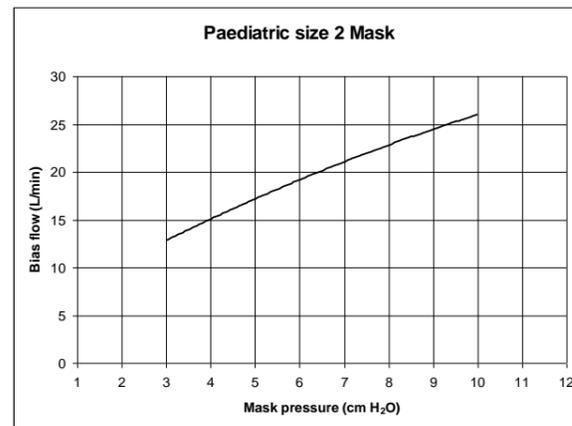
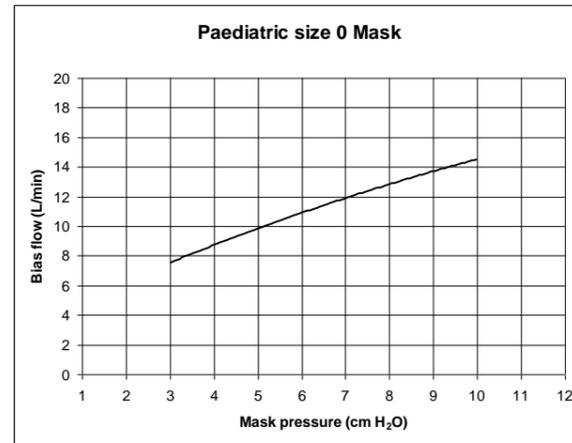


Technical Specifications

Pressure/Flow Curves



Order Codes

Description	Order Code
Concept Soft Paediatric Nasal CPAP Mask (Size 0)	AM001
Concept Soft Paediatric Nasal CPAP Mask (Size 2)	AM003



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 Protected by patents. Other patents pending.
Concept Soft is a registered trademark of Maskmedic Pty Ltd.
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Dead space information: The dead space of the *Concept Soft* paediatric mask is 8mL for size 0 and 21 mL for size 2.

Explanation: Dead space is the empty volume of the mask, not including straight part leading to the tube.

Pressure drop: The pressure drop between the mask and the patient connecting port at a flow rate of 50 l/min is 0.4cm H₂O, and at 100 l/min is 1.8cm H₂O.

Important Information (cont.)

- ⚠ **WARNING:** If oxygen is used with the CPAP system, the oxygen flow should only be turned on when the CPAP machine is operating.
Explanation: When the CPAP device is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate with the CPAP machine enclosure. This will create a risk of fire. This warning applies to most types of CPAP systems.
Note: At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and leak rate. This applies to most types of CPAP systems.
- ⚠ **WARNING:** Do not smoke while oxygen is in use.
- ⚠ **WARNING:** Do not place the CPAP machines above the child's head where it may be pulled down.
- ⚠ **WARNING:** Ensure the air tube is positioned so that it does not wrap or tangle around the child during child sleep movement.
- ⚠ **CAUTION:** Ensure the CPAP machine is located on a stable surface close to the patient. Patient movement during sleep may cause the air tube to pull and dislodge the CPAP machine.

SERVICE LIFE:

Expected service life is six months from start of use. Latest date to be used is five years from date of manufacture. This is shown as YYYY-MM-DD on the product label.

MASK DISPOSAL:

No parts of the mask are suitable for recycling after use. Home: dispose of mask parts in domestic waste. Hospital: Dispose of mask parts as biohazard. The *Concept Soft* mask system is latex-free.

MASK AND HEADGEAR SIZE:

Note: As the child grows, larger sizes of the mask and/or headgear may be required. Check with the child's physician to ensure correct sizes are fitted.

Concept™ Soft Paediatric Nasal CPAP Mask



INFORMATION FOR USERS

For use as an accessory with standard Continuous Positive Airway Pressure (CPAP) and bi-level positive airway treatment devices and other non-continuous ventilators. Intended for paediatric patients in medical facilities or home use.
 For single patient re-use only. Not for multi-patient use.

Fitting and Removing the Mask

Note: Before the first use, you should inspect the mask and headgear and clean as described in Cleaning, Handling and Storage.

Note: Adequate training in fitting the mask by a clinician or sleep technician is essential.

1. If not already assembled, attach the headgear and short-length tubing as shown in Figures 1 and 2. Ensure the label on the headgear is on the outside. After threading the headgear straps through the lugs secure them with the Velcro® tabs.
 2. Ensure the vent holes in the mask are not blocked (Figure 3).
 3. Connect the air tube and start the airflow generator on the pressure setting as advised by the child's physician.
 4. Fit the headgear over the child's head and position the mask so that it covers the child's nose as shown in Figures 3 to 5. If the headgear is too tight, loosen the headgear by re-positioning the Velcro® tabs.
 5. Adjust the headgear straps by tightening or loosening the straps and re-positioning the Velcro® tabs. It is recommended you adjust the straps in this order: top side straps (fig 3 & fig 4) and finally the bottom side straps (fig 5).
 6. Adjust the headgear straps and mask so that there are no air leaks and the mask is comfortable. Ensure that the bottom of the mask sits away from the child's nostrils. The bottom of the mask should sit just under their nostrils and above their top lip.
Note: Do not over-tighten the straps as this may cause the mask to sit incorrectly and may be uncomfortable. You should be able to easily slide one finger under the headgear.
 7. To remove the headgear, loosen one of the bottom side straps and carefully pull the headgear off over the child's head.
- ⚠ **WARNING:** Ensure that the mask does not cover the child's mouth.
- ⚠ **CAUTION:** If the mask causes sores or other injury, stop using the mask and consult the child's physician or sleep technician.

