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1.Understanding the Ventilation Mask

1.1Models:

FM-003-TM/FM-003-TL/FM-003-XL/FM-009-TM/FM-009-TL/FM-009-XL/FM-011-TM-NV/FM-011-TM-NVAAV/
FM-011-TL-NV/FM-011-TL-NVAAV/FM-011-XL-NV/FM-011-XL-NVAAV/FM-012-TM-NV/FM-012-TM-NVAAV/
FM-012-TL-NV/FM-012-TL-NVAAV/FM-012-XL-NV/FM-012-XL-NVAAV/FM-016-TS/FM-016-TS-NVAAV/
FM-016-TS-NF/FM-016-TS-NV/FM-016-TS-NVNF/FM-016-TM/FM-016-TM-NVAAV/FM-016-TM-NF/
FM-016-TM-NV/FM-016-TM-NVNF/FM-016-TL/FM-016-TL-NVAAV/FM-016-TL-NF/FM-016-TL-NV/
FM-016-TL-NVNF/FM-017-TS/FM-017-TM/FM-017-TL

1.2 Intended use:

The mask channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or Bi-level system.

Intended for single-patient re-use in the home environment and multi-patient re-use in the hospital / institutional environment.

Intended patient: The Ventilation mask is to be used by adult patients (>30 kg) for whom positive airway pressure has been prescribed.

Indications:

- Masks marked “NV” in model number:

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).

- Masks without “NV” in model number:

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).

Contraindications:

- (1) Impaired consciousness
- (2) Weak or absent spontaneous respiration; cardiac arrest
- (3) Inability to clear airway secretions or high aspiration risk

- (4) Severe dysfunction of major organs
- (5) Untreated pneumothorax or mediastinal emphysema
- (6) Severe abdominal distension; intestinal obstruction
- (7) Upper airway obstruction due to trauma, surgery, deformities of the face/maxillofacial region
- (8) Non-cooperation with NPPV (Non-Invasive Positive Pressure Ventilation); intolerance to nasal/full-face masks
- (9) Recent esophageal/gastrointestinal surgery or hemorrhage; compromised lower esophageal sphincter function; massive regurgitation; impaired cough reflex; hiatal hernia

- (10) Delayed motor response or cognitive impairment

Precautions (Use with Caution):

- (1) Facial deformities (e.g., nasal bridge collapse, severe micrognathia)
- (2) Hypersensitivity to mask materials (silicone, PVC, or thermoplastic elastomers)
- (3) Skin integrity issues at mask contact areas (e.g., abrasions, pressure ulcers, burns)

Intended user:The intended users are adults who are capable of understanding general operation of the device and the content of instruction manual, and can be either doctors or lay persons.

1.3 Components:

FM ventilation mask made by mask body, frame assembly,elbow assembly,headgear and optional accessories(Tee-junction,connector and breathing tube).

1.4 Performance Index:

- (1) Pressure flow curve

- The functional correlation between exhaust flow rates and applied pressure (4-30 cmH₂O) for the FM-003-TM/FM-003-TL/FM-003-XL/FM-009-TM/FM-009-TL/FM-009-XL/FM-016-TS-NF/
FM-016-TM/FM-016-TM-NF/FM-016-TL/FM-016-TL-NF/FM-017-TS/FM-017-TM/FM-017-TLventilation mask is quantified in the performance matrix displayed in Table 1 and Figure 1, and the tolerance is between -30% to 50%.

