



Cleaning / Disinfection Instructions of BMC's Masks

CE 0123

The Cleaning / Disinfection Instructions

This Instructions is intended for multipatient use of a BMC full face mask, nasal mask or nasal pillows interface ('mask') in a sleep lab, clinic or hospital. The Mask can be reused for multi-patient every time after thermal or chemical disinfection.

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 and disinfection of the mask in accordance with ISO17664.

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

Mask	Model	High level thermal disinfection	High level chemical disinfection	Validated Number of Cycles
iVolve Full Face Mask	BMC-FM	√	√	20
iVolve F1A Full Face Mask	BMC-FM1A	√	√	20
iVolve N2 Nasal Mask	BMC-NM2	√	√	20
F2 Full Face Mask	BMC-FM2	√	√	20
N4 Nasal Mask	NM4	√	√	20
Nasal Pillows Interface	P2/ P6	√	√	20
F1B Full Face Mask	F1B	√	√	20
Nasal Mask	N5/ N5+/N6	√	√	20
Nasal Mask	N5A/ N5A+	√	√	20
Nasal Mask	N5B/ N5B+	√	√	20
Full Face Mask	F5/F5A F5+/F5A+	√	√	20
Full Face Mask	F6	√	√	20
Nasal Pillows Interface	P2H	√	√	20
Nasal Mask	N5H	√	√	20
Nasal Mask	N5AH	√	√	20
Nasal Mask	N5BH	√	√	20
Full Face Mask	F5AS	√	√	20
Full Face Mask	F4	√	√	20

- ✧ Alternative disassembly available. See “Disassembling the masks” .
- ✧ If a healthcare facility requires an additional disinfection or sterilisation cycle after reassembly, the number of validated cycles must be halved.

Thermal Disinfection Procedures

Procedure the Mask by *Thermal Disinfection* as following procedures every time before multi-patient reuse:

a. Disassembly	Disassemble components of the Mask. Visually inspect to insure that all components are free from defects, tears, or other visible marks of deterioration, according to the User Manual .
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b. Cleaning and drying	<ol style="list-style-type: none">1) Soaking the components in a solution of Alconox by diluting with drinking quality water at 1% at 30 ±5°C for 10 minutes according to manufacturer's instructions.2) Whilst immersed in the solution, clean each component of the mask with a soft bristle brush for one minute . Pay particular attention to all crevices and cavities.3) Rinse the components twice by agitating them vigorously in drinking quality water (five litres per mask each time).4) Allow the mask components to air dry, out of direct sunlight.
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c. Disinfection and drying	<ol style="list-style-type: none">1) Soak the disinfectable mask components in a hot water bath using a temperature-time combination, ensuring there are no air bubbles:<ul style="list-style-type: none">• 70°C for 500 minutes(Not applicable to headgear)• 90°C for 5 minutes(Not applicable to headgear)• 90°C for 10 minutes(Applicable to headgear only)2) On completion, remove the mask components from the hot water bath.3) Allow the mask components to air dry, out of direct sunlight. <p>Note: It is recommended that parts with Short tube be Thermal Disinfection at 70°C as the Short tube will harden above 70°C.</p>
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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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Chemical Disinfection Procedures

Procedure the Mask by *chemical disinfection* as following procedures every time before multi-patient reuse:

✧ Headgear cannot be processed with chemical disinfection.

a. Disassembly	Disassemble components of the Mask. Visually inspect to insure that all components are free from defects, tears, or other visible marks of deterioration, according the <i>User Manual</i> .
b. Cleaning and drying	<ol style="list-style-type: none"> 1) Soaking the components in a solution of Alconox by diluting with drinking quality water at 1% at $30 \pm 5^{\circ}\text{C}$ for 10 minutes according to manufacturer's instructions. 2) Whilst immersed in the solution, clean each component of the mask with a soft bristle brush for one minute .Pay particular attention to all crevices and cavities. 3) Rinse the components twice by agitating them vigorously in drinking quality water (five litres per mask each time). 4) Allow the mask components to air dry, out of direct sunlight.
c. Disinfection 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 insructions: <ul style="list-style-type: none"> ➤ ortho-phthalaldehyde 0.55% (eg, CIDEX[®] OPA) at 20°C for 12 minutes 2) Rinse the mask components in drinking quality water (five litres per mask). Repeat the process by using drinking quality water for two more times. 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 <i>User Manual</i> .
f. Packaging and storage	Store in a dry, dust-free environment away from direct sunlight. Storage temperature: -20°C to 55°C .

Notes:

1. Failure to clean the mask components as indicated may result in inadequate disinfection. Please refer to Alconox Manufacturer's instructions for cleaning.
2. Please refer to the recommended disinfectant manufacturer's instructions for chemical high level disinfection.
3. Inspect the Mask components after processing. If any components are damaged, replace the mask.
4. Slight discoloration of the Mask components after processing is normal.