Amoul®

VK200
VK300

Safety and Performance Information
Ventilator

CE 2797

www.amoulmed.com

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Product Information

Description

Thank you for purchasing the ventilator.

Before using the device, please read and understand the contents of this User Manual carefully, so as to use the device correctly. After reading, please keep this User Manual properly and place it in an easily accessible place.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

Product name:	Ventilator
Specification/model:	VK200, VK300
EU REP	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg,Germany
Name of the Registrant:	Ambulanc (Shenzhen) Tech. Co., Ltd.
Address of the registrant:	Evergrande Fashion Huigu Building 1# 101, Fulong Road, Shanghenglang Community, Dalang Street, Longhua District, Shenzhen, Guangdong 518109, China
Name of the manufacturer:	Ambulanc (Shenzhen) Tech. Co., Ltd.
Manufacturing address:	3rd and 8th Floor, Block C, Building #5, and 1st to 10th Floor, Building #8, Skyworth Innovation Industry Park, Tangtou 1st Road, Shiyan, Baoan District, Shenzhen, Guangdong 518108, China
Production date	See the label on the main unit.
Service life:	10 years
Shelf life:	1 year
Software name:	Ventilator specific software
Software release version:	V1.0
Manual version:	1.2
Operator’s Manual revised on:	03/2026

⚠ Caution:

This device is not designed for homecare use.

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- Relevant electrical devices conform to the applicable national standards; and
- The product is used according to the User's Manual.

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Coverage of free service:
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Even within the warranty period, there are still exceptions due to the following artificial reasons:

- Artificial damages;
- Improper use;
- Grid voltage exceeds the specified range ofthe product;
- Force majeure; or

• Replacement of parts or consumables not authorized by Ambulanc (Shenzhen) Tech. Co., Ltd., or repair by non-authorized personnel ofAmbulanc (Shenzhen) Tech. Co., Ltd.

⚠ **Warning:**

Failure to implement a satisfactory repair/maintenance plan by hospitals or institutions responsible for the use of this device may result in device failure and may expose endanger to personal health.

Guarantee

Manufacturing process and raw materials:

Ambulanc (Shenzhen) Tech. Co., Ltd. guarantees that the device will be of free service for failures attributable to the manufacturing process and raw materials under normal use and maintenance conditions within the warranty period.

After-sales Service

After-sales Service Department of Ambulanc (Shenzhen) Tech. Co., Ltd.

Address: Building #8, Skyworth Innovation Valley, 1 Tangtou Road, Shiyan, Baoan District, Shenzhen China Postal code: 518108

Toll-free service hotline: 400-9969-120

Telephone: +86-755 26072215 Fax: +86-755 23016012

Website: http://www.amoulmed.com E-mail: service@amoulmed.com

Return

Return procedure

If you need to return a product to Ambulanc (Shenzhen) Tech. Co., Ltd., please follow the following steps:

- Obtain the right of return: Contact the Customer Service Department of Ambulanc (Shenzhen) Tech. Co., Ltd. and inform the Ambulanc product series number, which is marked on the outer shipping box. If the series number is not legible, the return will not be accepted. Please specify the product model number and briefly explain the reason for return.
- Freight fee: The user is responsible for the freight fee for the return of the device to Ambulanc (Shenzhen) Tech. Co., Ltd., including customs fees.

Important Information

1. After purchasing this product, the customer is fully responsible for the maintenance and management of this product.
2. Even within the warranty period, the warranty does not cover the following:

- Damages or losses caused by wrong use.
- Damages or losses caused by force majeure such as fire, earthquake, flood, or lightning.
- Damages or losses caused by failure to meet the use conditions specified for the system, such as inadequate power supply, incorrect installation, or poor environmental conditions.
- Shipping damages due to improper packaging on return.
- Damages or losses caused by failure to use the system in the area where it was originally purchased.
- Damages or losses due to the system not purchased from Ambulanc or its authorized distributors or agents.

3. This device can only be used by qualified medical personnel with professional qualification .
4. Unauthorized modification of the software or hardware or any other component of this product is prohibited.
5. Under no circumstances will Ambulanc be liable for problems, damages, or losses caused by reinstallation, alteration, or repair of the system by persons not designated by Ambulanc.
6. This system aims to provide doctors with auxiliary tools needed for clinical treatment.
7. Doctors should be responsible for the treatment. Ambulanc will not be liable for the treatment.
8. Be sure to back up important data to external storage media, such as clinical records, laptops, etc.
9. Ambulanc (Shenzhen) Tech. Co., Ltd. is not responsible for any loss of data stored in the system due to the operator’s error or abnormal conditions.
10. Ambulanc (Shenzhen) Tech. Co., Ltd. is not responsible for damages not caused by the defect of the device itself or damages caused by the user's operation error.
11. Ambulanc (Shenzhen) Tech. Co., Ltd. is not responsible for any damages caused by the

continued use of the device after the expiration date.

12. If a warranty claim is rejected, Ambulanc (Shenzhen) Tech. Co., Ltd. will not be responsible for round-trip transportation costs.

13. This Operator's Manual contains warnings about foreseeable potential hazards. It is important to maintain a high level of vigilance against hazards that are not explained at all times. Ambulanc (Shenzhen) Tech. Co., Ltd. is not responsible for damages or losses caused by negligence or disregard of the precautions set forth in this Operator's Manual.

14. Once the management of this system changes, this User Manual must be handed over.

Please keep this user manual properly. Once the administrator of this equipment system changes, this user manual must be handed over properly.

A notice to the user and/or patient: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Limitations of use are primarily identified when residual risks can only be controlled by informing the user.

Safety Instruction

Please read this safety instruction carefully. This safety instruction is an integral part of the device and must be accessible at all times. For safety reasons, please pay attention to the following precautions:

Safety information

Safety instructions are indicated in this User Manual as follows:

Mark Prompt	Related Instructions
⚠**Danger:**	Prompt urgent dangers, which, if not avoided, may result in death, serious personal injury, or property damage.
⚠**Warning:**	Warn patients and users of a potential risk of injury.
⚠**Caution:**	Provide warnings for situations that may cause damages to the device and may result in wrong therapeutic effects.
⚠**Note:**	Refer to the notes on the contents of this User Manual. The ventilator is referred to as "VK200/VK300" in the Manual.

