinfect the ultrasound system and transducer **whenever it has come into contact with blood, broken skin, mucosal membranes, or bodily fluids.**

Follow the manufacturer's instructions when using cleaners and disinfectants. The cleaners and disinfectants listed in the procedure are chemically compatible with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

WARNING

- ▶ To avoid electrical shock, before cleaning, disconnect the system from the power supply.
- ▶ Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as eyewear and gloves.

Caution

- ▶ Do not skip any steps or abbreviate the cleaning and disinfecting process in any way.
- ▶ Do not spray cleaners or disinfectants directly on the system surfaces or on system and transducer connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- ▶ Do not attempt to disinfect a transducer or transducer cable using a method or chemical that is not included here. This can damage the transducer and void the warranty.
- ▶ Use only FUJIFILM SonoSite recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage the System and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.

Note

- ▶ You must clean and disinfect both the ultrasound system and the transducer after each use, but only the transducer can be disinfected to a high level.
- ▶ For the purposes of cleaning and disinfecting, the battery should be considered as part of the ultrasound system, and not an accessory.

Cleaning and disinfecting the system and transducer (semi-critical)

To clean and disinfect the system and transducer

- 1 Turn off** the system by pressing the **Power button**.
- 2 Unplug** the power cord from the outlet.
- 3** Remove the disposable transducer sheath, if applicable.

4 Disconnect the transducer from the system. Temporarily place it where it will not cross-contaminate clean equipment or surfaces while you clean the ultrasound console.

5 Clean the exterior surfaces of the **ULTRASOUND SYSTEM** to remove any debris or bodily fluids. Use the following procedure:

a Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 8-2, "Cleaners and disinfectants compatible with FC1 system and transducers"** on page 138.

b Remove all gel, debris, and bodily fluids from the system.

c With a new wipe, clean the system, including the display, by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.

d Observe the minimum wet contact time recommended by the manufacturer. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.

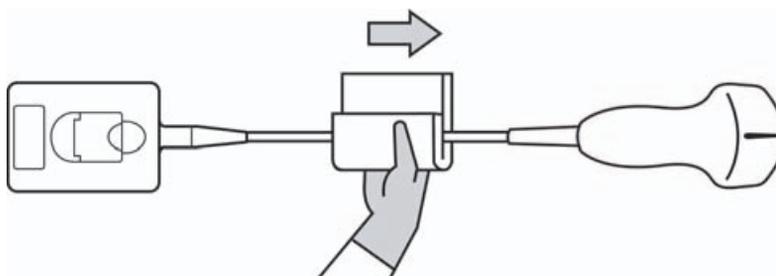
e Allow the ultrasound console to air dry in a clean, well-ventilated space.

6 Clean the **TRANSDUCER CABLE AND BODY** to remove any debris or bodily fluids. Use the following procedure:

a Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 8-2, "Cleaners and disinfectants compatible with FC1 system and transducers"** on page 138.

b Remove all gel, debris, and bodily fluids from the transducer.

c With a new wipe, clean the cable and transducer, starting from the cable, wiping toward the scanhead. This method helps to avoid cross-contamination.



Caution

Do not allow moisture near the electronic components of the connector.

d Observe the minimum wet contact time recommended by the manufacturer. Monitor the transducer for wet appearance. Re-apply with a new wipe if no longer wet.

7 Verify that all gel, debris, and bodily fluids have been removed from the system and transducer. If necessary, repeat steps 5 & 6 with a new wipe.

WARNING

Failure to remove all gel, debris, and bodily fluid could leave contaminants on the probe.

8 Prepare the disinfectant for use.

- a** Choose a high-level disinfectant from **Table 8-4, “High-level disinfectants compatible with FC1 transducers”** on page 146.
- b** Check the expiration date on the bottle to ensure the disinfectant has not expired.
- c** Mix or check that the disinfection chemicals have the concentration recommended by the manufacturer (for example, a chemical strip test).
- d** Check that the temperature of the disinfectant is within the manufacturer’s recommended limits.

9 Perform a high-level disinfection of the transducer. Use the following procedure:

- a** Immerse the transducer in a high-level disinfectant solution. See the chemical manufacturer’s recommendations for soak time.

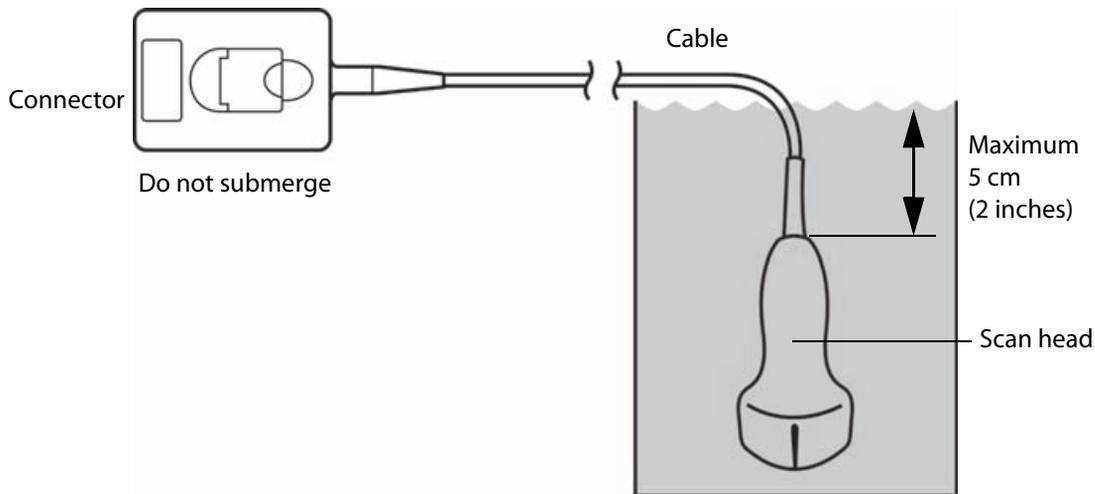
WARNING

High-level disinfectants can cause harm to the patient if not completely removed from the transducer. Follow the manufacturer’s rinse instructions to remove chemical residue.

Cautions

- ▶ Do not soak the transducer longer than recommended by the chemical manufacturer.
- ▶ Do not immerse the transducer connector in any disinfectant solution.
- ▶ Use only FUJIFILM SonoSite recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage or discolor the transducer and void the warranty.

- b** Ensure that the connector and most of the cable remain out of the fluid. You may submerge 2 inches (5 cm) of the cable proximal to the transducer scanhead.



10 Rinse the transducer **3 separate times** using the following procedure:

- a** Rinse the transducer in clean, running water according to the disinfectant manufacturer's instructions (at least 1 minute).
- b** Ensure that the connector and at least 12-18 inches (31-46 cm) of the cable from the connector remain dry.
- c** Repeat this step until the transducer has been rinsed 3 separate times.

11 Dry the transducer with a sterile, lint-free cloth.

12 Dispose of the disinfectant according to the manufacturer's guidelines.

13 Examine the transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, discontinue use of the transducer, and contact FUJIFILM SonoSite or your local representative.

Option **B** Clean and disinfect system and transducer to a low level (non-critical uses)

Use the following procedure to clean and disinfect the ultrasound system and transducer **if it has not come into contact with blood, broken skin, mucosal membranes, or bodily fluids.**

WARNING

If the system or transducer has come into contact with any of the following, use the high-level cleaning and disinfection procedure. See Option A, “**Clean and disinfect system and transducer to a high level (semi-critical uses)**” on page 130:

- ▶ Blood
- ▶ Broken skin
- ▶ Mucosal membranes
- ▶ Bodily fluids

Follow the manufacturer's instructions when using cleaners and disinfectants. The materials listed in the table below are chemically compatible with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

WARNING

- ▶ To avoid electrical shock, before cleaning, disconnect the system from the power supply.
- ▶ Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as eyewear and gloves.

Caution

- ▶ Do not spray cleaners or disinfectants directly on the system surfaces or on system and transducer connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- ▶ Use only FUJIFILM SonoSite-recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage the System and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.
- ▶ Do not attempt to disinfect a transducer or transducer cable using a method or chemical that is not included here. Doing so can damage the transducer and void the warranty.

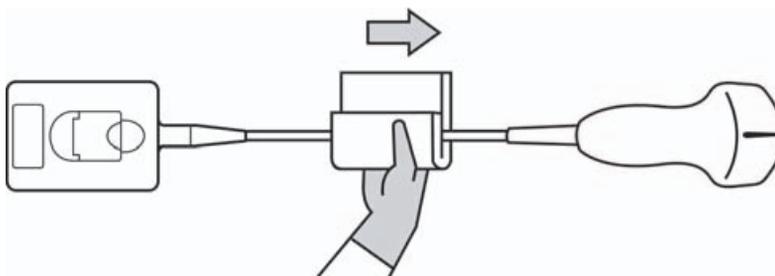
Note

For the purposes of cleaning and disinfecting, the battery should be considered as part of the ultrasound system, and not an accessory.

Cleaning and disinfecting the system and transducer (non-critical)

To clean and disinfect the system and transducer

- 1 **Turn off** the system by pressing the **Power button**.
- 2 **Unplug** the power cord from the outlet.
- 3 Remove the transducer sheath, if applicable.
- 4 **Disconnect** the transducer from the system. Temporarily place it where it will not cross-contaminate clean equipment or surfaces while you clean the ultrasound console.
- 5 **Clean** the exterior surfaces of the **ULTRASOUND SYSTEM** to remove any debris or bodily fluids. Use the following procedure:
 - a Use either a premoistened wipe or a soft cloth dampened with cleaner and disinfectant. Choose a cleaner from **Table 8-2, "Cleaners and disinfectants compatible with FC1 system and transducers"** on page 138.
 - b Remove all gel, debris, and bodily fluids from the system.
 - c With a new wipe, clean the system, including the display, by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.
 - d Observe the minimum wet contact time recommended by the manufacturer. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.
- 6 **Clean** the **TRANSDUCER CABLE AND BODY** to remove any debris or bodily fluids. Use the following procedure:
 - a Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 8-2, "Cleaners and disinfectants compatible with FC1 system and transducers"** on page 138.
 - b Remove all gel, debris, and bodily fluids from the transducer.
 - c With a new wipe, clean the cable and transducer, starting from the cable, wiping toward the scanhead. This method helps to avoid cross-contamination.



