T6 Safety and Performance Information

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Product information

Product name: Ventilator

Model: T6

Manufacturer name: Ambulanc (Shenzhen) Tech. Co., Ltd.

Manufacturer 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

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Version: 1.0

Notices: This instrument is not designed for household purposes.

1 Safety instructions

Warning: Make a warning for the conditions that may cause a risk of harm to patients and users.

Notice: Make a warning for the conditions that may cause damage to the device and may result in incorrect treatment.

Hint: Information alerts on the contents of this user instruction.

1.1 Overview

Warning:

- A functional check must be performed before using this equipment (see "11 Maintenance and Inspection").
- Follow the instructions in "9 Cleaning and Disinfection" to prevent infection or bacterial infection.
- T6 shall only be used after you are subjected to medical training and technical instructions on ventilator as improper use can cause serious bodily injury.
- Do not leave the patient or the ventilator during ventilation, so as to be able to make a timely response in the event of an emergency (such as deterioration of the patient's condition or machine failure), and to minimize the patient's injury.
- T6 may only be used for the specified purposes (see "2.1 Intended use").
- T6 is strictly prohibited in high-pressure applications (hyperbaric chamber).
- T6 is strictly prohibited in explosive or toxic environments.
- T6 is strictly prohibited in oxygen-rich or flammable environments.
- The device is not intended for use in the magnetic resonance imaging (**MRI**) environment.
- Use of antistatic or conductive masks or ventilator lines when using high-frequency surgical equipment may cause burns, so do not use antistatic or conductive masks or ventilator lines.
- This equipment cannot be used with nitric oxide.
- This equipment cannot be used with helium or mixtures containing helium.
- In case of respirator failure, if other ventilation methods cannot be applied immediately, it may result in patient death.
- Non-maintenance personnel are prohibited to open the T6 cover to change or modify any external or internal parts of T6.
- To avoid the risk of electric shock, the device can only be connected to a power socket with protective grounding. Do not use a power socket that is not connected with a grounding conductor.
- Do not open the enclosure of the equipment, otherwise there may be a risk of electric shock.

- Maintenance or upgrade of the equipment can only be carried out by the maintenance personnel trained and authorized by the company.
- When used outside the healthcare facility, T6 should be fixed on the road vehicle and operated by EMS personnel with a basic knowledge of mechanical ventilation.

Notices:

- When T6 is used together with devices that emit high-frequency radiation (e.g. mobile phones, radios), a distance of more than 1m must be maintained, otherwise it may cause dysfunction.
- When an external power supply is used to supply power for T6, always connect it to an easily pluggable interface so that it can be quickly unplugged in case of failure.
- When an external power supply is used to supply power for T6, ensure that the power cord does not form an obstruction. Please do not use the external power supply when it is not necessary (the battery power is less than 20% or the battery power is used uninterruptedly for a long time). Battery power is preferred.
- An alternative backup ventilator must be available in case of equipment failure.
- After the device is used in a dirtier environment, the filter shall be replaced as described in "11.14 Replace of filter cotton ".
- Do not immerse T6 in any liquid. If any liquid gets into the cover, it can cause damage to the device.

1.2 Safe use of oxygen

Warning:

- An explosion will be caused when the high-pressure oxygen meets any combustibles (grease, oil, and alcohol, etc.).
- Toxic effects may be caused when a patient is provided with the oxygen of high concentration for a long period of time. The endurance of patients will vary due to their age and physical conditions. Please use appropriate ventilation method according to patient's condition.
- The device and all joints shall be kept clean, and no oil or grease is allowed.
- Please wear clean medical gloves before operating the oxygen supply unit.
- No smoking or open flame is allowed near the device and related supporting facilities.

Notices:

- When installing and replacing oxygen cylinders, please manually tighten relevant knob switches on oxygen cylinders and pressure reducing valves. It is strictly prohibited to use any tools, so as not to damage the thread and sealing material due to excessive force, resulting in leakage.
- Please take measures to prevent dumping of oxygen cylinders. The dumping of oxygen cylinders would cause damage of the pressure reducing valve or oxygen valve, or even cause an explosion.
- The valve of the cylinders shall be opened slowly. Excessive opening of the valve will cause a sudden rise in pressure, which will impact the valve fittings and cause damage.
- The oxygen cylinders shall not be completely used up to avoid corrosion of cylinders caused by intrusion of moist air of surrounding environment.

