Procedure for disinfection and sterilization of HOFFRICHTER mask systems

HOFFRICHTER
Quality makes the Difference

Standard I Cirri Comfort I Pillow

Recommended and validated cleaning, disinfection and sterilization procedures according to ISO 17664

This brochure should be used as a guideline for preparations in institutions in which mask systems are used by more than one patient, such as sleep laboratories, sleep clinics and hospitals.
Mask users who themselves are the only person's to use the mask please adhere only to the recommendations for cleaning and care in the instructions for use delivered with the mask.
You can find which replacement parts are available for the individual mask systems at *www.hoffrichter.de*.

PREPARATION OVERVIEW

Which procedure for disinfection and sterilization can be used, and how many preparations are permissible in each case, depending on the mask system, can be found in the following overview.

Please note:

- If deviations are made from the instructions provided, in particular the number of preparation cycles, this will have a negative impact on the serviceability of the masks. In addition, the warranty claim, if it still exists, will expire.
- Should an additional disinfection/sterilization be required for your device, the number of the permissible preparation cycles specified here should be halved.
- Every preparation should be conducted in accordance with sections 1 through 7 whereby, depending on the type of preparation, only one of the steps between 3.1 and 3.5 will be applied.
- The headgear should be replaced on all masks after each patient change. Additionally, the connection hose should be replaced with a new one on the Cirri Comfort Mini Masks and the Nasal Pillow 4 in 1.

Cirri Comfort Nasal Mask ❶	Cirri Mini Comfort Nasal Mask ❷	Cirri Comfort Full Face Mask ❸	Cirri Comfort Full Face Mask NIPPV ❹	Nasal Pillow 4 in 1 ❺	Standard Nasal Mask ❻	Standard Full Face Mask ❼	Standard NIPPV Full Face Mask ❽	Standard NIPPV Full Face Mask ❾
								
Article no.: 00003497 00003486 00003487 00003488	Article no.: 00003551 00003552 00003498	Article no.: 00003483 00003484 00003485	Article no.: 00003489 00003490 00003491	Article no.: 00003499	Article no.: 00003440 00003434 00003435	Article no.: 00003441 00003436 00003437	Article no.: 00003461 00003442 00003438 00003462	Article no.: 00003439

Contained Information only refer to silicone and hard plastic items of the mask systems (excl. headgear) [1]	Cleaning	Disinfection			Sterilization			
		Chemical		Physical	Chemical		Physical	
		Manual	Ultrasonic	Thermal	Gas	Plasma (STERRAD)	Superheated steam (autoclave)	Hot air
Number of preparation cycles ❶ – ❽	Infinite[2]	50	40	40	25	25	10[3]	Not permissible
Number of preparation cycles ❾	Infinite[2]	100	80	80	50	50	10	Not permissible
Notes	-	-	Only in conjunction with chemical disinfection.	-	Do not use ethylene oxide gas!	-	-	-
See section	2	3.1	3.1	3.2	3.3	3.4	3.5	-

[1] Headgear must only be hand washed. When changing patients headgear must be replaced,
[2] Replace mask if there are cracks, tears or excessive discoloration,
[3] Silicone parts at 134°C, plastic parts at 121°C

IMPORTANT NOTES

- In any case, with our masks, observe the accompanying instructions for use.
- When using cleaning, disinfecting, or sterilization agents, and sterilization devices, always observe the manufacturer's instructions.
- The headgear material is heat-sensitive. Excessive heating (i.e. through long direct exposure to sunlight, drying with technical equipment, or irons) can lead to damages.

PREPARATION

1 DISASSEMBLING THE MASK

Disassemble the mask into its components.

2 CLEANING

The mask‘s headgear cannot be disinfected or sterilized and should be replaced after every patient change. The other components of the mask should be cleaned in a suitable cleaning solution with a soft brush. Ensure that all recesses and hollows are cleaned. When doing so follow the cleaning agent manufacturer‘s instructions.

Examples of suitable cleaning solutions:

- 1 % Alconox
- 0.5% Aniosyme DD1 (minimum 15 minute application time)

After cleaning thoroughly wash off the mask components with clear water (drinking water quality) and then let them air dry, while protecting them from exposure to direct sunlight.