Caution

Do not allow moisture near the electronic components of the connector.

- d** Observe the minimum wet contact time. Monitor the transducer for wet appearance. Re-apply with a new wipe if no longer wet.
- 7 Verify** that all gel, debris, and bodily fluids have been removed from the system and transducer. If necessary, repeat steps 5 and 6 with a new wipe.
 - 8 Allow** the ultrasound system, including the console and transducer, to air dry in a clean, well-ventilated space.
 - 9 Examine** the system, transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, do not use. Instead, contact FUJIFILM SonoSite or your local representative.

Storing the transducer

To store the transducer

- 1** Make sure the transducer has been cleaned and disinfected as detailed in this chapter.
- 2** Store the transducer so that it hangs freely and vertically, and observe the following precautions:
 - ▶ Store the transducer away from any contaminated transducers.
 - ▶ Store the transducer in an environment that is safe and has good airflow. Do not store the transducer in closed containers or where condensation may occur.
 - ▶ Avoid direct sunlight and exposure to x-rays. Recommended storage temperature range is between 0° C (32° F) and +45° C (113° F).
 - ▶ If using a wall-mounted rack for storage, ensure that:
 - ▶ It is securely mounted.
 - ▶ The storage slots do not mar the transducer or cause damage to the cable.
 - ▶ The rack is sized and positioned to prevent the transducer from inadvertently falling.
 - ▶ Make sure the connector is supported and secure.

Transporting the transducer

When transporting the transducer, you must take precautions to protect the transducer from damage and avoid cross-contamination. Be sure to use a container approved by your organization.

To transport a soiled transducer for cleaning

A soiled transducer is one that has been contaminated and must be cleaned before using it in an exam.

- 1 Place the transducer in a clean, approved container.

WARNING

To prevent cross-contamination or unprotected exposure of personnel to biological material, containers used to transport contaminated transducers should carry an ISO biohazard label similar to the following:



Caution

Ensure the transducer is dry before placing it in a closed container. Condensation from a damp transducer can damage the connector.

- 2 Transport the transducer in the container to the point of processing. Do not open the container until the transducer is ready to be cleaned.

Caution

Do not leave the transducer in a sealed container for long periods of time.

To transport a clean transducer

A clean transducer is one that has completed the cleaning and disinfection process, has been stored properly, and is ready to be used in an examination.

- 1 Place the transducer in a clean, approved container. To identify the transducer as clean, containers used to transport clean transducers should carry a cleanliness verification sticker or certificate.
- 2 Transport the transducer in the container to the point of use. Do not open the container until the transducer is ready to be used.

To ship a transducer

WARNING

Whenever possible, avoid shipping a contaminated transducer. Before shipping, ensure the transducer has been cleaned and disinfected using the steps detailed in this chapter or according to special instructions received from FUJIFILM SonoSite. If you are returning the transducer to FUJIFILM SonoSite, document the disinfection on a "Declaration of Cleanliness," and attach it to the packing list.

- 1 Place the transducer in the shipping container and seal it. Do not allow any part of the transducer to protrude from the container.
- 2 Ship the transducer using the following precautions:
 - ▶ Clearly label the container as fragile.
 - ▶ Do not stack items on top of the shipping container.

- ▶ Do not exceed the shipping temperature range: -35° C (-31° F) to +65° C (149° F).
- ▶ Do not open the shipping container until it reaches its final destination.
- ▶ After arrival, the transducer must be cleaned and disinfected before it can be used in an exam.

Compatible cleaners and disinfectants (system and transducers)

Table 8-2: Cleaners and disinfectants compatible with FC1 system and transducers

Disinfectants	FC1 System	FC1 Stand	C11xp	C35xp	C60xf	HFL38xp	HFL50xp	ICTxp	L25xp	L38xp	P21xp
Accel TB Wipes		✓									
Airkem A-33	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Alcohol-Ethanol	✓				✓	✓	✓	✓	✓	✓	✓
Anios Wipes	✓	✓				✓	✓	✓			
Aniosyme DD1- 5%	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Anioxide 1000	✓	✓									
Anioxy-Twin											
Asepti HB	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Asepti Steryl	✓										
Asepti Wipe II	✓	✓									
Baxedin Pre-Op	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓
Carpe Diem TB Wipes						✓	✓	✓			
Caviwipes		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Cidalkan	✓										

Table 8-2: Cleaners and disinfectants compatible with FC1 system and transducers

Disinfectants	FC1 System	FC1 Stand	C11xp	C35xp	C60xf	HFL38xp	HFL50xp	ICTxp	L25xp	L38xp	P21xp
Cidalkan Lingettes	✓										
Clinell Universal Sanitising Wipes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Clorox Germicidal Wipes			✓		✓	✓	✓	✓	✓	✓	✓
Clorox Hydrogen Peroxide Wipes	✓	✓									
Coverage Germicidal Surface Wipes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Coverage Plus Germicidal Surface Wipes				✓	✓	✓	✓	✓	✓	✓	✓
Coverage Spray					✓				✓	✓	✓
Coverage Spray TB		✓			✓	✓	✓	✓	✓	✓	✓
DisCide Ultra Disinfecting Towlettes	✓										
Dynacide PA	✓	✓	✓	✓	✓				✓	✓	✓
Echo Clean lingettes	✓					✓	✓	✓			
End Bac II	✓					✓	✓	✓			
Endosporine	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Envirocide		✓			✓				✓	✓	✓
GlucO Chlor Wipes			✓		✓	✓	✓	✓	✓	✓	✓
Hydrogen Peroxide 3%	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Table 8-2: Cleaners and disinfectants compatible with FC1 system and transducers

Disinfectants	FC1 System	FC1 Stand	C11xp	C35xp	C60xf	HFL38xp	HFL50xp	ICTxp	L25xp	L38xp	P21xp
Incidin Plus 1%	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Incidin Plus 3%		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Madacide-1				✓	✓	✓	✓	✓		✓	✓
Medzyme	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
MetriSponge			✓		✓	✓	✓	✓	✓	✓	✓
MetriZyme	✓										
Mikrobac Forte 2%	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
Mikrobac Tissues	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mikrozid Sensitive Wipes					✓				✓	✓	✓
Oxivir TB Wipes						✓	✓	✓			
Percept RTU Wipes			✓		✓	✓	✓	✓	✓	✓	✓
PI-Spray					✓	✓	✓	✓	✓	✓	✓
PI-Spray II	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Protex Spray	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Protex Wipes		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Rely+On Perasafe		✓		✓							
Reynard Neutral Detergent Wipes					✓				✓	✓	✓

Table 8-2: Cleaners and disinfectants compatible with FC1 system and transducers

Disinfectants	FC1 System	FC1 Stand	C11xp	C35xp	C60xf	HFL38xp	HFL50xp	ICTxp	L25xp	L38xp	P21xp
Reynard Surface Disinfection Wipes					✓				✓	✓	✓
Sani-Cloth AF	✓	✓				✓	✓	✓			
Sani-Cloth AF3	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Sani-Cloth Bleach Wipes	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓
Sani-Cloth HB	✓			✓	✓	✓	✓	✓	✓	✓	✓
Sani-Cloth Plus	✓	✓				✓	✓	✓			
SONO Ultrasound Wipes					✓				✓	✓	✓
Staphene						✓	✓	✓			
Steranios 2%	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Steranios 20%	✓	✓									
Super Sanicloth	✓										
Trigene Advance Wipes	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓
Tristel Solo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tristel Wipes				✓							
Tuffie 5 Wipes					✓				✓	✓	✓
Virex II 256	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Virex TB		✓			✓	✓	✓	✓	✓	✓	✓

Table 8-2: Cleaners and disinfectants compatible with FC1 system and transducers

Disinfectants	FC1 System	FC1 Stand	C11xp	C35xp	C60xf	HFL38xp	HFL50xp	ICTxp	L25xp	L38xp	P21xp
Virox 5 RTU Wipes		✓	✓	✓	✓				✓	✓	✓
Wet Task Wipes			✓		✓	✓	✓	✓	✓	✓	✓
Wex-Cide	✓	✓									
Wipes Plus Disinfecting Wipes			✓		✓	✓	✓	✓	✓	✓	✓
Wood Wyant Ultra Wipes	✓	✓									

Compatible cleaners and disinfectants (system accessories)

Table 8-3: Cleaners and disinfectants compatible with FC1 system accessories

Disinfectants	Power Supply	FC1 TTC	ECG Cable	Dual Foot Switch
Airkem A-33	✓	✓		
Alcohol-Ethanol		✓		
Alcohol - Isopropyl		✓	✓	✓
Anios Wipes	✓	✓		
Aniosyme DD1- 5%	✓			
Anioxide 1000	✓			
Asepti HB	✓	✓	✓	

