



**Disinfection/Sterilization
Instructions
of the Mask for Multi-Patient Use in
a Hospital/Institutional Environment**

The Disinfection/Sterilization Instructions

This Instructions is intended for multipatient use of a BMC full face mask, nasal mask or nasal pillows system (‘mask’) in a sleep lab, clinic or hospital. If you use the mask as a single user in the home, refer to the User Manual for cleaning instructions.

This Instructions describes BMC's recommended and validated procedures for cleaning, disinfection and sterilization of the mask in accordance with ISO 17664.

Note: Only masks listed in the table below have been validated for reprocessing between patients.

Mask	Model	High level thermal disinfection	CIDEX® OPA	Validated Number of Cycles
Willow Nasal Pillows System (for USA&Russia only)	BMC-PM	✓	✓	20
FeaLite Nasal Pillows System	BMC-PM	✓	✓	20
iVolve Nasal Mask	BMC-NM	✓	✓	20
iVolve Full Face Mask	BMC-FM	✓	✓	20
iVolve F1A Full Face Mask	BMC-FM1A	✓	✓	20
iVolve N2 Nasal Mask	BMC-NM2	✓	✓	20

- ✧ Replace Elbow of BMC-FM with new parts between patients.
- ✧ Alternative disassembly available. See “Disassembling the masks” .
- ✧ Short tube of BMC-PM assembly validated to 70° C.
- ✧ If a healthcare facility requires an additional disinfection or sterilisation cycle after reassembly, the number of validated cycles must be halved.

Disinfection/Sterilization Procedures

The Mask can be used for multi-patient.

A high level disinfection by thermal or chemical disinfection should be taken. Procedures the Mask by **Thermal Disinfection** as followed procedure every time before multi-patient reuse:

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- a. Disassembly Disassemble components of the Mask, removing headgear, connectors. Visually inspect to insure that all components are free from defects, tears, or other visible marks of deterioration, according the **User Manual**.
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- b. Cleaning and drying
- 1) Clean the individual parts of the mask with a soft bristle brush for one minute while soaking them in one the following detergents or disinfectants according to manufacturer's instructions. Pay particular attention to all crevices and cavities.
 - neodisher MediZym (concentration at 2% for 30 minutes),
 - Alconox (diluted at 1%).
 - 2) Rinse the components twice by agitating them vigorously in drinking quality water (five litres per mask).
 - 3) Allow the mask components to air dry out of direct sunlight.
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- c. Disinfection or sterilization and drying
- 1) Using a certified hot water disinfection system, soak the disinfectable mask components using a temperature-time combination¹:
EN ISO 15883-1:
 - 70°C for 100 minutes
 - 75°C for 30 minutes
 - 80°C for 10 minutes
 - 90°C for 1 minute.
 - 2) On completion, remove the mask components from the hot water disinfection system.
 - 3) Allow the mask components to air dry out of direct sunlight.
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- d. Inspection
- Perform a visual inspection of each mask component. If any visible deterioration of a mask component is apparent (cracking, crazing, tears etc), the mask component should be discarded and replaced. Slight discolouration of the silicone components may occur and is acceptable.
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- e. Reassembly
- Reassemble the mask according to the instructions in the ***User Manual***.
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- f. Packaging and storage
- Store in a dry, dust-free environment away from direct sunlight.
Storage temperature: -20° C to 55° C.
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✧ **Calculated and predicted from known thermal inactivation kinetics of vegetative micro-organisms subjected to thermal disinfection (EN/ISO 15883-1) and they are inclusive of the time-temperature combination recommended by the APIC (Associations for Professionals in Infection Control and Epidemiology) and RKI (Robert Koch Institute).**

Procedures the Mask by **CIDEX[®] OPA** as followed procedure every time before multi-patient reuse:

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| a. Disassembly | Disassemble components of the Mask, removing headgear, connectors. Visually inspect to insure that all components are free from defects, tears, or other visible marks of deterioration, according the User Manual . |
| b. Cleaning and drying | <ol style="list-style-type: none">1) Clean the individual parts of the mask with a soft bristle brush for one minute while soaking them in one the following detergents or disinfectants according to manufacturer's instructions. Pay particular attention to all crevices and cavities.<ul style="list-style-type: none">➤ neodisher MediZym (concentration at 2% for 30 minutes),➤ Alconox (diluted at 1%).2) Rinse the components twice by agitating them vigorously in drinking quality water (five litres per mask).3) Allow the mask components to air dry out of direct sunlight. |
| c. Disinfection or sterilization and drying | <ol style="list-style-type: none">1) Fully immerse and soak the disinfectable mask components in the following commercially available solutions according to the manufacturer's instructions:<ul style="list-style-type: none">➤ ortho-phthalaldehyde 0.55% (eg, CIDEX[®] OPA) for 20 minutesWhen using this solution follow the combinations:<ul style="list-style-type: none">➤ Alconox with CIDEX[®] OPA.2) Rinse the mask components in drinking quality water (five litres per mask).3) Allow the mask components to air dry out of direct sunlight. |
| d. Inspection | Perform a visual inspection of each mask component. If any visible deterioration of a mask component is apparent (cracking, crazing, tears etc), the mask component should be discarded and replaced. Slight discolouration of the silicone components may occur and is acceptable. |
| e. Reassembly | Reassemble the mask according to the instructions in the User Manual . |
| f. Packaging and storage | Store in a dry, dust-free environment away from direct sunlight.
Storage temperature: -20° C to 55° C. |
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Notes:

Before the disinfection/sterilization, make sure all the components have been cleaned. Inspect the Mask components after processing. If any components are damaged, replace the mask.

Slight discoloration of the Mask components after processing is normal. The headgear does not require disinfection and should not be washed in disinfection chemicals. Thoroughly washing the headgear between patients is acceptable.

- 1. Handwash the headgear in warm 30° C water using mild soap.*
- 2. Rinse well and allow it to air dry out of direct sunlight.*