1. Overview

⚠ **Danger:**

The ventilator does not contain any danger information.

⚠ **Warning:**

A function check must be performed before using the device (see "11 Maintenance and inspection").

Follow the instructions in "9 Cleaning and disinfection" to prevent infection or bacterial infection.

Only those who have received medical training and technical guidance on respiratory devices can use this device. Improper use may lead to patient death.

Do not leave the patient or the ventilator along during ventilation, to respond timely in case of emergencies (such as the patient's condition become worse or device malfunction) and avoid the injuries to the patient.

This ventilator can only be used for the specified purpose (see "2.1 Intended use").

Do not use this device in high-pressure applications (hyperbaric oxygen chambers).

Do not use this device in explosive or toxic environments.

Do not use this device in oxygen-rich or flammable environments.

Do not use this device in a magnetic resonance imaging (MRI) environment.

Do not use anti-static or conductive masks or breathing tubes when using high-frequency surgical devices, which may cause burns.

Do not use this device together with nitric oxide.

Do not use this device with helium or mixtures containing helium.

When the ventilator fails, the alternative ventilation shall be taken into use immediately, otherwise it may lead to patient death.

Non-maintenance personnel are prohibited from opening the hood of this ventilator to replace or modify external or internal parts. Conduct appropriate inspections and tests after maintenance to ensure safe use.

Use an external power supply (AC power supply) for power supply timely before the battery runs out of power.

Do not place the ventilator next to the barrier, as it will obstruct the flow of cold air and cause the device to overheat.

Set the alarm volume and alarm limit according to the actual situation of the patient. Do not rely solely on an audible alarm system for patient monitoring. Adjusting the alarm sound to a lower volume may pose a danger to the patient. Pay close attention to the actual clinical condition of the patient.

The physiological parameters and alarm information displayed on the display screen of this device are only for reference by clinical doctors and cannot be directly used as a basis for clinical treatment.

Handling of packaging materials must comply with local regulations or the hospital's waste disposal system. Packaging materials must be kept out of the reach of children.

All personnel should be aware of the risk of infection when dismantling or cleaning certain components of the ventilator.

Disposable accessories such as tubes and respiratory masks are only for single use by a single person. To avoid risks such as cross-infection or decreased measurement accuracy, they should be disposed of as medical waste after use and should not be reused.

Maintenance mode can only be used after disconnecting the device from the patient.

Positive pressure breathing may be accompanied by the following side effects: barotrauma, insufficient ventilation, excessive ventilation, and other hazards.

Using a ventilator near high-frequency electrosurgical devices, defibrillation devices, or shortwave therapy devices will pose an impact on the normal operation of the ventilator and a risk of harm to patients.

Do not use anti-static or conductive masks or breathing tubes when using high-frequency surgical devices, which may cause burns.

There must be alternative solutions to ensure sufficient level of monitoring if the internal monitoring system of the device fails. In any case, the operator of the ventilator must take responsibility for the patient's proper ventilation and safety.

According to regulatory requirements, this device should be monitored for oxygen concentration when applied to patients. If the device you are using is not equipped with this function or if the function is turned off, please use a monitor that meets the requirements of EN ISO 21647 for oxygen concentration monitoring.

All analog and digital devices connected to this system must be certified according to specified standards (such as GB 4943 Data Processing Equipment Standard and EN IEC 60601-1) Medical Electrical Equipment Standard). All configurations should follow the content of the valid version of the EN IEC 60601-1) system standard. The personnel responsible for connecting additional devices

to the input/output signal ports are responsible for configuring the medical system and ensuring that the system complies with the EN IEC 60601-1) standard.

When connecting peripherals or replacing oxygen sensors through signal input and output ports, it is not allowed to touch the patient at the same time to avoid causing the patient's leakage current to exceed the standard requirements.

If the air supply input system of the ventilator fails or is abnormal, contact the manufacturer for maintenance by designated personnel.

The ventilator cannot use helium (He) or helium mixtures.

Remove the mechanical arm to prevent the ventilator from tipping over before moving the ventilator.

The gas mixer of the ventilator used for oxygen and air does not contain grease and does not require degreasing treatment. Do not use lubricants containing oil or grease to prevent hose components from being contaminated by grease. Lubricants containing oil or grease will pose a risk of combustion or explosion when the concentration of the oxygen reaches a certain level.

The maximum operating pressure of the hose is 1.4 MPa at 21°C, it is necessary to check whether the air supply pressure meets the requirements for the usage of the hose before use.

The connector on the hose adopts a standard gas terminal joint with gas characteristics, making it impossible to interchange different types of gases and gases of the same type with different pressures.

Long-term exposure to acidic substances, alkaline substances, or ultraviolet rays will accelerate the aging of hoses.

Do not connect two or more hose components together in series.

The maximum load-bearing capacity of the ventilator support arm is 1 kg. Do not hang objects exceeding 1 kg.

Reset the altitude after installing the ventilator or replacing the main control board. Recalibrate the flow rate (manufacturer) after modifying the altitude setting value.

When disconnecting the quick connector, please operate with both hands to prevent potential injury caused by sudden pressure release.

Do not block the air inlet on the side of the ventilator.

Avoid using or stacking other devices near the ventilator to prevent electromagnetic interference from interrupting the operation of the ventilator. If it is necessary to use or stack other devices near the ventilator, it should be verified that the ventilator can operate normally in the set state while operating other devices.

Ensure that the ventilator is securely fixed to the trolley or placed on a safe and stable surface to avoid personal injury or device damages.

Be careful to avoid device damages caused by tipping over when moving the ventilator through obstacles (such as thresholds).

