

EN CPAP SILICONE NASAL MASK

REF:

LOT

Date of Manufacture:

Use By:

DeVilbiss[®] HEALTHCARE

Consult instructions for use

Not made with natural rubber latex.

INTENDED USE

The CPAP/VPAP Mask is intended to be used for patients who have been prescribed CPAP or VPAP therapy and are under the specific direction of a physician. It is used in conjunction with continuous positive airway pressure (CPAP/VPAP) devices in home, hospital and Institutional environments.

CONTRAINDICATIONS

This mask may not be suitable for patients with the following conditions: impaired cardiac sphincter function, excessive reflux, impaired cough reflex and hiatal hernia. It should not be used if the patient is unresponsive, obtunded, unable to remove the mask, or uncooperative.

WARNINGS

- This mask should only be used with CPAP systems recommended by your physician or respiratory therapist.
- Do not use this mask unless the CPAP or VPAP system is turned on and operating properly.
- Never block the mask's vent holes or exhalation port.

NOTE: CPAP systems are intended to be used with special masks with vent holes in either the connectors or the mask that allow continuous flow out of the mask. When the CPAP device is turned on and functioning properly, new air from the CPAP device flushes the exhaled air out through the mask's exhalation port. However, when the CPAP device is not operating, enough fresh air will not be provided through the mask and exhaled air may be rebreathed. Rebreathing of exhaled air for several minutes can in some circumstances lead to suffocation.

- If oxygen is used with the CPAP system, the oxygen flow must be turned off when the CPAP device is not in operation.

NOTE: When the CPAP device is not in operation and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the CPAP device's enclosure and create a risk of fire.

NOTE: At a fixed flow rate of supplemental oxygen, the inhaled oxygen concentration will vary depending on the pressure setting, patient's breathing pattern and leak rate.

- Do not smoke if oxygen is in use.
- Contact a health care professional in the event chest discomfort, shortness of breath, stomach distention, belching, or severe headache are experienced.
- Avoid eating or drinking three hours before using this mask to minimize the risk of vomiting during sleep.
- Do not use this mask if you are taking medication that may cause vomiting.

CAUTION: At low CPAP pressures the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing and some rebreathing may occur.

- Must only be used by persons who have received adequate training from qualified medical personnel.
- Used in combination with other medical devices might alter the performance of the mask.

CAUTION

USA federal law restricts this device to sale by or on the order of a physician.

The use of bleach, chlorine, alcohol or aromatic-based solutions may cause hardening and reduce the life of the product.

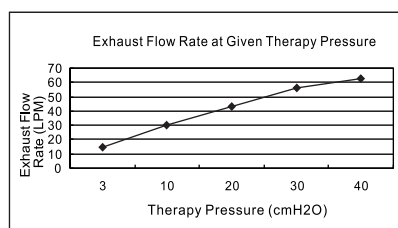
FEATURES

- One piece molded silicone rubber; small, light and comfortable.
- Clear mask allows a good view of mouth and nasal area.
- Low dead space results in low CO₂ build up.
- Dual swivel 360° rotating elbow and tubing connector.
- Headgear with Velcro fasteners provides maximum versatility and movement.

CLEANING INSTRUCTIONS

- Detach headgear from mask.
- Handwash gently with mild soap and warm water (30°C), rinse the mask and components thoroughly. **NOTE - Headgear should only be hand washed with mild soap by gently rubbing in warm water at 30°C. No washing machine, no ironing.**
- Allow mask and components to air dry before reusing. Do not place in direct sunlight.
- Replace mask if there are cracks, tears or excessive discoloration.
- The D100 is dishwasher safe if placed in top rack.

Size: Assembled Mask (without Headgear) - 146mm (H), 90mm (W), 69mm (D)	
Weight: Mask incl. Headgear: 88g; Headgear: 31g	
Materials used:	
Mask frame: Polycarbonate (PC)	Forehead Pad: Silicone
Headgear: Nylon + Spandex	Cushions: Silicone
The mask system does not contain latex materials. This product does not contain PVC or Phthalates.	



RESISTANCE (cmH ₂ O)	50LPM	100LPM
D100N	0.47	2.24

MODEL	VOLUME (ML)
D100N-S	124.5
D100N-M	129.8
D100N-L	144.6

Expected Service Life

- Mask Frame Components = 6 months
- Headgear = 3 months
- Mask Cushions = 3 months

Storage relative humidity: < 85%
 Operation temp: -18°C - 50°C
 Storage temp: -40°C - 60°C

Please follow assembly instructions below:

- Important Note:** When removing the mask for cleaning, there is no need to unfasten the Velcro tabs. Simply unclip the lower buckles and remove the upper headgear straps from the slots in the mask frame. Replace after cleaning.
- To remove the mask and headgear, simply unbuckle both buckles (A3 & A4) from the mask frame and pull off the mask.
- To reuse the mask and headgear, simply place upper headgear over head and hook both buckles.
- This product does not require maintenance.

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