Cleaning and Disinfecting X-Porte Products

SonoSite

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Introduction

SonoSite tests disinfectants and disinfectant devices for use with its systems, transducers, and accessories. This document includes instructions for cleaning and disinfecting the X-Porte ultrasound system, transducers, and accessories.

This document does not have the following regulatory information for disinfectants:

- USA FDA registration and listing, 510(k) clearance, and/or EPA registration
- CE approval

Before using a disinfectant, confirm that its regulatory status is appropriate for your jurisdiction and use. Verify expiration dates on chemicals.

When disposing of chemicals, follow manufacturer recommendations and local regulations.

WARNING:

Disinfectants and cleaning methods listed are recommended by SonoSite for compatibility with product materials, not for biological effectiveness. Refer to the disinfectant label instructions for guidance on disinfection efficacy and appropriate clinical uses.

The level of disinfection required for a device is dictated by the type of tissue it contacts during use. To avoid infection, ensure that the disinfectant type and the solution strength and duration are appropriate for the equipment. For information, see the disinfectant label instructions and the recommendations of the Association for Professionals in Infection Control and Epidemiology (APIC) and the FDA.

WARNING:

Caution:

To avoid infection:

- Always use protective eyewear and gloves when performing cleaning and disinfecting procedures.
- Ensure that the solution expiration date has not passed.

Ultrasound system

The ultrasound system includes the stand, clinical monitor, touch panel, system (engine), cups, and cable hooks.

WARNING:	To avoid electrical shock, before cleaning, disconnect the system from the power
	supply.

Caution:	Do not spray cleaners or disinfectant directly on the system surfaces. Doing so may
	cause solution to leak into the system, damaging the system and voiding the
	warranty.

Caution:	Do not use strong solvents such as thinner or benzene, or abrasive cleansers, since
	these will damage the exterior surfaces.

Use only recommended cleaners or disinfectants on system surfaces.

Immersion-type disinfectants are not approved for use on system surfaces.

Caution: When you clean the system, ensure that the solution does not get inside the system controls or the battery compartment.

Caution: Do not scratch the LCD screen.

Cleaning and disinfecting the ultrasound system

Clean the ultrasound system prior to disinfecting to remove any particulate matter or bodily fluids.

To clean and disinfect the ultrasound system

1 Turn off the system.

2 Disconnect the system from power: Press the Power button, listen for the audio tone, and then disconnect the AC input power cord from the stand base.

Caution:

Unplugging the AC power cord before you hear the tone may result in loss of data. If you don't hear a tone, then your system may be set up to mute all sounds. To reinstate sounds, see the topic titled "Audio settings" in the X-Porte Help.

- 3 Clean the exterior surfaces using a soft cloth lightly dampened in a mild soap or detergent cleaning solution to remove any particulate matter or body fluids.
 - Apply the solution to the cloth rather than the surface.
- 4 Mix the disinfectant solution compatible with the system, following disinfectant label instructions for solution strengths and disinfectant contact duration. See "Compatible disinfectants for the X-Porte ultrasound system."
- 5 Wipe surfaces with the disinfectant solution.
- 6 Air dry or towel dry with a clean cloth.

Compatible disinfectants for the X-Porte ultrasound system

You can disinfect the exterior surface of the ultrasound system, which includes the stand, clinical monitor, touch panel, system (engine), cups, and cable hooks, using any of the following chemically compatible disinfectants approved in your locale.

Table 1: Compatible disinfectants for the X-Porte ultrasound system

Disinfectant	
Airkem A-33	Hydrogen Peroxide (3%)
Anios Wipes	• Incidin Plus (1%)
Aniosyme DD1 (5%)	Incidin Plus (3%)
Anioxide 1000	Medzyme
• Asepti-HB	Metricide OPA Plus
Asepti-Wipe II	Mikrobac forte
Cidalkan Lingettes	Sani-Cloth HB
• Cidex	Simple Chlor
Cidex OPA	• Steranios 2%

Table 1: Compatible disinfectants for the X-Porte ultrasound system

Disinfectant	
Cidex Plus	• Steranios 20%
Clinell Universal Sanitising Wipes	Trigene Advance Wipes
Control III	• Virox 5 Wipes
Dynacide PA	• Wex-Cide
• Endosporine	

Transducers

Caution:

Caution:

WARNING:	To avoid electrical shock, before cleaning, disconnect the transducer from the
	custom

system.

Caution: Transducers must be cleaned after every use. Cleaning transducers is necessary prior to effective disinfection. Ensure that you follow the manufacturer's instructions when using disinfectants.

Caution: Do not use a surgeon's brush when cleaning transducers. Even the use of soft

brushes can damage a transducer. Use a soft cloth.

