



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

The Cleaning / Disinfection 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 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
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
F2 Full Face Mask	BMC-FM2	√	√	20
N4 Nasal Mask	NM4	√	√	20
P2 Nasal Pillows Interface	P2	√	√	20
F1B Full Face Mask	F1B	√	√	20
N5 Nasal Mask	N5	√	√	20

- ✧ **Alternative disassembly available. See “Disassembling the masks” .**
- ✧ **The validated thermal disinfection temperature of Short tube assembly of BMC-PM and P2 is 70° C.**
- ✧ **The validated thermal disinfection temperature of headgear is 95°C. Headgear cannot be processed with chemical disinfection.**
- ✧ **If a healthcare facility requires an additional disinfection or sterilisation cycle after reassembly, the number of validated cycles must be halved.**

Cleaning / Disinfection Procedures

The Mask can be used for multi-patient.
A high level disinfection by thermal or chemical disinfection should be taken.

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

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| 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> . |
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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 a solution of Alconox by diluting with drinking quality water at 1% at 20-25°C according to manufacturer's instructions. Pay particular attention to all crevices and cavities.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 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(Short tube assembly only)• 80°C for 50 minutes• 90°C for 5 minutes• 95°C for 10 minutes(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.
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.

Procedure the Mask by *chemical 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 the <i>User Manual</i> .
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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 a solution of Alconox by diluting with drinking quality water at 1% at 20-25°C according to manufacturer's instructions. Pay particular attention to all crevices and cavities. 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 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) at 20°C for 12 minutes 2) Rinse the mask components in drinking quality water (five litres per mask). Repeat the process by using fresh water for two more times. 3) Allow the mask components to air dry out of direct sunlight.
d. Inspection	<p>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.</p>
e. Reassembly	<p>Reassemble the mask according to the instructions in the User Manual.</p>
f. Packaging and storage	<p>Store in a dry, dust-free environment away from direct sunlight. Storage temperature: -20° C to 55° C.</p>

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.