6000S Safety and Performance Information

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Ambulanc is responsible for the effects on safety, reliability and performance of this product, only if:

- All installation operations, expansions, changes, modifications and repairs of this product are conducted by Ambulanc authorized personnel;
- The electrical installation of the relevant room complies with the applicable national and local requirements;
- The product is used in accordance with the instructions for use.

Warning

- This equipment must be operated by skilled/trained clinical professionals.
- It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.

Safety Information

Danger

Indicate an imminent hazard that, if not avoided, will result in death or serious injury.

Warning

Indicate a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.

Caution

Indicate a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

Note

Provide application tips or other useful information to ensure that you get the most from your product.

1. Overview

Product Information

Thank you for purchasing our Transport Ventilator

For the correct use of this device, please read and understand this User Manual carefully before use. After reading, please keep this Manual in an easily accessible place.

Product name:	**Transport Ventilator**
Model:	6000S
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
Version:	1.0
Release date:	2024.7.15

Warning

This device is not intended for home using!

CE 1639

2. Description

2.1 Intended use

The 6000S ventilator is intended to provide continuous ventilation for patients who require invasive or noninvasive respiratory support and weigh more than 10KG (Infants, children, adults). The 6000S Ventilator is intended for use in emergency treatment outside the hospital and inhospital transportation, and it runs under the central oxygen supply of the hospital or an oxygen cylinder pressure greater than 2.7Bar.

Warning

6000S Should not be used on neonatal patients.

2.2 Applications

You can use 6000S:

- To revive patients at the site of the emergency;
- For longer periods in more protracted emergencies, e.g. fire;
- For short-term O_2 inhalation using a respiration masks.

You can use 6000S while transporting patients:

- Between the various rooms and departments of a hospital;

- Between the hospital and other premises;
- In emergencies;
- When transport over considerable distances is planned.

6000S:

- Is designed to provide controlled ventilation to persons of **10kg** body weight or more;
- Is used to treat respiration arrest;
- Can be preset to parameters that ensure evenly balanced ventilation, provided that the selected Maximum ventilation pressure Pmax is not exceeded;
- Permits respiration-controlled oxygen inhalation in Demand mode.

2.3 Users qualification

6000S must only be used by persons who can verify that they have the following qualifications:

- A medical qualification and training in ventilation techniques.
- Training in the use of the 6000S by a person authorized by Ambulanc

  Improper use may lead to serious physical injury.

3. Safety instructions

3.1 Safe Using of Oxygen

Highly compressed oxygen can lead to spontaneous explosive reactions in combination with flammable substances (grease, oil, alcohol, disinfectants, etc,):

Warning

- All screw connections and other components of the ventilator must be kept absolutely free of oil and grease.
- Always wash your hands before starting to work on the oxygen supply.
- Smoking and open flames are strictly prohibited in the vicinity of all fittings containing or transporting oxygen.
- During assembly and when changing the oxygen cylinder, only hand pressure should be used when tightening the screw connections to the cylinder and to the pressure reducer. Never use tools for this purpose. Excessive tighten damages the screw threads and seals and can cause leaks.
- Protect oxygen cylinders from accidental falls. If a cylinder falls, the pressure reducer or the valve may break off and cause a violent explosion.

Caution

- Always open the valve of the oxygen cylinder slowly to prevent pressure damage to the other fittings.

- The oxygen cylinder should never be completely emptied as this may allow moisture-containing air to enter the cylinder and cause corrosion.
- Secure the oxygen cylinders so that they cannot fall over. If a cylinder falls on the pressure reducer or valve, these could break off, causing a violent explosion.

3.2 Patient Ventilation Hose System

Warning

- Risk of injury. Only use the Patient Hose System if you are a qualified medical professional and have received training in respiration techniques. Improper use may lead to serious physical injury.
- The Patient Hose System must be subjected to a functional check and visual inspection by the user before use. For this, refer to the instruction manual for the Patient Hose System.
- When connecting the patient valve, check that the direction of flow of the respiratory gas is correct. Make sure that the expiration opening of the patient valve is not covered or prevented from functioning, e.g., by the patient's position.
- Only use the Patient Hose System for the purpose described. For this, refer to the instruction manual for the Patient Hose System.
- The Patient Hose System is not suitable for hyperbaric use (pressure chamber).
- Also refer to the instruction manual for the Patient Hose System.

