| 文件类型 | 技术文件 | 项目编号 | 609 |
|---|---|---|---|
| 文件编号 | H-1.601.00137 | 打印要求 | ☑ 彩色 ☐ 黑白 |

# 609 用户使用说明书（英文）

参 考 资 料

| 文件编号 | 说明 |
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修 订 记 录

| 版本 | ECR/PCN TCN | 更 改 内 容 | 制 订 | 批准日期 |
|---|---|---|---|---|
| A1.0 | ECR20171163 | 新增 | 胡国权 | 2017.12.20 |
| A2.0 | ECR20180118 | 1） 更新 11.8 节的“ FIGURE 43”图<br>2） 更新 2.1、2.2 关于设备预期用途的说明。 | 胡国权 | 2018.01.28 |
| A3.0 | ECR20190207 | 新增第 16 章。 | 施丽迪 | 2019.02.28 |
| A4.0 | ECR20200407 | 修改 2.1 关于设备预期用途的说明 | 陈德伟 | 2020.05.08 |
| A5.0 | ECR20200609 | 优化呼吸模式介绍。 | 罗妙 | 2020.07.02 |
| B1.0 | ECR20201119 | 根据 ISO10651-3 标准新增 3.6 参数关联；修改地址信息、增加报警优先级说明等 | 谢荣锋 | 2020.11.02 |
| B2.0 | ECR20210102 | 修改 2.8.3 和 2.8.4 描述 | 陈德伟 | 2021.01.22 |
| B3.0 | ECR20210311 | 封面增加 CE0123 标示 | 谢荣锋 | |
| | | | | |
| | | | | |

| 发放部门 | ☑ 生产部 ☑ 采购部 ☑ 品质部 ☐ 市场部 ☑ 研发系统 |
|---|---|
| 存档方式 | ☑ 电子文档 ☑ 纸文档 ☐ 其它： |

| 制 订 | 谢荣锋 | 审 核 | 麦书刚 | 批 准 | 胡修 |
|---|---|---|---|---|---|
| 日 期 | 2021.03.25 | 日 期 | 2021.03.25 | 日 期 | 2021.03.25 |

CE 0123

Amoul®


# T5 User's Manual
# Emergency and Transport Ventilator

www.ambulgroup.com

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# Contents

# Product Information

Thank you for purchasing T5 Emergency 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) Technology Co. Ltd. | |
| Manufacturer address：3rd Floor, Block C, Building #5, Skyworth Innovation Industry Park, Tang Tou 1st Road, Shiyan , Baoan District, Shenzhen 518108, China | |
| Tel: +86-755- 26072210 | Fax:+86-755-23016012 |
| Website:www.ambulgroup.com | E-mail:manager@ambu-lanc.com |
| Product date：See host | |
| Service life：8 years | |
| Revision date：2021-03 | |

**Attention：**

This instrument is not intended for any family purpose.

# EC-Representative

| | |
|---|---|
| EC-Representative：Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80 20537,Hamburg,Germany | |
| Contact pers：Qiming Cheng | |
| Telephone: +49-40-2513175 | Fax: +49-40-255726 |

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# Statement

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Ambulanc reserves the right to change related technology without prior notice.

Ambulanc reserves the right to alter product specification without prior notice.

Ambulanc makes no warranty in any form concerning this manual, including (but not limited to) guarantee for implied marketability and adaptability for a specific purpose.

Ambulanc will, at its own discretion, take responsibility for safety, reliability and performance of the instrument in one of the following cases：

- any assembly, expansion, readjustment, improvement and repair operations are performed by any professional approved by Ambulanc;
- related electrical equipment is in compliance with national standards;
- the instrument is used in accordance with the operation instructions.

Ambulanc will be responsible for safety, reliability and operation condition of the product in one of the following cases：

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- the instrument is repaired or changed not by any personnel approved by Ambulanc;
- the product is not used correctly in compliance with this Operating Manual.

# Maintenance Service

**Scope of Charge-Free Service：**

- Charge-free service is provided for any equipment in the range of Ambulanc's warranty terms.

**Scope of Paid Service：**

- Paid service is provided for any equipment beyond the range of Ambulanc's warranty terms.

As well as in one of the following cases even during the warranty period:

- Damage caused by personal fault;
- Improper use;
- Grid voltage beyond the limits;
- Irresistible natural disaster;
- Use of spare part/ consumables not approved or machine service performed by personal not authorized by Ambulanc.

**Warning：**

Failure to implement a set of satisfactory service/maintenance plan by any hospital or institute responsible for using this instrument may cause malfunction of it or even endanger body health.

# Warranty

**Manufacturing Process and Raw Material：**

Ambulanc warrants that no failure will be resulted from any defect in manufacturing process or raw material when this instrument is used and serviced correctly.

# After-Sales Service Unit

After-Sales Service Dept., Ambulanc (Shenzhen) Technology Co. Ltd.

Address: 3rd Floor, Block C, Building #5, Skyworth Innovation Industry Park, Tang Tou 1st Road, Shiyan, Baoan District, Shenzhen 518108, China

Service Hot Line：400-9969-120

Tel：+86-755-26073861 Fax：+86-755-23016012

Web site: http://www.ambulgroup.com

E-MAIL: manager@ambu-lanc.com

# Return

## Return Procedure

Any return as necessary shall comply with the following procedure:

- Acquire right of return: Contact Ambulanc's customer service, and provide the product ID labeled on external packaging of the instrument, which must be legible for return approval. Indicate product model and describe the reason for return.
- Freight: Any expenses (including customs fee) incurred in transporting the instrument to Ambulanc shall be paid by the user.

# Important Information

1. After purchase of the product, the customer shall take full responsibility for maintenance and management of it.
2. Quality assurance will not cover the following even during the warranty period :

- any damage or loss resulted from improper use or misuse of the product;
- any damage or loss caused by force majeure such as fire, earthquake, flood or lightning;
- any damage or loss attributed to failure to meet any operating condition required for the system, such as insufficient power supply, improper installation or unfavorable environmental conditions;
- any damage or loss incurred due to use of the system in the region not initially intended for it; and
- any damage or loss caused due to purchase from any unauthorized dealer or agent.

3. This equipment can be used only by certified medical staff.
4. Any software or hardware of this product must not be changed or modified without authorization.
5. In any case Ambulanc will take no responsibility for problem, damage or loss resulted from re-installation, change or repair of the system performed not by personnel authorized by Ambulanc.
6. This system is intended to provide the data required for clinical diagnosis for physicians. The physician takes responsibility for diagnosis process. Ambulanc takes no responsibility for any diagnosis process.
7. Be sure to back any key data to external storage medium, such as clinography and notes.
8. Ambulanc takes no liability for loss of data stored in the system due to

the operator's fault or any exceptional condition.

9. This manual contains warnings for foreseeable potential hazards. User shall keep watch at any time for any hazard not stated in the manual. Ambulanc takes no responsibility for damage or loss resulted from negligence or failure to observe the preventive measures stated in this manual.
10. This manual must be handed over to the successor when the system administrator is changed.

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# 1 Equipment Description

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 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

- A functional inspection must be performed before use of the equipment (refer to Section 7 - Functional Inspection).
- Please observe the instructions in Section 6 - Sanitization to prevent infection or bacillosis.

⚠ **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 Amoul 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.

**⚠ 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.

## 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 Ventilation/Operation

- During ventilation, uninterrupted observation of both the patient and respiratory equipment must be performed.
- Prolonged breathing through respirator may result in atrophy of patient's respiratory muscles.
- Lengthy ventilation may cause patient's respiratory tract dry. Make sure sufficient natural air is available for adjustment of respiration.
- Make high-pressure ventilation in a short time under instruction of an physician. Because uninterrupted high-pressure ventilation for a long time may injure a patient. Guarantee unimpeded respiratory hose of patient to prevent influencing ventilation function of equipment.