Table 1:						
Pressure (hPa)	4	10	16	20	25	30
Flow Rate (L/min)	24	37	51	58	64	69

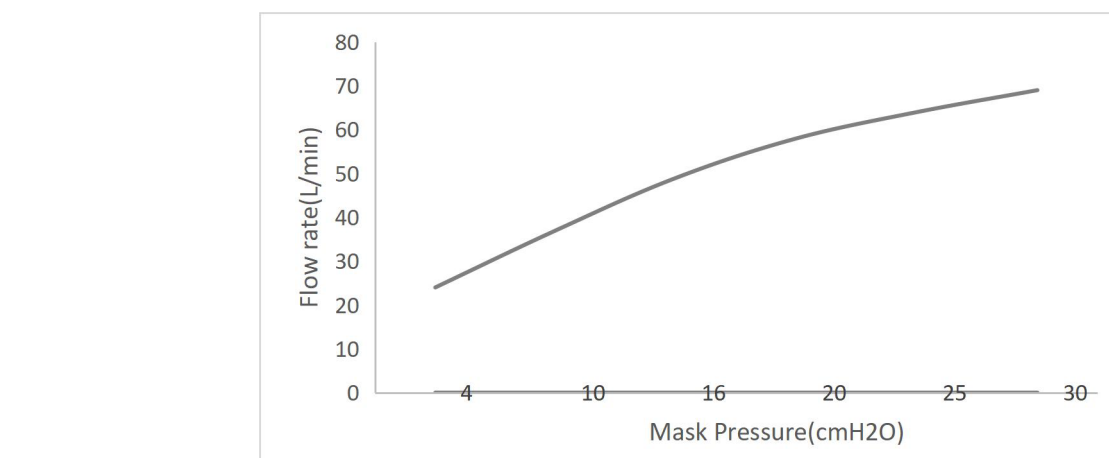


Figure 1: Mask Pressure and flow rate

- The functional correlation between exhaust flow rates and applied pressure (4-30 cmH₂O) for the FM-011-TM-NV/FM-011-TM-NVAAV/FM-011-TL-NV/FM-011-TL-NVAAV/FM-011-XL-NV/FM-011-XL-NVAAV/
FM-012-TM-NV/FM-012-TM-NVAAV/FM-012-TL-NV/FM-012-TL-NVAAV/FM-012-XL-NV/FM-012-XL-NVAAV/
FM-016-TS-NV/FM-016-TS-NVNF/FM-016-TS-NVAAV/FM-016-TM-NV/FM-016-TM-NVNF/FM-016-TM-NVAAV/
FM-016-TL-NV/FM-016-TL-NVNF/FM-016-TL-NVAAV ventilation mask is quantified in the performance matrix displayed in table 2.

Tabel 2:

Pressure(hPa)	Flow rate(L/min)
4~20	<6
20~30	<12

- (2) Resistance:

at 50 L/min≤0.7 cmH₂O;
at 100 L/min≤1.8cmH₂O

Anti Asphyxia Valve open-to-atmosphere pressures≤2.5 cmH₂O

Anti Asphyxia Valve closed-to-atmosphere pressures≤3.0 cmH₂O

- (3) Sound:

Declared dual-number noise emission values in accordance with ISO 4871

The A-weighted sound power level of the mask is less than or equal to 42dB

The A-weighted sound pressure level of the mask at a distance of 1m is less than or equal to 35dB

1.5 Combined Compatible Products & Operation:

1.5.1 Permitted matching devices

Breathing tube: CE marked, comply with EN ISO 5367, equipped with standard 22 mm coaxial cone connector.

Positive airway pressure device: continuous positive airway pressure (CPAP) or Bi-level system with CE marking, shall meet the requirements of EN ISO 80601-2-70 and have a conical 22 mm size male connector or socket conforming, applicable working pressure range: 4–30 cmH₂O.

Accessories:Comply with EN ISO 5367, equipped with standard 22 mm coaxial cone connector.

1.5.2 Connection operation steps

Turn off the ventilator power first; fully insert the mask elbow into the breathing tube, then wear the mask according to the fitting steps in Clause 2.1.

1.5.3 Safety restrictions & risks

Only use equipment within the pressure range of 4–30 cmH₂O. Mismatched pressure will cause excessive leakage and rebreathing risk.

2.Use and Maintenance

2.1 Fitting the mask:

Note: Before fitting, please ensure that the upper headgear straps are properly secured through the buckle on the top side of the frame. Pull the strap to take up any slack and make sure the strap will not loosen.

