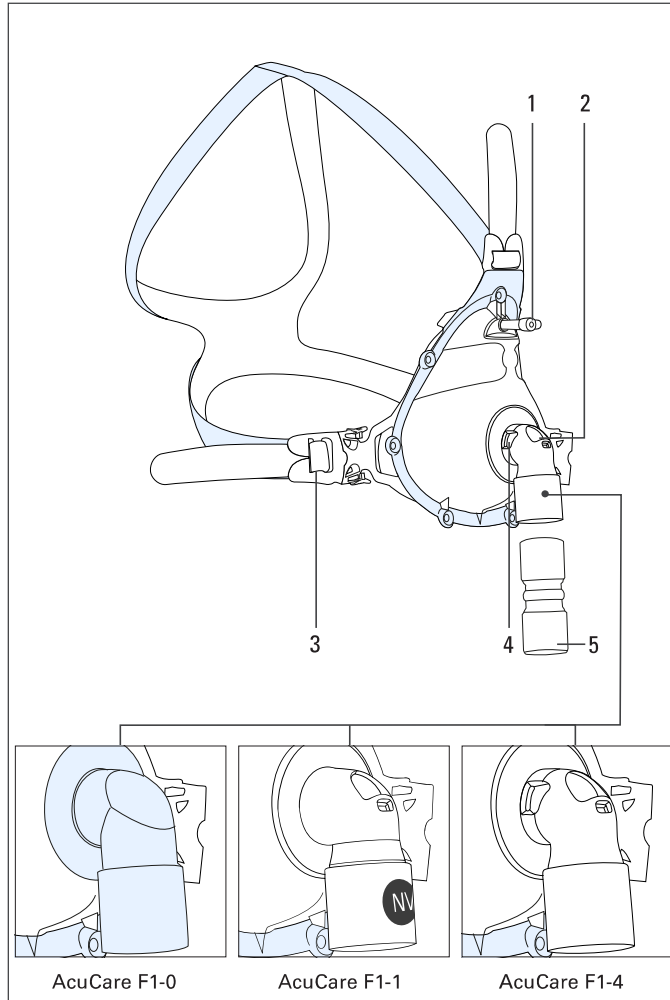




AcuCare™ F1-0
Hospital masks F1-1
F1-4

User guide
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- 1 Port / Anschluss / Port / Presa / Puerto / Porta/ Poort

 - 2 Valve (AcuCare F1-1 and AcuCare F1-4 only) /
Ventil (nur AcuCare F1-1 und AcuCare F1-4) /
Valve (AcuCare F1-1 et AcuCare F1-4 uniquement) /
Valvola (solo AcuCare F1-1 e AcuCare F1-4) /
Válvula (solo AcuCare F1-1 e AcuCare F1-4) /
Válvula (só AcuCare F1-1 e AcuCare F1-4) / Klep (alleen AcuCare F1-1 e AcuCare F1-4)

 - 3 Quick release clip / Schnell zu öffnender Clip / Clip de retrait rapide /
Fermaglia sgancio rapido / Broche de liberación rápida / Clipe de libertação rápida /
Snelklem

 - 4 Vent (AcuCare F1-4 only) / Luftauslassöffnung (nur AcuCare F1-4) /
Orifice de ventilation (AcuCare F1-4 uniquement) /
Foro per l'esalazione (sólo AcuCare F1-4) /
Ventilación sólo AcuCare F1-4) / Respiradouro (só AcuCare F1-4) /
Ventilatieopening (alleen AcuCare F1-4)