## 1.5 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).

## 1.6 Software

Many quality assurance measures have been taken in development of equipment software to minimize the risks potentially caused by software defect.

## 1.7 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 recommended in the manual or original spare parts.

## 1.8 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).

# 1.9 Symbols that

Description ICONS and symbols

| SYMBOL | DESCRIPTION | SYMBOL | DESCRIPTION |
|---|---|---|---|
|  | Refer to the document attached for more details |  | Refer to the document attached/manual |
|  | Date of production |  | BF type applications |
| IPX4 | Waterproof level |  | Do not reject into dustbin |
|  | Adapter off |  | Non-ionizing radiation |
|  | Power supply by adapter |  | Main Unit Switch |
|  | Power supply by battery |  | Battery level indication |
|  | menu |  | Alarm mute |
|  | Lock/unlock |  | Manual ventilation |
|  | Air inlet |  | PEEP control |
|  | Manufacturers | | |
|  | The product contains some hazardous substance. Use it at ease in the eco-friendly service life but put it in the recovery cycle system after it is beyond the eco-friendly service life which is 20 years. | | |
|  | It conforms to EU Medical Devices Directive 2007/47/EC and meets CE symbol in basic requirements in Appendix I of the Directive. | | |

# 2 Equipment Description

## 2.1 Purpose

The T5 ventilator is intended to provide continuous ventilation for patients who require invasive or non-invasive respiratory support (Infants, children, adults), with a tidal volume greater than 50ml. The T5 ventilator is intended for use in out-of-hospital emergency treatment (first aid treatment on the ground or at sea) and in-hospital transportation run under the central oxygen supply of the hospital or an oxygen cylinder pressure greater than 2.7Bar.

## 2.2 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.

## 2.3 Scope of Application

T5 can be applied in the following cases:

**Emergencies**

- First-aid resuscitation on the site;
- Ongoing emergency lasting for a long time (e.g. fire); and
- Temporary oxygen uptake via respiratory mask and ventilation via tracheal cannula.

**Transfer of patient**

- During first-aid treatment on surface or at sea;
- During transfer from ward to treatment room in hospital;
- During transfer from hospital to any other location.
- Use in other situations according to medical advice of physician.

**Temporary ventilation in hospital**

- Recovery room;
- ICU;
- Preparation for operation and the stage subsequent thereto;
- Emergency room.

## 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 Shenzhen Amoul Technology Limited.
- Improper operation of the equipment may cause serious injury to persons (the operator and patient).

## 2.5 The main composition of

T5 Emergency Ventilator The main composition of

consists of a main unit, respiratory valve, and rechargeable lithium battery.

All components necessary for T5 operating as a ventilation system have been designed by Amoul.

## 2.6 Main Unit

T5 can be used for treatment of breathlessness and to provide breathing support. By means of adjustable respiration parameter, you can keep ventilation through the respirator consistent with patient's own breath.

- This unit provides two ventilation control modes, pressure control and volume control.
- Inspiration triggering mode for this unit is pressure activation.
- This equipment provides electronic PEEP function.
- This unit allows ten respiration modes (IPPV/ V-A/C /V-SIMV/ P-A/C /P-SIMV/PCV/CPAP/CPR/Manual/HFNC) which can be selected to meet patient's breathing in various states.

- This equipment can make adjustment to oxygen concentration.
- The large 7" screen provided for the equipment displays patient's breathing parameters and pressure curve,
- The screen is furnished with touch control function.

## 2.7 Patient Respiratory Hose and Accessories

The inhaled air is conveyed to the patient through patient respiratory hose assembly, including respiratory hose and patient respiratory valve.

- **Two optional types of respiratory hoses are available:**

1. Recyclable respiratory hose.
2. Disposable respiratory hose.

- **Patient breathing valve:**

furnished with power-controlled PEEP valve structure for high-precision control of positive end-expiratory pressure (PEEP) and continuous positive airway pressure (CPAP).

## 2.8 T5 Main Unit instruction

### 2.8.1 Main Unit-Front View

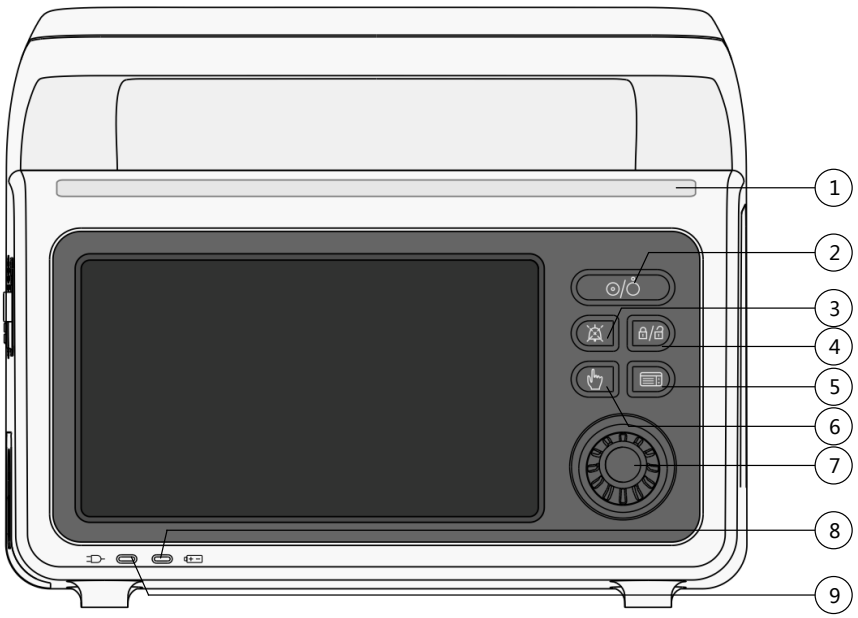



FIGURE 1 Main Unit ( Front View )

| PARTS | DESCRIPTION |
|---|---|
| **1 Warning LED** | When it alarms, it displays red and yellow flicker, signaling different alarm priority levels. Red=top priority, yellow=intermediate priority, off=no alarm. |
| **2 Start/Shut Down button** | Press it to start. ,Long press it for 3 seconds to shut down the equipment. |
| **3 Acoustic alarm mute button** | Press it to keep acoustic alarm mute for a certain period (up to 120 seconds). When the alarm stays mute, the indicator LED next to it will be turned on, but any visual alarm (e.g. warning LED, status bar) will not be disabled. |
| **4 Screen locking button** | It is used for locking touch screen. When touch screen is enabled, press the button and the touch screen will be disabled; otherwise, press the button and the touch screen will be enabled. |
| **5 Main menu button** | Press it to access main menu, which contains time, system, calibration and record settings and system information. |
| **6 Manual ventilation control button** | Press it to manually control ventilation mode. |
| **7 Navigation knob** | Used to access various operation interfaces as shown below:<br>Turn the knob to forward and backward move the focus; press the button to enter the page selected or select the selected label or save settings; while setting parameters, forward turn to add selected parameters to be set and backward turn to decrease selected parameters to be set. |
| **8 Battery indicator** | In charging, its indicator will flicker; when it is fully charged or its battery is being used, its indicator will be normally on. |

| | |
|---|---|
| | Tips: It indicates whether the respirator depends on internal battery or external power supply in operation. |
| **9 Indicator of external power supply** | The indicator will be normally on when T5 connects to power adapter.<br>Tips: When the respirator is switched from external power supply to internal power supply, the respirator is still normally working. |