Step	Operation instruction	Graphical representation
1	Before wearing the mask, attach the clips to the headgear.	
2	Place the headgear on your head, and place the ventilation mask on your nose and mouth, attach the clips to the mask frame.	
3	Adjust the upper strap after the clips is attached, sits comfortably.	

4	Repeat the step 2, adjust the headgear and sits comfortably	
5	After wearing the headgear, it is suitable for fit two fingers and do not be too tight to ensure a comfortable fit.	
6	Adjust the headgear straps evenly, and connect the tube and the ventilation mask.	

2.2 Processing instruction

2.2.1 For mask Parts:

Manufacturer: GuangDong EDA Technology Co., Ltd.
Method:See in below table
SymbolN.A.

Devices:This processing instruction is suitable for all models of Ventilation Mask.
Processing requirements for first and interval use: Have to clean and disinfect the mask before first use, or when no use over than one week.

Limitations on processing	Reuse: 30 times ● These devices are designed for 30 repeated uses when in accordance with reprocessing instructions. These devices are supplied non-sterile as indicated on the packaging labels. Process through cleaning and disinfection after each use. Care in use and handling will help ensure the useful life. ● It is recommended to establish a procedural review (before and after each use) by which the mask showing such damage or wear are either sent for refurbishing, discarded and/or replaced.
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INSTRUCTIONS

Initial treatment at the point of use	Step 1: Press the Start/Stop button of the ventilator to stop mask and ventilator, then turn off the power of ventilator. Step 2: Remove the mask and headgear from your face by removing the clips from the sides of the mask. Step 3: Remove the mask from the breathing machine before cleaning. ● Undo and remove the upper-half headgear straps out of the hole on the mask frame, and the headgear will clean according 2.2.2. ● Remove the cushion from the mask frame. Step 4: Rinse the all parts of mask with clean water until no obvious soil stay in the
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RESCOMF®



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The website of Electronic manual is http://www.rescomf.com/en/products_class.asp?xid=45

- If you have any following symptoms occur: flushing skin, chest discomfort, shortness of breath, stomach distension, severe headache, tearing, runny nose, etc when using this ventilation mask, please consult your physician or healthcare professional.
- This ventilation mask is intended for the purposes described in this manual only, please contact your physician or healthcare professional or distributor if in doubt.
- It is recommended to replace the ventilation mask after 6 months of use, please contact your physician or healthcare professional or distributor if necessary.
- The device does Not intended to administer medicinal products, tissues etc.
- The device does not include medicinal substance or biological material.
- The device is not invasive device, and no consist of CMR substances.
- Please read the section of Combined Compatible Products & Operation before connecting external ventilation equipment.

3.Symbols:

Caution! Refer to the attached documents	Latex Free	Non-sterile	Manufacturer
Catalogue number	Batch code	Refer to the user manual	Date of manufacture
Medical Device	Use-by date	Temperature Limit	Humidity Limitation
Atmospheric pressure limitation	Authorized Representative in European Community.	Unique device identifier	