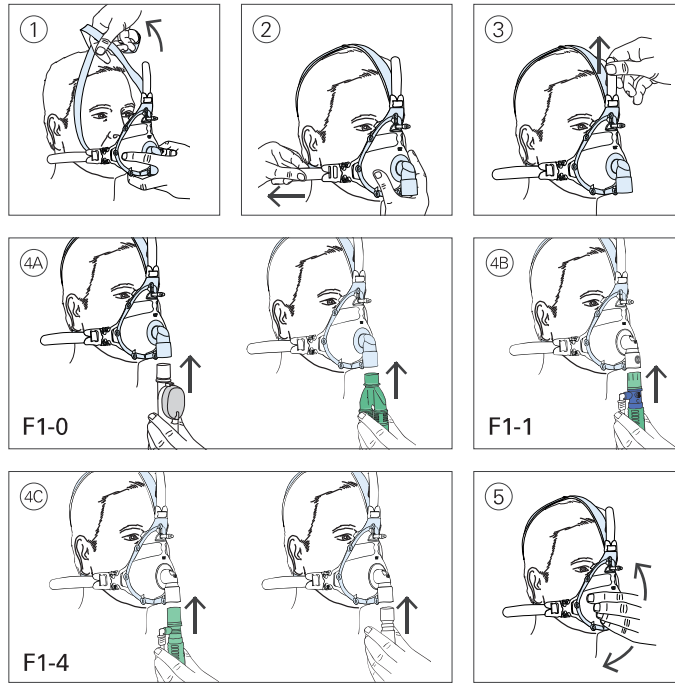
 - 5 Connector 22M - 22M (AcuCare F1-4 only) /
Adapter 22 AD - 22 AD (nur AcuCare F1-4) /
Raccord 22M - 22M (AcuCare F1-4 uniquement) /
Raccordo 22M - 22M (sólo AcuCare F1-4) /
Connector recto 22M - 22M sólo AcuCare F1-4) /
Connector 22M - 22M (só AcuCare F1-4) / Connector 22M - 22M (alleen AcuCare F1-4)

S: Small / Small / Petit / Small / Pequeña / Pequena / mall

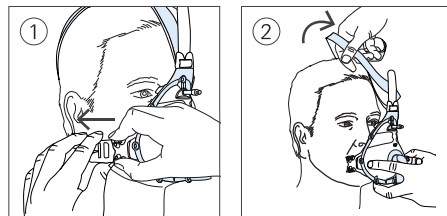
M: Medium / Medium / médium / medium / mediana / média / medium

L: Large / Large / Grand / Large / Grande / Grande / Large

Fitting / Anlegen / Mise en place / Applicazione / Colocación / Colocação / Opzetten



Removal / Abnehmen / Retrait / Rimozione / Para quitarla / Remoção / Afnemen



ENGLISH

AcuCare™

Hospital full face masks

Thank you for choosing the AcuCare range.

This guide covers the following variants, which are shown at the front of the guide:

- AcuCare F1-0 Hospital non-vented full face mask (blue elbow to indicate that the mask does not include its own passive venting mechanism or an AAV)
- AcuCare F1-1 Hospital non-vented full face mask with AAV (clear elbow with "NV" blue dot to indicate that the mask does not incorporate its own passive venting mechanism)
- AcuCare F1-4 Hospital vented full face mask (clear elbow to indicate that the mask incorporates a built-in passive venting mechanism and an AAV).

Using this guide

Please read the entire guide before use. When following instructions, refer to the images at the front of the guide.

Intended Use

Intended use for AcuCare F1-0

The AcuCare F1-0 mask is a non-invasive accessory used for channeling airflow to a patient from an active-exhaust-valve ventilator system.

The mask is:

- to be used on patients weighing > 30 kg, for whom non-invasive positive airway pressure therapy has been prescribed.
- a disposable device, intended for short-term treatment (up to 7 days) of a single patient, in the hospital environment only.
- intended to be used with breathing circuits or positive pressure ventilation (PPV) devices that provide their own method of venting expired or supplemental gasses.

Intended use for AcuCare F1-1

The AcuCare F1-1 mask is a non-invasive accessory used for channelling airflow to a patient from a positive airway pressure (PAP) device.

The mask is:

- to be used on patients weighing > 30 kg, for whom non-invasive positive airway pressure therapy has been prescribed.
- a disposable device, intended for short-term treatment (up to 7 days) of a single patient, in the hospital environment only.
- intended to be used with breathing circuits or positive pressure ventilation (PPV) devices that provide their own method of venting expired or supplemental gasses.

Intended use for AcuCare F1-4

The AcuCare F1-4 mask is a non-invasive accessory used for channelling airflow to a patient from a positive airway pressure (PAP) device.

The mask is:

- to be used on patients weighing > 30 kg, for whom non-invasive positive airway pressure therapy has been prescribed.
- a disposable device, intended for short-term treatment (up to 7 days) of a single patient, in the hospital environment only.

Intended patient population/medical conditions

AcuCare F1-0 and F1-1 (Non-Vented)

Obstructive pulmonary diseases (eg, chronic obstructive pulmonary disease), restrictive pulmonary diseases (eg, diseases of the lung parenchyma, diseases of the chest wall, neuromuscular diseases), central respiratory regulation diseases, and obesity hypoventilation syndrome (OHS).

AcuCare F1-4 (Vented)

Obstructive pulmonary diseases (eg, chronic obstructive pulmonary disease), restrictive pulmonary diseases (eg, diseases of the lung parenchyma, diseases of the chest wall, neuromuscular diseases), central respiratory regulation diseases, obstructive sleep apnoea (OSA) and obesity hypoventilation syndrome (OHS).