3.3 Accessories/spare parts

Caution

- Protect silicone/rubber parts against UV light and prolonged direct exposure to sunlight to prevent them becoming brittle.
- We recommend that work such as inspections and repairs should be carried out by the manufacturer, Ambulanc, or by a technician expressly authorized by Ambulanc.
- Malfunctions and a lack of biocompatibility may result if products from other manufacturers are used. Please bear in mind that in these cases all warranty rights and liability shall become void if the accessories recommended in the instruction manual or original replacement parts are not used.

4. Installation

Warning

After installation, you must make function check to ensure reliable operation.

4.1 Connecting the oxygen cylinder

Warning

- Risk of explosion! Wash your hands thoroughly before doing any work on the oxygen supply. Hydrocarbon compounds (e.g. oil, grease, cleaning alcohol, hand cream or adhesive plasters) can cause explosive reactions if they come into contact with highly compressed oxygen.
- **Never use wrenches or other tools to tighten or loosen the screw connections.**

4.2 Connecting the new cylinder

Caution

- Make sure that the patient is not connected up to the 6000S when you are establishing the gas supply. Otherwise, the automatic self-test of machine will lead to incorrect results.
- When doing this, hold the valve opening away from your body in such a way that any flying particles cannot injure yourself or other people.

4.3 Ventilation Hose System

Caution

Only grasp the ventilation hose by its ends. Otherwise the hose may be damaged.

Warning

We strongly recommend to use the original Accessories supplied by Ambulanc only, malfunctions and a lack of biocompatibility may result if products from other manufacturers are used. Please bear in mind that in these cases all warranty rights and liability shall become void if the accessories recommended in the instruction manual or original replacement parts are not used.

5. Using the ventilator

5.1 Switching on/ self test

Warning

The automatic self-test is not a substitute for the functional check. Before using the unit, always carry out a functional check. That is the only way to ensure that the unit is fully functional.

5.2 Selecting the ventilation settings

Warning

The No Air Mix setting should be used when the surrounding atmosphere is polluted or has a low oxygen content or when indication requires this.

5.3 Selecting ventilation mode

Caution

When the trigger pressure is set incorrectly or the patient's spontaneous breathe is improved, this ventilation will result excessive ventilation on patient.

5.4 Ending ventilation

Caution

Never empty the oxygen cylinder completely. Always ensure that there is a certain residual pressure in the cylinder when you return it for filling, as this prevents moist ambient air from entering and causing corrosion.

5.5 Battery management

Attention

1） In the use of emergency power it can't charge. Only in case of using an adapter it can charge.

2） In order to use batteries for a long-term normal use, it is recommended to charge and discharge once every 3 months.

6. Hygienic preparation

6.1 6000S

Caution

Never immerse 6000S in disinfectants or other liquids. Otherwise damage may be caused to the unit, thus endangering users and patients.

6.2 Ventilation hose

Caution

Always grasp the hoses at the end, as shown in the drawing, otherwise the hoses may be damaged or torn off. Close both ends of the pressure gauge hose.

6.3 Pressure gauge tube

Caution

Allow the component to dry thoroughly. If any water is left in the pressure gauge tube of the ventilation hose, the unit may not function correctly.

6.4 Fittings

Caution

1. Never immerse fittings in disinfectant or other fluids. Just wipe over with disinfectant. Fluids must not get into the pressure reducer. Otherwise explosions might occur.

If in exceptional cases you have no alternative but to disinfect by wiping, take particular care to prevent any fluid getting into the pressure reducer.

2. In addition to the risk of explosion, there also the risk of disinfectant getting into the patient's respiratory tract with the oxygen and leading to injury.

6.5 Cleaning, disinfecting and sterilizing

Caution

Then allow the components to dry thoroughly. If any water is left in the patient valve or the pressure gauge hose of the ventilation hose, the unit may not function correctly.

7. Functional checks

7.1 Checking for leaks in the system

Caution

The screwed unions of the oxygen lines must only be tightened by hand.

7.2 Checking the patient valve

Caution

When reassembling, make sure that the one-way valve membrane is correctly positioned.

7.3 Checking the alarm systems

Warning

In the case of the stenosis alarm and the disconnection alarm, the alarm signal (or message) is only set off when the cause of the alarm is repeated in two successive inspiration phases. This prevents the alarm being triggered by a very short-lived dysfunction.

Warning

In this test the rise in pressure is so strong that the pressure gauge needle may over into the red zone. There are technical reasons for this, and it does not indicate any malfunction.

8. Servicing

8.1 Battery

Warning

The 7.4V lithium battery is a special battery for this unit. Use only battery supplied by Ambulanc.

If the device is not using over 3 months, we strongly recommend conducting a charge – discharge every three months.

If the device is not using over 1 year, we recommend replacing a new battery before reusing.

