### SPACELABS HEALTHCARE

PRODUCTS COVERED	Monitors, Modules, Transmitters, Cables, Leadwires, and Displays
TITLE	Cleaning, Disinfecting and Sterilization
NUMBER	077-0349-00 Rev. F
DATE	3 January 2025

### Purpose

To provide customers with a detailed procedure for cleaning, disinfecting, and sterilization, with warnings and recommendations of proper cleaning agents.

Only use the following disinfectant and cleaning solution products that have been tested with Spacelabs products.

Always follow the solution manufacturer's instructions for diluting concentrates. Stronger concentrations may damage the product.

# Revision History:

Rev F: After revision E removed both the Revision History and the Gaseous Hydrogen Peroxide sections, Revision F includes both sections.

Rev E: Added general statement of the cleaning or disinfecting agents that are not specified. Verified the Sani-Cloth product names.

Rev D: Added Gaseous Hydrogen Peroxide options.

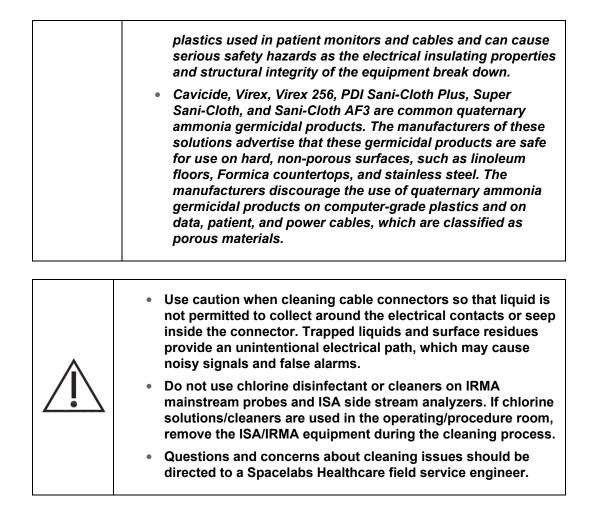
Rev C: Added the no-touch spatial disinfectant methods

Rev B: Added displays to devices

Rev A: Initial release

# Warnings, Cautions, and Notes – All Listed Products

	<ul> <li>Use only recommended cleaning solutions, or you may void the manufacturer's warranty.</li> </ul>
	<ul> <li>Harsh chemical agents degrade plastics and will compromise the safety of the device. Some germicidal and other harsh cleaning compounds are known to damage some plastics by weakening the structural integrity and compromising the electrical insulating properties.</li> </ul>
	<ul> <li>Disconnect the equipment from the patient and the electrical supply before cleaning.</li> </ul>
	<ul> <li>Do not allow liquid to enter the interior of the module or monitoring equipment.</li> </ul>
	<ul> <li>Do not immerse the equipment or cables in water or cleaning solutions.</li> </ul>
	Do not autoclave.
	<ul> <li>Accelerated Hydrogen Peroxide (AHP) and quaternary ammonia-based products ARE NOT RECOMMENDED for cleaning monitors and cables. These chemicals degrade</li> </ul>



#### Note:

- For cleaning instructions for an Original Equipment Manufacturer (OEM) device, refer to the user manual for that product.
- Accelerated Hydrogen Peroxide (AHP) contains hydrogen peroxide and low concentrations of phosphoric acid. AHP is different from cleaners containing hydrogen peroxide mixed with alcohols and specifically NOT recommended for cleaning Spacelabs Healthcare products.
- Over time, repeated use of a chlorine bleach solution may cause some colors to fade.
- After cleaning ECG leadwires, remove the ECG lead wires from the lead block and thoroughly dry them at the lead block ends and at the lead connector ends. Thorough drying will prevent residual moisture from providing a low-current path between leads, which can interfere with lead off detection and cause false asystoles.
- Follow your hospital protocol for the handling of blood and body fluids.
- Where provided, obey the manufacturers' instructions concerning disposable and reusable supplies.
- As applicable, obey your hospital protocol concerning cleaning, disinfection, and/or sterilization of reusable supplies.
- Obey hospital protocols to dispose of used and contaminated single-use accessories.