Table 8-3: Cleaners and disinfectants compatible with FC1 system accessories

Disinfectants	Power Supply	FC1 TTC	ECG Cable	Dual Foot Switch
Asepti Steryl	✓			
Asepti Wipe II	✓	✓		
Baxedin Pre-Op		✓		
Carpe Diem TB Wipes		✓		
Caviwipes	✓	✓	✓	
Cidalkan	✓	✓		
Clinell Universal Sanitising Wipes	✓	✓		
Clorox Germicidal Wipes	✓	✓		
Control III	✓	✓		
Coverage Germicidal Surface Wipes	✓	✓		
Coverage Plus Germicidal Surface Wipes	✓	✓		
Coverage Spray	✓	✓		
DisCide Ultra Disinfecting Towlettes	✓	✓		
Dynacide PA	✓	✓		
Echo Clean lingettes	✓	✓	✓	
End Bac II	✓	✓		

Table 8-3: Cleaners and disinfectants compatible with FC1 system accessories

Disinfectants	Power Supply	FC1 TTC	ECG Cable	Dual Foot Switch
Endosporine	✓			
Envirocide	✓	✓		
Gluco Chlor Wipes	✓	✓		
Hydrogen Peroxide 3%	✓	✓	✓	
Incidin Plus 1%	✓	✓		
Incidin Plus 3%	✓	✓		
Medzyme	✓	✓		
MetriZyme		✓		
Mikrobac Forte 2%		✓		
Mikrobac Tissues		✓		
Percept RTU Wipes	✓			
PI-Spray	✓			
PI-Spray II	✓	✓		
Rely+On Perasafe	✓	✓		
Sani-Cloth AF		✓		
Sani-Cloth Bleach Wipes	✓			

Table 8-3: Cleaners and disinfectants compatible with FC1 system accessories

Disinfectants	Power Supply	FC1 TTC	ECG Cable	Dual Foot Switch
Sani-Cloth HB	✓	✓	✓	
Sani-Cloth Plus	✓	✓	✓	
Simple Chlor		✓	✓	
Staphene	✓	✓		
Steranios 2%	✓	✓	✓	
Steranios 20%	✓			
Super Sani-Cloth	✓	✓	✓	
Trigene Advance Wipes	✓	✓		
Tristel Solo	✓	✓		
Tristel Wipes	✓	✓		
Virex II 256		✓	✓	
Virex TB	✓	✓		
Virox 5 RTU Wipes	✓	✓	✓	
Wet Task Wipes	✓	✓		
Wex-Cide	✓	✓		
Wipes Plus Disinfecting Wipes	✓	✓		

Table 8-3: Cleaners and disinfectants compatible with FC1 system accessories

Disinfectants	Power Supply	FC1 TTC	ECG Cable	Dual Foot Switch
Wood Wyant Ultra Wipes		✓		

Compatible high-level disinfectants (transducers)

Table 8-4: High-level disinfectants compatible with FC1 transducers

High-level Disinfectants	C11xp	C60xf	HFL38xp	HFL50xp	ICTxp	L25xp	L38xp	P21x
Cidex	✓	✓	✓	✓	✓	✓	✓	✓
Cidex OPA	✓	✓	✓	✓	✓	✓	✓	✓
Metricide OPA Plus	✓	✓	✓	✓	✓	✓	✓	✓
Nanosonics Trophon EPR	✓	✓	✓	✓	✓	✓	✓	✓
Cidex Plus	✓	✓	✓	✓	✓	✓	✓	✓

CHAPTER 9

Cleaning and disinfecting the M-Turbo ultrasound system

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This chapter contains instructions for cleaning and disinfecting the M-Turbo ultrasound system, transducers, and accessories. Use the FUJIFILM SonoSite recommendations when cleaning or disinfecting your ultrasound system, transducer, and accessories. Use the cleaning recommendations in the component manufacturer’s instructions when cleaning or disinfecting your components.

The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.

See www.sonosite.com/transducers for images of transducers.

Also included is a listing of disinfectants that SonoSite has tested and deemed compatible with the M-Turbo system, transducers, and accessories. This information is presented in the following tables.

- ▶ **Table 9-2, “Cleaners and disinfectants compatible with M-Turbo system and transducers”** on page 158 shows compatibility between disinfectants, the system, and transducers.
- ▶ **Table 9-3, “Cleaners and disinfectants compatible with M-Turbo system accessories”** on page 162 shows compatibility between disinfectants and accessories.

- ▶ **Table 9-4, “High-level disinfectants compatible with M-Turbo transducers”** on page 167 shows compatibility between high-level disinfectants and transducers.

Note

- ▶ The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.
- ▶ For cleaning the TEE_{Ex} transducer, refer to the cleaning and disinfection instructions in the *TEE_{Ex} User Guide*.
- ▶ For cleaning the TEE_{Xi} transducer, refer to the cleaning and disinfection instructions in the *TEE_{Xi} User Guide*.

Before getting started

- ▶ Follow the disinfectant manufacturer’s recommendations regarding appropriate personal protective equipment (PPE), such as protective eyewear and gloves.
- ▶ Inspect the system and transducer to determine that they are free of any unacceptable deterioration, such as corrosion, discoloration, pitting, or cracked seals. If damage is evident, discontinue use, and contact FUJIFILM SonoSite or your local representative.
- ▶ Confirm that cleaning and disinfecting materials are appropriate for your facility’s use. FUJIFILM SonoSite tests cleaners and disinfectants for use with the FUJIFILM SonoSite systems and transducers.
- ▶ Disinfectants and cleaning methods listed in this chapter are recommended by FUJIFILM SonoSite for material compatibility with the products.
- ▶ Ensure that the disinfectant type and the solution strength and duration are appropriate for the equipment and application.
- ▶ Follow manufacturer recommendations and local regulations, when preparing, using and disposing of chemicals.

WARNING

- ▶ Ensure that cleaning and disinfecting solutions and wipes are not expired.
- ▶ Some cleaners and disinfectants can cause an allergic reaction to some individuals.

Caution

- ▶ Do not allow cleaning solution or disinfectant into the system connectors, or transducer connector.
- ▶ Do not use strong solvents such as thinner or benzene, or abrasive cleansers, since these will damage the exterior surfaces. Use only FUJIFILM SonoSite recommended cleaners or disinfectants.

Cleaning and disinfecting

Determining the required cleaning and disinfecting level

WARNING

The cleaning instructions contained in this chapter are based on requirements mandated by the American Food and Drug Administration (FDA). Failure to follow these instructions may result in cross contamination and patient infection.

The level of cleaning and disinfecting required for the system is dictated by the type of tissue it contacts during use. Use **Table 9-1, “Choosing a cleaning and disinfecting method”** to determine the level of cleaning and disinfecting required.

Table 9-1: Choosing a cleaning and disinfecting method

Did any part of the system or transducer come in contact with broken skin, blood, mucosal membranes, or bodily fluids?	
YES	Came in contact with broken skin, blood, mucosal membranes, or bodily fluids. 
OR	
NO	Did not come in contact with broken skin, blood, or bodily fluids. 
Option A Go to “Clean and disinfect system and transducer to a high level (semi-critical uses)” on page 150.	
Option B Go to “Clean and disinfect system and transducer to a low level (non-critical uses)” on page 154.	

Spaulding classifications

Spaulding classifications (non-critical, semi-critical) determine the approach for cleaning and disinfecting medical equipment based on the device, the way it has been used, and the risk of infection. The system and transducers are designed for use within the Spaulding classifications of non-critical and semi-critical uses.

Option **A** Clean and disinfect system and transducer to a high level (semi-critical uses)

Use this procedure to clean and high-level disinfect the ultrasound system and transducer **whenever it has come into contact with blood, broken skin, mucosal membranes, or bodily fluids.**

Follow the manufacturer's instructions when using cleaners and disinfectants. The cleaners and disinfectants listed in the procedure are chemically compatible with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

WARNING

- ▶ To avoid electrical shock, before cleaning, disconnect the system from the power supply.
- ▶ Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as eyewear and gloves.

Caution

- ▶ Do not skip any steps or abbreviate the cleaning and disinfecting process in any way.
- ▶ Do not spray cleaners or disinfectants directly on the system surfaces or on system and transducer connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- ▶ Do not attempt to disinfect a transducer or transducer cable using a method or chemical that is not included here. This can damage the transducer and void the warranty.
- ▶ Use only FUJIFILM SonoSite recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage the System and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.

Note

- ▶ You must clean and disinfect both the ultrasound system and the transducer after each use, but only the transducer can be disinfected to a high level.
- ▶ For the purposes of cleaning and disinfecting, the battery should be considered as part of the ultrasound system, and not an accessory.

Cleaning and disinfecting the system and transducer (semi-critical)

To clean and disinfect the system and transducer

- 1 Turn off** the system by pressing the **Power button**.
- 2 Unplug** the power cord from the outlet.
- 3** Remove the disposable transducer sheath, if applicable.

4 Disconnect the transducer from the system. Temporarily place it where it will not cross-contaminate clean equipment or surfaces while you clean the ultrasound console.

5 Clean the exterior surfaces of the **ULTRASOUND SYSTEM** to remove any debris or bodily fluids. Use the following procedure:

a Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 9-2, "Cleaners and disinfectants compatible with M-Turbo system and transducers"** on page 158.

b Remove all gel, debris, and bodily fluids from the system.

c With a new wipe, clean the system, including the display, by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.

d Observe the minimum wet contact time recommended by the manufacturer. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.

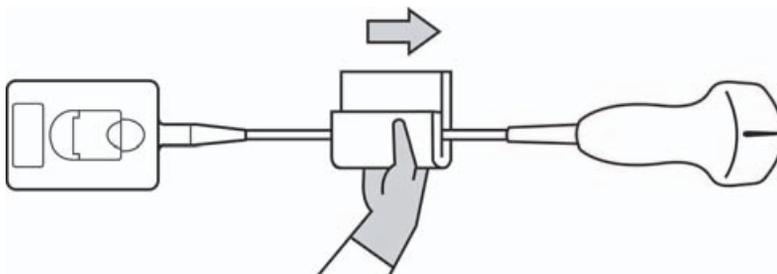
e Allow the ultrasound console to air dry in a clean, well-ventilated space.