8.2 Change Filter

Warning

Must not be the case without filters operate ventilator. Otherwise, the machine's performance will be impaired, or the machine will be damaged.

8.3 Storage

Warning

Remember that the ventilator still requires servicing at the specified intervals even when in storage; otherwise it cannot be used when removed from storage.

9. Technical data

9.1 Specifications

CE classification	Class IIb

10. Storage and transportation

Warning!

When the storage condition is beyond the required working environment, the device should be placed in a standard environment at least 8 hours before enter into standby

state.

11. Electromagnetic Capability

<table>
<tr><td colspan="4">GUIDANCE AND DECLARATION - ELECTROMAGNETIC EMISSION</td></tr>
<tr><td colspan="4">The 6000S is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</td></tr>
<tr><td colspan="2">EMISSIONS TEST</td><td>COMPLIANCE</td><td>ELECTROMAGNETIC ENVIRONMENT - GUIDANCE</td></tr>
<tr><td colspan="2">RF distortion
CISPR 11</td><td>Group 1</td><td>The 6000S uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td colspan="2">RF distortion CISPR 11</td><td>Class B</td><td rowspan="3">The 6000S is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td colspan="2">Harmonic distortion
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td colspan="2">Voltage fluctuations/Flicker distortion IEC 61000-3-3</td><td>Complies</td></tr>
<tr><td colspan="4">GUIDANCE AND DECLARATION - ELECTROMAGNETIC IMMUNITY</td></tr>
<tr><td colspan="4">The 6000S is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</td></tr>
<tr><td>IMMUNITY TEST</td><td>IEC60601 TEST LEVEL</td><td>COMPLIANCE LEVEL</td><td>ELECTROMAGNETIC ENVIRONMENT - GUIDANCE</td></tr>
<tr><td>ESD
IEC 61000-4-2</td><td>± 6 kV contact
± 8 kV air</td><td>± 8 kV contact
± 15 kV air</td><td>Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.</td></tr>
<tr><td>EFT
IEC 61000-4-4</td><td>±2 kV for power supply lines ±1 kV for input/output lines</td><td>±2 kV for power supply lines ±1 kV for input/output lines</td><td rowspan="2">Mains power quality should be that of a typical commercial or hospital environment.</td></tr>
<tr><td>Surge
IEC 61000-4-5</td><td>±1 kV differential</td><td>±1 kV differential mode ±2 kV</td></tr>
</table>

	mode ±2 kV common mode	common mode	
Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 6000S requires continued operation during power mains interruptions, it is recommended that the 6000S be powered from an uninterruptible power supply or a battery.

GUIDANCE AND DECLARATION - ELECTROMAGNETIC IMMUNITY			
The6000S transport ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
IMMUNITY TEST	IEC60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands	3Vrms (V1)	Portable and mobile RF communications equipment should be used no closer to any part of the6000S transport ventilator, including cables, than the recommended separation distance calculated from the

	10 Vrms 150 kHz to 80 MHz in ISM bands	10Vrms (V2)	equation applicable to the frequency of the transmitter. Recommended separation distance
Radiated RF IEC61000-4-3	10V/m (80MHz～2.5GHz)	30V/m (E1)	$d = \left[\frac{3.5}{V1}\right]\sqrt{P}$ $d = \left[\frac{12}{V2}\right]\sqrt{P}$ $d = \left[\frac{12}{E1}\right]\sqrt{P}$ 80 MHz～800 MHz $d = \left[\frac{23}{E1}\right]\sqrt{P}$ 800 MHz～2.5 GHz Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the6000S transport ventilator is used exceeds the applicable RF compliance level above, the6000S transport ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the6000S transport ventilator

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

Recommended separation distances between portable and mobile RF communications equipment and the6000S transport ventilator.

The6000S transport ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the6000S transport ventilator as recommended below, according to the maximum output power of the communications equipment.

Separation Power(W) / distance (m)	0.01	0.1	1	10	100

Frequency(Hz)						
150KHz～80MHz	Outside ISM bands $d=\left[\frac{3.5}{V1}\right]\sqrt{P}$	0.04	0.11	0.35	1.11	3.5
	ISM bands $d=\left[\frac{12}{V2}\right]\sqrt{P}$	0.04	0.11	0.35	1.11	3.5
80MHz～800MHz	$d=\left[\frac{12}{E1}\right]\sqrt{P}$	0.04	0.11	0.35	1.11	3.5
800MHz～2.5GHz	$d=\left[\frac{23}{E1}\right]\sqrt{P}$	0.07	0.22	0.7	2.21	7.00

For transmitters rated at a maximum output power not listed above, the recommended separation distances in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 2: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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