Clinical benefits

AcuCare F1-0 and F1-1

The clinical benefit of non-vented masks is the provision of effective therapy delivery from a therapy device to the patient.

AcuCare F1-4

The clinical benefit of vented masks is the provision of effective therapy delivery from a therapy device to the patient.

GENERAL WARNINGS

- As with all masks, some rebreathing may occur at low pressures.
- The mask must not be used without qualified supervision for patients who are unable to remove the mask themselves.
- This mask is not for use on patients with impaired laryngeal reflexes or other conditions predisposing to aspiration in the event of regurgitation or vomiting.
- The mask should not be worn unless the ventilator system is turned on and operating properly.
- Follow all precautions when using supplemental oxygen.
- Oxygen supports combustion. Oxygen must not be used while smoking or in the presence of an open flame. Only use oxygen in well ventilated rooms.
- If oxygen is used with the ventilator, the oxygen flow must be turned off when the ventilator is not operating, so that unused oxygen does not accumulate within the device enclosure and create a risk of fire.
- At a fixed rate of supplemental oxygen flow (if used), the inhaled oxygen concentration varies depending on the pressure settings, patient breathing pattern, mask size selection and leak rate.
- The technical specifications of the mask are provided so you can check that they are compatible with the ventilator. If used outside specification or if used with incompatible devices, the seal and comfort of the mask may not be effective, optimum therapy may not be achieved, and leak, or variation in the rate of leak, may affect the ventilator function.
- Discontinue using this mask if the patient has ANY adverse reaction to the use of the mask.
- Using a mask may cause tooth, gum or jaw soreness or aggravate an existing dental condition. If symptoms occur, consult a dentist.

- Refer to your ventilator manual for details on settings and operational information.
- Do not expose the mask to direct sunlight.
- Remove all packaging before using the mask.
- (AcuCare F1-1 and AcuCare F1-4 only) The elbow and valve assembly have specific safety functions. The mask should not be worn if the valve is damaged as it will not be able to perform its safety function. The mask should be replaced if the valve is damaged, distorted or torn.
- (AcuCare F1-4 only) The vent holes must be kept clear.

Note:

For any serious incidents that occur in relation to this device, these should be reported to ResMed and the competent authority in your country.

Using your mask

The masks in this guide incorporate:

- a standard female 22mm tapered fitting for external connection to the ventilator
- a standard Luer port for pressure sampling or supplemental oxygen if required.

Fitting

Notes:

- A sizing template is located on the mask packaging to help you determine the correct mask size.
 - Inspect the mask before use and replace it if any parts are damaged.
 - Do not overtighten the straps, as air fills the dual-wall cushion and provides a comfortable seal.
 - For the best seal, the side straps should be tighter than the top strap.
1. Position the mask cushion over the patient's nose and mouth and pull the headgear over their head.
 2. While holding the mask against the patient's face, pull each of the side straps back along the side of the patient's face. The straps should

- pass below the patient's ears. The side arms on the mask should bend back as you tighten the straps.
3. Gently adjust the top strap.
 4. Start ventilation according to the ventilator system operating instructions and connect the mask to the ventilator system.
 5. If 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.

Removal

1. Unclip the headgear from the mask using the quick release clip.
2. Pull the mask and headgear up over the patient's head.

Cleaning

The mask (with headgear) is disposable and should be discarded if heavily soiled. If the inside of the mask is lightly soiled, it may be cleaned by wiping with a clean cloth and water. Do not disassemble the mask.

WARNING

Always follow cleaning instructions. Some cleaning products may damage the mask, its parts and their function, or leave harmful residual vapours.

CAUTION

- Do not expose any part of the mask or tubing to direct sunlight as it may deteriorate.
- If any visible deterioration of a mask system component is apparent (cracking, discolouration, tears etc.), the mask system should be discarded and replaced.
- Discard the mask (and headgear) if heavily soiled, particularly if the vent holes are blocked.

Troubleshooting

Problem/possible cause	Solution
Mask is uncomfortable	
Headgear straps are too tight.	The cushion membrane is designed to inflate against the patient's face to provide a comfortable seal with low headgear tension. Adjust straps evenly. Ensure that the headgear straps are not too tight and that the cushion is not crushed or creased.
Mask could be the wrong size.	Check the patient's size against the fitting template located on the mask packaging.
Mask leaks around the face.	
Cushion membrane is creased or folded.	Refit the mask according to the instructions. Ensure that you position the cushion correctly on the patient's face before pulling headgear over their head. Do not slide the mask down the patient's face during fitting as this may lead to folding or curling of the cushion.
Mask could be the wrong size.	Check the patient's size against the fitting template located on the mask packaging.