Using a non-recommended cleaning or 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.

Do not allow cleaning solution or disinfectant into the transducer connector.

Caution: Do not allow disinfectant to contact metal surfaces. Use a soft cloth lightly dampened in a mild soap or compatible cleaning solution to remove any

 $\ disinfectant\ that\ remains\ on\ metal\ surfaces.$

Caution: Attempting to disinfect a transducer or transducer cable using a method other than the one included here can damage the transducer and void the warranty.

Clean the transducer prior to disinfecting to remove any particulate matter or bodily fluids. To disinfect the transducer and its cable, use the immersion method or the wipe method.

You can disinfect the transducer, scanning surface, and cable using a compatible disinfectant or disinfectant device:

- For disinfectants compatible with standard transducers, see "Compatible disinfectants for standard transducers."
- For disinfectants compatible with specialty transducers, such as the ICTxp, see "Compatible disinfectants for specialty transducers." SonoSite recommends the use of high-level disinfectants with specialty transducers, such as the ICTxp.

Cleaning and disinfecting transducers

To clean a transducer

- 1 Disconnect the transducer from the system.
- 2 Remove any transducer sheath.
- 3 Clean the surface using a soft cloth lightly dampened in a mild soap or detergent cleaning solution.
- 4 Apply the solution to the cloth rather than the surface.
- 5 Rinse with water or wipe with water-dampened cloth; then wipe with a dry cloth.

To disinfect a transducer (wipe method)

- 1 Clean the transducer.
- 2 Mix the disinfectant solution compatible with the transducer, following disinfectant label instructions for solution strengths and disinfectant contact duration.
- 3 Wipe surfaces with the disinfectant solution.
- 4 If the disinfectant's instructions include rinsing, rinse with water or wipe with a water-dampened cloth. Then air dry, or dry with a clean cloth.
- 5 Examine the transducer and cable for damage such as cracks, splitting, or fluid leaks.

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

To disinfect a transducer (immersion method)

- 1 Clean the transducer.
- 2 Mix the disinfectant solution compatible with the transducer, following disinfectant label instructions for solution strengths and disinfectant contact duration.
- 3 Immerse the transducer into the disinfection solution not more than 12-18 inches (31-46 cm) from the point where the cable enters the connector. Follow the instructions on the disinfectant label for the duration of the transducer immersion.
- 4 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 cloth.
- 5 Examine the transducer and cable for damage such as cracks, splitting, or fluid leaks.
 - If damage is evident, discontinue use of the transducer, and contact SonoSite or your local representative.

Compatible disinfectants for standard transducers

Table 2: Disinfectant-device compatibility with X-Porte standard transducers

Device	С60хр	L38xp	HFL50xp	L25xp	P21xp
Nanosonics Trophon EPR*	✓	✓	✓	✓	✓

^{√-} Acceptable for use

Table 3: Disinfectant compatibility with X-Porte standard transducers

Disinfectant	С60хр	L38хр	HFL50xp	L25xp	P21xp
Accel Intervention Wipes		✓		✓	✓
Accel TB Wipes	✓		✓		
Airkem A-33	✓	✓	✓	✓	✓
Alcohol-Reagent-Ethanol		✓		✓	✓
Anios Wipes	✓	✓	✓	✓	✓
Aniosyme DD1 (5%)	✓	✓	✓	✓	✓
Asepti-HB		✓		✓	✓
Asepti-Wipe II	✓	✓	✓	✓	✓
Bacoban		✓		✓	✓
Baxedin Pre-Op	✓	✓	✓	✓	✓
Carpe Diem TB Wipes	✓	✓	✓	✓	✓
CaviWipes	✓	✓	✓	✓	✓
Cidalkan		✓		✓	✓
Cidalkan Lingettes		✓		✓	✓

^{*} For information and guidance on disinfection effectiveness and appropriate clinical use, see the manufacturer's user manual.

Table 3: Disinfectant compatibility with X-Porte standard transducers

Disinfectant	С60хр	L38хр	HFL50xp	L25xp	P21xp
Cidex	✓	✓	✓	✓	✓
Cidex OPA	✓	✓	✓	✓	✓
Cidex Plus	✓	✓	✓	✓	✓
Cleanisept Wipes		✓		✓	✓
Clinell Universal Sanitising Wipes	✓	✓	✓	✓	✓
Clorox Germicidal Wipes	✓	✓	✓	✓	✓
Control III		✓		✓	✓
Coverage Germicidal Surface Wipes	✓	✓	✓	✓	✓
Coverage Plus Germicidal Surface Wipes	✓	✓	✓	✓	✓
Coverage Spray		✓		✓	✓
DisCide Ultra Disinfecting Towlettes		✓		✓	✓
Dispatch Wipes		✓		✓	✓
Dynacide PA		✓		✓	✓
Echo Clean Lingettes	✓	✓	✓	✓	✓
End-Bac II	✓	✓	✓	✓	✓
Endosporine	✓	✓	✓	✓	✓
Envirocide		✓		✓	✓
Gluco Chlor Wipes	✓	✓	✓	✓	✓
Hydrogen Peroxide (3%)	✓	✓	✓	✓	✓
Incidin Plus (1%)	✓	✓	✓	✓	✓
Incidin Plus (3%)	✓	✓	✓	✓	✓
Korsolex Extra		✓		✓	✓