Press the brake plate to avoid damages caused by accidental movement when stopping the movement of the ventilator.

Avoid using contaminated air. When using air as the device air supply for ventilation, if there is

air pollution, harmful substances may enter the patient's pipeline.

To prevent device failure from causing harm to patients, when the [Technical Error**] alarm occurs, immediately remove the device, record the fault code, and contact the Company's After-sales Service Department.

Do not spill or spray liquids onto the ventilator to avoid causing malfunctions.

For the circuit equiped with the humidifier, ensure that the length of the patient circuit from the humidifier to the Y-shaped connector is greater than 1.2 meters, to reduce the temperature of the gas outlet and avoid harm to the patient.

If there are doubts about the AC power cord, the device should be temporarily operated by internal batteries.

The nebulization or humidification device may increase the resistance of the respiratory system filter, and the operator should pay attention to the increase of resistance and blockage of the respiratory system filter.

Nebulization may affect the ventilation accuracy of the ventilator.

The ventilator cannot use nitric oxide gas (NO).

Check if the alarm limit setting is reasonable before ventilation.

Connect the device to a power socket easy to plug and unplug when using the power supply, so that the power plug can be easily and quickly unplugged in the event of a malfunction.

Do not modify this device.

Stop using this ventilator immediately and contact the Company's After-sales Service Department after the buzzer alarms.

Lay the cable for the infant and toddler flow sensor to avoid the risk of patients getting entangled or accidentally removing the tube.

System leaks, such as those caused by airbag-free tracheal catheters, may affect readings related to airflow, including airflow, pressure, dead space, CO2 production, and other breathing mechanics parameters.

Do not remove or replace fuses or perform any maintenance tasks when the ventilator is connected to the patient. This kind of task must be performed without the patient using the ventilator.

Ensure that the AC power cord is unplugged before removing or replacing the fuse.

If the same or similar device used in the corresponding independent area uses different alarm presets, there may be potential hazards. Read the manual to confirm the alarm preset of the ventilator before use.

To avoid the risk of electric shock, this device must be connected to a power grid with grounding protective .

If the ventilator is expected to be connected to an independent power supply, the power supply should be designated as part of the ventilator.

Do not place the ventilator in a location where it is difficult to disconnect the device.

⚠ Caution:

When this ventilator works closely with the devices emitting high-frequency radiation such as mobile phones and radios , this may cause function faults,please keep a distance of more than 1 m

away from the high-frequency device.

When powering this ventilator with an external power supply, always connect it to an interface that is easy to plug and pull out so that it can be removed quickly in case of a fault.

When powering this ventilator with an external power supply, ensure that the power cord will not form any obstruction.

To avoid the risk of electric shock, the device can only be connected to a grounding protective power socket. If there is no earthed conductor, the socket is not allowed.

Do not open the casing of the device, otherwise there may be a risk of electric shock. The repair or upgrade of the device can only be carried out by maintenance personnel trained and authorized by the Company.

If there are doubts about the integrity of the installation or wiring of external protective wires, the device should be temporarily operated by internal batteries.

Be sure to provide alternate auxiliary breathing devices to prevent device failure.

Do not immerse this ventilator in liquid. If liquid enters the hood, it may cause damages to the device.

The ventilator must be regularly maintained and inspected by personnel who have received professional training.

To ensure safety, it is important to always prepare a spare artificial ventilator.

Once the ventilator is connected to the patient, there should always be a dedicated person to supervise and monitor the operation of the device.

During the operation of the ventilator, do not disassemble the inhalation safety valve and exhalation valve, unless in standby mode.

Please use the accessories specified in this Operator’s Manual to ensure the safety of patients.

When the device and its accessories are about to exceed their lifetime, they must be disposed of in accordance with relevant local regulations or hospital regulations.

Electromagnetic fields can affect the performance of this device, therefore other devices used near this device must comply with the corresponding EMC requirements. Mobile phones, X-rays, or MRI devices are all possible interference sources as they can emit high-intensity electromagnetic radiation.

This system can operate correctly at the anti-interference level indicated in this Operator’s Manual. If the interference level is higher than this level, it may triger alarms and cause mechanical ventilation stop working. Be careful to avoid false alarms caused by high-intensity electric fields in the system.

Please confirm that the voltage and frequency of the power supply comply with the device label or the requirements specified in this Operator’s Manual before connecting the device to the power supply.

Please install or transfer the device properly to prevent it from falling, collision, strong vibrations, or other damages due to external mechanical forces.

Check for any damages or air leakage in the reusable respiratory circuit before each use. If present, do not use this circuit.

Disconnect the power plug of the ventilator to achieve electrical isolation between the circuit of the ventilator and the electrodes of the input power supply.

Do not use air supply hose assemblies that are worn out or contaminated with combustible materials such as oil and grease to reduce the risk of fire.

Clinical doctors are responsible for ensuring that the ventilator is set up correctly.

When setting up the ventilator, make sure to select the correct patient type and connect the appropriate respiratory circuit to prevent injury to the patient. Ensure that the ventilator has passed system self-check or pipeline testing before being applied to each patient.

Calibrate the flow sensor before using the ventilator or when there is a deviation in the measurement value.

Ensure that the ventilation parameters of the ventilator are set correctly before ventilation to prevent injury to the patient.

Replace failed chemical oxygen sensors or use external monitoring devices that meet the requirements of ISO 21647 in a timely manner to ensure the accuracy of oxygen concentration monitoring.

Fan failure may cause an increase in oxygen concentration inside the device, leading to a risk of fire.

To reduce the risk of explosion, do not forcefully open the chemical oxygen sensor or put it into fire.

Avoid high airway pressure when using a mask for ventilation. It may cause gastric dilation.

During non-invasive ventilation, if the peak pressure exceeds 33 cmH2O, it may increase the risk of gastric distention. Invasive ventilation mode should be considered when using pressure exceeding 33 cmH2O.

To reduce the risk of fire, only use hoses approved for medical purposes and used to connect oxygen supply and ventilators.