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- Before using, check whether the output and tubing of the ventilator are compatible with the ventilation mask. (The ventilation mask's connector is a 22mm conical joint according to ISO 5356-1)
- When using NV, NVNF, NVAAB, AAV ventilation masks, must have appropriate qualified supervisors, because the patient can not be awake under extreme hypoxia or high carbon dioxide, But unable to take off the mask.
- When using NV, NVNF, NVAAB, AAV ventilation masks, it can only be used with breathing equipment with alarm function, preventing problems such as low pressure, pipeline shedding, power supply interruption, insufficient gas sources.
- NV, NVNF, NVAAB, AAV ventilation masks can only be used under the supervision of a doctor and cannot be used at home.
- Ventilation masks may reduce mask safety or alter mask functions when used in conjunction with other medical devices that are not intended to be used. (such as medical humidifiers, nebulizers, temperature and humidity exchangers (HME), filters, self-regulating devices, additional oxygen supply, or any exhaust port).
- The ventilator system must be turned on and working properly, otherwise the ventilation mask.
- Do not block or try to seal the exhaust hole of the mask during using.
- Oxygen flow must be turned off when the flow generator is not operating, so that unused oxygen does not accumulate within the flow generator enclosure and create a risk of fire.
- At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration varies, depending on the pressure settings, patient breathing pattern, mask, point of application and leak rate. This warning applies to most CPAP or BiPAP ventilators.
- Do not use open fire when using oxygen.
- If the pressure of CPAP or BiPAP is low, part of the exhaled gas may be inhaled again, which causes harm to the human body.
- Discontinue using this ventilation mask if you have ANY adverse reaction to the use of the mask, and consult your physician or sleep therapist or healthcare professional or distributor.
- Using a ventilation mask may cause tooth, gum or jaw soreness or aggravate an existing dental condition. If symptoms occur, please consult your physician or dentist or healthcare professional or distributor.

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nature, it is recommended that the user maintain and inspect it on a regular basis, and replace the mask system or any components if deemed necessary.

For a patient/ user/ third party in the European Union and in countries with identical regulatory regime (Regulation (EU) 2017/745 on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/ or its authorized representative and to your national authority.

The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website:

https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

2.6 Troubleshooting

Problem	Possible reason	Possible solution
Mask won't seal properly or is uncomfortable	Mask may have been fitted incorrectly or is incorrectly adjusted	Carefully follow instructions in "Fitting the Mask". Check headgear is not over-tightened. Revolve the main frame to find a suitable position.
	Mask is wrong size.	Talk to your clinician.
	Mask body may be dirty.	Clean mask body according to instructions in "Cleaning the Mask in the Home".
Mask is too noisy.	Mask assembly is incorrectly.	Reassemble mask.
	Vents are blocked or partially blocked.	Clean vents according to instructions in "Cleaning the Mask in the Home"

2.7 Warning:

- Check that the patient's face whether is suitable for the size of ventilation mask.
- Before using, read the user's manual and fully understand how to use.
- For patients requiring prolonged mask wear (>4 consecutive hours), apply protective dressings to high-risk facial pressure points (nasal bridge, zygomatic arches) prior to mask application to reduces interface pressure.
- Before installing or wearing, please check all parts, if there is damaged, cracked, etc., please replace them in time.

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- (1) Disassemble the mask and move the headgear away the frame.
 - (2) Handwash the headgear in warm water (approximately 30°C) with mild liquid detergent.
 - (3) Rinse the headgear under running water. Inspect to ensure the headgear is clean and detergent free. Wash and rinse again, if necessary.
 - (4) Squeeze the headgear to remove excess water.
 - (5) Leave the headgear to air dry out of direct sunlight.
- Attention:
- The headgear is a fabric part, do not machine wash and dry in the dryer.
 - This headgear is a consumable, and the firmness of the paste will decrease after repeated cleaning.
 - It is recommended to wash once a week.

2.3 Disposal:

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

2.4 Environmental conditions requirements:

- (1) Operating condition:
Operating temperature: +5°C to +40°C
Operating humidity: 0% ~ 93%.
- (2) Storage and transport condition:
Storage temperature : -20°C ~ -55°C;
Relative humidity : ≤93%;
Atmospheric pressure:70Kpa~106Kpa;
Storage conditions : Keep in the original packaging, protected from dust and avoid exposure to direct sunlight.Storage conditions : Keep in the original packaging, protected from dust and avoid exposure to direct sunlight.

2.5 Service life:

Period of validity: 5 years.

