

T5 Safety and Performance Information

Contents

T5 Safety and Performance Information	1
1. Safety instructions	4
1.1. Warning, Attention and tips	4
1.2. Overview	4
1.3. Safe Use of Oxygen	6
1.4. Patient Respiratory Hose Assembly	6
1.5. Accessories/Spare Parts	7
1.6. Battery	7
2. Equipment Description	7
2.1. Intended Purpose	7
2.2. Indication	8
2.3. Contraindications	8
2.4. User Qualification	8
3. Installation	8
3.1. Overview	8
4. Ventilation Operation	9
4.1. Execution of Ventilation	9
4.2. Examine Patient Breathing Valve	10
4.3. Machine Function Inspection	10
4.4. Battery	10
4.5. Replace Filter	11
4.6. Storage	11
5. Technical Parameters	11
5.1. Medical Devices Management Category	11
6. EMC	11
6.1. EMR Statement	11
6.2. EMI Statement - Requirements for All Equipment and Systems	12
6.3. Guide and Manufacturer Statement – EMI	13
6.4. Recommended isolation distance	14
6.5. Information on T5 Patient's Physiological Signals	15
6.6. Basic EMC Properties of T5 Emergency and Transport Ventilator	15
7 Storage and Transport	16

Product Information

Thank you for purchasing T5 Emergency and Transport Ventilator.

Before using the equipment, please read this manual carefully and understand the information contained in it so as to operate it properly. Keep this manual properly in any accessible place.

Product name : Emergency and Transport Ventilator

Model : T5

Manufacturer : 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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Attention :

This instrument is not intended for any family purpose.

1. Safety instructions

Please read these safety instructions carefully. These safety instructions are an integral part of the equipment and must be kept accessible for review whenever necessary. For purpose of safety, the following information must be paid attention to.

1.1. Warning, Attention and tips

The following safety marks are used in this user manual:



Warning :

Indicating any risk of harm to patient and/or user.



Attention :

Indicating potential equipment damage and undesired treatment effect.



Tip :

Giving useful indicative information.

1.2. Overview



Warning :

- **【After the training】** You can operate T5 only after you have been provided with proper medical training in and technical guidance on respiration equipment. Improper use of it may cause serious injury to body.
- **【Do not leave T5 in ventilation】** Do not leave a patient or respirator in ventilation to respond in time to any emergency (such as patient's worsening state of an illness or machine fault) to minimize the patient's injury.
- T5 can be used for the intended purpose (refer to Section 2.1 - Purpose for more details).
- **【Hyperbaric chamber】** Do not use T5 in hyperbaric application (hyperbaric chamber).
- **【Danger】** Do not use T5 in any explosive or toxic environment.
- **【Fire】** Do not use T5 in any oxygen-rich or inflammable environment.
- **【Maintenance personnel qualification】** This equipment can be repaired and maintained only by Ambulanc or any professionals authorized by it.
- **【Please do not open】** Only maintenance personnel can open the cover, replace or modify spare parts outside and inside T5.

- This ventilator is intended to be continuously attended by an operator. Failure to be in close proximity to this ventilator can contribute to patient death or serious injury.
- Do not cover the ventilator or place in a position that affects proper operation, including applicable examples.
- Don't place the emergency and transport ventilator in a position where is difficult to operate the disconnection device.
- Always have immediate access to an alternative means of ventilation, which is ready for use, in order to reduce the possibility of patient death or additional deterioration of health.
- Do not add any attachments or accessories to the ventilator that are not listed as intended for use in combination with the ventilator in the instructions for use of the ventilator or accessory, as the ventilator might not function correctly, leading to the risk of patient death or additional serious deterioration of health.
- When using humidification, the breathing system filters can require more frequent replacement to prevent increased resistance and blockage.
- Statement to the effect that a potential hazard can exist if different alarm pre-sets are used for the same or similar equipment in any single area
- Before use the T5 device, it shall be connected to a grounded socket.
- Electrically conductive hoses or tubing are not to be used in the ventilator breathing system