Ensure that the back of the ventilator was not blocked, so as to reduce the risk of fire.

Turn off the oxygen supply when the ventilator is not in a ventilation mode to reduce the risk of fire.

Avoid storing the ventilator in an environment exceeding 50°C for a long time. It may cause damages or shorten lifetime of the internal batteries and chemical oxygen sensors.

Transport the ventilator with original packaging materials.

To avoid fire, only specified fuses or those of the same type, rated voltage, and rated current as existing fuses can be used. If you need to replace the fuse, please contact the Company's After-sales Service Department.

The ventilator is suitable for use in patient environments.

Additional porous sockets and extension cords cannot be connected to this system.

Ensure that the casters and brake plates are operating properly and that the ventilator main unit is locked onto the trolley before moving the ventilator.

Use dry and clean medical compressed air and oxygen as the air supply. The moisture in the air supply may cause the device malfunction.

⚠ **Note:**

Place the ventilator and its components in a position that is easy to observe, operate, and maintain.

Please place this Operator's Manual near this device for easy and timely access when needed.

The software of this device is developed in accordance with the requirements of EN IEC 62304, minimizing the possibility of risks caused by program error.

This Operator's Manual introduces this product according to the most complete configuration. The product you purchased may not have certain configurations or functions.

Please note the symbol information on the component:

- Class I special waste: Used batteries must be replaced and scrapped in accordance with local regulations. They cannot be disposed of as general waste. In some areas, there are no recycling facilities.
- Class II special waste: Used waste oxygen concentration sensors must be replaced and discarded in accordance with local regulations. These should not be considered as normal waste.
- Some components of hazardous waste (infectious) devices cannot be considered as normal waste.
- All discarded (disposable) parts must be disposed of in an environmentally friendly manner in accordance with hospital regulations.
- Excess liquid (produced during cleaning and disinfection, etc.) should not accumulate in expired sensor probes for a long time, otherwise, the function of the ventilator will be affected.
- Do not allow sharp tools to come into contact with the touch screen.

It is recommended to use at least one spare battery as a backup power source for the ventilator.

1.1.Use oxygen

⚠ **Warning:**

The hyperbaric oxygen can cause an explosion when it is exposed to combustible materials (such as lubricating grease, machine oil, ethyl alcohol, etc.).

Providing patients with high concentration of oxygen for a long period of time will cause toxicity. Patients can tolerate different periods of time depending on their age and physical condition, so please use appropriate ventilation methods according to their conditions.

The device and all connectors should be kept clean, machine oil or lubricating grease is strictly prohibited.

Wear clean medical gloves before operating the oxygen supply device.

Smoking and lighting are strictly prohibited near devices and related supporting facilities.

⚠ **Caution:**

When installing and replacing the oxygen cylinder, manually tighten the relevant knob switches on the oxygen cylinder and pressure reducing valve. It is strictly prohibited to use tools to prevent excessive force from damaging the threads and sealing materials, which will result in leakage.

Please take measures to prevent the oxygen cylinder from overturning. The overturning of the

oxygen cylinder may damage the pressure reducing valve or air valve, and in severe cases it may cause an explosion.

Opening the cylinder valve slowly, excessive and fast opening the valve may cause a sudden increase in pressure, which can impact the valve accessories and cause damages.

Do not exhaust the oxygen cylinder completely to avoid corrosion of the gas cylinder due to the invasion of humid air in the surrounding environment.

1.2. Ventilation/Operation

During the ventilation, it is necessary to continuously observe the patient and the respiratory device.

Relying on the ventilator for breathing for a long time will result in the respiratory muscles atrophy in patients.

Long-term ventilation will result in dryness of the respiratory tract.

Ensure the smoothness of the breathing tube and inspiratory end connected to patients to avoid affecting the ventilation function of the device.

Do not place the ventilator next to the barrier, as it will obstruct the flow of cold air and cause the device to overheat.

1.3. Patient respiratory circuit assemblies

⚠ Warning:

Professional medical training and technical guidance of respiratory devices are required when using the patient breathing tube assemblies. Improper use may result in serious physical injury.

Please refer to the relevant content in this Operator’s Manual for functional and visual inspection of the breathing tube assembly before use.

Check whether the gas flow direction delivered to the patient is correct and whether the breathing tube is smoothly compliance before connecting the patient.

Only use the patient breathing tube assembly for the stated purpose.

Patient breathing tube assemblies are not suitable for high-pressure applications (such as hyperbaric oxygen chambers).

1.4. Accessories/Spare parts

⚠ Caution:

Only the manufacturer Ambulanc (Shenzhen) Tech. Co., Ltd. or authorized professionals can perform maintenance measures such as inspection and overhaul work.

Using accessories from other manufacturers may lead to failure and incompatibility. Please remember that the warranty obligations will become invalid if users fail to use the accessories recommended in this Operator’s Manual or the original spare parts

For reused accessories, please refer to the manufacturer's instructions for cleaning and disinfection before use, to avoid the risk of cross-infection, single-use accessories cannot be used

twice, it cannot be sterilized.

2. Device Description

2.1.Intended use

This product is intended for use in intensive care environments within professional medical institutions, or during transportation within professional medical institutions. It provides ventilation assistance and respiratory support for adults, pediatric and infants. This product should be operated by well-trained and authorized medical personnel.

2.2.Indications

1. Acute respiratory distress syndrome (ARDS) : new onset or worsening of respiratory symptoms with bilateral opacities on chest radiography and a PaO2:FIO2 ratio 300 mm Hg or less while receiving PEEP of 5 cm H2O or higher.

2. Respiratory failure : Severe impairment of lung ventilation and/or gas exchange, resulting from various causes, leads to ineffective gas exchange, causing hypoxemia with or without hypercapnia, and a series of physiological and metabolic disturbances. Under normal atmospheric pressure at rest, breathing room air, and excluding conditions such as intracardiac shunt and primary reduction in cardiac output, arterial oxygen partial pressure (PaO2) is less than 8 kPa (60 mmHg), or accompanied by carbon dioxide partial pressure (PaCO2) higher than 6.65 kPa (50 mmHg).