## 2.8.2 Main Unit-Rear View

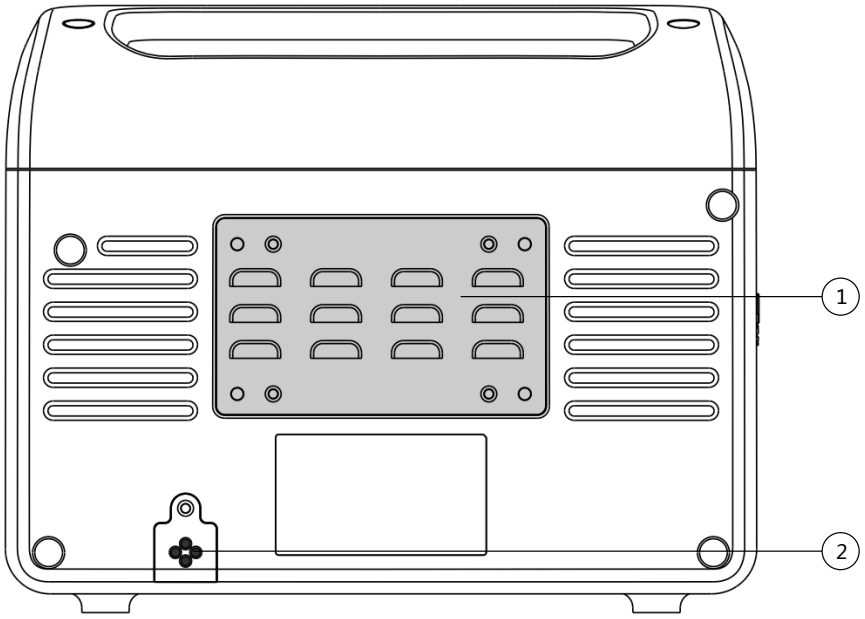



FIGURE 2 Main Unit ( Rear View )

| PARTS | DESCRIPTION |
|---|---|
| **1 Radiating panel** | It is used for radiating host, which must not be blocked. |
| **2 Air inlet** | Air inlet and safety valve outlet, which shall not be blocked. |

## 2.8.3 Main Unit-Left View

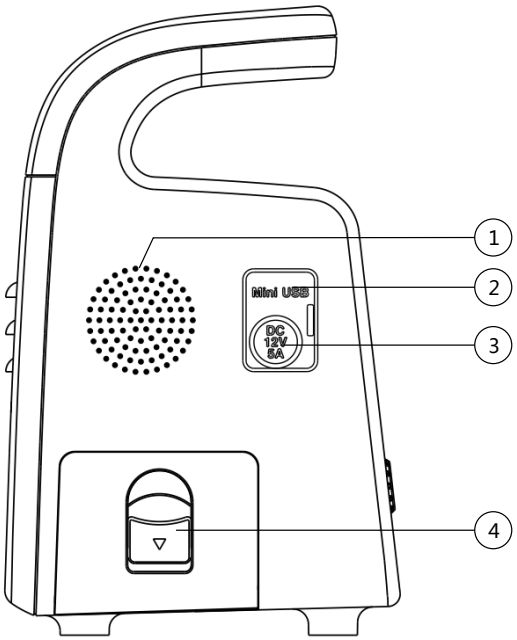



FIGURE 3 Main Unit ( Left View )

| PARTS | DESCRIPTION |
|---|---|
| **1 Speaker** | For acoustic indication or alarm. |
| **2 USB port** | Covered with a rubber cap, and used for software maintenance and upgrade. |
| **3 DC port** | Covered with a rubber cap, and used for connection of power adapter or used for DC power supply on ambulance or helicopter. |
| **4 battery cartridge** | For mounting of battery. |

## 2.8.4 Wain Unit-Right View

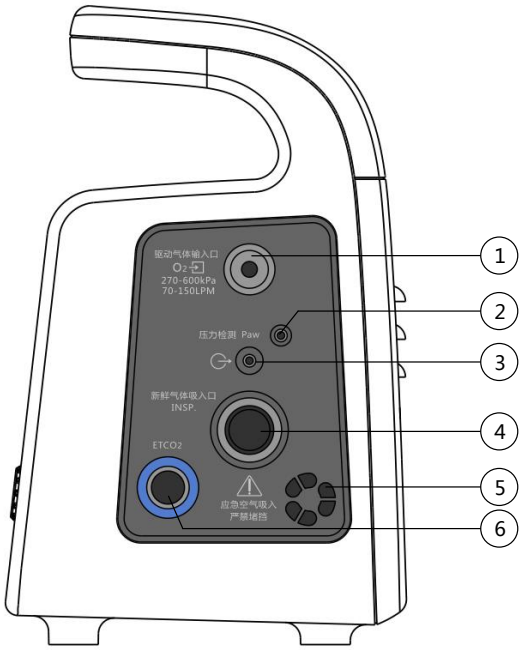



FIGURE 4 Main Unit ( Right View )

| PARTS | DESCRIPTION |
|---|---|
| **1 O2 source interface** | For connection to O2 source. |
| **2 pressure measurement port** | Used for measurement of airway pressure |
| **3 PEEP air supply port** | For connection of white hose in respiration hose loop. |
| **4 fresh air outlet** | For connection of respiration hose to patient. |
| **5 air inlet** | For inhalation of emergency air. |
| **6 ETCO2 port** | Connect CO2 |

# 3 Interface description

## 3.1 Composition of main interface

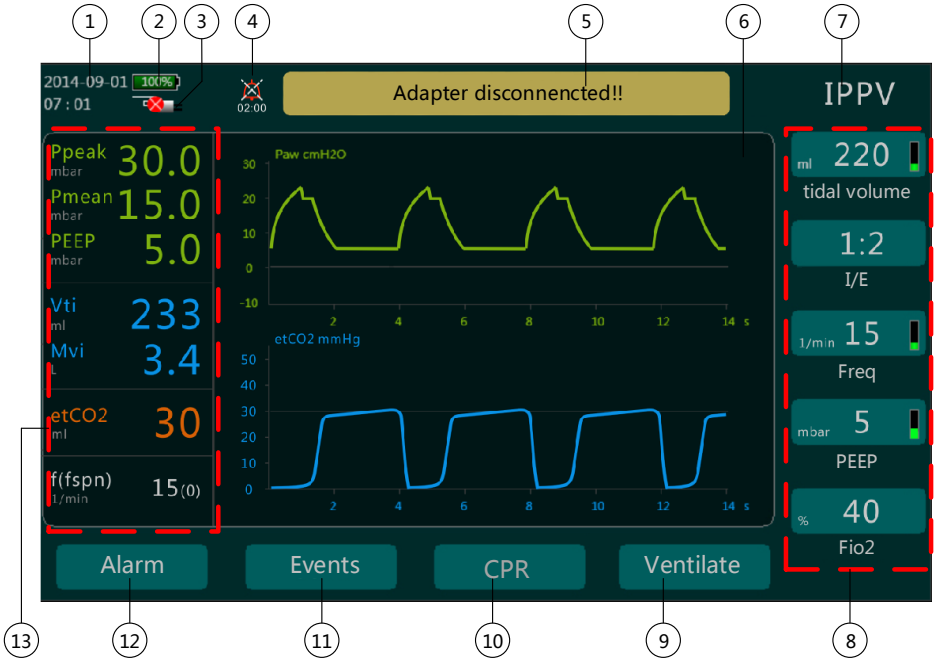



FIGURE 5 Main interface

| PARTS | DESCRIPTION |
|---|---|
| **1 Time/date** | For real-time display of current time and date. |
| **2 Battery state** | battery level or recharging state. |
| **3 Adapter state** | For real-time indication of current power adapter status |
| **4 Alarm mute icon** | For real-time indication of alarm mute status. |
| **5 Warning message indication** | Real-time indication of warning message. |
| **6 Waveform** | Real-time display of current respiration parameter in the form of waveform. |
| **7 Ventilation mode** | For indication of current user ventilation mode and re-selection of mode from a drop list. |
| **8 Main ventilation** | When selected, you can change parameter |

| | |
|---|---|
| **parameter setting** | value for current mode by using the navigation knob. |
| **9 Ventilate** | Use it to access Ventilate. |
| **10 CPR** | For real-time display of current CPR function status. |
| **11 Logs** | Use it to access system logs. |
| **12 Alarm limits** | Use it to access alarm limits. |
| **13 Real-time parameter monitoring** | For monitoring of real-time measurement of respiration parameters on the ventilator. |

**Caution :**

Any operation which is accessible with touch screen is also accessible with the navigation knob.