Table 3: Disinfectant compatibility with X-Porte standard transducers

Disinfectant	С60хр	L38xp	HFL50xp	L25xp	Р21хр
Madacide 1	✓	✓	✓	✓	✓
Medzyme	✓	✓	✓	✓	✓
Metricide OPA Plus	✓	✓	✓	✓	✓
MetriSponge	✓	✓	✓	✓	✓
Mikrobac Forte 2%	✓	✓	✓	✓	✓
Mikrobac Tissues	✓	✓	✓	✓	✓
Oxivir TB Wipes	✓	✓	✓	✓	✓
PerCept RTU Wipes	✓	✓	✓	✓	✓
Protex Spray	✓	✓	✓	✓	✓
Protex Wipes	✓	✓	✓	✓	✓
Sani-Cloth AF	✓	✓	✓	✓	✓
Sani-Cloth AF3	✓	✓	✓	✓	✓
Sani-Cloth Bleach Wipes	✓	✓	✓	✓	✓
Sani-Cloth HB	✓	✓	✓	✓	✓
Sani-Cloth Plus	✓	✓	✓	✓	✓
Sekusept		✓		✓	✓
Staphene	✓	✓	✓	✓	✓
Steranios (2%)	✓	✓	✓	✓	✓
Trigene Advance Wipes	✓	✓	✓	✓	✓
Tristel Solo	✓	✓	✓	✓	✓
T-Spray	✓	✓	✓	✓	✓
T-Spray II	✓	✓	✓	✓	✓

Table 3: Disinfectant compatibility with X-Porte standard transducers

Disinfectant	С60хр	L38xp	HFL50xp	L25xp	P21xp
Virex II 256	✓	✓	✓	✓	✓
Virex TB	✓	✓	✓	✓	✓
Virox 5 RTU Wipes		✓		✓	✓
Wet Task Wipes	✓	✓	✓	✓	✓
Wet Wipe Disinfection		✓		✓	✓
Wipes Plus Disinfecting Wipes	✓	✓	✓	✓	✓
✓- Acceptable for use					

Compatible disinfectants for specialty transducers

SonoSite recommends the use of high-level disinfectants with specialty transducers. In the U.S., 510(k)-approved high-level disinfectants compatible with SonoSite specialty transducers include Cidex, Cidex OPA, Cidex Plus, Metricide OPA Plus, and the Nanosonics Trophon EPR disinfectant device.

Disinfectant-device compatibility with X-Porte specialty transducers (ICTxp)

The Nanosonics Trophon EPR disinfectant device is acceptable for use with X-Porte speciality transducers. For information and guidance on disinfection effectiveness and appropriate clinical use, see the manufacturer's user manual.

Disinfectant compatibility with X-Porte specialty transducers (ICTxp)

The following disinfectants are acceptable for use with X-Porte specialty transducers:

- Cidex
- Cidex OPA
- Cidex Plus
- Metricide OPA Plus

Accessories

To clean the footswitch or ECG cable, see "Cleaning the footswitch or ECG cable."

Use the cleaning and disinfecting recommendations in the peripheral manufacturer's instructions when cleaning or disinfecting peripherals.

WARNING:

To avoid electrical shock, always disconnect the power supply before cleaning the PowerPark.

Cleaning and disinfecting accessories

Clean accessories prior to disinfecting. You can disinfect the exterior surface of accessories using a recommended disinfectant. See "Disinfectant compatibility with SonoSite accessories."

To clean and disinfect accessories

- 1 If necessary, unplug the power supply, and detach any cables.
- 2 Clean the exterior surfaces of the accessory using a soft cloth lightly dampened in a mild soap or detergent cleaning solution to remove any particulate matter or body fluids.
 - Apply the solution to the cloth rather than the surface.
- 3 Mix the disinfectant solution compatible with the accessory, following disinfectant label instructions for solution strengths and disinfectant contact duration. See "Disinfectant compatibility with SonoSite accessories."
- 4 Wipe surfaces with the disinfectant solution.
- 5 Air dry or towel dry with a clean cloth.