3. Chronic obstructive pulmonary embolism (COPD) : severe breathing difficulties and respiratory failure during acute exacerbation of COPD patients.

4. Cardiogenic pulmonary edema: characterized by the development of acute respiratory failure associated with the accumulation of fluid in the lung’ s alveolar spaces due to an elevated cardiac filling pressure.

5. Pneumonia: characterized by inflammation of the lungs caused by bacterial, viral, or fungal infection, leading to fluid or pus-filled alveoli, with symptoms like cough, fever, rapid breathing and difficulty breathing.

6. Respiratory distress: refers to severe symptoms of oxygen deficiency due to inadequate respiratory function, including rapid breathing, wheezing, nasal flaring, and increased respiratory effort, commonly seen in acute respiratory distress syndrome (ARDS) and other acute lung injuries.

7. Congenital heart disease: refers to a structural abnormality of the heart developed during fetal growth, potentially causing abnormal blood flow, resulting in compromised cardiopulmonary function and respiratory difficulty.

8. Bronchiolitis: refers to a common respiratory condition in infants caused by viral infection, leading to inflammation of the small airways, with symptoms like wheezing, cough, and rapid breathing, primarily affecting young children.

2.3.Contraindications

This device has no unconditional contraindications, but the patients with some special symptoms, such as acute massive hemoptysis, tension pneumothorax, and pulmonary bulla, should

be treated appropriately before put into use. For patients with severe imbalances in bilateral lung respiratory dynamic parameters, bilateral lung ventilation should be adopted as much as possible. Patients with low blood volume or low blood pressure, as well as those with craniocerebral injury and hypertension intracranial, should strictly be treated follow the indications for mechanical ventilation , otherwise, it will aggravate the primary disease and cause serious adverse consequences. The following situations are listed as relative contraindications for ventilation with a ventilator.

(1) Patients with respiratory failure accompanied by pulmonary bulla;
(2) Patients with tension pneumothorax and mediastinal emphysema who have not undergone drainage;
(3) Massive hemoptysis or severe asphyxia due to aspiration;
(4) Acute myocardial infarction;
(5) Left heart failure;
(6) Hypotensive shock;
(7) Active tuberculosis.

2.4. Clinical benefit

The Ventilator improves patient oxygenation (within 72 hours after ventilation).

2.5. Residual risks and side effects

One or more risks arising from all identified hazardous conditions have been brought under control and within acceptable limits. After all risk control measures have been implemented, no new risks have been created.

The residual risks are within the acceptable range after risk control.

2.6. Intended use environment

This product is intended to be used in intensive care environments within professional medical institutions, or during transportation within professional medical institutions. Do not use this device in a magnetic resonance imaging (MRI) environment.

2.7. User qualification

The operator who uses this ventilator must meet the following conditions:

1. This product should be operated by well-trained and authorized medical personnel.

2. Trained in the clinical application of this ventilator approved by Ambulanc (Shenzhen) Tech. Co., Ltd.

⚠ **Caution:**

Improper use may cause serious damage to personnel (users and patients).

3. Device Installation and Component Connection

⚠ **Warning:**

- After installation, a function check must be performed (see 11 Maintenance and Inspection)

to ensure that the device can be used properly.

- Do not use anti-static or conductive masks or breathing tubes when using high-frequency surgical devices, which may cause fire.
- After each replacement of accessories or components such as circuits, humidifiers, or respiratory filters, a system self-check must be performed again to ensure the optimal functioning of the ventilator.
- When adding accessories or other parts or components to the respiratory system of the ventilator, there is a risk of increased inspiratory and expiratory resistance in the system.

3.1. Packed items

This ventilator is packaged in one box, see 12 Supply Configuration for the packed items.

1. Immediately verify if all items listed on the configuration list are included after opening the packaging box;

2. Familiarize the controls and features of the main unit, and study the functions of buttons, switches, indicators, and connection ports.

3.2. Environmental requirements

Do not install, operate, store, or transport the device beyond the following specified limits.

Operation conditions

Temperature: 5°C−40°C

Humanity: 5%−95% (no condensation)

Atmospheric pressure: 50 kPa−106 kPa

Storage and transportation conditions

Temperature: -20°C−60°C

Humanity: 5%−95% (no condensation)

Atmospheric pressure: 50 kPa−106 kPa

Do not expose the device to direct sunlight;

Do not store the device in areas with high temperature variations;

Do not store the device near the heating device;

Do not store the device in areas with high vibration amplitude;

Do not operate or store the device in an environment with flammable gases or anesthetics;

Do not operate or store the device in a dusty environment.

⚠ Caution:

Please ensure that this device meets the environmental requirements for operating, otherwise it may not conform to the technical specifications claimed in this Operator's Manual and may result in unpredictable consequences such as device damages.

3.3. Connect the air supply pipeline

⚠ Caution:

- Carefully inspect the oxygen supply interface to ensure there is no leak. Excessive leakage

will cause the oxygen concentration in the surrounding environment of the device to exceed the normal atmosphere, creating a potentially dangerous oxygen-rich environment.

- Be careful when placing the air supply hose to avoid exposure to environments that may cause damage to the hose, such as cutting or heating.
- Compressed gas must be dry, dust-free, and oil-free. The pressure range of the air supply must be within the range of 280 kPa to 600 kPa, otherwise, the normal function and performance of the ventilator cannot be guaranteed.

3.4.Install spare gas cylinders

⚠ **Careful:**

Ensure that the spare gas cylinder is equipped with a pressure reducing valve.

3.5.Install the mechanical arm

⚠ **Warning:**

Check the safety of the mechanical arm joints and connections as needed to avoid accidental injury to the patient.

Install the mechanical arm that meets specifications. The mechanical arm components and installation steps described in this section are for reference only. Please refer to the Operator's Manual provided with the mechanical arm for installation and use.