6 Clean the TRANSDUCER CABLE AND BODY to remove any debris or bodily fluids. Use the following procedure:

a Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 9-2, "Cleaners and disinfectants compatible with M-Turbo system and transducers"** on page 158.

b Remove all gel, debris, and bodily fluids from the transducer.

c With a new wipe, clean the cable and transducer, starting from the cable, wiping toward the scanhead. This method helps to avoid cross-contamination.



Caution | Do not allow moisture near the electronic components of the connector.

d Observe the minimum wet contact time recommended by the manufacturer. Monitor the transducer for wet appearance. Re-apply with a new wipe if no longer wet.

7 Verify that all gel, debris, and bodily fluids have been removed from the system and transducer. If necessary, repeat steps 5 & 6 with a new wipe.

WARNING

Failure to remove all gel, debris, and bodily fluid could leave contaminants on the probe.

8 Prepare the disinfectant for use.

- a** Choose a high-level disinfectant from **Table 9-4, “High-level disinfectants compatible with M-Turbo transducers”** on page 167.
- b** Check the expiration date on the bottle to ensure the disinfectant has not expired.
- c** Mix or check that the disinfection chemicals have the concentration recommended by the manufacturer (for example, a chemical strip test).
- d** Check that the temperature of the disinfectant is within the manufacturer’s recommended limits.

9 Perform a high-level disinfection of the transducer. Use the following procedure:

- a** Immerse the transducer in a high-level disinfectant solution. See the chemical manufacturer’s recommendations for soak time.

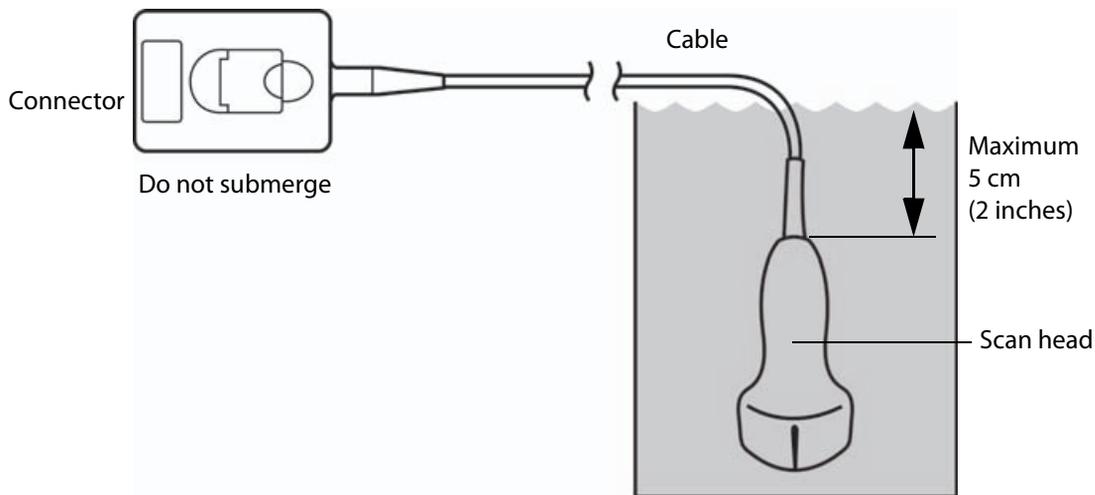
WARNING

High-level disinfectants can cause harm to the patient if not completely removed from the transducer. Follow the manufacturer’s rinse instructions to remove chemical residue.

Cautions

- ▶ Do not soak the transducer longer than recommended by the chemical manufacturer.
- ▶ Do not immerse the transducer connector in any disinfectant solution.
- ▶ Use only FUJIFILM SonoSite recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage or discolor the transducer and void the warranty.

- b** Ensure that the connector and most of the cable remain out of the fluid. You may submerge 2 inches (5 cm) of the cable proximal to the transducer scanhead.



10 Rinse the transducer **3 separate times** using the following procedure:

- a** Rinse the transducer in clean, running water according to the disinfectant manufacturer's instructions (at least 1 minute).
- b** Ensure that the connector and at least 12-18 inches (31-46 cm) of the cable from the connector remain dry.
- c** Repeat this step until the transducer has been rinsed 3 separate times.

11 Dry the transducer with a sterile, lint-free cloth.

12 Dispose of the disinfectant according to the manufacturer's guidelines.

13 Examine the transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, discontinue use, and contact FUJIFILM SonoSite or your local representative.

Option **B** Clean and disinfect system and transducer to a low level (non-critical uses)

Use the following procedure to clean and disinfect the ultrasound system and transducer **if it has not come into contact with blood, broken skin, mucosal membranes, or bodily fluids.**

WARNING

If the system or transducer has come into contact with any of the following, use the high-level cleaning and disinfection procedure. See Option A, **“Clean and disinfect system and transducer to a high level (semi-critical uses)”** on page 150:

- ▶ Blood
- ▶ Broken skin
- ▶ Mucosal membranes
- ▶ Bodily fluids

Follow the manufacturer's instructions when using cleaners and disinfectants. The materials listed in the table below are chemically compatible with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

WARNING

- ▶ To avoid electrical shock, before cleaning, disconnect the system from the power supply.
- ▶ Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as eyewear and gloves.

Caution

- ▶ Do not spray cleaners or disinfectants directly on the system surfaces or on system and transducer connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- ▶ Use only FUJIFILM SonoSite-recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage the System and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.
- ▶ Do not attempt to disinfect a transducer or transducer cable using a method or chemical that is not included here. Doing so can damage the transducer and void the warranty.

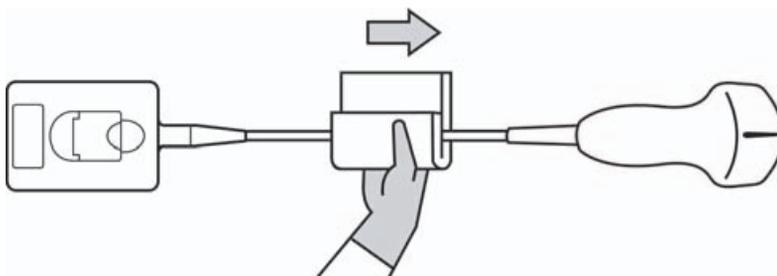
Note

For the purposes of cleaning and disinfecting, the battery should be considered as part of the ultrasound system, and not an accessory.

Cleaning and disinfecting the system and transducer (non-critical)

To clean and disinfect the system and transducer

- 1 **Turn off** the system by pressing the **Power button**.
- 2 **Unplug** the power cord from the outlet.
- 3 Remove the transducer sheath, if applicable.
- 4 **Disconnect** the transducer from the system. Temporarily place it where it will not cross-contaminate clean equipment or surfaces while you clean the ultrasound console.
- 5 **Clean** the exterior surfaces of the **ULTRASOUND CONSOLE** to remove any debris or bodily fluids. Use the following procedure:
 - a Use either a premoistened wipe or a soft cloth dampened with cleaner and disinfectant. Choose a cleaner from **Table 9-2, "Cleaners and disinfectants compatible with M-Turbo system and transducers"** on page 158.
 - b Remove all gel, debris, and bodily fluids from the system.
 - c With a new wipe, clean the system, including the display, by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.
 - d Observe the minimum wet contact time recommended by the manufacturer. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.
- 6 **Clean** the **TRANSDUCER CABLE AND BODY** to remove any debris or bodily fluids. Use the following procedure:
 - a Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 9-2, "Cleaners and disinfectants compatible with M-Turbo system and transducers"** on page 158.
 - b Remove all gel, debris, and bodily fluids from the transducer.
 - c With a new wipe, clean the cable and transducer, starting from the cable, wiping toward the scanhead. This method helps to avoid cross-contamination.



Caution

Do not allow moisture near the electronic components of the connector.

d Observe the minimum wet contact time. Monitor the transducer for wet appearance. Re-apply with a new wipe if no longer wet.

- 7 Verify** that all gel, debris, and bodily fluids have been removed from the system and transducer. If necessary, repeat steps 5 and 6 with a new wipe.
- 8 Allow** the ultrasound system, including the console and transducer, to air dry in a clean, well-ventilated space.
- 9 Examine** the system, transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, do not use the transducer. Instead, contact FUJIFILM SonoSite or your local representative.

Storing the transducer

To store the transducer

- 1** Make sure the transducer has been cleaned and disinfected as detailed in this chapter.
- 2** Store the transducer so that it hangs freely and vertically, and observe the following precautions:
 - ▶ Store the transducer away from any contaminated transducers.
 - ▶ Store the transducer in an environment that is safe and has good airflow. Do not store the transducer in closed containers or where condensation may occur.
 - ▶ Avoid direct sunlight and exposure to x-rays. Recommended storage temperature range is between 0° C (32° F) and +45° C (113° F).
 - ▶ If using a wall-mounted rack for storage, ensure that:
 - ▶ It is securely mounted.
 - ▶ The storage slots do not mar the transducer or cause damage to the cable.
 - ▶ The rack is sized and positioned to prevent the transducer from inadvertently falling.
 - ▶ Make sure the connector is supported and secure.

Transporting the transducer

When transporting the transducer, you must take precautions to protect the transducer from damage and avoid cross-contamination. Be sure to use a container approved by your organization.

To transport a soiled transducer for cleaning

A soiled transducer is one that has been contaminated and must be cleaned before using it in an exam.

- 1 Place the transducer in a clean, approved container.

