

CLEANING AND DISINFECTION OF MASKS IN HEALTH CARE SETTINGS

This guide is intended for multi-patient use of the Breas Apto® N01 Nasal 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 at home, please refer to your User Instructions.

1

Reprocessable Mask Components

For disassembly, please refer to the User Instructions.

Mask Component	Replace after each use	Total Cycles of Cleaning	Cleaning	Thermal Disinfection In line with EN ISO 15883, the uncertainty range for disinfection temperatures is -0 °C and +5 °C			Chemical Disinfection
			Solution of mildly alkali anionic detergent	1 min at 90 °C (194 °F)	10 mins at 80 °C (176 °F)	30 mins at 75 °C (167 °F)	CIDEX™ OPA Orthophthalaldehyde 0.55 %
Elbow	None**	30	✓	✓	✓	✓	✓
Frame			✓	✓	✓	✓	✗
Cushion*			✓	✓	✓	✓	✓
Headgear clips			✓	✓	✓	✓	✓
Headgear			✓	✓	✓	✓	✗

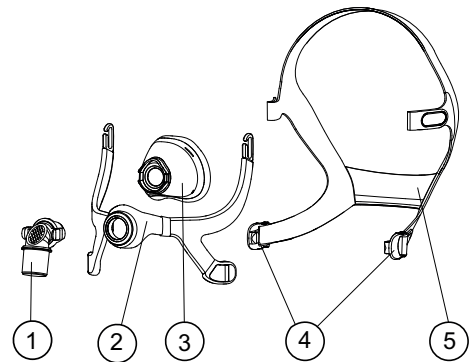
* Replace cushion if it discolours.

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



Mask Components

- 1. Elbow
- 2. Frame
- 3. Cushion
- 4. Headgear clips
- 5. Headgear



2 Healthcare Multi-Patient Reuse Instructions

Point of Use	Remove any gross soiling on the mask by wiping or rinsing in potable water.
Disassembly	1. Unhook headgear clips from frame. 2. Unwrap headgear top strap from frame. 3. Unwrap headgear from headgear clips. 4. Remove cushion from frame. 5. Remove elbow from cushion.
Manual Cleaning	Soak all reprocessable parts of the mask in a solution of mildly alkali, anionic detergent e.g. Alconox* according to the manufacturer's instructions (at 1 % concentration and 50 °C for 10 mins), ensuring that no air bubbles are present on the device surface. 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. Pay close attention to crevices, cavities and corners, such as the join between the silicone seal and plastic housing. For the headgear and frame with frame cover, Submerge in 5 litres of demineralised water while agitating and squeezing for at least 30 seconds. Repeat submerged rinse. Repeat submerged rinse as necessary to ensure that all detergent residue is removed. For all other mask components, rinse by submerging in 5 litres of demineralised water and agitating for at least 10 seconds. Repeat rinse.
Post Cleaning	Inspect each component and if required, repeat washing until visually clean.
Drying	Allow the mask components to air dry out of direct sunlight.
* Alconox is a trademark of Alconox, Inc. ** Cidex is a trademark of of Advanced Sterilization Products, a division of Ethicon Inc., a Johnson & Johnson Company.	

Thermal Disinfection	Run a disinfection cycle in an automatic washer-disinfector using one of the time/temperature combinations shown below. 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 A0 of 600. • 1 min at 90 °C (194 °F) • 10 mins at 80 °C (176 °F) • 30 mins at 75 °C (167 °F)
Chemical Disinfection	Immerse completely in an undiluted bath of CIDEX** OPA, 0.55 % ortho-phthaldehyde, at 20 °C for 12 minutes, ensuring that no air bubbles are present on the device surface. Rinse thoroughly following the manufacturer's rinsing instructions.
Drying	Allow all components to air dry out of direct sunlight.
Maintenance, Inspection Prior to Next Use	1. If contaminated with blood, please discard safely and replace the contaminated component between use. 2. Before each use, inspect for deterioration. If any visible deterioration of a mask component is apparent (cracking, crazing, tears etc), the mask component should be discarded and replaced. Slight discoloration of the silicone components may occur and is acceptable.
Preparation after: Reassembly	1. Attach and press cushion onto frame. 2. Attach elbow onto frame and cushion. 3. Place frame cover back onto frame. 4. Attach headgear clip to headgear lower strap. 5. Attach top headgear strap on the frame.
Packaging and storage	Store in a dry, dust-free environment away from direct sunlight. Storage temperature: -20 °C to 60 °C
* Alconox is a trademark of Alconox, Inc. ** Cidex is a trademark of of Advanced Sterilization Products, a division of Ethicon Inc., a Johnson & Johnson Company.	

3 Warnings, Cautions and Limitations on Processing

WARNING!



Clean and disinfect as described in this manual only. The use of other intervals, methods, agents, or exceeding the number of processing cycles, may compromise the function of the mask and consequently the safety or the quality of the therapy. Other methods and agents may also leave cleaning residues, resulting in adverse reactions

CAUTION!



- Do not clean the mask with products containing, antibacterial agents, antiseptic, bleach, chlorine or moisturizer.
- Do not clean the mask in a dishwasher.
- Do not clean the mask in a washing machine.
- Failure to fully disassemble the mask may compromise the effectiveness of cleaning and may result in a range of harms, some of which are severe.
- If the mask weakens or cracks, discontinue use and seek replacement immediately.

Limitations on Processing

The mask system has a delicate cushion membrane that seals against the face. Sterilization may compromise the function of the mask.