3.6.Install the patient exhalation valve

⚠ **Warning:**

The manufacturer Ambulanc (Shenzhen) Tech. Co., Ltd. shall not be responsible for any performance issues caused by the use of breathing tube assemblies provided by other manufacturers.

3.7.Adult breathing circuit components and their connection

⚠ **Caution:**

- Insert the breathing hose on the fresh gas intake and do not bend any other connected air pipes.
- When selecting the CO2 module, connect one end of the CO2 module to the patient end and the other end to the CO2 sampling port.
- Clean the accumulated liquid in the water collection cup in a timely manner to avoid liquid reflux to the breathing tube, which may cause inaccurate or faulty measurements.

⚠ **Warning:**

- Grasp the breathing hose and rotate it for insertion and removal, otherwise it may be damaged or torn off during insertion and removal.
- Ensure that the length of the patient pipeline from the humidifier to the Y-shaped connector is greater than 1.2 meters, to reduce the temperature of the gas in the pipeline and avoid harm to the

patient.

- If disposable breathing hose components are used, they should be disposed of after use.
- To minimize the risk of bacterial contamination or physical damages, carefully disassemble and install the bacterial filter.
- To prevent patient or ventilator contamination, bacterial filters should be continuously used between the ventilator and the patient's inspiratory branch.

⚠ **Careful:**

- The use of an expiratory filter may lead to a sharp increase in expiratory impedance. Excessive expiratory impedance may endanger ventilation and increase the patient's respiratory work and intrinsic PEEP.
- The breathing tube should meet the requirements of ISO 5367.
- Bacterial filters should meet the requirements of ISO 23328-1 ISO 23328-2.
- The heat and moisture exchanger (HME) should comply with the requirements of ISO 9360-1 and ISO 9360-2.

3.8.Install the humidifier

⚠ **Warning:**

To prevent injuries to patients and damages to the device, do not turn on the humidifier when the ventilator is not calibrated and not ventilated.

To prevent injuries to patients and damages to the device, ensure that the humidifier is set at the appropriate temperature and humidity.

When installing the humidifier, ensure that the humidifier interface is placed lower than the breathing interface of the ventilator and the patient.

⚠ **Caution:**

The humidifier should comply with the requirements of ISO 8185 standard. The humidifier components and installation steps described in this section are for reference only.

3.9.Connect the nebulizer

⚠ **Caution:**

Please install a nebulizer that meets the specifications. The nebulizer components and installation steps described in this section are for reference only. Please refer to the Operator’s Manual provided with the nebulizer for installation and use.

To prevent exhalation valve blockages caused by nebulization administration, only medically approved drugs for nebulization should be used, and the exhalation valve diaphragm should be regularly checked, cleaned, or replaced.

Do not use an expiratory filter or heat and humidity exchanger in the breathing tube during nebulization, as it can cause blockage of the expiratory end filter, greatly increasing air resistance and hindering ventilation.

Connect the nebulizer to the inspiratory branch. Connecting a nebulizer between the patient's connection port and the endotracheal tube will increase the dead space.

4. Interface Description

4.1.Record interface

⚠ **Note**

Pausing or disabling the alarm will not save as an event.

Stored events are not affected by power loss.

If the storage events is reached the maximum storage capacity, new stored events will automatically overwrite the earliest events.

5. Tool interface

5.1.Nebulization

⚠ **Caution:**

- EtCO2 cannot be measured in the environment of aerosol drugs. Before starting the nebulization function, the EtCO2 monitoring module should be removed. The sampling and monitoring of the EtCO2 module will be temporarily suspended.
- When the patient type is infants and pediatric, the nebulization function is ineffective.
- When the oxygen supply type is low-pressure oxygen, the nebulization function cannot be activated.
- During nebulization, medication may block the exhalation valve and flow sensor. Check and clean them after nebulization.
- When the inspiratory flow rate is below 15 L/min, the nebulization function is not available.
- The increase in gas caused by the use of nebulizers may affect the accuracy of the ventilator.

5.2.Phlegm suction

⚠ **Caution:**

- After phlegm suction is initiated, P0.1, PEEPi, and NiF will not be able to start.
- In standby mode, oxygen therapy, or CPRV mode, the system cannot start O2 ↑ phlegm suction.

5.3.Function

5.3.1. Expiration hold

⚠ **Caution:**

- There should be at least one inspiration phase between two expiration holds.
- In standby mode, the system does not respond to the expiration hold button operation.
- During the PEEPi and P0.1 measurement periods, the system did not respond to the

expiration hold button operation.

5.3.2. Inspiration hold

⚠ **Caution:**

- There should be at least one expiration phase between two inspiration holds.
- In standby mode, the system does not respond to the inspiration hold button operation.
- During PEEPi, P0.1, and NIF measurements, the system does not respond to the inspiration hold button operation.

5.3.3. Manual respiration

⚠ **Caution:**

- Clicking the [Manual Respiration] icon button during inspiration cannot initiate manual respiration.
- In standby mode, the system cannot initiate manual respiration.
- During PEEPi, P0.1, and NiF measurements, the system does not respond to manual respiration button operations.

5.4.Diagnosis

5.4.1. Oral closure pressure P0.1

⚠ **Caution:**

Not available in CPAP/PSV, HFNC, CPR modes, and for infants and pediatric.

5.4.2. Intrinsic PEEPi

⚠ **Caution:**

PEEPi function is not available in CPAP/PSV mode.

During PEEPi measurement, manual respiration, inspiration hold, and expiration hold functions cannot be activated.

Not available in HFNC and CPR modes, and for infants and pediatric.

5.4.3. NiF

⚠ **Caution:**

Not available in HFNC and CPR modes, and for infants and pediatric.

5.5.SI

⚠ Caution:

During the SI, use pure oxygen ventilation or high-concentration oxygen ventilation.

When patients have autonomous respiration, it is not recommended to use the SI function.

If the patient's physiological state is abnormal, it is recommended to terminate the process of SI.