# Recommended Cleaners – All Listed Products

- Mild soap and water solution
- U.S. Pharmacopoeia (USP) green soap
- Sodium hypochlorite solution (1:10 dilution of household chlorine bleach in water)
- Phenolic germicidal detergent (1% aqueous solution)
- Glutaraldehyde (2.4%) (Cidex)
- Isopropyl alcohol (70% solution)
- PDI Sani-Cloth Bleach (sodium hypochlorite 0.63%)

The preliminary results of our first batch of impact tests after 4 weeks of continuous exposure indicate that once-a -shift cleaning with the Ready-To-Use Cleancide Wipes, Meliseptol Wipes, PDI Super Sani-Cloth Wipes (purple lid), or SONO Ultrasound Wipes should not cause any harm to the white Lexan plastic that we use in our current monitor products.

## Recommended Cleaners – Monitors, Modules, and Displays ONLY

In addition to recommended cleaners, the following products can also be used on monitors, modules and displays.

- Diversey Oxivir wipes (benzyl alcohol 1 to 5% and hydrogen peroxide 0.5 to 2%)
- Clorox Healthcare wipes (benzyl alcohol 1 to 5% and hydrogen peroxide 0.5 to 2%)

## Cleaning Monitors, Displays, Modules, and Cables

To clean monitors, displays, modules, and cables:

- 1. Prepare the cleaning solution according to the manufacturer's instructions.
- 2. Wet a clean cloth with the selected cleaning solution.
- 3. Remove excess liquid from the cloth and squeeze dry.
- 4. Wipe exposed surfaces of the equipment and cables.
- 5. Remove any soap residue by gently wiping with a clean damp cloth.
- 6. Wipe dry with a clean dry cloth.

### Cleaning ECG Leadwires

Inspect the leadwire sockets for contamination. If necessary, flush using a syringe and clean using a toothpick. Once clean, Spacelabs Healthcare recommends wetting the sockets with 70% isopropyl alcohol to provide low level disinfection. This agent can be left to dry naturally and does not require any rinse procedures.

### Note:

After cleaning ECG leadwires, remove the ECG leadwires from the lead block and thoroughly dry them at the lead block ends and at the lead connector ends. Thorough drying will prevent residual moisture from providing a low-current path between leads, which can interfere with lead off detection and cause false asystoles.

### Cleaning Telemetry Transmitters

Recommended cleaning solutions

• Mild soap and water solution

- U.S. Pharmacopoeia (USP) green soap
- Sodium hypochlorite solution (1:10 dilution of household chlorine bleach in water)
- Isopropyl alcohol (70% solution)
- Phenolic germicidal detergent solution (follow the manufacturer's product label for acceptable use-dilution amounts and instructions)

#### Note:

- Repeated use of a chlorine bleach solution can cause some colors to fade.
- DO NOT use chlorine bleach solution inside the battery compartment.

To clean the display

ONLY clean the display with a soft cloth moistened with either 70% isopropyl alcohol solution or soapy water.

To clean or disinfect the buttons.

- 1. Wet a small brush with a mild soap solution to clean the buttons.
- 2. Gently scrub around and across the buttons.
- 3. Dry the buttons with a rubbing action.
- 4. Use the same method to disinfect the buttons.

Spacelabs Healthcare recommends that you to wet the area with 70% isopropyl alcohol to provide low-level disinfection. Allow this agent to dry naturally—no rinse procedures are necessary.

To clean the battery cover and compartment

- 1. With the battery cover closed, clean around the battery cover release with a small brush using a mild soap solution. Use the same method to disinfect with 70% isopropyl alcohol to provide low-level disinfection.
- 2. Open the battery cover and inspect the hinges and catch for contamination. If necessary, use a syringe to flush with isopropyl alcohol and a small brush to clean the cover. Take care not to deform the cover spring.
- 3. Clean the inside of the battery compartment with a small brush or cloth using 70% isopropyl alcohol. Take care not to deform the metal tabs.
- 4. Once clean, Spacelabs Healthcare recommends that you wet the area with 70% isopropyl alcohol to provide low-level disinfection. Allow this agent to dry naturally—no rinse procedures are necessary.

Note:

Use ONLY isopropyl alcohol inside the battery compartment.

To clean and disinfect the rest of the transmitter.

1. Remove the batteries and CLOSE the battery cover.

Notes:

- Obey your hospital protocol for the handling of blood and body fluids.
- Use ONLY the recommended cleaning solutions or damage to the transmitter can occur leading to device failure.
- 2. Remove the ECG leadwires, grouper, and SpO2 cable (if fitted).