WARNING

To prevent cross-contamination or unprotected exposure of personnel to biological material, containers used to transport contaminated transducers should carry an ISO biohazard label similar to the following:



Caution

Ensure the transducer is dry before placing it in a closed container. Condensation from a damp transducer can damage the connector.

- 2 Transport the transducer in the container to the point of processing. Do not open the container until the transducer is ready to be cleaned.

Caution

Do not leave the transducer in a sealed container for long periods of time.

To transport a clean transducer

A clean transducer is one that has completed the cleaning and disinfection process, has been stored properly, and is ready to be used in an examination.

- 1 Place the transducer in a clean, approved container. To identify the transducer as clean, containers used to transport clean transducers should carry a cleanliness verification sticker or certificate.
- 2 Transport the transducer in the container to the point of use. Do not open the container until the transducer is ready to be used.

To ship a transducer

WARNING

Whenever possible, avoid shipping a contaminated transducer. Before shipping, ensure the transducer has been cleaned and disinfected using the steps detailed in this chapter or according to special instructions received from FUJIFILM SonoSite. If you are returning the transducer to FUJIFILM SonoSite, document the disinfection on a "Declaration of Cleanliness," and attach it to the packing list.

- 1 Place the transducer in the shipping container and seal it. Do not allow any part of the transducer to protrude from the container.
- 2 Ship the transducer using the following precautions:

- ▶ Clearly label the container as fragile.
- ▶ Do not stack items on top of the shipping container.
- ▶ Do not exceed the shipping temperature range: -35° C (-31° F) to +65° C (149° F).
- ▶ Do not open the shipping container until it reaches its final destination.
- ▶ After arrival, the transducer must be cleaned and disinfected before it can be used in an exam.

Compatible cleaners and disinfectants (system and transducers)

Table 9-2: Cleaners and disinfectants compatible with M-Turbo system and transducers

Disinfectants	M-Turbo System	H-Universal Stand	C8x	C11x	C60x	C60xi	HFL38x	HFL50x	ICTx	L25x	L38x	L38xi	L52x	P10x	P11x	P21x	SLAx
Accel Intervention Wipes													✓				
Accel Prevention Wipes																	
Accel TB Wipes	✓	✓															
Airkem A-33	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Alcohol-Ethanol		✓				✓		✓		✓			✓				
Anios Wipes	✓	✓						✓					✓				
Aniosyme DD1-5%	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Anioxide 1000		✓															
Anioxy-Twin																	
Asepti HB	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Asepti Steryl																	

Table 9-2: Cleaners and disinfectants compatible with M-Turbo system and transducers

Disinfectants	M-Turbo System	H-Universal Stand	C8x	C11x	C60x	C60xi	HFL38x	HFL50x	ICTx	L25x	L38x	L38xi	L52x	P10x	P11x	P21x	SLAx
Asepti Wipe II		✓															
Bacoban	✓																
Bacoban WB	✓																
Baxedin Pre-Op			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Carpe Diem TB Wipes							✓										
Caviwipes		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Cidalkan															✓		
Cidalkan Lingettes		✓													✓		
Cleanisept Wipes	✓																
Clinell Universal Sanitising Wipes		✓		✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓
Clorox Germicidal Wipes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓		✓	✓
Clorox Hydrogen Peroxide Wipes		✓															
Control III		✓													✓		
Coverage Germicidal Surface Wipes		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Coverage Plus Germicidal Surface Wipes			✓		✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓

Table 9-2: Cleaners and disinfectants compatible with M-Turbo system and transducers

Disinfectants	M-Turbo System	H-Universal Stand	C8x	C11x	C60x	C60xi	HFL38x	HFL50x	ICTx	L25x	L38x	L38xi	L52x	P10x	P11x	P21x	SLAX
Coverage Spray		✓				✓											
Coverage Spray TB	✓		✓		✓	✓	✓	✓	✓		✓	✓		✓		✓	✓
DisCide Ultra Disinfecting Towelettes															✓		
Dynacide PA	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓
Echo Clean lingettes	✓							✓					✓				
End Bac II								✓					✓				
Endosporine	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓
Envirocide		✓				✓											
Gluco Chlor Wipes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Hydrogen Peroxide 3%	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Incidin Plus 1%		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Incidin Plus 3%		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Madacide-1			✓		✓	✓	✓	✓			✓	✓	✓	✓		✓	✓
Medzyme	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
MetriSponge			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
MetriZyme															✓		

Table 9-2: Cleaners and disinfectants compatible with M-Turbo system and transducers

Disinfectants	M-Turbo System	H-Universal Stand	C8x	C11x	C60x	C60xi	HFL38x	HFL50x	ICTx	L25x	L38x	L38xi	L52x	P10x	P11x	P21x	SLAX
Mikrobac Forte 2%		✓	✓		✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Mikrobac Tissues		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Oxivir TB Wipes							✓										
Percept RTU Wipes	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
PI-Spray		✓			✓	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓
PI-Spray II	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Protex Spray	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Protex Wipes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Rely+On Perasafe		✓											✓		✓		
Sani-Cloth AF		✓						✓					✓				
Sani-Cloth AF3		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓
Sani-Cloth Bleach Wipes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sani-Cloth HB	✓		✓		✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Sani-Cloth Plus	✓	✓						✓									
Simple Chlor	✓														✓		
Staphene								✓					✓				
Steranios 2%	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Table 9-2: Cleaners and disinfectants compatible with M-Turbo system and transducers

Disinfectants	M-Turbo System	H-Universal Stand	C8x	C11x	C60x	C60xi	HFL38x	HFL50x	ICTx	L25x	L38x	L38xi	L52x	P10x	P11x	P21x	SLAX
Steranios 20%		✓															
Trigene Advance Wipes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tristel Solo		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tristel Wipes	✓														✓		
Virex II 256		✓		✓		✓		✓		✓			✓		✓		
Virex TB		✓				✓		✓					✓				
Virox 5 RTU Wipes		✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓
Wet Task Wipes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Wex-Cide	✓	✓													✓		
Wipes Plus Disinfecting Wipes	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Wood Wyant Ultra Wipes		✓													✓		

Compatible cleaners and disinfectants (system accessories)

Table 9-3: Cleaners and disinfectants compatible with M-Turbo system accessories

Disinfectants	M-Turbo TTC	Footswitch	PowerPack	PowerPark	Power Supply	ECG Cable	Mini-Dock
Accel Intervention Wipes	✓						

Table 9-3: Cleaners and disinfectants compatible with M-Turbo system accessories

Disinfectants	M-Turbo TTC	Footswitch	PowerPack	PowerPark	Power Supply	ECG Cable	Mini-Dock
Accel TB Wipes	✓			✓			
Airkem A-33	✓	✓	✓	✓			✓
Alcohol-Ethanol	✓						
Alcohol - Isopropyl	✓		✓			✓	
Anios Wipes	✓	✓	✓	✓			✓
Aniosyme DD1- 5%	✓	✓	✓	✓			✓
Anioxide 1000	✓	✓	✓	✓			✓
Asepti HB	✓	✓	✓	✓		✓	✓
Asepti Steryl	✓	✓	✓				✓
Asepti Wipe II	✓	✓	✓	✓			✓
Baxedin Pre-Op	✓		✓				✓
Carpe Diem TB Wipes			✓				
Caviwipes	✓	✓	✓	✓		✓	✓
Cidalkan	✓	✓	✓				✓
Cidalkan Lingettes	✓	✓					✓
Clinell Universal Sanitising Wipes	✓	✓	✓	✓			✓
Clorox Germicidal Wipes		✓	✓				✓

Table 9-3: Cleaners and disinfectants compatible with M-Turbo system accessories

Disinfectants	M-Turbo TTC	Footswitch	PowerPack	PowerPark	Power Supply	ECG Cable	Mini-Dock
Clorox Hydrogen Peroxide Wipes	✓	✓	✓	✓			✓
Control III	✓	✓	✓	✓			✓
Coverage Germicidal Surface Wipes	✓	✓	✓				
Coverage Plus Germicidal Surface Wipes	✓	✓	✓				✓
Coverage Spray	✓		✓				✓
Coverage Spray TB	✓		✓				✓
DisCide Ultra Disinfecting Towlettes	✓	✓	✓				✓
Dynacide PA	✓	✓	✓	✓			✓
Echo Clean lingettes	✓	✓	✓	✓		✓	✓
End Bac II	✓	✓	✓				✓
Endosporine	✓	✓	✓	✓			✓
Envirocide	✓	✓	✓	✓			✓
Gluco Chlor Wipes		✓					✓
Hydrogen Peroxide 3%	✓	✓	✓	✓		✓	✓
Incidin Plus 1%	✓	✓	✓	✓			✓
Incidin Plus 3%	✓	✓	✓	✓			✓

Table 9-3: Cleaners and disinfectants compatible with M-Turbo system accessories

Disinfectants	M-Turbo TTC	Footswitch	PowerPack	PowerPark	Power Supply	ECG Cable	Mini-Dock
Medzyme	✓	✓	✓	✓			✓
Mikrobac Forte 2%	✓	✓	✓	✓			
Mikrobac Tissues	✓		✓	✓			✓
Oxivir TB Wipes	✓		✓				✓
Percept RTU Wipes		✓	✓	✓			✓
PI-Spray	✓	✓	✓				✓
PI-Spray II	✓	✓	✓	✓			✓
Protex Spray	✓		✓	✓			
Protex Wipes	✓	✓	✓	✓			
Rely+On Perasafe	✓	✓	✓	✓			✓
Sani-Cloth AF	✓		✓	✓			
Sani-Cloth AF3		✓		✓			
Sani-Cloth Bleach Wipes	✓	✓	✓				✓
Sani-Cloth HB	✓	✓	✓			✓	✓
Sani-Cloth Plus	✓		✓	✓		✓	✓
Simple Chlor	✓		✓	✓		✓	
Staphene	✓	✓	✓				

