

High-Level Disinfection of the F&P SleepStyle Accessories

High-level disinfection cleaning is required when the device is intended for multi-patient use. For reprocessing between patients, follow the cleaning and then high-level disinfection instructions below.

Cleaning Instructions Before Disinfection

1. Wipe the exterior of the device and the chamber housing with a clean, damp (not dripping) cloth and warm soapy water using a mild dishwashing detergent.
2. Leave to dry out of direct sunlight or heat.
3. Hand-wash the water chamber, chamber seal, breathing tube, outlet seal and elbow in a tub of warm, soapy water with a mild dishwashing detergent. Ensure all visible soil is removed.
4. Rinse thoroughly in a tub of clean water for 30 seconds. Ensure that all soap residue has been removed.
5. Repeat the rinsing process again, using clean water.
6. Hang the breathing tube, with both ends pointing to the floor, to dry away from direct sunlight or heat.
7. Leave the water chamber, chamber seal, outlet seal and elbow to dry out of direct sunlight or heat.

Note: If dirt remains inside the breathing tube after rinsing, use a soft, non-metallic brush, to remove it. Rinse the tube again. If the dirt cannot be removed, the breathing tube should be replaced. Failure to properly clean these items may result in inadequate disinfection. Please refer to the cleaning instructions in section 10.2.1 - **Cleaning of the F&P SleepStyle Clinician Guide**. Before cleaning the device and its accessories, please read the warnings and cautions on the back of this document.

	Materials	High Level Disinfection Options				
		Thermal Disinfection		Chemical Disinfection		
		75 °C (167 °F) for 30 minutes	90 °C (194 °F) for 1 minute	CIDEX™ OPA	Anioxide™ 1000	gigasept® FF
 900SPS101 Chamber Seal	Silicone	✓	✓	✓	✓	✓
 900SPS141 Outlet Seal	Silicone	✓	✓	✓	✓	✓
 900SPS100 Water Chamber	Polypropylene Copolymer Stainless Steel	✓	✓	✓	✓	✓
 900SPS122 Elbow	Polypropylene Copolymer	✓	✓	✓	✓	✓

Breathing Tube	Materials	High Level Disinfection Options				
		Thermal Disinfection		Chemical Disinfection		
		75°C (167 °F) for 30 minutes	90 °C (194 °F) for 1 minute	CIDEX™ OPA	Anioxide™ 1000	gigasept® FF
 900SPS120 ThermoSmart Heated Breathing Tube	Polypropylene Polyolefin Elastomers (POE)	⚠ No	⚠ No	✓	✓	✓
 900SPS121 Standard Breathing Tube*	Polyethylene Polypropylene Thermoplastic Vulcanizates (TPV)	✓	⚠ No	✓	✓	✓

*Higher temperatures (above 75 °C) may damage the Standard Breathing Tube.

Note: High level disinfection may be repeated 20 times per part, then they should be replaced. The air filter must be replaced between patients. Refer to section 10.4 – Replacing the Air Filter between Patients of the F&P SleepStyle Clinician Guide. The information provided in this document is an indication only and it is the user's responsibility to qualify any deviations from the recommended methods. Please refer to section 10.2 – Cleaning and High-Level Disinfection of the Device and Accessories of the F&P SleepStyle Clinician Guide for the most up-to-date information. The device lid does not require high-level disinfection.

Thermal Disinfection Instructions

1. Immerse the disassembled parts in a water bath. Ensure that no air bubbles are trapped inside the standard breathing tube.
2. Increase the water bath temperature to 75 °C (167 °F).
3. Soak for 30 minutes.
4. Air-dry out of direct sunlight or heat.

Note: Higher temperatures may damage the standard breathing tube. The elbow, water chamber, chamber seal and outlet seal can be thermally disinfected separately from the standard breathing tube in a water bath at 90 °C (194 °F) for 1 minute.

Warnings

To avoid incorrect therapy:

Do not clean or disinfect the ThermoSmart Heated Breathing Tube with hot water. This may cause deformation of the tube and reduce therapeutic pressure.

Chemical Disinfection Instructions

1. Immerse the disassembled parts in a cleaning solution using CIDEX OPA, anioxyde 1000, or gigasept FF. Follow the manufacturer's instructions for concentration, temperature, and time.
2. Ensure that no air bubbles are trapped inside the breathing tube. Please note that the ThermoSmart Heated Breathing Tube is buoyant so will need to be submerged (for example, in a metal tray with a mesh top).
3. Thoroughly rinse each part in a tub of water by immersing completely for a minimum of 1 minute.
4. Repeat the rinsing process again.
5. Air-dry out of direct sunlight or heat.

Warnings to consider when cleaning the SleepStyle CPAP and its accessories.

To avoid electric shock:

- Do not use bleach, alcohol, or cleaners with citrus or other natural oils. These substances may degrade the device and accessories.
- Do not immerse the device in water or any other liquid.

To avoid incorrect therapy:

Only clean the device and accessories according to the cleaning instructions outlined above. You can also refer to the complete disassembly for cleaning and high-level disinfection as outlined in section 10 – Multi-Patient Use of the F&P SleepStyle Clinician Guide.

Cautions to consider when cleaning the SleepStyle CPAP and its accessories.

General:

Replace the device and accessories if there is any sign of cracking, deformation, discoloration or leaking. It is recommended that you inspect the device, ThermoSmart Heated Breathing Tube or Standard Breathing Tube, Water Chamber, Chamber Seal, Outlet Seal, Air Filter and Elbow, on a regular basis after cleaning. The air filter must be replaced between patients. Refer to section 10.4 – Replacing the Air Filter between Patients of the F&P SleepStyle Clinician Guide for more details regarding Replacement Parts.

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