## 3.2 Main menu instruction

In the main menu, you may optimize host settings to adapt to different service conditions. Call out main menu by machinery button of <Main menu> and call out required setting interface by navigation knob or touch:


FIGURE 6 Meun

| PARTS | DESCRIPTION |
|---|---|
| **1 Ventilate** | Set ventilation in current mode. |

| | |
|---|---|
| **2 Alarm** | Set alarm volume and way. |
| **3 System** | Set screen brightness, unit, desktop style, waveform style, voice, and ETCO2. |
| **4 Time** | Set system time of equipment |
| **5 Calibration** | Calibrate equipment's air proportion valve, oxygen proportion valve and PEEP proportion valve. |
| **6 About Host** | View the equipment's main software version No. and control software version No. |

### 3.2.1 Full Ventilation Parameters Setting

You can set ventilation control parameters based on patient's respiratory physiological characteristics ( As shown below ) .

The setting procedure is given below :

1. Select Ventilation button by using the navigation knob to pop up ventilation setting window.
2. Select the ventilation parameter value to be changed by pressing navigation knob or directly clicking on it.
3. Modify the selected ventilation parameter value and press navigation knob again to confirm the modification.
4. Repeat Steps 2 and 3 to modify other parameter limits.
5. Exit from the main menu by clicking on "X" button or pressing Main Menu button again, Cancel parameter modification.


FIGURE 7 Ventilate

## 3.2.2 Setting Alarm Volume

In the main menu interface, select < Alarm > soft button and enter the alarm setting interface(As shown below).

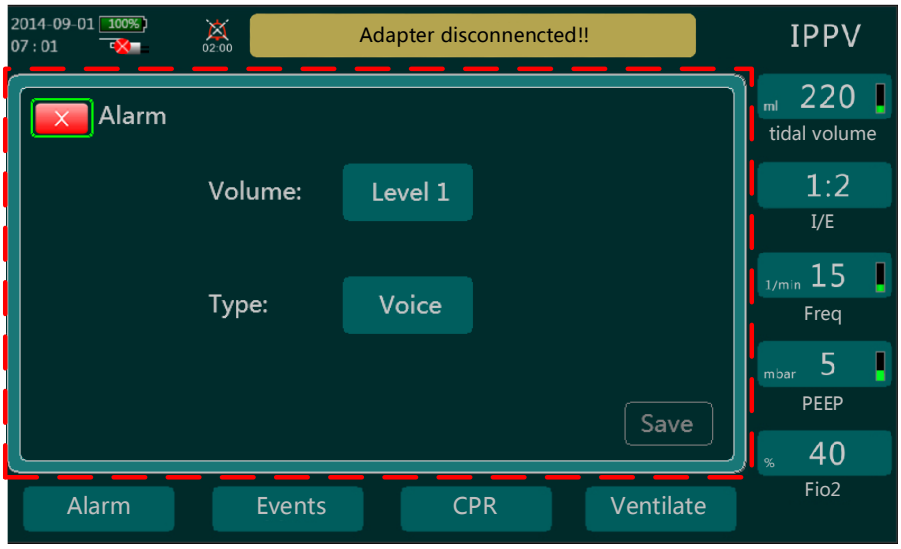



FIGURE 8 Alarm

| PARTS | DESCRIPTION |
|---|---|
| **1 Volume** | By default three levels are available. The available options are: shut down, Level 1, Level 2, and Level 3. |
| **2 Type** | The default mode is voice alarm. The available options are buzzer and voice alarm. |

Alarm sound pressure range: within a distance of one meter, the peak volume range of the audible alarm generated by the device is 45dB(A) ~ 85 dB(A).

Access authorization: When access to the operation interface is restricted, the manufacturer or its authorized professionals must enter the password for access.

## 3.2.3 System Settings

In the main menu interface, select < System setting > soft button to enter the system setting interface(As shown below).


FIGURE 9 System

| PARTS | DESCRIPTION |
|---|---|
| **1 Luminance** | By default two levels are available. The available options are: Level 1, Level 2, and Level 3. |
| **2 Pressure unit** | The default unit is mbar. The available options are mbar, hPa, and cmH2O. |
| **3 Desktop style** | The default style is Dark Green. The available options are Dark Green, Dark Blue and Gray White. |
| **4 Waveform style** | The default style is Filling. The available options are Filling and Solid Line. |
| **5 Language** | The default language is Chinese. The available options are Chinese and English, Turkish. |
| **6 $EtCO_2$** | Open or close. |
| **7 HFNC** | Open or close. |

### 3.2.4 Time setting

In the main menu interface, select < Time > soft button to enter the time interface(As shown below).

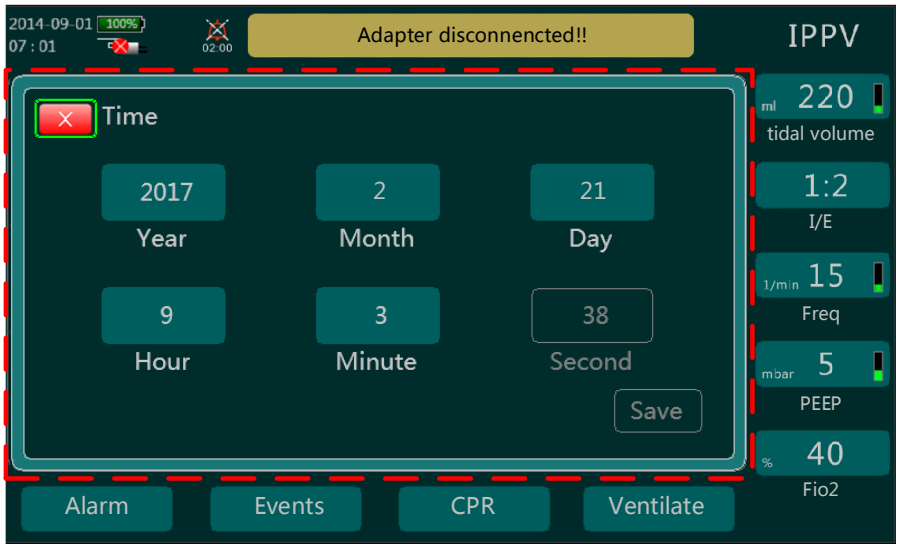



FIGURE 10 Time

### 3.2.5 Calibration

In the main menu interface, select <Calibration> soft button to enter calibration interface to calibrate air proportion valve, oxygen proportion valve and PEEP proportion valve (as shown in the following figure).


FIGURE 11 Calibration

### 3.2.6 About Host

In the main menu interface, select <About host> soft button to view software version (as shown in the following figure).