The service life of the mask system is dependent on the intensity of usage, maintenance, and environmental conditions to which the mask is used or stored. As this mask system and its components are modular in

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	use instructions of the disinfectant being used.
Drying	Step 1: Then hang the masks in a ventilated environment for more than 4 hours to air dry. Step 2: After drying, check that the masks are free from blood stains, stains, damage, aging and cracks.
Maintenance, inspection and testing	Visible criteria for product inspection: ● Check that the mask is free of dirt or water stains. ● If any visible deterioration of a system component is apparent (cracking, discoloration, tears etc.), the component should be discarded and replaced. Reassembly: ● Attach the cushion to the frame by aligning the circular openings and pushing together until retained. ● With the Rescomf logo on the headgear facing outside and upright, thread the upper headgear straps into the frame slots from the inside. Fold them over to secure.
Packaging	The masks after disinfection are stored in clean and dry containers or clean bags for use. Do not wear gloves with talcum powder when packing to prevent talcum powder from entering the mask inside; When packing, check whether the articles are complete to prevent missing parts.
Sterilization	N.A.
Storage	Storage temperature : -20°C ~ -55°C; Relative humidity : ≤93%; Atmospheric pressure:70Kpa~106Kpa Storage conditions : Keep in the original packaging, protected from dust and avoid exposure to direct sunlight.
Warning	• Regularly clean your mask according to this manual to maintain the quality of your mask and to prevent the growth of germs that can adversely affect your health. • Do not use cleaning solutions containing bleach, alcohol, preservatives, water softeners, moisturizers to clean any parts of the ventilation mask, these solvents may damage the product and shorten the service life of the product.

Please record the number of uses in the following table after each use:

Number of uses	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Mark "✓" after each use															
Number of uses	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Mark "✓" after each use															

2.2.2 For the headgear:

Before cleaning and disinfection, the headgear should be separated from other parts and cleaned separately.

The cleaning requirements are as follows:

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		mask when there is obvious soil or contamination in the mask after detaching the mask from tube and ventilator.
Preparation before cleaning		Step 1: Please check the mask for any damage before cleaning. If there are any holes, tear or crack, the mask should be replaced after dissemble the mask. Step 2: Please check if there is dirt, blood or sputum scab in the mask, it must be cleaned within half an hour. Step 3: Prepare Liquid container which can accommodate the mask, Enzyme-containing cleaning solution and an effective chlorine solution containing 500mg/L. Note: If the cleaning agent or disinfectant actually used differs from the above usage method, follow the use instructions of the cleaning agent or disinfectant being used.
	Automated	N.A. The product cannot be automatically cleaned, which may cause product damage and affect product performance.
Cleaning:	Manual	Step 1: Please use clean water to wash the dirt, blood or sputum scab and other dirt in the mask firstly. Step 2: Soak the mask in enzyme-containing cleaning solution for 2~3 minutes, then rinse with clean water for 1~2 minutes. Suggest using the clean enzymatic detergent from Metrex. Step 3: After cleaning, check that there is no dirt, blood or sputum scab inside the mask and other dirt can be disinfected. Otherwise, please repeat above Step 1 to Step 2. Note: ● Do not soak mask in hot water, alcohol, non-designated disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not exceed one hours soaking in ANY solution. ● Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents to wash the masks, they will damage the masks. ● Manual cleaning effect has its instability, it is recommended to strictly follow the instructions when cleaning. ● If the cleaning agent actually used differs from the above usage method, follow the use instructions of the cleaning agent being used.
	Automated	N.A. The product cannot be automatically disinfected, which may cause product damage (it may cause mask wrinkles/deformation or damage, accelerate mask aging et.,) and affect product performance.
Disinfection:	Manual	Step 1: Soak the cleaned mask with an effective chlorine solution containing 500mg/L for 30~35 minutes to disinfect it; The mask must be completely immersed in disinfectant during immersion disinfection. Step 2: After soaking, rinse with pure water or cold boiled water for 1~3 minutes and soak for 30~35 minutes. Note: ● Manual disinfection effect has its instability, it is recommended to strictly follow the instructions during disinfection. ● If the disinfectant actually used differs from the above usage method, follow the

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