1.3 Patient ventilator line components

Warning:

- Professional medical training and technical guidance on the ventilator must be provided during use of the patient ventilator line assembly, as improper use may result in serious bodily injury.
- Relevant contents in the Operation Manual shall be referred to, and functional inspection and visual inspection shall be carried out before use of the ventilator line components.
- Before connecting it with the patient, check that flow direction of the oxygen provided to the patient is correct and the ventilator line is smooth.
- The patient ventilator line components can only be used for the specified purposes.
- The patient ventilator line components are not suitable for high-pressure applications (e.g. hyperbaric chamber).

1.4 Accessories/spare parts

Notices:

- [Prevention of exposure] Measures shall be taken to protect silicone and rubber parts from being exposed to ultraviolet light and long hours of direct sunlight, which would otherwise cause brittleness of these parts.
- [Only use the approved accessories] Failure may be caused due to incompatibilities arising from using of accessories from other manufacturers. **Please keep in mind that the rights and obligations of the warranty will expire if:** any accessories not recommended in the Operation Manual or any non-original spare part is used.

1.5 Battery

Warning:

[Low battery power] When there is a low battery power alarm, please do any of the followings:

- Replace the battery with a fully charged one.
- Connect the external power supply of T6.

Notices:

[Maintaining of battery installation] In order to enable continuous operation of T6, it is recommended that a fully charged battery shall be installed at all times (even when an external power supply is connected to supply power).

2 Overview

2.1 Intended use

The ventilator is intended to provide ventilation assistance and breathing support for adult, pediatric and infant patients. The ventilator is intended to be used in intensive care situations within a professional healthcare facility and also suitable for all types of ambulances for emergency transport of the patient. The ventilator should be operated by properly-trained and authorized medical staffs.

2.2 Indications

1. Acute respiratory distress syndrome (ARDS)
2. Respiratory failure
3. Chronic obstructive pulmonary embolism (COPD)
4. Cardiogenic pulmonaryedema

2.3 Contraindications

Using noninvasive ventilation is contraindicated if any of the following conditions are met:

- Partial or complete airway obstruction
- Gastrointestinal bleeding
- Anatomic or subjective intolerance of NIV interface

2.4 Intended operating environment

The ventilator is intended to be used in intensive care situations within a professional healthcare facility and also suitable for all types of ambulances for emergency transport of the patient.

2.5 User qualification

The ventilator should be operated by properly-trained and authorized medical staffs.

3 Installation

Warning: After installation, you must carry out functional inspection (by referring to the "11 Maintenance and inspection") to ensure that the device works properly.

Notices:

1. The monitor hole to which the blue line is attached shall be placed near the patient.
2. Connect the transparent PU tube of flow sensor to white interface of mainframe, and connect the blue PU tube to the blue interface.
3. Insert the respiratory hose into the fresh air inlet. Be careful not to bend other connected lines.
4. For the connection between other accessories and how to connect them to the patient, please refer to above diagram, "Connection of double-line accessories".
5. When the ETCO2 module is selected, connect one end of the mainstream CO2 module to the patient, connect the other end to the respiratory line with flow sensor, and connect the ETCO2 data acquisition line to ETCO2 sampling port at the same time.

Warning:

- Grasp both ends of the respiratory hose, PU tube and nebulizer connecting tube, and rotate them to insert and pull out, otherwise the respiratory hose may be damaged or broken when inserting and pulling out the respiratory hose.
- The turbofan will cause heating of the gas. Ensure that length of the patient line from humidifier to Y-shaped connector is greater than 1.2 m, in order to reduce temperature of the gas in the line and to avoid causing injuries to the patient.
- If disposable respiratory hose assembly is used, it shall be discarded after use.

⚠ **Warning:** The manufacturer, **Ambulanc (Shenzhen) Tech. Co., Ltd**., is not responsible for any performance problems caused by use of the respiratory line components provided by other manufacturers.

4 Special functions

⚠ **Notices：**

- The use of recruitment maneuvers is not recommended when the patient is breathing spontaneously.
- If the patient's physiological status is abnormal, it is recommended to terminate the recruitment process.
- It's not available with infant types.

5 Operations

⚠**Notices:**

- The automatic self-inspection function is not intended as a substitute for function inspection. When using the machine, function inspection of the machine shall be carried out according to the contents described in "10 Maintenance and inspection".
- Each time the patient type is switched, the system must be calibrated before ventilation can be initiated.

⚠**Notices:**

- Each time the patient type is switched, the system must be calibrated before ventilation can be initiated.
- If the previous patient ventilation is selected, the machine will use the previous patient ventilation setting and alarm setting by default.

⚠**Notices:**

- Setting of alarm limits shall be checked when switching from noninvasive to invasive ventilation.

⚠**Notices:**

- Do not attempt to use noninvasive ventilation on a patient with endotracheal intubation.