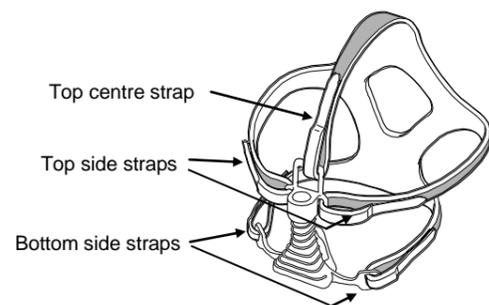


Figure 1

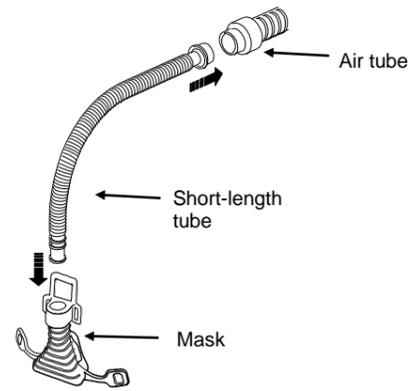


Figure 2

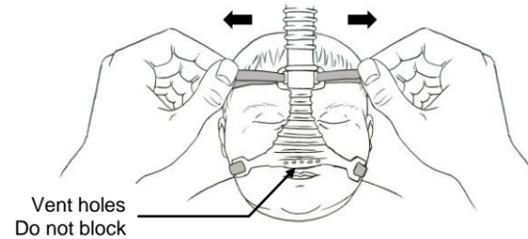


Figure 3



Figure 4

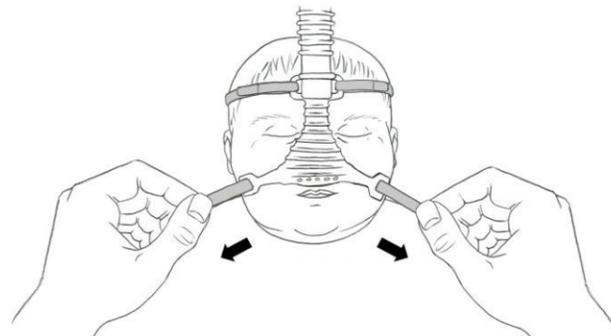


Figure 5

Cleaning, Handling and Storage

⚠ **WARNING:** The Concept Soft mask is for single patient use. To avoid the risk of cross-infection, do not reuse between patients.

1. The mask must be cleaned daily.
2. Wash the mask by hand with warm water and mild detergent such as Palmolive® Original, rinse and thoroughly dry.
3. Ensure the mask is clean and dry before storage.
4. The tubing must be cleaned regularly, using warm water and mild detergent then rinsing thoroughly.
Hint: To dry out the tubing blow air through it with the CPAP machine.
5. Headgear strap should be hand-washed separately, at least once a week, in mild detergent and warm water. Rinse well and allow to air dry out of direct sunlight.
6. The mask, headgear and attachments should be checked for damage and wear after each use and any worn or damaged components should be replaced.

Notes:

- The mask system does not need to be disassembled for daily cleaning.
- If the short-length tube needs to be disconnected from the mask or from the main air tube, do so by holding the swivel. This will avoid stretching and damaging the short-length tube.
- If the swivels need to be disconnected from the short-length tube, do so by holding the tube at the cuff. This will avoid stretching and damaging the short-length tube.

CAUTIONS:

- ⚠ To avoid UV damage do not dry the mask or its parts in direct sunlight.
- ⚠ Do not use abrasive cleaners (e.g. dishwasher detergent) to clean the mask. These may damage the mask or leave unwanted residues.
- ⚠ Do not use chlorine, bleach, alcohol, antibacterial soaps or aromatic-based solutions to clean the mask. These may cause hardening of the mask and deterioration.
- ⚠ Do not iron, dry clean or expose the mask and tubing to direct sunlight.
- ⚠ Check the mask and tubing for wear and replace any worn components.

Important Information

- ⚠ **WARNING:** Patients with depressed arousal response must only use this mask under strict medical supervision. Consult the child's physician or respiratory therapist before use.
- ⚠ **WARNING:** The mask is contraindicated for patients with Primary Hypoventilation Syndrome.
- ⚠ **WARNING:** The mask system contains some small parts which may cause choking, check for loose parts before every use. Ensure mask is secured when not in use to prevent tampering by the child or siblings.
- ⚠ **WARNING:** Long-term use and/or over-tightening of the headgear may impact the child's facial development. In the case of long-term use, medical supervision should be ensured.
- ⚠ **WARNING:** Ensure the child's mouth is not obstructed.
- ⚠ **WARNING:** Use only with recommended CPAP or bi-level equipment as recommended by the child's physician or sleep technician. Ensure the machine is fitted with a "mask-off" alarm. Do not use the mask unless it is connected to a CPAP or bi-level machine that is turned on and running at a pressure of at least 4cm H₂O (min). Ensure mask ventilation holes are not blocked. Operating pressure range is 4–20cm H₂O.
Explanation: CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, fresh air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation. This warning applies to most types of CPAP systems.
- ⚠ **CAUTION:** At low CPAP pressures the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing (see the Pressure/Flow Curve in Technical Specifications). Some rebreathing may occur.
- ⚠ **WARNING:** Do not use the mask with electrically conductive air tubing.