SI function cannot be used in the following situations: when the patient type is infants and pediatric; in the process of phlegm suction; in the oxygen therapy process.

5.6.P-V tool

⚠ Caution:

It cannot be used when the patient type is pediatric or infants and pediatric.

It cannot be used in CPAP/PSV, non-invasive, and asphyxia ventilation modes.

It cannot be used during nebulization or phlegm suction and within 1 minute thereafter, and cannot be used within 1 minute after the last P-V test.

6. Alarm

6.1.Alarm information

⚠Warning:

- A potential hazard exists if different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating room.
- When the alarm system is powered off, the equipment will save the alarm before the power failure. The stored alarm message does not change with the time of outage.

7. Operation

7.1.Self Check

⚠ Caution:

1．Do not perform the system selfcheck when the system is connected to the patient.

2．During the system selfcheck, do not operate the machine airway components, especially avoid moving or squeezing the respiration pipeline.

3．It is recommended to disconnect the ventilator from the humidifier before the system selfcheck.

⚠ Caution:

The automatic system self-check function cannot replace functional tests. When using this machine, it is essential to Maintenance and inspection conduct functional tests as described.

Each time you switch patient types, the system selfcheck must be performed, then initiate the ventilation.

7.2. Select patient type

⚠ Caution:

Each time you switch patient types, the system selfcheck muse be performed, then initiate the ventilation.

The corresponding tidal volume can be set by setting the ideal weight.

If [Last Patient] ventilation is selected, the machine will default to the previous patient's ventilation and alarm settings.

7.3. Ventilation type selection

⚠ Caution:

This ventilator has two ventilation modes: invasive ventilation and non-invasive ventilation.

When switching from non-invasive ventilation to invasive ventilation, it is important to check the alarm limit settings.

7.3.1. Invasive ventilation

⚠ Caution:

Please do not attempt to use non-invasive ventilation on intubated patients.

7.3.2. Non-invasive ventilation

⚠ Caution:

For patients who lack spontaneous respiration or have irregular spontaneous respiration, please do not use non-invasive ventilation.

Non-invasive ventilation is intended to provide supplemental ventilatory support for patients with regular spontaneous respiration.

Please do not attempt to use non-invasive ventilation on intubated patients.

7.4. Ventilation settings

7.4.1. Pressure Synchronized Intermittent Mandatory Ventilation (P-SIMV)

⚠ Warning:

When using this method, if the patient's condition deteriorates and spontaneous respiration suddenly ceases, hypoventilation or hypoxia may occur.

7.5. Automatic compensation

7.5.1. Tube compensation

⚠ **Caution:**

Tube compensation may result in automatic triggering. If automatic triggering occurs, first check the patient, respiratory circuit, and other possible causes.

7.6. Enter standby

⚠ **Caution:**

To prevent harm to patients due to lack of ventilation support, ensure there is alternative ventilation available before entering standby mode. Also, verify that no patients are connected to the ventilator when entering standby mode.

To prevent overheating of gases that could harm patients or damage respiratory pipeline, ensure to turn off the humidifier when entering standby mode.

7.7. Turn off the ventilator

⚠ **Caution:**

Do not deplete oxygen cylinders completely. When returning cylinders for refilling, always ensure there is residual pressure left in the cylinder to prevent humid air from the surroundings entering and causing rusting.

Check the pressure gauge that displays the cylinder pressure on the pressure reducing valve to determine the gas storage status of the cylinder. If the pressure gauge indicates below 5 MPa (including 5 MPa, approximately 725 PSI), a new oxygen cylinder must be replaced.

Close the air outlet valve of the oxygen cylinder.

7.8. Data export

⚠ **Caution:**

If you need to view the exported information, contact our after-sales department.

8. CO2 monitoring

8.1. CO2 monitoring setup

⚠ **Caution:**

In the environments where aerosolized medications are used, CO2 monitoring should be disabled. Remove the CO2 module before activating the nebulization function.

Please ensure that the patient's cardiopulmonary status is stable to obtain the most accurate CO2 measurement results.

The exhalation valve of this ventilator is a check valve. In normal or single fault conditions, the sampled gas from the EtCO2 module will be discharged through the expiration pipeline and will not return to the respiratory system.

The CO2 module is enable by default. CO2 monitoring starts automatically after the it is connected. If the ventilator loses power unexpectedly, the CO2 module stops working. When the

circuit is power on, CO2 monitoring starts automatically.

Since the mainstream CO2 module is directly connected to the sampling gas in the breathing tube, there is no water vapor treatment system, so the operator no need to intervene in the temperature and humidity of the gas

9. Cleaning and disinfection

9.1. Ventilator main unit

⚠ **Caution:**

Peracetic acid and formaldehyde fumigation are prohibited during disinfection of the complete machine.

The configuration of disinfectants should be carried out according to the manufacturer's instructions.

9.2. Valve accessories

⚠ **Warning:**

Dangers of explosion! Do not put valve accessories (pressure reducing valves and oxygen cylinders) into disinfectants or other liquids. Only wipe them for disinfection. No liquid is allowed to flow into the pressure reducing valve, otherwise it may cause an explosion.

If it is necessary to disinfect the pressure reducing valve and the matching oxygen cylinder, wipe them with a clean soft cloth. Soft cloth can be used for drying or moistening with clean water.

10. Maintenance and inspection

10.1. Check the patient's exhalation valve

⚠ **Caution:**

Be sure to place the unidirectional diaphragm correctly during installation.

10.2. Machine function check

⚠ **Warning:**

If any problems are found during the inspection, it is prohibited to be put into use on the patients!

Connect the power supply and air supply, and check whether the power supply and air supply are normal.

Power-on self-test.

After starting the ventilator, a power-on self-test will be performed by the system. Mainly check whether each sensor works normally.

Test of the apnea alarm.

The detailed steps are as follows:

Set the apnea alarm time to 15 seconds.