Cleaning the footswitch or ECG cable

To clean the footswitch

Use the disinfecting recommendations in the peripheral manufacturer's instructions when disinfecting the footswitch.

Caution:

To avoid damaging the footswitch, do not sterilize. It is not intended for use in a sterile environment.

- 1 Dampen a non-abrasive cloth with one of the following products:
 - Isopropyl alcohol
 - Soap and water
 - Cidex
 - Sodium Hypochlorite 5.25% (Bleach) diluted 10:1

2 Wring out cloth until slightly wet and then gently rub soiled area until clean.

To clean and disinfect the ECG cable (wipe method)

Caution: To avoid damaging the ECG cable, do not sterilize.

- 1 Remove the cable from the system.
- 2 Clean the surface using a soft cloth lightly dampened in a mild soap or detergent cleaning solution.

Apply the solution to the cloth rather than the surface.

- 3 Wipe the surfaces with any of the following products:
 - Bleach (sodium hypochlorite)
 - Cidex disinfectants
 - Green soap
- 4 Air dry or towel dry with a clean cloth.

Compatible disinfectants for accessories

Table 4: Disinfectant compatibility with SonoSite accessories

PowerPark Docking Station	ECG cable	AC/DC power supply	Digital video cable	Triple Transducer Connect
\checkmark		\checkmark	\checkmark	\checkmark
				✓
				✓
	✓			
	Docking	Docking	PowerPark Docking Station ECG cable AC/DC power supply	PowerPark Docking ECG cable AC/DC power supply Digital video cable

Table 4: Disinfectant compatibility with SonoSite accessories (continued)

Disinfectant	PowerPark Docking Station	ECG cable	AC/DC power supply	Digital video cable	Triple Transducer Connect
Anios Wipes	✓		✓	✓	✓
Aniosyme DD1 (5%)	✓		✓	✓	✓
Anioxyde 1000	✓		\checkmark	\checkmark	\checkmark
Asepti-HB	✓		✓	✓	✓
Asepti-Steryl			✓		✓
Asepti-Wipe II	✓		✓	✓	✓
Baxedin Pre-Op					✓
CaviWipes	✓	✓	✓		✓
Cidalkan			✓		✓
Cidalkan Lingettes				✓	✓
Cidalkan Wipes					✓
Cidex	✓		✓	✓	✓
Cidex OPA	✓		✓	✓	✓
Cidex Plus	✓		✓	✓	✓
Clinell Universal Sanitising Wipes			✓	✓	✓
Clorox Germicidal Wipe			✓		

Table 4: Disinfectant compatibility with SonoSite accessories (continued)

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Disinfectant	PowerPark Docking Station	ECG cable	AC/DC power supply	Digital video cable	Triple Transducer Connect
Control III	✓		✓	✓	✓
Coverage Germicidal Surface Wipes			✓		✓
Coverage Plus Germicidal Surface Wipes			✓		✓
Coverage Plus Wipes					✓
Coverage Spray			✓		✓
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			✓		✓

Table 4: Disinfectant compatibility with SonoSite accessories (continued)

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Disinfectant	PowerPark Docking Station	ECG cable	AC/DC power supply	Digital video cable	Triple Transducer Connect
Medzyme	✓		✓	✓	✓
Metricide OPA Plus	✓		✓	✓	✓
Mikrobac Forte 2%				✓	
Nu-Cidex	✓				
PerCept RTU Wipes	✓		✓		
Rely+On PeraSafe	✓		✓		✓
Sani-Cloth Bleach Wipes			✓		
Sani-Cloth HB			✓	✓	✓
Sani-Cloth Plus	✓	✓	✓		✓
Simple Chlor				✓	✓
Sporicidin	✓		✓		✓
Staphene			✓		✓
Steranios 2%	✓		✓	✓	✓
Steranios 20%	✓		✓	✓	✓
Super Sani-Cloth		✓	✓		✓
T-Spray			✓		

Table 4: Disinfectant compatibility with SonoSite accessories (continued)

Disinfectant	PowerPark Docking Station	ECG cable	AC/DC power supply	Digital video cable	Triple Transducer Connect
T-Spray II	✓		✓		✓
Trigene Advance Wipes			✓	✓	✓
Tristel Solo	✓		✓		✓
Tristel Wipes			✓		✓
Virex 256	✓		✓		
Virex II 256					✓
Virex TB			✓		✓
Virox 5 RTU Wipes	✓		✓	✓	✓
Wet Task Wipes			✓		✓
Wex-Cide	✓		✓	✓	✓
Wipes Plus Disinfecting Wipes			✓		✓
Wood Wyant Ultra Wipes					✓
√- Acceptable for use					

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All other trademarks are the property of their respective owners.

Caution:

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

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