 **Caution :**

- **【Other equipment】** Any device or equipment emitting high-frequency radiation (e.g. cell phone, radio) must be kept a minimum distance of 1 meter from T5 to prevent any malfunction in it.
- **【The power converter】** When the respirator is powered by any external power supply, the power supply shall be connected to a pluggable interface so that it can be disconnected quickly in case of failure.
- **【External power supply】** When the respirator is powered by an external power supply, please ensure that the power line shall not hinder. If not necessary (when battery capacity is lower than 20% or T5 is used in an uninterrupted way for a long time), please do not use any external power supply; instead, please give priority to power T5 by internal battery.
- **【The standby】** An alternative secondary respiration device must be provided in case of failure of the primary equipment.
- **【Replace Filter】** After the equipment is used in any dusty environment, replace the filter in accordance with Section 9.4 - Replace Filter.

- **【Liquid】** Please do not immerse T5 in any liquid. If liquid penetrates into cover, it shall lead to damage of equipment.
- The responsible organization is responsible for ensuring the compatibility of the ventilator and all of the parts used to connect to the patient before use
- The T5 emergency and transport ventilator is to be equipped with monitoring equipment that conforms with this manual before being put into service.

1.3. Safe Use of Oxygen

Warning :

- High-pressure oxygen and combustible (lubricating grease, engine oil, alcohol, etc.) may give rise to an explosion when they meet each other.
- Supply of oxygen in high concentration to a patient for a long time may generate toxic effect. Patients differ in bearing duration due to age, physical condition, etc. So please adopt proper way of ventilation according to a patient's condition.
- Keep equipment and all joints clean and free from any engine oil or lubricating grease.
- Before operating oxygen supply device, please wear a clean pair of medical gloves.
- No open flame nearby equipment and related supporting facilities.

Caution :

- While installing and replacing an oxygen cylinder, please manually screw down knob switches on the oxygen cylinder and reducing valve. Do not use any tool to prevent overexerting yourself from damaging thread and sealing materials and leading to leakage.
- Please take measures to prevent an oxygen cylinder from toppling and falling. A toppling and falling oxygen cylinder may damage reducing valve or oxygen valve and even lead to an explosion in serious condition.
- Slowly open oxygen cylinder valve because it may give rise to sharp rise of pressure to impact valve parts and result in their damage by opening oxygen cylinder valve too intensely and quickly.
- Do not completely use up oxygen in the oxygen cylinder to prevent humid air in surrounding environment from flowing into the oxygen cylinder to corrode the oxygen cylinder.

1.4. Patient Respiratory Hose Assembly

Warning :

- Those using patient's respiratory hose assembly must have taken professional medical training and technical instruction on respiratory equipment for improper use may lead to serious physical injury.
- Please refer to related contents in the manual and make functional test and visual inspection before using respiratory hose assembly.
- Before connecting to patient, please check whether direction of oxygen flow transported to patient is correct and whether the respiratory hose is unimpeded.
- Patient respiratory hose assembly can be used only for the intended purpose.
- Patient respiratory hose assembly is unsuitable for high pressure applications (hyperbaric chamber).

1.5. Accessories/Spare Parts

Caution :

- **【To prevent the sun】** Proper measures shall be taken to prevent prolonged exposure of any rubber parts to UV or direct sun and brittleness caused thereby.
- **【Use approved accessories only】** Use of accessories of other manufacturers may give rise to fault due to incompatibility. Please bear in mind that warranty rights and liabilities shall be invalidated in such cases: do not use accessories not recommended in the manual or original spare parts.

1.6. Battery

Warning :

【Low battery】 When T5 alarms in low battery, please make any of the following operations:

- Replace battery by fully charged battery.
- Connect T5 with external T5 power supply.

Attention:

【Keep battery installation】 In order to enable T5 to make sustainable operation, it is advised to always install fully charged battery (even though when T5 is powered by external power supply).