Set the respiration mode to CPAP/PSV, while timing, record the time when the ventilator generates an apnea alarm, and compare it with the set value. The testing time value should be between 13s and 17s.

Check the upper limit alarm function of airway pressure.

The detailed steps are as follows:

The ventilator is set to V-A/C ventilation mode.

Set Vt to 600 ml, I: E to 1:2, and Freq to 10.

Set the upper limit of airway pressure alarm to 20 mbar.

Block the patient's exhaust port of the exhalation valve with your hand, so that the airway pressure is higher than 20 mbar. At this time, an audible and visual alarm of high airway pressure should be generated. After releasing the hand for about 10 seconds, the alarm disappears.

Inspection of respiratory system integrity alarm function.

The detailed steps are as follows:

The ventilator is set to A/C ventilation mode.

Set Vt to 600 ml, I: E to 1:2, Freq to 10, the upper limit of airway pressure alarm to 30 mbar.

If the patient end of the pipeline is not connected to the test lung, the system should generate an unconnected audible and visual alarm after two respiration cycles. After connecting the test lung, the alarm should be disappeared.

Inspection of low battery level alarm function.

The detailed steps are as follows:

During the self-check process when the ventilator is connected, an automatic low battery level alarm will be detected. If the ventilator is connected and works normally without an alarm when the oxygen cylinder is opened, the voltage of the battery is in normal.

Inspection of pressure triggering function.

The detailed steps are as follows:

The ventilation mode is set to CPAP/PSV, and the CPAP pressure is set to 0.

Set the trigger pressure to −3 mbar.

When inhaling through the mask, the ventilator should deliver air when the inhalation negative pressure reaches -3 mbar. The ventilator should stop delivering air when the support pressure reaches the target pressure. It waits for the next trigger for ventilation.

10.3. Oxygen concentration calibration

⚠ **Caution:**

To ensure accuracy, please ventilate normally at a 21% oxygen concentration for 1−3 minutes before performing oxygen concentration calibration.

When the calibration succeeds, the accuracy of the monitored oxygen concentration can be verified with an oxygen meter. The specific steps are as follows:

Connect according to Figure 55, set the ventilation mode and parameters according to the standard settings, and set the oxygen concentration of the ventilator to 21%, 40%, 60%, 70%, and 100% respectively. Set the oxygen meter to the oxygen concentration monitoring state. After the output is stable, compare the measured value of the oxygen meter with the oxygen concentration setting value of the ventilator, and the result should be ± (2.5 vol.%+2.5% of the actual reading).

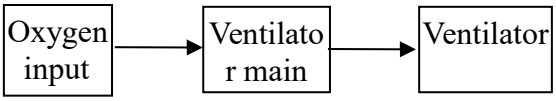

Figure 60 Oxygen concentration test connection diagram

10.4. Battery management

10.4.1. Battery state indication

Warning:

- If any problems are found during the inspection, it is prohibited to be put into use on the patients!
- Be sure to use the battery from Ambulanc (Shenzhen) Tech. Co., Ltd., otherwise the machine may fail to work normally.
- Do not short-circuit the battery;
- Do not heat or burn the battery;
- The battery life of this product is approximately 10,000 hours.
- Avoid using the battery near heat sources;
- Do not wet the battery;
- Avoid charging the battery near fire sources or in direct sunlight;
- Charge the battery with a dedicated charger and in a correct way;
- Do not use the battery together with other batteries;
- Keep the battery away from children;
- Do not place it on the charger for a long time;
- Keep the leaky battery away from the fire;
- Avoid using the battery in strong sunlight.

10.5. Storage

Important:

When the stored device are taken from the warehouse, the ventilator should be kept in the room temperature for hours bofore put into use.

11. Supply Configuration

11.1. Optional configuration

⚠ **Caution:**

The accessories listed in this chapter are applicable to this ventilator. The hospital is responsible for ensuring compatibility between the ventilator and its accessories. Incompatibility between the ventilator and its accessories can reduce the performance of the ventilator.

The specific configuration is subject to the packing list.

11.2. Parameter specifications

11.2.1. Alarm Parameter

⚠ **Caution:**

When the ventilator operates beyond the manufacturer's specified range, there is a possibility of malfunction. Ensure that this ventilator operates under specified working conditions to maintain stable operation.

The total response time of the carbon dioxide system is 1s.

The total response time of the oxygen concentration system is 3 minutes.

The time required for the oxygen concentration to increase from 10% to 90% is 3 minutes.

When the storage conditions exceed the working conditions and the storage state transitions to the usage state, it should be placed in a standard environment for more than 8 hours.

When the operating pressure of the ventilator exceeds the range specified by the manufacturer, there will be significant deviations in the performance of the ventilator, and excessive operating pressure may damage internal sensors. Ensure that the working pressure of this ventilator is within the specified range to maintain stable operation.

11.3. Schematic diagram of airway

⚠**Note:**

If necessary, Ambulanc can provide circuit diagrams, component lists, drawing annotations, calibration rules, or other data that helps maintenance personnel repair ventilator components that can be repaired by the manufacturer's designated maintenance personnel as required.

12. EMC

12.1. Electromagnetic emission declaration

⚠ **Caution:**

The ventilator complies with the electromagnetic compatibility requirements of IEC 60601-1-2: 2007 , ISO 80601-2-12: 2011, and ISO 80601-2-55: 2018 standards.

Users should install and use this device in accordance with the electromagnetic compatibility information provided in the accompanying documents.

Portable and mobile radio frequency (RF) communication devices may affect the performance of this ventilator, so it is necessary to avoid strong electromagnetic interference when in use, e.g., near cell phones or microwave ovens.

Guidelines and the manufacturer's statement are detailed in the following table.

⚠ **Warning:**

This ventilator should not be used in close proximity to or stacked with other devices. If it must be so, it should be observed to verify that it is able to operate properly in the configuration in which it is used;

The use of accessories and cables other than those specified may result in an increase in emission or a decrease in immunity of this ventilator, except for cables sold by the manufacturer as spare parts for internal components.

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