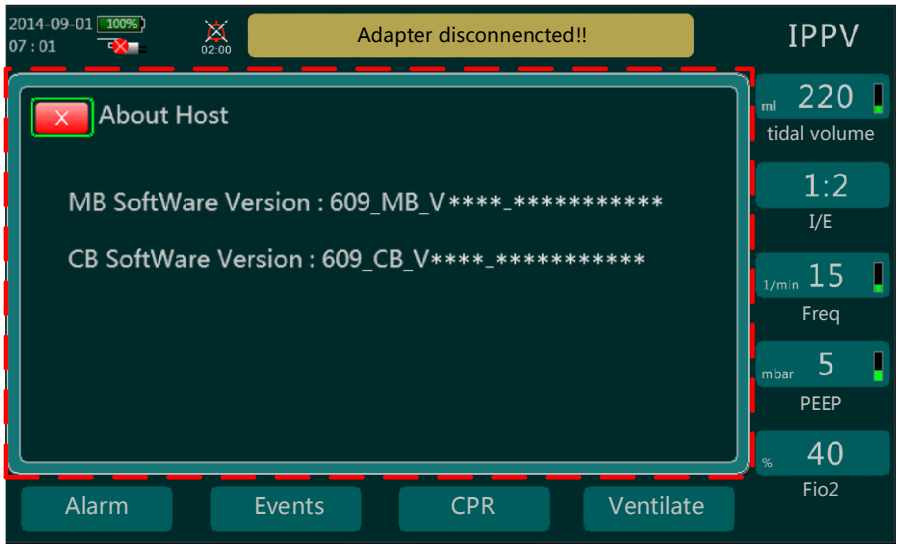



FIGURE 12 About Host

## 3.3 Alarm Message

Press the alarm tips button in the main interface and it will display alarm information in the top priority. If there are many alarms,

You can access alarm message by pressing alarm indication button in main interface (As shown below).


FIGURE 13 Alarm Table

Each type of alarm corresponds to an alarm priority level, thus resulting in

multiple types of alarm. In case of any abnormality, medical workers will be effectively reminded of handling the abnormality to avoid any possible accident. The following describes the alarm function in detail:

- **priority :**

| Type | LCD | LED | Voice alarm | Remark |
|---|---|---|---|---|
| High-priority alarm | The alarm zone in the main interface changes to red and shows the corresponding alarm text plus !!! | The red light blinks Blinking frequency: 0.5s/time | 1. Five consecutive beep sounds: "Beep--beep--beep----beep-beep-"; pulse interval time: \|0.1s\|0.1s\|0.5s\|0.1s\|; pulse duration: 0.2s; pulse train interval time: 7s; 2. Voice prompt | The form of voice alarm depends on the setting of alarm type. See "3.2.2 Data Management Function, Alarm Setting"。 |
| Medium priority alarm | The alarm zone in the main interface changes to red and shows the corresponding alarm text plus !! | The yellow light blinks Blinking frequency: 2s/time | 1. Three consecutive beep sounds: "Beep beep beep"; pulse interval time: \|0.1s\|0.1s\|; pulse duration: 0.1s; pulse train interval time: 24s; 2. Voice prompt | The form of voice alarm depends on the setting of alarm type. See "3.2.2 Data Management Function, Alarm Setting" |

- **Alarm List: (Note: In the sequence of alarm priority from high to low)**

| No. | Name | Level | Condition | Remark |
|---|---|---|---|---|
| 1 | No gas supply pressure | High level alarm | No gas supply pressure | Technical alarm |
| 2 | High airway pressure | High level alarm | Airway pressure is above upper threshold | Physiological alarm |
| 3 | Low airway pressure | High level alarm | Airway pressure is below lower threshold | Physiological alarm |

| | | | | |
|---|---|---|---|---|
| 4 | High minute ventilation | High level alarm | Minute ventilation is above upper threshold | Physiological alarm |
| 5 | Low minute ventilation | High level alarm | Minute ventilation is below lower threshold | Physiological alarm |
| 6 | High EtCO2 | High level alarm | EtCO2 is above upper threshold | Physiological alarm |
| 7 | Low EtCO2 | High level alarm | EtCO2 is below lower threshold | Physiological alarm |
| 8 | Patient apnea | High level alarm | Patient apnea time is above upper threshold | Physiological alarm |
| 9 | Breathing hose disconnected | High level alarm | Breathing hose disconnected | Technical alarm |
| 10 | Battery level is too low | High level alarm | Battery level is lower than 10% | Technical alarm |
| 11 | Insufficient gas supply pressure | Medium level alarm | Gas supply pressure is below lower threshold | Technical alarm |
| 12 | High Vt | Medium level alarm | Tidal volume is above upper threshold | Physiological alarm |
| 13 | Low Vt | Medium level alarm | Tidal volume is below lower threshold | Physiological alarm |
| 14 | High respiratory frequency | Medium level alarm | Respiratory frequency is above upper threshold | Physiological alarm |
| 15 | Low battery | Medium | Battery level is lower | Technical |

| | | | | |
|---|---|---|---|---|
| | Medium | level alarm | than 20% | alarm |
| 16 | Adapter disconnected | Medium level alarm | The power adapter is disconnected | Technical alarm |

- **Voice alarm: In actual sound alarms, either voice alarm or buzzer alarm can be selected.**

| No. | Voice prompt | Meaning | Level |
|---|---|---|---|
| 1 | No gas supply pressure | No gas supply pressure | High level alarm |
| 2 | Check the airway to eliminate airway obstruction | High airway pressure | High level alarm |
| 3 | Check the airway to eliminate tube disconnection | Low airway pressure | High level alarm |
| 4 | Check the airway to eliminate excessive ventilation | High minute ventilation | High level alarm |
| 5 | Check the airway to eliminate inadequate ventilation | Low minute ventilation | High level alarm |
| 6 | Check the patient's condition to eliminate carbon dioxide retention | High EtCO2 | High level alarm |
| 7 | Check the patient's condition to eliminate patient oxygenation | Low EtCO2 | High level alarm |
| 8 | Check the patient's condition to eliminate apnea of the patient | Patient apnea | High level alarm |
| 9 | Breathing hose disconnected | Breathing hose disconnected | High level |

| | | | |
|---|---|---|---|
| | | | alarm |
| 10 | Battery level is too low. Please replace the battery Battery level is too low | Battery level is too low | High level alarm |
| 11 | Check the gas supply condition to eliminate insufficiency of gas supply pressure | Insufficient gas supply pressure | Medium level alarm |
| 12 | High Vt | High Vt | Medium level alarm |
| 13 | Check the mask wearing condition to eliminate ventilation leakage | Low Vt | Medium level alarm |
| 14 | Check the patient's condition to eliminate rapid shallow breathing of the patient | High respiratory frequency | Medium level alarm |
| 15 | Battery level is too low. Please charge in time | Battery level is Too low | Medium level alarm |
| 16 | Device fault. Check the power supply condition of the adapter | Adapter disconnected | Medium level alarm |

- **Multiple alarms:**

| **Situation** | **LED** | **LCD** | **Horn alarm** |
|---|---|---|---|
| Multiple high level alarms coexist | The prompt zone only displays the alarm message with the highest priority; the alarm interface shows all alarm messages | The red light blinks Blinking frequenc y: 0.5s/time | For voice alarms, corresponding voice prompts will be given; for "beep beep beep" alarms, alarms will be given according to the high priority "beep beep beep" alarm type |
| Multiple medium | The prompt zone only displays the | The yellow light blinks | For voice alarms, corresponding voice |

| | | | |
|---|---|---|---|
| lev<br>el alarms<br>coexist | alarm message with the highest priority; the alarm interface shows all alarm messages | Blinking frequency: 2s/time | prompts will be given; for "beep beep beep" alarms, alarms will be given according to the medium priority "beep beep beep" alarm type |
| High and medium lev<br>el alarms coexist。 | The prompt zone only displays the alarm message with the highest priority; the alarm interface shows all alarm messages | The red light blinks Blinking frequency: 0.5 s/time | For voice alarms, corresponding voice prompts will be given; for "beep beep beep" alarms, alarms will be given in the form of high priority "beep beep beep" alarms |

**Alarm response and lifting:**

The system can respond to at most 4 alarms simultaneously, so the Alarm Table shows at most 4 alarm messages.

| Situation | Introduction | Remark |
|---|---|---|
| Alarm response | When an alarm is triggered, there will be corresponding LCD, LED and voice responses. | |
| Alarm lifting | If the alarm condition is false, the alarm will be lif ted and alarm response ceased. | |
| Alarm muting | Press the Mute key to turn on or off the sound. During the period when an alarm is muted, if a new alarm is triggered, the alarm sound will be turned on again . | The alarm muting time is 120s; after pressing the Mute key, the 120s sound will be turned off. If the alarm still exists 120s later, the sound will be turned on again. |

## 3.4 Review Events

You can review system logs by clicking on Events button in main interface (As shown below).