Table 9-3: Cleaners and disinfectants compatible with M-Turbo system accessories

Disinfectants	M-Turbo TTC	Footswitch	PowerPack	PowerPark	Power Supply	ECG Cable	Mini-Dock
Steranios 2%	✓	✓	✓	✓		✓	✓
Steranios 20%	✓	✓	✓	✓			✓
Super Sani-Cloth	✓	✓	✓	✓			✓
Trigene Advance Wipes	✓	✓	✓				✓
Tristel Solo	✓	✓	✓	✓			✓
Tristel Wipes	✓	✓	✓				✓
Virex II 256	✓		✓			✓	
Virex TB		✓	✓				✓
Virox 5 RTU Wipes	✓		✓	✓		✓	
Wet Task Wipes	✓	✓	✓				✓
Wex-Cide	✓		✓	✓			✓
Wipes Plus Disinfecting Wipes		✓	✓	✓			✓
Wood Wyant Ultra Wipes	✓						✓

Compatible high-level disinfectants (transducers)

Table 9-4: High-level disinfectants compatible with M-Turbo transducers

High-level Disinfectants	C11x	C60x	C60xi	C8x	HFL38x	HFL50x	ICTx	L25x	L38x	L38xi	L52x	P10x	P11x	P21x	SLAx
Cidex	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓		✓	✓
Cidex OPA	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		✓	✓
Metricide OPA Plus	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Nanosonics Trophon EPR	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓		✓	✓
Revital-Ox Resert HLD													✓		
Cidex Plus	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

CHAPTER 10

Cleaning and disinfecting the NanoMaxx ultrasound system

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This chapter contains instructions for cleaning and disinfecting the NanoMaxx ultrasound system, transducers, and accessories. Use the FUJIFILM SonoSite recommendations when cleaning or disinfecting your ultrasound system, transducer, and accessories. Use the cleaning recommendations in the component manufacturer’s instructions when cleaning or disinfecting your components.

The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.

See www.sonosite.com/transducers for images of transducers. Also included is a listing of disinfectants that SonoSite has tested and deemed compatible with the NanoMaxx system, transducers, and accessories.

This information is presented in the following tables.

- ▶ **Table 10-2, “Cleaners and disinfectants compatible with NanoMaxx system and transducers”** on page 180 shows compatibility between disinfectants, the system, and transducers.
- ▶ **Table 10-3, “Cleaners and disinfectants compatible with NanoMaxx system accessories”** on page 184 shows compatibility between disinfectants and accessories.

- ▶ **Table 10-4, “High-level disinfectants compatible with NanoMaxx transducers”** on page 187 shows compatibility between high-level disinfectants and transducers.

Note

The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.

Before getting started

- ▶ Follow the disinfectant manufacturer’s recommendations regarding appropriate personal protective equipment (PPE), such as protective eyewear and gloves.
- ▶ Inspect the system and transducer to determine that they are free of any unacceptable deterioration, such as corrosion, discoloration, pitting, or cracked seals. If damage is evident, discontinue use, and contact FUJIFILM SonoSite or your local representative.
- ▶ Confirm that cleaning and disinfecting materials are appropriate for your facility’s use. FUJIFILM SonoSite tests cleaners and disinfectants for use with the FUJIFILM SonoSite systems and transducers.
- ▶ Disinfectants and cleaning methods listed in this chapter are recommended by FUJIFILM SonoSite for material compatibility with the products.
- ▶ Ensure that the disinfectant type and the solution strength and duration are appropriate for the equipment and application.
- ▶ Follow manufacturer recommendations and local regulations, when preparing, using and disposing of chemicals.

WARNINGS

- ▶ Ensure that cleaning and disinfecting solutions and wipes are not expired.
- ▶ Some cleaners and disinfectants can cause an allergic reaction to some individuals.

Caution

- ▶ Do not allow cleaning solution or disinfectant into the system connectors, or transducer connector.
- ▶ Do not use strong solvents such as thinner or benzene, or abrasive cleansers, since these will damage the exterior surfaces. Use only FUJIFILM SonoSite recommended cleaners or disinfectants.

Cleaning and disinfecting

Determining the required cleaning and disinfecting level

WARNING

The cleaning instructions contained in this chapter are based on requirements mandated by the American Food and Drug Administration (FDA). Failure to follow these instructions may result in cross contamination and patient infection.

The level of cleaning and disinfecting required for the system is dictated by the type of tissue it contacts during use. Use **Table 10-1, “Choosing a cleaning and disinfecting method”** to determine the level of cleaning and disinfecting required.

Table 10-1: Choosing a cleaning and disinfecting method

Did any part of the system or transducer come in contact with broken skin, blood, mucosal membranes, or bodily fluids?	
YES	Came in contact with broken skin, blood, mucosal membranes, or bodily fluids. 
OR	
NO	Did not come in contact with broken skin, blood, or bodily fluids. 
Option A Go to “Clean and disinfect system and transducer to a high level (semi-critical uses)” on page 172.	
Option B Go to “Clean and disinfect system and transducer to a low level (non-critical uses)” on page 176.	

Spaulding classifications

Spaulding classifications (non-critical, semi-critical) determine the approach for cleaning and disinfecting medical equipment based on the device, the way it has been used, and the risk of infection. The system and transducers are designed for use within the Spaulding classifications of non-critical and semi-critical uses.

Option **A** Clean and disinfect system and transducer to a high level (semi-critical uses)

Use this procedure to clean and high-level disinfect the ultrasound system and transducer **whenever it has come into contact with blood, broken skin, mucosal membranes, or bodily fluids.**

Follow the manufacturer's instructions when using cleaners and disinfectants. The cleaners and disinfectants listed in the procedure are chemically compatible with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

WARNING

- ▶ To avoid electrical shock, before cleaning, disconnect the system from the power supply.
- ▶ Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as eyewear and gloves.

Caution

- ▶ Do not skip any steps or abbreviate the cleaning and disinfecting process in any way.
- ▶ Do not spray cleaners or disinfectants directly on the system surfaces or on system and transducer connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- ▶ Do not attempt to disinfect a transducer or transducer cable using a method or chemical that is not included here. This can damage the transducer and void the warranty.
- ▶ Use only FUJIFILM SonoSite recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage the System and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.

Note

- ▶ You must clean and disinfect both the ultrasound system and the transducer after each use, but only the transducer can be disinfected to a high level.
- ▶ For the purposes of cleaning and disinfecting, the battery should be considered as part of the ultrasound system, and not an accessory.

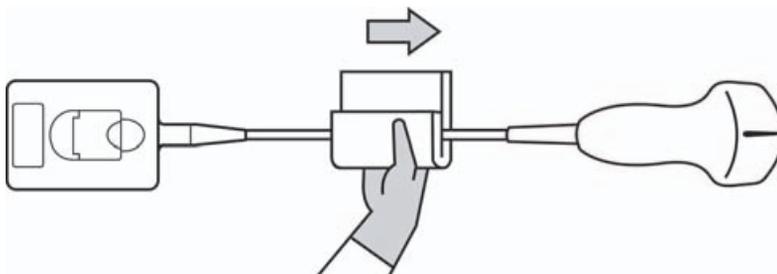
Cleaning and disinfecting the system and transducer (semi-critical)

To clean and disinfect the system and transducer

- 1 Turn off** the system by pressing the **Power button**.
- 2 Unplug** the power cord from the outlet.
- 3** Remove the disposable transducer sheath, if applicable.

- 4 Disconnect** the transducer from the system. Temporarily place it where it will not cross-contaminate clean equipment or surfaces while you clean the ultrasound console.
- 5 Clean** the exterior surfaces of the ULTRASOUND CONSOLE to remove any debris or bodily fluids. Use the following procedure:
- a** Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 10-2, “Cleaners and disinfectants compatible with NanoMaxx system and transducers”** on page 180.
 - b** Remove all gel, debris, and bodily fluids from the system.
 - c** With a new wipe, clean the system, including the display, by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.
 - d** Observe the minimum wet contact time recommended by the manufacturer. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.
 - e** Allow the ultrasound console to air dry in a clean, well-ventilated space.
- 6 Clean** the **TRANSDUCER CABLE AND BODY** to remove any debris or bodily fluids. Use the following procedure:

- a** Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 10-2, “Cleaners and disinfectants compatible with NanoMaxx system and transducers”** on page 180.
- b** Remove all gel, debris, and bodily fluids from the transducer.
- c** With a new wipe, clean the cable and transducer, starting from the cable, wiping toward the scanhead. This method helps to avoid cross-contamination.



Caution | Do not allow moisture near the electronic components of the connector.

- d** Observe the minimum wet contact time recommended by the manufacturer. Monitor the transducer for wet appearance. Re-apply with a new wipe if no longer wet.

7 Verify that all gel, debris, and bodily fluids have been removed from the system and transducer. If necessary, repeat steps 5 & 6 with a new wipe.

WARNING

Failure to remove all gel, debris, and bodily fluid could leave contaminants on the probe.

8 Prepare the disinfectant for use.

- a** Choose a high-level disinfectant from **Table 10-4, “High-level disinfectants compatible with NanoMaxx transducers”** on page 187.
- b** Check the expiration date on the bottle to ensure the disinfectant has not expired.
- c** Mix or check that the disinfection chemicals have the concentration recommended by the manufacturer (for example, a chemical strip test).
- d** Check that the temperature of the disinfectant is within the manufacturer’s recommended limits.