- 3. Inspect the transmitter for contamination. If necessary, do steps 4 and 5 to clean the transmitter.
- 4. Rub the transmitter with a cloth wetted in a mild soap solution.
- 5. Dry the transmitter thoroughly.
- 6. Prepare the cleaning solution according to instructions from the manufacturer.
- 7. Wet a clean cloth with the selected cleaning solution.
- 8. Remove excess liquid from the cloth and squeeze dry.
- 9. Wipe all exposed surfaces of the equipment and cables.
- 10. Leave the transmitter wet with solution for the required contact time.
- 11. To remove any soap residue, gently wipe with a clean damp cloth.
- 12. Wipe dry with a clean dry cloth. Remove disinfectant residues in accordance with the disinfectant labelling.

Operations manuals for all products are available at www.manuals.spacelabshealthcare.com.

### No-touch spatial disinfectant methods

The most common disinfectant methods at present are ultraviolet (UV) light devices and gaseous hydrogen peroxide systems.

### UV Lighting

Effect on Spacelabs monitoring equipment.

Daily exposure to UV disinfectant lighting systems should not have any impact on Spacelabs patient monitors. The plastic used in the manufacture of Spacelabs patient monitors is rated for continuous outdoor use. It carries a UL rating of F1 which includes prolonged exposure to the full spectrum of UV light.

#### Description

UV (Ultraviolet) light refers to the region of the electromagnetic spectrum between visible light and x-rays. The wavelength of the band is between 400 and 10 nanometers (nm). This electromagnetic radiation is not visible to the human eye, because it has a shorter wavelength and higher frequency than the light that our brain perceives as images. UV-B (320 - 290 nm) is the band that causes sunburns with prolonged exposure with an increased risk of skin cancer and other cellular damage. About 95% of all UV-B is absorbed by the ozone in Earth's atmosphere. UV-C (290 - 100 nm) is extremely harmful and is almost completely absorbed by Earth's atmosphere. It is commonly used as a disinfectant in food, air, and water as it kills microorganisms by destroying their cells' nucleic acids.

According to articles available on the <u>National Institutes of Health</u>, there are two main types of portable UV devices that produce UV light across the disinfecting spectrum (320 -100 nm): those that emit a continuous dose of UV light through a mercury bulb, and those that use a pulsed xenon light. The recommended time to run the device depends upon the manufacturer. Mercury UV-C devices may take as much as 45 minutes to deliver a single cycle adequate to disinfect an entire room. The pulsed xenon system (developed by Xenex Disinfection Service, 2017) is capable of disinfecting a

comparable room in 20 minutes. Studies have shown that both types of systems reduce pathogens on both porous and nonporous hospital surfaces.

The plastic used in the manufacture of Spacelabs patient monitors is rated for continuous outdoor use. It carries a UL rating of F1 which includes prolonged exposure to the full spectrum of UV light.

### Gaseous Hydrogen Peroxide

Effect on Spacelabs monitoring equipment:

No adverse effects have occurred during prolonged exposure testing with 3% Hydrogen Peroxide on the plastics used in Spacelabs monitors.

Description

Vaporized Hydrogen Peroxide (VHP) can be used to disinfect large quantities of Personal Protective Equipment (PPE). Gaseous hydrogen peroxide has been shown to be effective against a wide range of bacterial and viral organisms. This method starts with 35% medical grade Hydrogen Peroxide. The Hydrogen Peroxide is processed in a Gaseous Decontamination Generator to create and maintain a vapor concentration ranging from 500 to 750 ppm. The VHP is injected into the closed chamber, where the Relative Humidity may be reduced to as low as 20% and the chamber temperature may be elevated up to 350 C. The highest concentrations at the highest temperatures and the lowest RH seem to be most effective in the shortest period of time.

One of the Spacelabs recommended cleaning solutions is 3% Hydrogen Peroxide. Chemical exposure tests have been conducted with 3% Hydrogen Peroxide (30,000 ppm) that simulate daily cleanings over the projected life of the product.

#### **NIH Articles**

- <u>NIH Hydrogen Peroxide or Chlorine Dioxide for Space Applications</u>
- <u>NIH Portable Ultraviolet Light Surface-Disinfecting Devices</u>

Thank you again for choosing Spacelabs Healthcare.