⚠**Notices:**

- Non-invasive ventilation shall not be used in patients with no or irregular autonomous respiration.
- Non-invasive ventilation is expected to provide supplementary ventilation support for patients with regular autonomous respiration.
- Do not attempt to use noninvasive ventilation on a patient with endotracheal intubation.

Warning:

When this mode is used, hypoventilation or hypoxia may occur if the disease worsens and autonomous respiration suddenly stops.

Notices：

- Automatic tube compensation may result in automatic triggering. If automatic triggering occurs, first check the patient, breathing circuit, and other possible causes.

Notices:

1. In order to prevent any injuries to the patient due to lacking of ventilation support, it is necessary to ensure that alternative ventilation is available before entering standby and that no patient is connected to the ventilator at the time of entering standby.
2. In order to prevent the patient from being injured or the respiratory line from being damaged by overheating of gas, the humidifier shall be turned off when it enters standby.

Notices:

The oxygen cylinder shall not be run out completely. It is always necessary to ensure that there is residual gas pressure in the cylinder when you return it to refill, which will prevent moisture air in the surrounding environment from getting in and causing corrosion.

1. The pressure gauge indicating pressure of the cylinder on the pressure reducing valve shall be checked to determine gas storing condition of the cylinder. If indication of the pressure gauge is less than 5MPa (including 5MPa, about 725PSI), the oxygen cylinder must be replaced with a new one.
2. The outlet valve on the oxygen cylinder shall be closed.

Notices:

- A valid calculation value is only displayed when the high pressure oxygen supply is connected.
- This parameter is automatically zeroed after shutdown and restart

6 CO_2 monitoring

Notices:

- CO_2 cannot be measured in the environment of aerosol drugs, so the CO_2 module shall be removed when nebulization function is enabled. The patient's cardiopulmonary state shall be ensured to be stable, so that the most accurate CO_2 measurements can be obtained.

7 Cleaning and disinfection

7.1 T6 mainframe

Notices:

1. When disinfecting the whole machine, fumigating with peracetic acid and formaldehyde is forbidden.
2. The disinfectants shall be prepared according to instructions of the manufacturer.

7.2 Valve accessories

Warning:

Danger of explosion! Valve accessories (pressure reducing valves, oxygen cylinders, etc.) shall not be put into disinfectants or other liquids. Only wiping and disinfecting are allowed. Any liquid is never allowed to flow into the pressure reducing valve, otherwise it will cause an explosion.

If it is really necessary to disinfect the pressure reducing valve and the supporting oxygen cylinder, please wipe with a piece of clean soft cloth. The soft cloth can be dry or moistened with clean water.

8 Maintenance and inspection

Notices: During installation, it is necessary to note that the one-way diaphragms are in the correct position.

Warning:

If any problems are found during the inspection, it must not be used for patients!

1. Connect the power supply and gas source, and check whether the power supply and gas source are normal.
2. Power-on self-inspection. After the ventilator is started, the system will start the power-on self-inspection. It is mainly to check if each sensor works normally.

Notices : Before oxygen concentration calibration, set 21% FiO2 and start the ventilation for 1-3 minutes.

Notices:

- During zerio calibration of gas line, no patient or any device that may generate flow shall be connected to the T6.

Warning:

If any problems are found during the inspection, it must not be used for patients!

1. The battery specified by Ambulanc (Shenzhen) Tech. Co., Ltd. must be used, or the machine may not work normally.
2. Short-circuit of battery is prohibited;
3. Never heat or burn the battery;
4. Avoid using the battery near any heat sources;
5. Never wet the battery;
6. Avoid charging in the vicinity of fire or in direct sunlight;
7. Use a special charger and charge properly;

8. Do not mix with other batteries;
9. Keep the battery away from children;
10. Do not connect with the charger for a long period of time;
11. The leaky battery shall not be kept close to the fire;
12. Avoid using the battery in strong sunlight.

⚠ **Warning:** Use of the ventilator without a filter shall be prohibited, in order to avoid affecting performance of the machine, or even cause damage to the machine.

⚠ **Important:** The stored device must comply with the time limit for maintenance and must not be taken out from the warehouse for direct use.

9 T6 accessories

⚠ **Notices:**

- The accessories listed in this section are applicable to the ventilator. The hospital shall be responsible for ensuring the compatibility between ventilator and accessories. Incompatibility between the ventilator and accessories may degrade performance of the ventilator.
- The specific configuration is subject to the packing list.

10 Product specifications

Medical device management category	
Category	Category IIb medical devices
Installation and use classification	Mobile equipment

11 Storage and transportation

⚠ **Warning:** When the storage conditions exceed requirements of the working environment, it shall be placed in the standard environment for more than 8 hours before it can be used when it is changed from storage state to operating state.