9 Perform a high-level disinfection of the transducer. Use the following procedure:

- a** Immerse the transducer in a high-level disinfectant solution. See the chemical manufacturer’s recommendations for soak time.

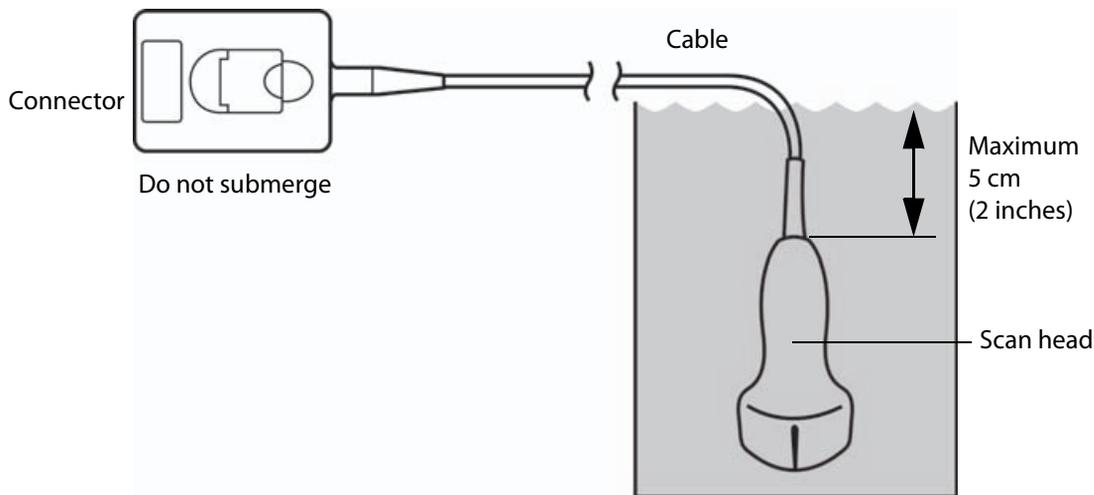
WARNING

High-level disinfectants can cause harm to the patient if not completely removed from the transducer. Follow the manufacturer’s rinse instructions to remove chemical residue.

Cautions

- ▶ Do not soak the transducer longer than recommended by the chemical manufacturer.
- ▶ Do not immerse the transducer connector in any disinfectant solution.
- ▶ Use only FUJIFILM SonoSite recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage or discolor the transducer and void the warranty.

- b** Ensure that the connector and most of the cable remain out of the fluid. You may submerge 2 inches (5 cm) of the cable proximal to the transducer scanhead.



10 Rinse the transducer **3 separate times** using the following procedure:

- a** Rinse the transducer in clean, running water according to the disinfectant manufacturer's instructions (at least 1 minute).
- b** Ensure that the connector and at least 12-18 inches (31-46 cm) of the cable from the connector remain dry.
- c** Repeat this step until the transducer has been rinsed 3 separate times.

11 Dry the transducer with a sterile, lint-free cloth.

12 Dispose of the disinfectant according to the manufacturer's guidelines.

13 Examine the transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, discontinue use of the transducer, and contact FUJIFILM SonoSite or your local representative.

Option **B** Clean and disinfect system and transducer to a low level (non-critical uses)

Use the following procedure to clean and disinfect the ultrasound system and transducer **if it has not come into contact with blood, broken skin, mucosal membranes, or bodily fluids.**

WARNING

If the system or transducer has come into contact with any of the following, use the high-level cleaning and disinfection procedure. See Option A, “**Clean and disinfect system and transducer to a high level (semi-critical uses)**” on page 172:

- ▶ Blood
- ▶ Broken skin
- ▶ Mucosal membranes
- ▶ Bodily fluids

Follow the manufacturer's instructions when using cleaners and disinfectants. The materials listed in the table below are chemically compatible with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

WARNINGS

- ▶ To avoid electrical shock, before cleaning, disconnect the system from the power supply.
- ▶ Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as eyewear and gloves.

Caution

- ▶ Do not spray cleaners or disinfectants directly on the system surfaces or on system and transducer connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- ▶ Use only FUJIFILM SonoSite-recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage the System and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.
- ▶ Do not attempt to disinfect a transducer or transducer cable using a method or chemical that is not included here. Doing so can damage the transducer and void the warranty.

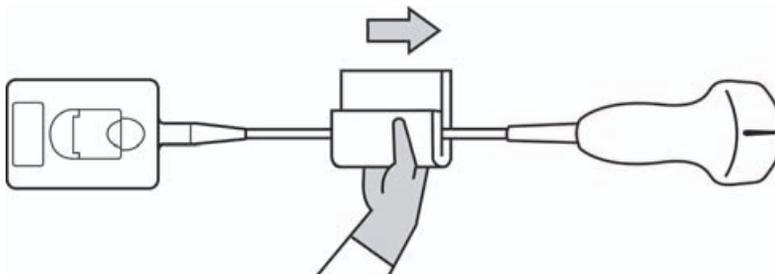
Note

For the purposes of cleaning and disinfecting, the battery should be considered as part of the ultrasound system, and not an accessory.

Cleaning and disinfecting the system and transducer (non-critical)

To clean and disinfect the system and transducer

- 1 Turn off** the system by pressing the **Power button**.
- 2 Unplug** the power cord from the outlet.
- 3** Remove the transducer sheath, if applicable.
- 4 Disconnect** the transducer from the system. Temporarily place it where it will not cross-contaminate clean equipment or surfaces while you clean the ultrasound console.
- 5 Clean** the exterior surfaces of the **ULTRASOUND CONSOLE** to remove any debris or bodily fluids. Use the following procedure:
 - Use either a premoistened wipe or a soft cloth dampened with cleaner and disinfectant. Choose a cleaner from **Table 10-2, “Cleaners and disinfectants compatible with NanoMaxx system and transducers”** on page 180.
 - Remove all gel, debris, and bodily fluids from the system.
 - With a new wipe, clean the system, including the display, by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.
 - Observe the minimum wet contact time. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.
- 6 Clean** the **TRANSDUCER CABLE AND BODY** to remove any debris or bodily fluids. Use the following procedure:
 - Use either a premoistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from **Table 10-2, “Cleaners and disinfectants compatible with NanoMaxx system and transducers”** on page 180.
 - Remove all gel, debris, and bodily fluids from the transducer.
 - With a new wipe, clean the cable and transducer, starting from the cable, wiping toward the scanhead. This method helps to avoid cross-contamination.



Caution

Do not allow moisture near the electronic components of the connector.

- d** Observe the minimum wet contact time recommended by the manufacturer. Monitor the transducer for wet appearance. Re-apply with a new wipe if no longer wet.
- 7 Verify** that all gel, debris, and bodily fluids have been removed from the system and transducer. If necessary, repeat steps 5 and 6 with a new wipe.
 - 8 Allow** the ultrasound system, including the console and transducer, to air dry in a clean, well-ventilated space.
 - 9 Examine** the system, transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, do not use. Instead, contact FUJIFILM SonoSite or your local representative.

Storing the transducer

To store the transducer

- 1** Make sure the transducer has been cleaned and disinfected as detailed in this chapter.
- 2** Store the transducer so that it hangs freely and vertically, and observe the following precautions:
 - ▶ Store the transducer away from any contaminated transducers.
 - ▶ Store the transducer in an environment that is safe and has good airflow. Do not store the transducer in closed containers or where condensation may occur.
 - ▶ Avoid direct sunlight and exposure to x-rays. Recommended storage temperature range is between 0° C (32° F) and +45° C (113° F).
 - ▶ If using a wall-mounted rack for storage, ensure that:
 - ▶ It is securely mounted.
 - ▶ The storage slots do not mar the transducer or cause damage to the cable.
 - ▶ The rack is sized and positioned to prevent the transducer from inadvertently falling.
 - ▶ Make sure the connector is supported and secure.

Transporting the transducer

When transporting the transducer, you must take precautions to protect the transducer from damage and avoid cross-contamination. Be sure to use a container approved by your organization.

To transport a soiled transducer for cleaning

A soiled transducer is one that has been contaminated and must be cleaned before using it in an exam.

- 1 Place the transducer in a clean, approved container.

WARNING

To prevent cross-contamination or unprotected exposure of personnel to biological material, containers used to transport contaminated transducers should carry an ISO biohazard label similar to the following:



Caution

Ensure the transducer is dry before placing it in a closed container. Condensation from a damp transducer can damage the connector.

- 2 Transport the transducer in the container to the point of processing. Do not open the container until the transducer is ready to be cleaned.

Caution

Do not leave the transducer in a sealed container for long periods of time.

To transport a clean transducer

A clean transducer is one that has completed the cleaning and disinfection process, has been stored properly, and is ready to be used in an examination.

- 1 Place the transducer in a clean, approved container. To identify the transducer as clean, containers used to transport clean transducers should carry a cleanliness verification sticker or certificate.
- 2 Transport the transducer in the container to the point of use. Do not open the container until the transducer is ready to be used.

To ship a transducer

WARNING

Whenever possible, avoid shipping a contaminated transducer. Before shipping, ensure the transducer has been cleaned and disinfected using the steps detailed in this chapter or according to special instructions received from FUJIFILM SonoSite. If you are returning the transducer to FUJIFILM SonoSite, document the disinfection on a "Declaration of Cleanliness," and attach it to the packing list.

- 1 Place the transducer in the shipping container and seal it. Do not allow any part of the transducer to protrude from the container.
- 2 Ship the transducer using the following precautions:
 - ▶ Clearly label the container as fragile.
 - ▶ Do not stack items on top of the shipping container.

- ▶ Do not exceed the shipping temperature range: -35° C (-31° F) to +65° C (149° F).
- ▶ Do not open the shipping container until it reaches its final destination.
- ▶ After arrival, the transducer must be cleaned and disinfected before it can be used in an exam.

