

Summary

This document provides customers with information on cleaning and high-level disinfection of the EchoNous Vein probe. The information is intended to assist customers in determining a cleaning and disinfection strategy for the EchoNous Vein. The document will be periodically updated as more cleaning and disinfection products are tested.

Validations

The Vein probe passed the performance criteria for manual cleaning, limiting the protein residual to $<6.4 \mu\text{g}/\text{cm}^2$ and the residual carbohydrate limit to $<1.8 \mu\text{g}/\text{cm}^2$.

Using 5% Fetal Bovine Serum to represent contact with blood during a peripheral access procedure, the Vein probe passed the performance criteria for high-level disinfection for the following organisms.

- *Escherichia coli* (Pass Criteria: 6 log₁₀ reduction)
- *Klebsiella pneumoniae* (Pass Criteria: 6 log₁₀ reduction)
- *Pseudomonas aeruginosa* (Pass Criteria: 6 log₁₀ reduction)
- *Staphylococcus aureus* (Pass Criteria: 6 log₁₀ reduction)
- *Mycobacterium terrae* (Pass Criteria: 6 log₁₀ reduction)

Vein Cleaning and Disinfection Instructions

Vein Probe Cleaning

The following cleaning instructions must be followed for the Vein Probe. The Vein Probe must be cleaned after each use. Cleaning the Probe is an essential step before effective disinfection.

Before cleaning the Probe, read the following warnings and cautions.

Warnings

Do not disconnect the Probe from the Hub. Always disconnect the Probe from power by disconnecting the Stand from AC mains before cleaning and disinfection.

After cleaning, you must disinfect the Vein Probe by following the appropriate instructions.

Always use protective eyewear and gloves when cleaning and disinfecting any equipment.

Cautions

When cleaning and disinfecting the Probe, do not allow any fluid to enter electrical connections or metal portions of the USB connector.

Use only EchoNous-recommended wipes. Using a non-recommended wipe can damage the Probe and void the warranty.

CLEANING STEPS

After each use, disconnect the Probe from power by disconnecting the Stand from AC mains. Remove any accessories attached to, or covering the Probe, such as needle guide, needle bracket and sheath (probe cover).

NOTE

- *The needle guide is single-use disposable.*
- *The needle bracket is reusable and must be cleaned using the same methods as the Probe.*

Remove all ultrasound gel from the Probe face by using an approved pre-saturated disinfectant wipe. Choose an EchoNous-approved wipe from Table 1 below.

Obtain a new wipe. Remove any particulate matter, gel or fluids that remain on the Probe using a new pre-saturated wipe. If necessary, clean the Probe with additional wipes to remove all visible contaminants.

TABLE 1: CLEANING WIPES PRIOR TO HIGH-LEVEL DISINFECTION

Product	Company	Active Ingredient(s)
Sani-Cloth Plus	PDI Inc.	n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides . 0.125% n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides. 0.125%
Sani-Cloth AF3	PDI Inc.	n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides. 0.14% n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides. 0.14%
Super Sani-Cloth	PDI Inc.	n-Alkyl dimethyl ethylbenzyl ammonium chlorides – 0.25%, n-Alkyl dimethyl benzyl ammonium chlorides – 0.25%, Isopropyl Alcohol 55%
CaviWipes	Metrex	Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride 0.28% Isopropanol 17.20%
Bleach Germicidal	Clorox Healthcare	Sodium Hypochlorite, 0.55%

- *Wipe to be used for cleaning prior to Probe disinfection.*

LINEAR PROBE HIGH-LEVEL DISINFECTION

Use the following steps to high-level disinfect the Linear Probe whenever it has come into contact with blood, broken skin or bodily fluids (semi-critical use). High-level disinfection of the Linear Probe typically uses an immersion method with high-level disinfectants or chemical sterilants. Before performing the following steps, read the following warnings and cautions.

Warning

Always disconnect the Probe from power by disconnecting the Stand from AC mains during cleaning and disinfection.

Before disinfection, clean the Probe by following the appropriate cleaning instructions listed above in order to remove all gels, fluids and particulates that may interfere with the disinfection process.

Always use protective eyewear and gloves when disinfecting any equipment.

Caution

When disinfecting the Probe, do not allow any fluid to enter electrical connections or metal portions of the USB connector.

Do not attempt to disinfect the Probe using a method that is not included in these instructions. This can damage the Probe and void the warranty.

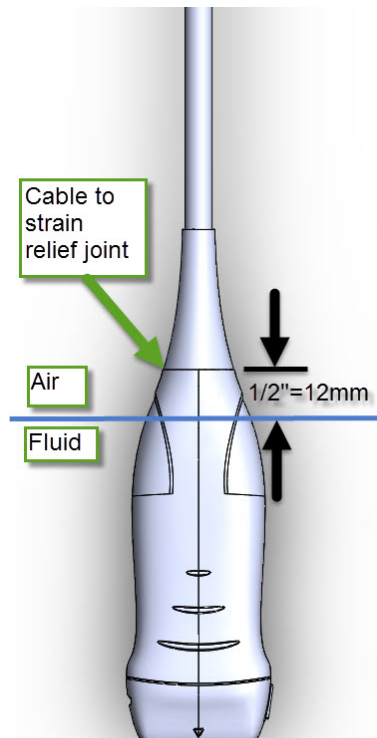
Use only EchoNous-recommended disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage the Probe and void the warranty.

DISINFECTATION STEPS

After cleaning, choose a high-level disinfectant that is compatible with the Linear Probe. For a list of compatible disinfectants, see Table: Disinfectant Solutions for Probe Immersion.

Follow the disinfectant label instructions for preparation, temperature, solution strength, and duration of contact. Ensure that the solution strength and duration of contact are appropriate for the intended clinical use of the device (semi-critical). If a pre-mixed solution is used, be sure to observe the solution expiration date.

Immerse the Linear Probe into the disinfectant as shown in the figure below. The probe may be immersed only up to the immersion point shown. No other part of the Probe, such as cable, strain relief, or connector can be soaked or immersed in fluids.



Follow the instructions on the disinfectant label for the duration of immersion (minimum wet contact time). Do not immerse the probe longer than the minimum time needed for semi-critical level of disinfection.

Rinse the probe in clean water up to the point of immersion to remove chemical residue. Do not soak or immerse any other part of the Probe, such as cable, strain relief, or connector.

Air dry or use a soft sterile cloth to dry the probe.

Wipe the strain relief and first 18 inches (45 cm) of the Probe cable with an approved Wipe from Table 1.

Examine the probe for damage such as cracks, splitting, or sharp edges. If damage is evident, discontinue use of the probe and contact your EchoNous representative.

TABLE 2: DISINFECTANT SOLUTIONS FOR PROBE IMMERSION

Choose an EchoNous-approved high-level disinfectant from the table below.

Product	Company	Active Ingredient(s)	Contact Conditions
Cidex OPA Solution	Advanced Sterilization Products	0.55% ortho phthaldehyde	12 min at 20°C

- *Check the expiration date on the bottle to ensure the disinfectant has not expired.*

Mix or check that the disinfection chemicals have the concentration recommended by the manufacturer (for example, a chemical strip test).

Check that the temperature of the disinfectant is within the manufacturer's recommended limits.

Following the disinfection process, rinse the Probe thoroughly to remove the chemical disinfectant residue. Generally, three separate rinses or as directed by the disinfectant manufacturer's instructions.