Technical Specifications

The following general specifications are applicable to all masks in this guide.

General specifications

Environmental conditions	Operating temperature: +5°C to +40°C Operating humidity: 15% to 95% non-condensing Storage and transport temperature: -20°C to +60°C Storage and transport humidity: up to 95% non-condensing
Gross dimensions Not including headgear	Small: 148 mm (H) x 221 mm (W) x 102 mm (D) Medium: 158 mm (H) x 230 mm (W) x 105 mm (D) Large: 165 mm (H) x 234 mm (W) x 107 mm (D)
Compatibility	For a full list of compatible devices for this mask, see the Mask/Device Compatibility List on www.resmed.com on the Products page under Service & Support. If you do not have internet access, please contact your ResMed representative.

Technical Specifications: AcuCare F1-0

Pressure (cm H₂O)	Flow (L/min)
0 to 20	<6
20 to 40	<12
Therapy pressure	0 to 40 cm H ₂ O
Dead space information	Physical dead space (mask and elbow) using the large cushion is 342 mL.
Resistance	Drop in pressure measured (nominal) at 50 L/min: 0.4 cm H ₂ O at 100 L/min: 1.2 cm H ₂ O

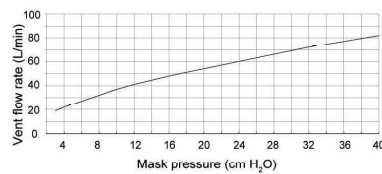
Technical Specifications: AcuCare F1-1

Pressure (cm H₂O)	Flow (L/min)
3 to 20	<6
20 to 40	<12

Therapy pressure	3 to 40 cm H ₂ O	
Dead space information	Physical dead space (mask and elbow) using the large cushion is 366 mL.	
Resistance with Anti Asphyxia Valve (AAV) closed to atmosphere	Drop in pressure measured (nominal)	at 50 L/min: 0.5 cm H ₂ O at 100 L/min: 1.1 cm H ₂ O
Inspiratory and expiratory resistance with Anti Asphyxia Valve (AAV) open to atmosphere	Inspiration at 50 L/min Expiration at 50 L/min	1.0 cm H ₂ O 1.5 cm H ₂ O
Anti Asphyxia Valve (AAV) open-to-atmosphere pressure	≤2 cm H ₂ O	
Anti Asphyxia Valve (AAV) closed-to-atmosphere pressure	≤2 cm H ₂ O	

Technical Specifications: AcuCare F1-4

Pressure-flow curve The mask contains passive venting to protect against rebreathing. As a result of manufacturing variations, the vent flow rate may vary.



Pressure (cm H ₂ O)	Flow (L/min)
3	19
10	37
20	54
30	69
40	82

Therapy pressure	3 to 40 cm H ₂ O	
Dead space information	Physical dead space (mask and elbow) using the large cushion is 364 mL.	
Resistance with Anti Asphyxia Valve (AAV) closed to atmosphere	Drop in pressure measured (nominal) at 50 L/min: 0.5 cm H ₂ O at 100 L/min: 1.2 cm H ₂ O	
Inspiratory and expiratory resistance with Anti Asphyxia Valve (AAV) open to atmosphere	Inspiration at 50 L/min	0.6 cm H ₂ O
	Expiration at 50 L/min	0.8 cm H ₂ O
Anti Asphyxia Valve (AAV) open-to-atmosphere pressure	≤2 cm H ₂ O	
Anti Asphyxia Valve (AAV) closed-to-atmosphere pressure	≤2 cm H ₂ O	
Sound	DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level of the mask is 42 dBA, with uncertainty of 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is 34 dBA, with uncertainty of 3 dBA.	

Storage

Ensure that the mask is thoroughly clean and dry before storing it for any length of time. Store the mask in a dry place out of direct sunlight.

Disposal

This product and packaging do not contain any hazardous substances and may be disposed of in accordance with local environmental regulations.

Symbols

The following symbols may appear on your product or packaging:

LATEX? This product is not made with natural rubber latex.



Medical Device



Importer



Non-vented mask



Anti-asphyxia valve



Vented mask

See symbols glossary at [ResMed.com/symbols](https://www.resmed.com/symbols).