

This guide is intended for multi-patient use of the F&P Nova Micro™ nasal pillows mask in the hospital, or other clinical settings, where proper disinfection of the device must occur between patients. When using the mask for single-patient use in the home, please refer to your Nova Micro Instructions for Use under ‘Cleaning Your Mask at Home’.

Mask Components	Thermal Disinfection <i>In line with EN ISO 15883, the uncertainty range for disinfection temperature is -0 °C and +5 °C.</i>			Chemical Disinfection	Sterilization
	1 min at 90 °C (194 °F)	10 mins at 80 °C (176 °F)	30 mins at 75 °C (167 °F)	CIDEX™1 OPA, MetriCide™2 OPA Plus or RAPIDCIDE™3 OPA/28	STERRAD™4
F&P Nova Micro Nasal Pillows Mask • Cushion* • Frame Assembly**	Maximum of 25 cycles			Maximum of 25 cycles	-
F&P Nova Micro Headgear • Headgear***					-

\*Replace the cushion if it becomes discolored.

\*\*Frame Assembly includes: Frame, Tube and Swivel.

\*\*\*If contaminated with blood, please replace the contaminated component between patients.



Each cycle is limited to one day of use.

### General Warnings and Cautions

The instructions provided in this guide have been validated as being capable of preparing the masks for reuse. Fisher & Paykel Healthcare does not recommend any deviations from the recommended method of reprocessing.

<b>Warning</b>	Deviations from the recommended methods of reprocessing may result in inadequate disinfection/sterilization and adverse health effects.
<b>Warning</b>	Frequency of cleaning, methods of cleaning or the use of cleaning agents, other than those specified in the accompanying documents or exceeding the number of processing cycles, can have an adverse effect on the mask and consequently the safety or the quality of the therapy.
<b>Caution</b>	Only clean the mask with cleaning products specified in the cleaning instructions of this guide, as any other products may result in an adverse reaction if cleaning residue is left behind.
<b>Caution</b>	Do not clean the mask with products containing alcohol, antiseptic, bleach, chlorine or moisturizer as these may compromise the function of the mask.
<b>Caution</b>	Do not clean the mask in a dishwasher as this may compromise the function of the mask.


## Validated Disinfection and Sterilization Procedures

<b>Point of Use (optional)</b>	Any gross soiling on the mask may be removed by wiping or rinsing with potable water.		
<b>Disassembly</b>	Disassemble the mask according to the 'Disassembling your mask' instructions provided in the Nova Micro Instructions for Use, then peel open the straps on the Headgear.  <b>Caution:</b> Failure to fully disassemble the mask may compromise the effectiveness of cleaning and the subsequent disinfection steps which may result in a range of harms, some of which are severe.		
<b>Cleaning</b>	<i>Cleaning the Cushion and Frame Assembly</i>	<ol style="list-style-type: none"> <li>Soak Cushion and Frame Assembly in a solution of mild alkaline anionic detergent according to the manufacturer's instructions (e.g. Alconox™<sup>5</sup> at 1% concentration and 50 °C) for 10 minutes, ensuring that no air bubbles are present on the device surface.</li> <li>Using a soft non-metallic brush (e.g. medium-hard toothbrush), vigorously brush the mask parts until visibly clean but not for less than 10 seconds. An additional narrow bottle brush is required to access the Mask Tube. Pay close attention to crevices, cavities and corners, such as the internal surfaces of the cushion and frame.</li> <li>Manually rotate both ends of the tube where it joins the swivel and the frame for at least 10 seconds each, while submerged in the detergent solution.</li> <li>Rinse by submerging in 5 liters of fresh demineralized water and agitating for at least 10 seconds.</li> <li>Manually rotate both ends of the tube where it joins the swivel and the frame for at least 10 seconds each, while submerged in the demineralized water.</li> <li>Repeat the submerged rinse in fresh demineralized water.</li> <li>Ensure the Cushion and Frame Assembly are visibly clean before continuing. If not, repeat steps 1-6.</li> </ol>	
	<i>Cleaning the Headgear</i>	<ol style="list-style-type: none"> <li>Soak the Headgear in a solution of mild alkaline anionic detergent according to the manufacturer's instructions (e.g. Alconox at 1% concentration and 50 °C) for 10 minutes, ensuring that no air bubbles are present on the device surface.</li> <li>Using a soft non-metallic brush (e.g. medium-hard toothbrush), scrub the headgear until visibly clean but not for less than 30 seconds. Pay close attention to crevices, cavities and corners.</li> <li>Rinse under running water for at least 30 seconds, intermittently wringing the fabric.</li> <li>Submerge in 5 liters of demineralized water while agitating and squeezing for at least 30 seconds.</li> <li>Repeat submerged rinse in fresh demineralized water. Ensure that all detergent residue is removed by repeating submerged rinse as many times as necessary.</li> <li>Ensure the headgear is visually clean before continuing. If not, repeat steps 1-5.</li> </ol>	
<b>Drying</b>	Make sure mask components are thoroughly dry before continuing by leaving them to air dry out of direct sunlight. Failure to do this may result in ineffective disinfection.		
<b>Disinfection</b>	<b>Thermal Disinfection</b>	<b>Chemical Disinfection</b>	<b>Sterilization</b>
	Run a disinfection cycle in a legally marketed automatic washer-disinfector using one of the time/temperature combinations shown in the reprocessing table. These time/temperature combinations are consistent with EN ISO 15883 and are equivalent in terms of known thermal inactivation kinetics of vegetative microorganisms, meeting an A <sub>0</sub> of 600.	<b>For all reprocessable components:</b>	
		<ol style="list-style-type: none"> <li>Immerse completely in an undiluted bath of CIDEX OPA, MetriCide OPA Plus or RAPICIDE OPA/28 at 20 °C, ensuring that no air bubbles are present on the device surface.</li> <li>Manually rotate the tube where it joins the frame for at least 10 seconds while submerged.</li> <li>Leave the mask parts to soak for 12 minutes.</li> <li>Repeat steps 2 and 3.</li> <li>Rinse thoroughly following the manufacturer's rinsing instructions. Manually rotate the tube where it joins the frame for at least 10 seconds while rinsing.</li> </ol>	 <b>Caution:</b> The use of STERRAD or Autoclave as a reprocessing method may lead to mask degradation and adverse health effects.
<b>Drying</b>	Allow all components to air dry out of direct sunlight.		
<b>Inspection</b>	Before each use, inspect the mask for deterioration. If any visible deterioration of a mask component is apparent, the mask component should be discarded and replaced.		
<b>Reassembly</b>	Reassemble the mask according to the 'Assembling your mask' instructions provided in the Nova Micro Instructions for Use. To ensure traceability, mask components belonging to an individual mask must be reassembled back into the same mask after cleaning, excluding the components requiring replacement as marked in the reprocessing table.		
<b>Storage</b>	Ensure the mask is completely dry before storing. Store in clean conditions out of direct sunlight. Storage temperature: -20 °C to 50 °C (-4 °F to 122 °F).		

- CIDEX is a trademark of ASP Global Manufacturing GmbH.
- MetriCide is a trademark of Metrex Research LLC.
- RAPICIDE is a trademark of Medivators Inc.
- STERRAD is a trademark of ASP Global Manufacturing GmbH.
- Alconox is a trademark of Alconox, Inc.

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