2. Equipment Description

2.1. Intended Purpose

The T5 ventilator is intended for continuous ventilation of pediatric patients weighing over 10kg and adults,

requiring invasive and non-invasive respiratory support with a tidal volume greater than 50mL. It is designed for use in out-of-hospital emergency care scenarios (such as ground or maritime first aid) and intra-hospital transfers, compatible with hospital central oxygen supply or oxygen cylinders maintaining pressure exceeding 2.7 Bar.

2.2. Indication

- Acute respiratory distress syndrome (ARDS)
- Respiratory failure
- Chronic obstructive pulmonary embolism (COPD)

2.3. Contraindications

Bullae of lung, pneumothorax, hemoptysis, active tuberculosis, bronchopleural fistula, pleural effusion, acute myocardial infarction.



Warning :

T5 is suitable for patient's tidal volume more than 50ml, offering A/C, invasive and noninvasive ventilation support.

2.4. User Qualification

The person operating T5 must be qualified and meet the following conditions:

- Provided with proper medical training in and technical guidance on respiration equipment.
- Provided with training in clinical application with T5 by Ambulanc (Shenzhen) Tech. Co., Ltd.
- Improper operation of the equipment may cause serious injury to persons (the operator and patient).

3. Installation

3.1. Overview



Warning :

After mounting, you must perform a functional inspection (refer to Section 7 - Functional Inspection) to ensure proper operation of the equipment.

- Before operating oxygen supply device, please wear a clean pair of medical gloves. Hydrocarbon (such as engine oil, lubricating grease, alcohol, hand cream, or adhesive plaster) may lead to an explosion by contacting high-pressure oxygen.
- Do not use wrench or any tool to tighten or loosen any connecting nut.



Warning :

- When connecting gas supply equipment, make sure the patient is not connected to T5. Or otherwise automatic self-detection feature of the equipment may start and cause negative effect.
- Keep the valve port from body to avoid potential personal injury!
 1. Connect reducing valve to port of the cylinder. Tighten the nut by hand.
 2. Screw the pressure hose with 9/16-18UNF connecting nut into the outlet of reducing valve.
 3. Connect the other end of the pressure hose to the air source port on T5.

 **Warning :**

Handle breathing hose, PU hose and rubber hose by holding ends of them to prevent any damage to or break of them.

Any disposal hose assembly shall be disposed after being used.

 **Warning :**

The manufacturer Ambulanc (Shenzhen) Tech. Co., Ltd. shall not be liable for any product performance problem resulting from use of respiratory hose assembly provided by any other manufacturer.

4. Ventilation Operation

 **Caution :**

Self-checking should not be a substitute for functional inspection.

 **Caution :**

Sign can be applied only based on V-AC, but not independently.

4.1. Execution of Ventilation

 **Attention :**

Do not use up any oxygen cylinder. Make sure there is residual pressure inside the cylinder when it is returned so as to prevent entry of wet air into it and corrosion caused thereby.

1. Check the pressure meter on the reducing valve to be aware of the oxygen storage in it. Make replacement with a new oxygen cylinder if the reading on pressure meter is 5 MPa (approx. 725 PSI) or lower.
2. Shut off the outlet valve on the oxygen cylinder.
3. At this moment a voice prompt "shut down oxygen cylinder" will be given.

 **Caution :**

1. When the ventilator is being used in an ambulance, the battery shall not be recharged. The battery can be recharged only when a power adapter is being used.

2. To ensure normal operation of the battery, it is recommended to recharge and discharge it once every 6 months.
3. If the ventilator will not be used for a long period of time, the battery shall be taken out, or the battery will be over-discharged and the charging time will be significantly prolonged. The stored battery shall be charged incompletely every 6 months to maintain a power of 40%-60%. The battery shall be fully charged before use.

 **Caution :**

Do not fumigate the whole unit with acidum peraceticum or methanal.

 **Warning :**

Risk of explosion! Do not soak any valve fitting into any disinfectant or other liquid. Disinfect the valve fittings only by wiping with soft cloth. Do not make any liquid enter the reducing valve, or otherwise the valve may explode.