FIGURE 14 Events

Up to 50 items of log message can be stored in the system. The older Events will be overwritten by the newer ones. In reviewing logs, pay attention to the following:

- Events message structure: time + type + content of message.
- Events time: the time of recording the Events.
- Events type: alarm message, user access message, and system operation message. (for the time being only alarm message is available)
- Events message: specific message description.
- Events color: red - high priority; yellow - medium priority; black - low priority.

## 3.5 Setting of Alarm Limits

In the main menu interface, select < Alarm Limits > soft button to enter the Alarm Limits interface, You can set alarm limits based on patient's respiratory physiological characteristics(As shown below).


FIGURE 15 Alarm

| PARTS | PARTS |
|---|---|
| 1 Upper airway pressure limit | 6 Suffocation duration |
| 2 Lower airway pressure limit | 7 Upper tidal volume limit |
| 3 Upper ventilation rate (per min.) limit | 8 Lower tidal volume limit |
| 4 Lower ventilation rate (per min.) limit | 9 Upper EtCO2 limit |
| 5 Upper respiration frequency limit | 10 Lower EtCO2 limit |

## 3.6 Ventilation mode Parameter linkage relationship:

| No. | Target Parameter | Linkage parameters | Interdependence | Note |
|---|---|---|---|---|
| | Vt | Finsp | Vt= (Finsp*1000/60)*(Tinsp-Tinsp*Tplat) | Finsp：Inspiratory flow<br>Tinsp：Inspiration time<br>Tplat： Plateau time<br>Tplat=Platform time ratio*$T_i$ |
| | Finsp | Vt | Vt= (Finsp*1000/60)*(Tinsp-Tinsp*Tplat) | / |

| | | | | |
|---|---|---|---|---|
| | Tplat | Finsp | Vt= (Finsp*1000/60)*(Tinsp-Tinsp*Tplat) | / |
| | I:E | Tinsp, Te, Finsp t | Tinsp:Te = I :E<br>Tinsp + Te = 60/Freq<br>Vt= (Finsp*1000/60)*(Tinsp-Tinsp*Tplat) | Te：Expiration time<br>Freq：Respiratory rate |
| | Freq | Tinsp, Te, Finsp t | Tinsp:Te = I:E<br>Tinsp + Te = 60/Freq<br>Vt= Finsp*1000/60)*(Tinsp-Tinsp*Tplat) | / |
| | Trigger mode | Trigger pressure | When the triggering mode is pressure triggering, the triggering pressure can be set; When the trigger mode is off, the trigger pressure cannot be set. | / |
| | PEEP | $P_{insp}$ | Ensure the PEEP is 5cmH2O lower than the inspiratory pressure | / |
| | $P_{insp}$ | PEEP | Ensure inspiratory pressure is at least 5cmH2O higher than PEEP | / |
| | $T_i$ | Freq | Not less than 0.2s | / |
| | $T_e$ | I:E | Not less than 0.2s | / |
| | Trigger pressure | PEEP | The trigger pressure is lower than PEEP | / |
| | CPAP | Fapnea | CPAP is lower than asphyxiation pressure | / |

# 4 Installation

## 4.1 Overview

Generally, T5 needs to be mounted only fixed onto an ambulance, helicopter or aircraft. In such case, we will supply a specific mounting bracket as an accessory.

If T5 is supplied by being fixed completely onto a stretcher or packed in a first-aid package as an assembly, this equipment is well ready for use without mounting.

**Warning :**

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

## 4.2 Boxed object

T5 Emergency Ventilator is packaged in a single case. For details on packing list, refer to "10. T5 Supplies Configuration".

## 4.3 Install the battery

T5 is equipped with chargeable lithium battery which is installed as shown in the following figure.

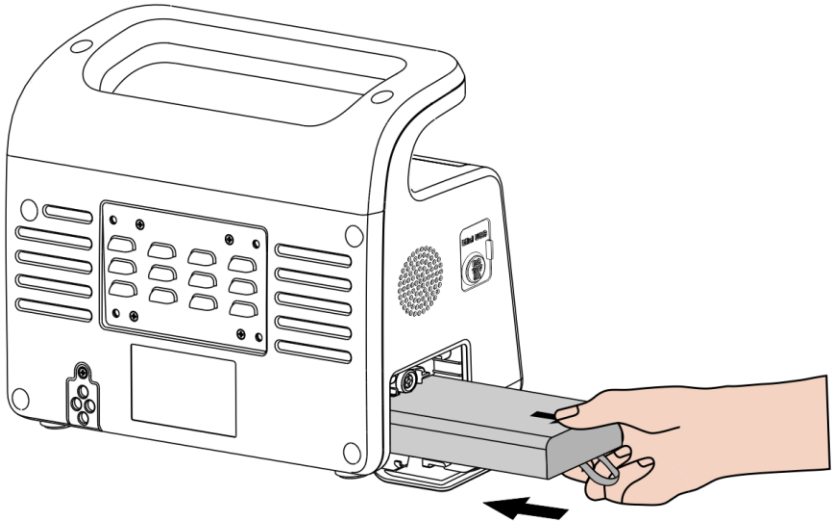


FIGURE 16 Install the battery

## 4.4 Connection of Oxygen Cylinder

**Warning :**

- 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.

## 4.5 Removal of Empty Cylinder

1. 1. Shut off the air valve of the cylinder.

- Start T5 by using the Start-Shut Down button, so as to release any residual oxygen and relieve any pressure inside the equipment.
- Release the switching valve by hand only when the reading on reducing valve is 0 bar.

2. Shut down T5.
3. Loosen the connecting nut on the cylinder by hand.

## 4.6 Connection of New Cylinder

1. Open the valve on new cylinder for a short moment and then shut it off, so as to remove any potential dirt at the outlet.

**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!

2. Connect reducing valve to port of the cylinder. Tighten the nut by hand.
3. Screw the pressure hose with 9/16-18UNF connecting nut into the outlet of reducing valve.
4. Connect the other end of the pressure hose to the air source port on T5.

## 4.7 Patient Respiratory Hose Assembly and Its Connection

T5 provides a reusable or disposable respiration management assembly. The assembly will be connected to the respirator and related accessories in accordance with the following procedure(As shown below).

1. Connect respiratory hose, patient valve in the respiratory hose assembly

in accordance with the following method.

2. Connect the rubber hose of patient value to pressure monitoring port on the main unit.
3. Connect the pu hose of patient valve to PEEP port on the main unit.
4. Connect breathing hose to the fresh gas intake. Be sure not to bend any connected air hose.
5. For connection between any other accessories and to the patient, refer the following Hose Accessories Connection Diagram.
6. In optional configuration of ETCO2 module, connect one end of mainstream CO2 module to patient and the other end to respiratory valve of patient and connect ETCO2 data acquisition line to ETCO2 sampling port.