Compatible cleaners and disinfectants (system and transducers)

Table 10-2: Cleaners and disinfectants compatible with NanoMaxx system and transducers

Disinfectants	NanoMaxx System	V-Universal Stand	C11n	C60n	ICTn	L25n	L38n	L52n	P21n
Accel TB Wipes	✓								
Airkem A-33	✓	✓	✓	✓	✓	✓	✓	✓	✓
Alcohol-Ethanol	✓	✓		✓	✓	✓	✓	✓	✓
Anios Wipes	✓	✓							
Aniosyme DD1- 5%	✓	✓	✓	✓	✓	✓	✓	✓	✓
Asepti HB	✓		✓	✓	✓	✓	✓	✓	✓
Baxedin Pre-Op	✓	✓	✓	✓	✓	✓	✓	✓	✓
Caviwipes			✓	✓	✓	✓	✓	✓	✓
Cidalkan Lingettes	✓	✓							
Clinell Universal Sanitising Wipes	✓	✓	✓	✓	✓	✓	✓	✓	✓
Clorox Germicidal Wipes	✓		✓	✓	✓	✓	✓	✓	✓
Clorox Hydrogen Peroxide Wipes	✓	✓							

Table 10-2: Cleaners and disinfectants compatible with NanoMaxx system and transducers

Disinfectants	NanoMaxx System	V-Universal Stand	C11n	C60n	ICTn	L25n	L38n	L52n	P21n
Control III	✓	✓							
Coverage Germicidal Surface Wipes	✓	✓	✓	✓	✓	✓	✓	✓	✓
Coverage Plus Germicidal Surface Wipes				✓	✓		✓		✓
Coverage Spray		✓		✓	✓		✓		✓
Coverage Spray TB	✓			✓	✓		✓		✓
Dynacide PA	✓	✓	✓	✓	✓	✓	✓	✓	✓
Echo Clean lingettes	✓								
Endosporine	✓	✓	✓	✓	✓	✓	✓	✓	✓
Envirocide		✓		✓	✓		✓		✓
Glucol Chlor Wipes			✓	✓	✓	✓	✓	✓	✓
Hydrogen Peroxide 3%	✓	✓	✓	✓	✓	✓	✓	✓	✓
Incidin Plus 1%	✓	✓	✓	✓	✓	✓	✓	✓	✓
Incidin Plus 3%	✓	✓	✓	✓	✓	✓	✓	✓	✓
Madacide-1				✓	✓		✓	✓	✓
Medzyme	✓	✓	✓	✓	✓	✓	✓	✓	✓
MetriSponge			✓	✓	✓	✓	✓	✓	✓

Table 10-2: Cleaners and disinfectants compatible with NanoMaxx system and transducers

Disinfectants	NanoMaxx System	V-Universal Stand	C11n	C60n	ICTn	L25n	L38n	L52n	P21n
Mikrobac Forte 2%		✓		✓	✓		✓		✓
Mikrobac Tissues	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mikrozid Sensitive Wipes				✓	✓		✓		✓
Oxivir TB Wipes	✓								
Percept RTU Wipes	✓	✓	✓	✓	✓	✓	✓	✓	✓
PI-Spray		✓		✓	✓		✓		✓
PI-Spray II	✓	✓	✓	✓	✓	✓	✓	✓	✓
Protex Spray	✓		✓	✓	✓	✓	✓	✓	✓
Protex Wipes	✓	✓	✓	✓	✓	✓	✓	✓	✓
Rely+On Perasafe	✓								
Reynard Neutral Detergent Wipes				✓	✓		✓		✓
Reynard Surface Disinfection Wipes				✓	✓		✓		✓
Sani-Cloth AF	✓	✓							
Sani-Cloth AF3	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sani-Cloth Bleach Wipes	✓		✓	✓	✓	✓	✓	✓	✓
Sani-Cloth HB	✓			✓	✓		✓		✓

Table 10-2: Cleaners and disinfectants compatible with NanoMaxx system and transducers

Disinfectants	NanoMaxx System	V-Universal Stand	C11n	C60n	ICTn	L25n	L38n	L52n	P21n
Sani-Cloth Plus	✓								
Simple Chlor	✓								
SONO Ultrasound Wipes				✓	✓		✓		✓
Steranios 2%	✓	✓	✓	✓	✓	✓	✓	✓	✓
Steranios 20%	✓	✓							
Trigene Advance Wipes	✓		✓	✓	✓	✓	✓	✓	✓
Tristel Solo	✓		✓	✓	✓	✓	✓	✓	✓
Tristel Wipes	✓								
Tuffie 5 Wipes				✓	✓		✓		✓
Virex II 256	✓		✓	✓	✓	✓	✓	✓	✓
Virex TB	✓	✓		✓	✓		✓		✓
Virox 5 RTU Wipes	✓	✓	✓	✓	✓	✓	✓	✓	✓
Wet Task Wipes	✓	✓	✓	✓	✓	✓	✓	✓	✓
Wex-Cide	✓	✓							
Wipes Plus Disinfecting Wipes	✓	✓	✓	✓	✓	✓	✓	✓	✓
Wood Wyant Ultra Wipes		✓							

Compatible cleaners and disinfectants (system accessories)

Table 10-3: Cleaners and disinfectants compatible with NanoMaxx system accessories

Disinfectants	Power Supply	Dock	PowerPack	PowerPark	Field Case
Accel TB Wipes				✓	
Airkem A-33	✓	✓	✓	✓	✓
Alcohol - Isopropyl					
Anios Wipes	✓	✓	✓	✓	
Aniosyme DD1- 5%	✓	✓	✓	✓	
Anioxide 1000	✓	✓	✓	✓	
Asepti HB	✓	✓	✓	✓	✓
Asepti Steryl	✓	✓	✓		
Asepti Wipe II		✓	✓	✓	
Baxedin Pre-Op	✓	✓	✓		
Carpe Diem TB Wipes			✓		
Caviwipes	✓	✓	✓	✓	
Cidalkan	✓	✓	✓		
Cidalkan Lingettes	✓	✓			
Clinell Universal Sanitising Wipes	✓	✓	✓	✓	
Clorox Germicidal Wipes	✓	✓	✓		
Clorox Hydrogen Peroxide Wipes	✓	✓	✓	✓	
Control III	✓	✓	✓	✓	
Coverage Germicidal Surface Wipes	✓				

Table 10-3: Cleaners and disinfectants compatible with NanoMaxx system accessories

Disinfectants	Power Supply	Dock	PowerPack	PowerPark	Field Case
Coverage Plus Germicidal Surface Wipes	✓	✓			
Coverage Spray		✓	✓		
Coverage Spray TB	✓	✓	✓		
DisCide Ultra Disinfecting Towlettes	✓	✓	✓		
Dynacide PA		✓	✓	✓	
Echo Clean lingettes	✓	✓	✓	✓	
End Bac II	✓	✓	✓		
Endosporine	✓	✓	✓	✓	
Envirocide	✓	✓	✓	✓	
Gluko Chlor Wipes	✓	✓	✓		
Hydrogen Peroxide 3%	✓	✓	✓	✓	✓
Incidin Plus 1%	✓	✓	✓	✓	
Incidin Plus 3%	✓	✓	✓	✓	
Medzyme	✓	✓	✓	✓	
Mikrobac Forte 2%			✓	✓	
Mikrobac Tissues	✓	✓	✓	✓	
Mikrozid Tucher	✓				
Oxivir TB Wipes		✓	✓		
Percept RTU Wipes	✓	✓	✓	✓	✓
PI-Spray	✓	✓	✓		

Table 10-3: Cleaners and disinfectants compatible with NanoMaxx system accessories

Disinfectants	Power Supply	Dock	PowerPack	PowerPark	Field Case
PI-Spray II	✓	✓	✓	✓	✓
Protex Spray			✓	✓	
Protex Wipes			✓	✓	
Rely+On Perasafe	✓	✓	✓	✓	
Sani-Cloth AF			✓	✓	
Sani-Cloth AF3			✓	✓	
Sani-Cloth Bleach Wipes	✓	✓	✓		
Sani-Cloth HB	✓	✓	✓		
Sani-Cloth Plus	✓	✓		✓	✓
Staphene	✓		✓		
Steranios 2%	✓	✓	✓	✓	
Steranios 20%	✓	✓	✓	✓	
Super Sani-Cloth	✓	✓			
Trigene Advance Wipes	✓	✓			
Tristel Solo	✓	✓	✓	✓	✓
Tristel Wipes	✓	✓			
Virex II 256			✓	✓	
Virex TB	✓	✓	✓		
Virox 5 RTU Wipes			✓	✓	
Wet Task Wipes	✓	✓	✓		

Table 10-3: Cleaners and disinfectants compatible with NanoMaxx system accessories

Disinfectants	Power Supply	Dock	PowerPack	PowerPark	Field Case
Wex-Cide		✓	✓	✓	
Wipes Plus Disinfecting Wipes	✓	✓	✓	✓	
Wood Wyant Ultra Wipes		✓			

Compatible high-level disinfectants (transducers)

Table 10-4: High-level disinfectants compatible with NanoMaxx transducers

High-level Disinfectants	C11n	C60n	ICTn	L25n	L38n	L52n	P21n
Cidex	✓	✓	✓	✓	✓		✓
Cidex OPA	✓	✓	✓	✓	✓	✓	✓
Metricide OPA Plus	✓	✓	✓	✓	✓	✓	✓
Nanosonics Trophon EPR	✓	✓	✓	✓	✓		✓
Cidex Plus	✓	✓	✓	✓	✓	✓	✓

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