Where disinfection is absolutely necessary, please wipe the reducing valve and the oxygen cylinder with a clean soft cloth, which is dry or slightly soaked with clean water.

4.2. Examine Patient Breathing Valve

 **note :**

In assembly pay attention to the one-way diaphragms are located at the proper position.

4.3. Machine Function Inspection

 **Warning :**

In case of any problem during inspection, stop using it for the patient!

4.4. Battery

 **Warning :**

1. A battery as specified by Ambulanc must be used, or otherwise the machine may operate improperly.
2. Short circuiting of battery is prohibited.
3. Heating or burning battery is strictly forbidden.
4. Avoid using battery near any heat source.
5. Wetting battery is prohibited.
6. Avoid recharging battery near any heat source or in direct sunlight.
7. Recharge battery properly with dedicated charger.
8. Do not use the battery with any other battery.

9. Keep the battery out of children's reach.
10. Do not leave the battery mounted in a charger for a long period.
11. Keep leaking battery off fire.
12. Avoid using the battery in strong sunlight.

4.5. Replace Filter

Warning :

The ventilator must not be operated without installation of filter. Or otherwise the equipment performance will be impaired or the equipment is damaged.

4.6. Storage

Important :

Even the equipment in storage shall be maintained at the specified maintenance interval before being used.

5. Technical Parameters

5.1. Medical Devices Management Category

Medical Devices Management Category	
Category	Class IIb

Caution :

1. The ventilator may fail when operating not under the conditions as specified by the manufacturer. Make sure that the ventilator operates under the conditions as specified by the manufacturer to ensure stable service.
2. The ventilator may be subject to performance degradation when operating not under the conditions as specified by the manufacturer. Excessive operating pressure may damage interior sensor. Make sure that the ventilator operates within the operating pressure range as specified by the manufacturer to ensure stable service.

6. EMC

6.1. EMR Statement

EMR Statement
T5 can be used in the following specific EMR environment, in which user shall ensure to operate this equipment.

EMR Testing	Compliance Testing	EMR Environment Guide
Radio frequency radiation (CISPR 11)	Group 1	T5 generates radio frequency energy only when operating its internal functions. Therefore, this ventilator emits very small amount of radio frequency radiation and it is unlikely to cause any EMI to electronic equipment nearby.
Radio frequency radiation (CISPR 11)	Category B	T5 is applicable in all facilities, including domestic and public LV power supply network directly connected to house.
Harmonic wave radiation (IEC 61000-3-2)	Category A	
Voltage fluctuation and flicker emission (IEC 61000-3-3)	Acceptable	

6.2. EMI Statement - Requirements for All Equipment and Systems


EMI Statement - Requirements for All Equipment and Systems			
T5 can be used in the following specific EMR environments, and the user shall ensure to operate this equipment in the following EMR environments.			
EMI Type	YY0505 Testing Grade	Compliance Grade	EMR Environment Guide
ESD (IEC 61000-4-2)	Contact discharge: $\pm 8\text{kV}$ Air discharge: $\pm 15\text{kV}$	Contact discharge: $\pm 8\text{kV}$ Air discharge: $\pm 15\text{kV}$	The ground shall be of wood, concrete or ceramics. In case of composite paving material, the relative humidity shall be at least 30%.
EFT (IEC 61000-4-4)	To power cable: $\pm 2\text{kV}$ To long I/O cable: $\pm 1\text{kV}$	To power cable: $\pm 2\text{kV}$ To long I/O cable: $\pm 1\text{kV}$	Power supply grade shall be minimally the grade for typical commercial or medical environment.
Surging (IEC 61000-4-5)	DM: $\pm 1\text{kV}$ CM: $\pm 2\text{kV}$	DM: $\pm 1\text{kV}$ CM: $\pm 2\text{kV}$	
Power frequency magnetic field (50/60Hz) (IEC 61000-4-8)	3A/m	3A/m	Power frequency magnetic field shall be of the horizontal characteristics as in typical commercial or medical environment.
Voltage sag, short interruption and variation (IEC 61000-4-11)	< 5%UT (> 95% fall, UT), 0.5 cycle;	< 5%UT (> 95% fall, UT), 0.5 cycle;	Power supply grade shall be minimally the grade for typical commercial or medical environment. It is recommended to use UPS to ensure continuous operation of this product even in case of AC
	40%UT(60% fall, UT), 5 cycles;	40%UT(60% fall, UT), 5 cycles;	
	70%U T (30%	70%U T (30% fall,	