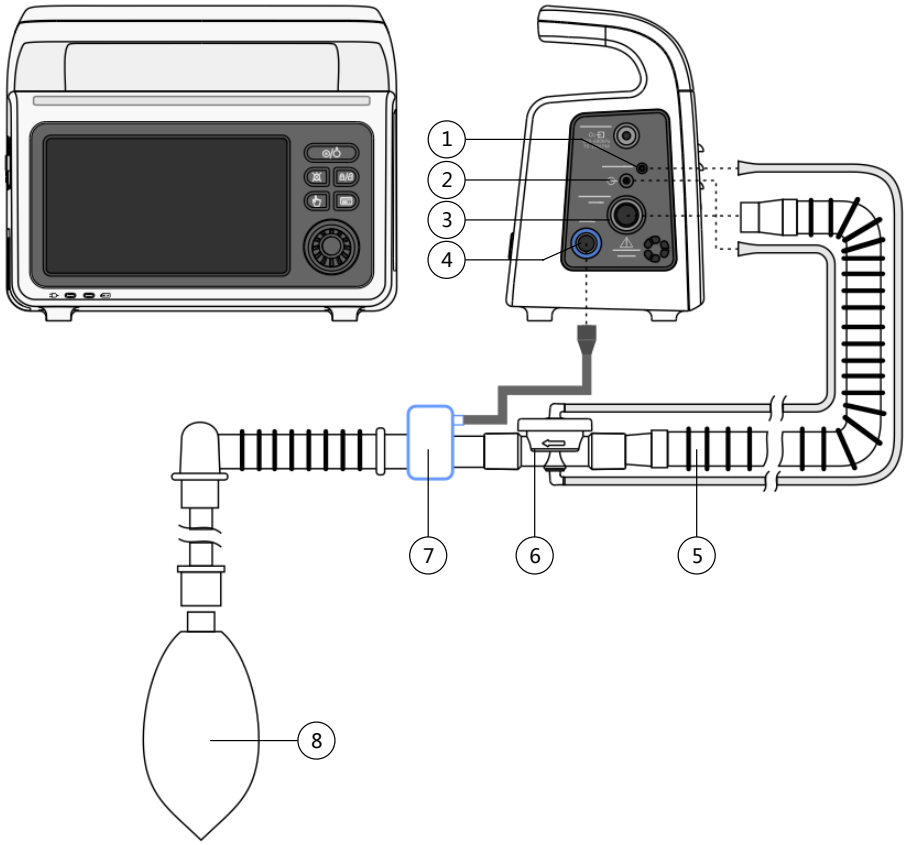



FIGURE 17 Accessories Connection Diagram

| PARTS | PARTS |
|---|---|
| **1 pressure measuring port** | **5 Hose** |
| **2 PEEP Port** | **6 patient Valve** |
| **3 fresh gas intake (to patient)** | **7 Mainstream CO2 module (used in optional configuration)** |
| **4 ETCO2 port** | **8 simulative lung(patient)** |

**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.

## 4.8 Patient Breathing Valve

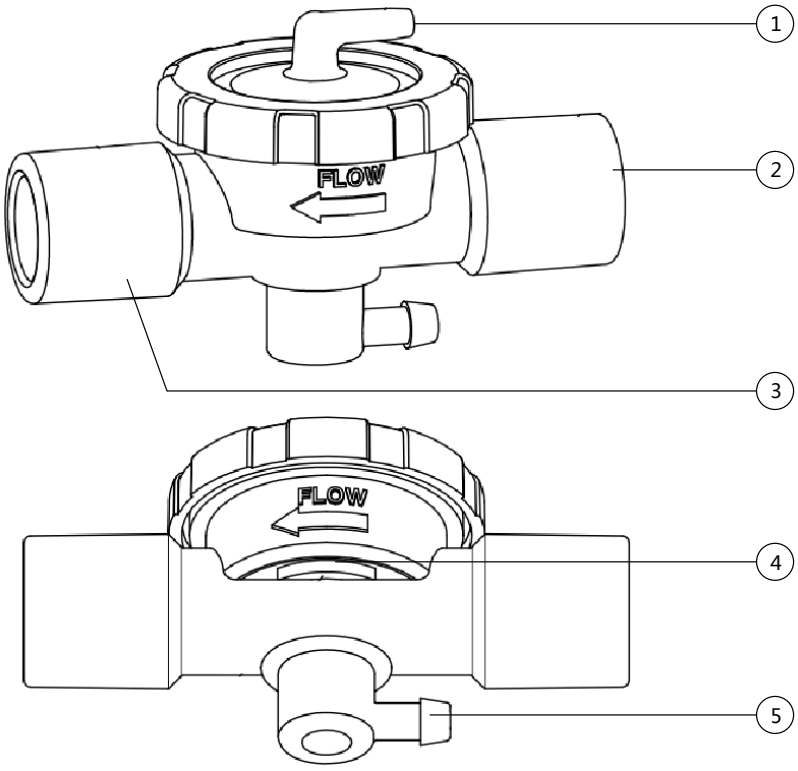



FIGURE 18 Patient Breathing Valve

| PARTS | DESCRIPTION |
|---|---|
| **1 PEEP air source port (self-reliant unit)** | Connect to PEEP air supply port on main unit. |
| **2 Air inlet (self-reliant unit)** | Connect to fresh air inlet of main unit. |
| **3 Patient connection port (for connection of mask/ cannula)** | Connect to the patient. |
| **4 Air outlet** | Patient's expired air outlet, which shall |

| | |
|---|---|
| | not be blocked. |
| **5 Airway pressure measuring port** | Connect to pressure measuring port on main unit. |

**Warning：**

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

# 5 Ventilation Operation

## 5.1 Calibration of Touch Screen

For the initial operation, the system will automatically enter touch screen calibration. User can click the touch points to finish calibration of the first (at the lower left corner) and the second (at the upper right corner) points, and then click a third point at any position of the screen to complete the calibration procedure (As shown below).


FIGURE 19 Click on the bottom left corner


FIGURE 20 Click on the top right corner

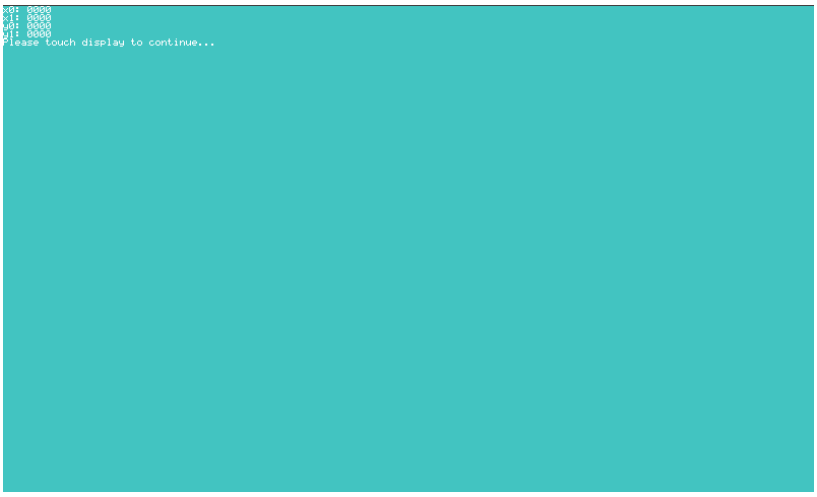



FIGURE 21 Click on any location

## 5.2 Startup-Self-Checking

1. Slowly open the switching valve on the oxygen cylinder. Current pressure of the cylinder can be read out on the pressure meter of the reducing valve.
2. Calculate the ventilation duration which the current storage volume can maintain (refer to Calculation of Oxygen Storage/Ventilation Duration). You need to replace the oxygen cylinder at a proper time to ensure the respirator can operate for a period of sufficient length, for example, when pressure of the cylinder is lower than 50 bar.
3. Press down Start/Shut Down button to start T5. At this moment a progress bar indication self-checking is displayed on the screen. Upon end of the bar, the main interface appears, and voice prompts are given by the system, such as "open oxygen cylinder", "select respiration mode" and "adjust settings".
4. If self-checking fails, the following frame will be displayed on the screen. At this moment the respirator is unavailable.

