

ResMed Hospital Full Face Mask

The RESMED HOSPITAL FULL FACE MASK is intended for single patient use for adult patients (>30 kg) prescribed continuous positive airway pressure or bilevel therapy in hospitals or clinics.

This is a disposable mask. It is intended to be used for the short-term (maximum seven days) treatment of a single patient only, then discarded.

MEDICAL INFORMATION

Note: *The mask system does not contain latex materials. If the patient has ANY reaction to any part of the mask system, discontinue use.*

CONTRAINDICATION

- This mask may not be suitable for patients at risk of reflux of gastric contents.
- Supervision is recommended if the patient has a reduced level of consciousness or is unable to remove the mask.



WARNINGS

- This mask is not suitable for providing life support ventilation.
- This mask should be used only with CPAP or bilevel systems recommended by a physician or respiratory therapist. A mask should not be used unless the CPAP or bilevel system is turned on and operating properly. **The exhalation device (vent) should never be blocked. The exhalation device must not be used for any medical procedure.**

Explanation of the Warning: CPAP or bilevel systems are intended to be used with special masks with connectors which have vent holes or separate exhalation devices to allow continuous flow of air out of the mask. When the CPAP or bilevel device is turned on and functioning properly, new air from the flow generator flushes the exhaled air out through the mask exhalation port. However, when the CPAP or bilevel device is not operating, enough fresh air may 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 models of CPAP or bilevel systems.

Note: *The mask includes an anti-asphyxia valve to help reduce rebreathing of exhaled air in the event that the CPAP or bilevel device is not operating properly.*

- The exhaust vent flow is lower at lower mask pressures (see Pressure/Flow Curve). If the mask pressure during expiration is too low, there may not be enough exhaust vent flow to completely flush the air delivery hose of exhaled air before the start of the next inspiration.
- Discard the mask if heavily soiled (eg, gastric contents).
- If oxygen is used with the CPAP or bilevel device, the oxygen flow must be turned off when the flow generator is not operating.

Explanation of the Warning: When the CPAP or bilevel device is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the flow generator enclosure. Oxygen accumulated in the CPAP or bilevel device enclosure will create a risk of fire. This warning applies to most types of CPAP or bilevel flow generators.

- Please refrain from smoking while oxygen is in use.
- Using a mask may cause tooth, gum or jaw soreness or aggravate an existing dental condition. If symptoms occur, consult your physician or dentist.

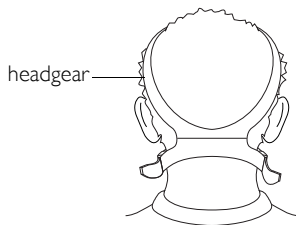
Note: At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate.

FITTING THE MASK

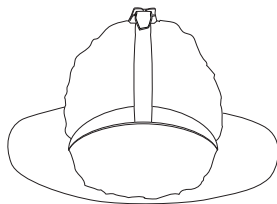
The RESMED HOSPITAL FULL FACE MASK is supplied fully assembled.

Note: Inspect the mask and replace it if any parts are damaged.

- 1 Connect one end of the main air tubing to the flow generator and the other end to the swivel. Turn the flow generator on. See “Technical Specifications” for information on the correct flow generator setting.
- 2 Place the mask cushion over the patient’s nose and mouth and pull the headgear over their head.



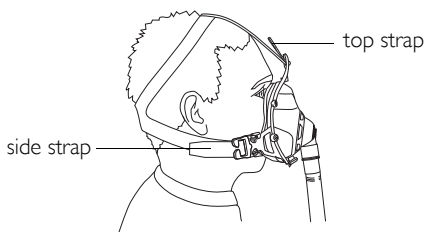
Back view



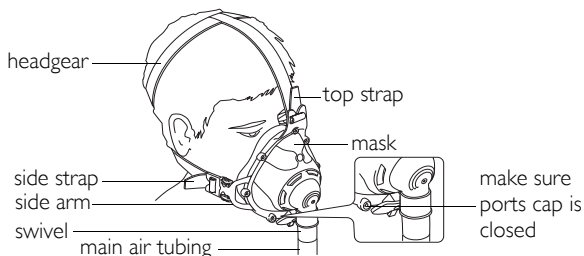
Top view

- 3 Gently tighten the headgear straps:
 - a first, pull the side straps back along the side of the patient's face.
 - b then, adjust the top strap.