	fall, U T), 25 cycles; < 5% UT(> 95% fall, UT), 5s;	U T), 25 cycles; < 5% UT(> 95% fall, UT), 5s;	power outage.
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6.3. Guide and Manufacturer Statement – EMI

Guide and Manufacturer Statement - EMI

T5 Emergency and Transport Ventilator is intended for the following EMI environments, and T5 purchaser or user shall ensure to operate T5 in these EMI environments:

EMI Test	IEC 60601 Test Level	Compliance Level	EM Environment - Guide
Radio frequency transmission IEC 61000-4-6	3 V (effective value) 150 kHz~80 MHz (except ISM bands)	3V (effective value)	<p>Any portable or mobile radio frequency communication equipment shall not be used in a distance closer to any part of T5 Emergency and Transport Ventilator (including cable) than as recommended. Such distance is determined based on a formula related to transmitter frequency.</p> <p>Recommended Distance</p> $d = \left[\frac{3.5}{V1} \right] \sqrt{P}$ $d = \left[\frac{12}{V2} \right] \sqrt{P}$ $d = \left[\frac{12}{E1} \right] \sqrt{P} \quad 80 \text{ MHz} \sim 800 \text{ MHz}$ $d = \left[\frac{23}{E1} \right] \sqrt{P} \quad 800 \text{ MHz} \sim 2.5 \text{ GHz}$ <p>where,</p> <p>: the maximum rated output power (in Watt) of transmitter provided by its manufacturer;</p> <p>d: the recommended distance (in meter)</p> <p>b. The field strength of fixed radio frequency transmitter is determined based on the survey at EMI locationc, and each frequency range should be lower than Compliance Level.</p> <p>Interference may occurs near the equipment attached with the following signs.</p> 
Radio frequency radiation IEC 61000-4-3	10V (effective value) 150kHz~80M Hz (ISM banda)	10V (effective value)	
	10V/m 80 MHz ~ 2.5 GHz	30V/m	

Note 1 :

For frequency of 80MHz and 800MHz, a formula in respect of high frequency should be used.

Note 2 :

As EM transmission is affected by absorption and reflection of buildings, objects and human bodies, these guidelines may not be applicable to all circumstances.

- a) ISM bands between 150kHz and 80MHz are 6.765MHz~6.795MHz, 13.553MHz~13.567MHz, 26.957MHz~27.283MHz and 40.66MHz~40.70MHz.
- b) ISM bands between 150kHz and 80MHz and compliance levels between 80MHz and 2.5GHz are used to reduce the possibility of interference resulted from mobile/portable communication devices which are accidentally taken into patient's location. For this reason, additional factor 10/3 is used for calculation of recommended distance to the transmitter within these frequency ranges.
- c) Theoretically, field strength of fixed transmitters, such as wireless (cellular/cordless) phone and mobile ground radio base station, amateur radio, FA/FM radio broadcast and TV broadcast, cannot be estimated accurately. Evaluation of EMI environment of fixed radio frequency transmitter should take into consideration survey at EM locations. If field strength measured at the place where T5 Emergency and Transport Ventilator is located is higher than the aforesaid applicable radio frequency compliance level, then T5 Emergency and Transport Ventilator shall be observed to verify its normal operation. If any abnormal property is found, related remedial measure may be required, such as re-adjustment of orientation or position of T5 Emergency and Transport Ventilator.
- d) Throughout the frequency range of 150kHz~80MHz, the field strength should be lower than 3V/m.