3 DISINFECTION/STERILIZATION

Prior to the start of a disinfection or sterilization a precise cleaning is mandatorily required. (see section “Cleaning”).

3.1 MANUAL/ULTRASONIC-CHEMICAL DISINFECTION

Submerge the mask components in a commercially available disinfection solution after cleaning. Ensure that all components are completely wetted including the recesses and hollows.

Examples of suitable disinfection solutions and application times:

- 30 Minutes in 0.15 % peracetic acid (i.e. Anioxyde 1000, when cleaning with Aniosyme DD1)
- 20 Minutes in 0.55 % Ortho-Phthalaldehyde (i.e. CIDEX OPA, when cleaning with Alconox)
- 20 Minutes in 3.40 % Glutaraldehyde (i.e. CIDEX Plus, when cleaning with Alconox)

For chemical disinfection in an ultrasonic bath the disinfection agent used must be suitable for use in the ultrasonic bath. The application time of the disinfection solution according to the manufacturer‘s specifications must also be adhered to in the ultrasonic bath. In manual cleaning and disinfection, as well as ultrasonic baths, the cleaning and disinfectant effect, is influenced by high contamination. In the event of visible dirt the solution should be changed.
After the application time has elapsed thoroughly wash off the mask components with clear water (drinking water quality) and then let them air dry while protecting them from exposure to direct sunlight.

3.2 THERMAL DISINFECTION

For a thermal disinfection the cleaning should be conducted using Alconox. The disinfectable mask components must, depending on the temperature setting, remain in the hot water of the certified thermal disinfection system for a specific amount of time (EN ISO 15883-1):

- 100 minutes at 70 °C
- 30 minutes at 75 °C
- 10 minutes at 80 °C
- 1 minute at 90 °C

  These time-temperature combinations were calculated and specified based on known thermal inactivation kinetics of vegetative microorganisms which were subjected to a thermal disinfection (EN/ISO 15883-1). They include the recommended time-temperature combinations of APIC (Associations for Professionals in Infection Control and Epidemiology) and RKI (Robert Koch Institute).

Then take the mask components out of the disinfection system and let them air dry while protecting them from exposure to direct sunlight.

3.3 GAS STERILIZATION

Pack the completely dried mask components in accordance with the manufacturer‘s instructions for use for your low-temperature steam and formaldehyde sterilizer. Conduct the sterilization in accordance with the manufacturer‘s instructions for use for your low-temperature steam and formaldehyde sterilizer.

3.4 CHEMICAL PLASMA STERILIZATION (STERRAD)

For sterilization the cleaning should be done using Alconox.
Pack the completely dried mask components in accordance with the manufacturer‘s instructions for use for your STERRAD system. Using bags is not recommended. Conduct the sterilization in accordance with the manufacturer‘s instructions for use for your STERRAD system.

3.5 SUPERHEATED STEAM (AUTOCLAVE)

❶ – ❽: Sterilize the plastic parts of the mask (mask frame, exhalation valve, hose connection) in an autoclave at a maximum 121 °C. The silicone parts can be autoclave at a maximum 134°C.
❾: Sterilize the plastic and silicone parts of the mask in an autoclave at a maximum 134 °C.
The duration of the sterilization is e.g. depending on the autoclave, the number of components to be sterilized and the hospital’s guidelines.

4 INSPECTION

Every mask component must be inspected for visible damage after disinfection/sterilization. Every component that shows signs of wear and tear (rips, breaks, etc.) should be replaced. Possible discolorations of the silicon parts are harmless and not a reason for replacement.

5 PUT THE MASK TOGETHER

Put the mask together.

6 PACKAGING AND STORAGE

Store the mask system until use, keeping it safe from dirt and contamination in a tearproof, closed plastic bag in a location away from direct sunlight. It should be stored at temperature between - 20 °C up to + 60 °C.

7 DOCUMENTATION OF THE PREPARATION

In order to avoid exceeding the number of recommended preparation cycles we recommend documenting the preparation of every mask system.

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