Note: Make sure the side straps pass below the patient's ears. The side arms on the mask will bend back as you tighten the side straps. Do not over tighten the straps.



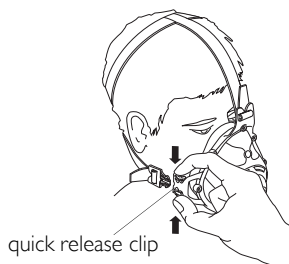
4 The fitted mask should look like this:



5 If the patient feels air leaks around the cushion, reposition the mask on the patient's face to achieve a better seal. You may also need to readjust the headgear straps.

REMOVING THE MASK

To remove the mask, squeeze one of the quick release clips, and pull the mask and headgear up over the patient's head.



DAILY CLEANING OF THE MASK (OR AS REQUIRED)

Disconnect the main air tubing from the swivel.

The **RESMED HOSPITAL FULL FACE MASK** may be cleaned and re-used on a single patient. This applies for a maximum of seven days, after which the mask should be discarded. The mask may be cleaned using a 70% v/v isopropyl alcohol swab or by wiping with a damp, soapy cloth. If using a damp cloth, use mild soap or diluted dishwashing detergent. Allow to air dry out of direct sunlight.

Notes:

- *Do not disassemble the mask.*
- *Discard the mask if heavily soiled.*



CAUTIONS

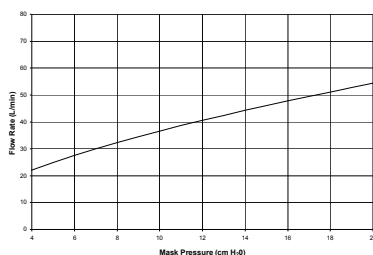
- Do not use solutions containing bleach, chlorine, aromatics, moisturizers, antibacterial agents, or scented oils to clean any part of the system or air tubing. These solutions may cause damage and reduce the life of the product.
- Do not expose any part of the system or tubing to direct sunlight as it may deteriorate.
- If any visible deterioration of a component is apparent (cracking, crazing, tears, etc), replace the mask.
- Check the vent holes for blockage. Ensure the vent holes are cleaned regularly.

TECHNICAL SPECIFICATIONS

PRESSURE / FLOW CURVE

Note: As a result of manufacturing variations, the vent flow may vary from the values listed in the following table.

Pressure (cm H ₂ O)	Flow (L/min)
4	22
8	32
12	41
16	48
20	54



FLOW GENERATOR SETTING

Select "Mir Full" as the mask option when using the ResMed Hospital Full Face Mask with ResMed flow generators that have mask setting options.

DEAD SPACE INFORMATION

Explanation: Dead space is the empty volume of the mask up to the elbow.

The dead space of the mask varies according to cushion sizes but is less than 317 mL.

ENVIRONMENTAL CONDITIONS

Operating Temperature: 5°C (41°F) to 40°C (104°F)

Operating Humidity: 15–95% relative humidity

SYMBOLS WHICH APPEAR ON THE DEVICE



Attention, consult accompanying documents.



ResMed Mask



European Authorised Representative



Manufacturer

S: Small; M: Medium; L: Large

REPLACEMENT PARTS

Part No. Item

60700	ResMed Hospital Full Face Mask System, Small
60701	ResMed Hospital Full Face Mask System, Medium
60702	ResMed Hospital Full Face Mask System, Large
60710	Headgear (10pk.)

**Manufacturer:**

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ResMed Corp 9001 Spectrum Center Boulevard San Diego CA 92123 USA.

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See www.resmed.com for other ResMed locations worldwide.



For patent information, see www.resmed.com/ip

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