6.4. Recommended isolation distance

Recommended distance between portable and mobile RF communication equipment and T5 Emergency and Transport Ventilator

T5 Emergency and Transport Ventilator is intended for use in RFI-controlled EMI environments. Based on the maximum rated power of related communication equipment, purchaser or user can prevent EMI by maintaining the minimum distance between portable and mobile RF communication equipment and T5 Emergency and Transport Ventilator as recommended below.

Max. Output Power of Transmitter (W)	Distance (m) for Transmitters of Various Frequencies			
	150 kHz~80 MHz (except ISM bands) $d = 1.17\sqrt{P}$	150 kHz~80 MHz (ISM bands) $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 0.4\sqrt{P}$	800 MHz~2.5 GHz $d = 0.767\sqrt{P}$
0.01	0.12	0.12	0.04	0.08
0.1	0.38	0.38	0.13	0.24

1	1.2	1.20	0.40	0.77
10	3.8	3.80	1.30	2.40
100	12.00	12.00	4.00	7.70

For any maximum rated output power which is not listed in the table above, the recommended distance d (in meter) can be determined based on the formula in the corresponding volume of transmitter frequency, where p is the maximum rated output power in (Watt) of transmitter provided by its manufacturer.

Note 1 :

For frequency of 80MHz and 800MHz, a formula in respect of high frequency should be used.

Note 2 :

ISM bands between 150kHz and 80MHz are 6.765MHz~6.795MHz, 13.553MHz~13.567MHz, 26.957MHz~27.283MHz and 40.66MHz~40.70MHz.

Note 3 :

Additional factor 10/3 is used for calculation of recommended distance to the transmitter within frequency ranges of 150kHz ~ 80MHz and 80MHz~2.5GHz, so as to reduce the possibility of interference resulted from mobile/portable communication devices which are accidentally taken into patient's location.

Note 4 :

As EM transmission is affected by absorption and reflection of buildings, objects and human bodies, these guidelines may not be applicable to all circumstances.

6.5. Information on T5 Patient's Physiological Signals

Information on T5 Patient's Physiological Signals

The physiological frequency range of the patients for whom T5 Emergency and Transport Ventilator is used is between 5bpm and 40bpm.

Warning :

Operation of the equipment or system at a frequency lower than the aforesaid range may cause incorrect results.

6.6. Basic EMC Properties of T5 Emergency and Transport Ventilator

Basic EMC Properties of T5 Emergency and Transport Ventilator

T5 Emergency and Transport Ventilator will operate based on the parameters as set. For more details see Section 11 in the manual. User can give alarm based on real-time monitoring of operation state of T5 Emergency and Transport Ventilator, and ensure accuracy of the following parameters in EMC environment instructed for T5 Emergency and Transport Ventilator.

I/E	Adjustable between 9:1 and 1:9 with allowance of $\pm 15\%$
Ventilation rate per min. (MV)	1~45L/min. with allowance of $\pm 0.5L/min$ or $\pm 20\%$, whichever is the larger
Airway pressure monitoring	-20~100cmH ₂ O with allowance of $\pm 2cmH_2O$ or $\pm 15\%$, whichever is the larger

Activation pressure	-20~20cmH ₂ O with allowance of ± 1 cmH ₂ O or $\pm 15\%$, whichever is the larger
Parameters of EMC Cable Material	
Adapter input power cable	0.8 \pm 0.01m
Adapter output power cable	1.45 \pm 0.05m

 **Caution :**

- EMC of the location where this environment is mounted and used shall be adequately take into consideration in accordance with the said guidelines.
- Any equipment on or near T5 ventilator may still cause interference with T5 even though it is CISPR compliant, so user shall verify whether T5 operates normally before using it for patent.
- Application of any unapproved part or component to this equipment may impair its electromagnetic immunity and increase its EME.

7 Storage and Transport

 **Warning :**

When it is moved out from a storage condition not meeting the foregoing, this equipment shall be placed in a standard environment for at least 8 hours before being used.