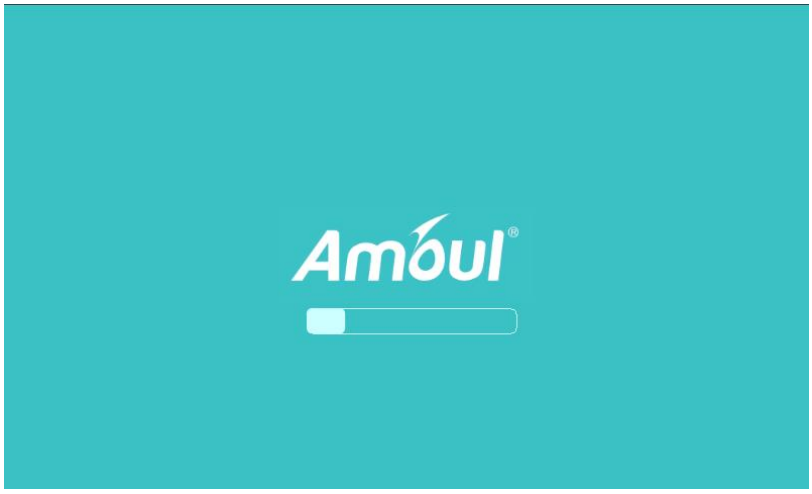



FIGURE 22 Startup-Self-Checking


FIGURE 23 Error code

5. It indicates that the main unit operates normally when no error message is displayed on the main interface. At this moment the respirator will not execute any ventilation mode or parameter, but pop up a Select Emergency Ventilation Mode dialog for your selection.

- You can directly confirm the dialog and respirator will execute the default ventilation mode and parameters.
- Alternatively you can click on Ventilation Mode and select the desired mode from the drop down list, and then set the related parameters in the pop-up parameter setting window and save it, and respirator will execute your selection.

**A detailed description of the aforesaid operations is given in the following section.**

6. After setting respiration parameters and ventilation mode, make connection to the patient.
7. During ventilation, adjust respiration parameters as necessary for the patient.

**Caution :**

Self-checking should not be a substitute for functional inspection. Before using the equipment, functional inspection shall be performed in accordance with Section 7 - Functional Inspection.

## 5.3 Select Ventilation Mode

To select ventilation mode, click on Ventilation Mode and select the desired mode from the drop down list(As shown below).

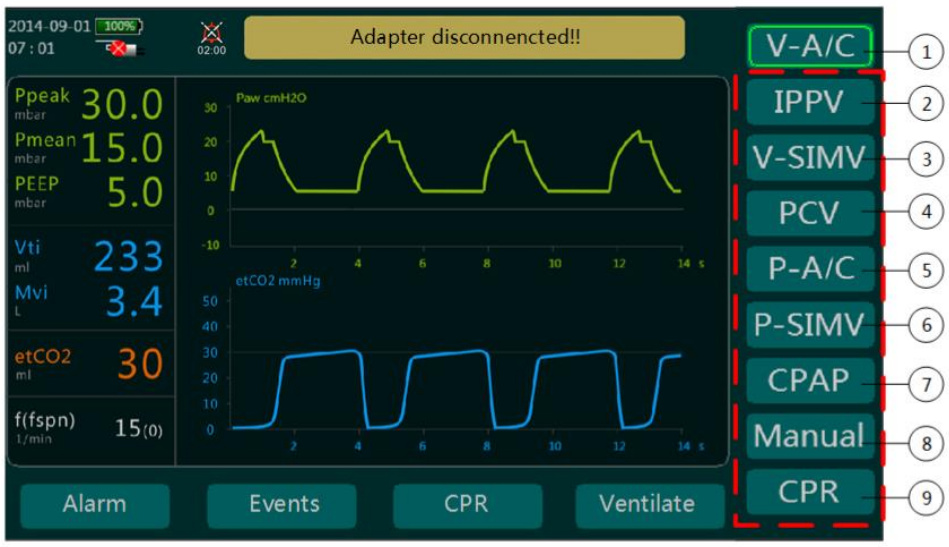



FIGURE 24 Ventilation Mode

| PARTS | PARTS |
|---|---|
| 1 V-A/C Mode | 6 P-SIMV Mode |
| 2 IPPV Mode | 7 CPAP Mode |
| 3 V-SIMV Mode | 8 Manual Mode or HFNC Mode |
| 4 PCV Mode | 9 CPR Mode |
| 5 P-A/C Mode | |

## 5.4 Main Ventilation Parameters Setting

For convenience of operation and review, 5 major ventilation parameters are provided at the right side of the main interface (As shown below).

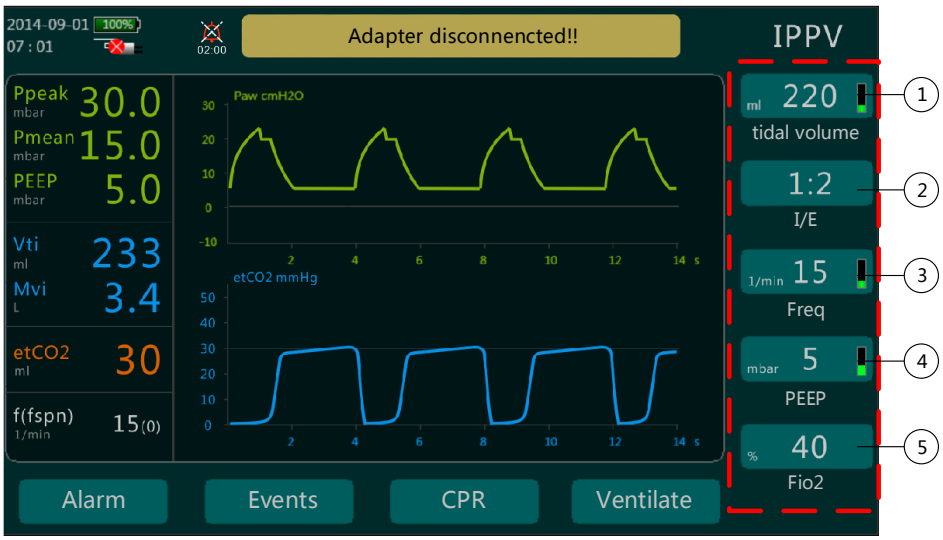



FIGURE 25 Main Ventilation Parameters

| PARTS | PARTS |
|---|---|
| **1 Inspiratory pressure (tidal volume in case of volume control mode)** | |
| **2 Inhalation/expiration ratio (I/E)** | **4 PEEP (or CPAP)** |
| **3 Respiration frequency** | **5 Oxygen concentration** |

# 5.5 Details on Ventilation Modes

T5 allows different ventilation modes based on patient's condition.

## 5.5.1 IPPV and PCV

- **IPPV**

In case of mechanical ventilation in IPPV (Intermittent Positive Pressure Ventilation), the respirator always offers positive pressure ventilation, supplying rising pressure during inspiration and baseline pressure during expiration. In other word, consecutive respiration support is provided for breathless patient and each respiration is mandatory. T5 operates in volume-controlled IPPV, where air in preset tidal volume is conveyed to the patient at a constant flow rate and preset respiration frequency and for the preset respiration duration, so that the patient will obtain stable tidal volume in variable pressure, with inspiration peak pressure kept high in case of poor compliance or high air duct resistance and low in case of good conformity or low airway resistance. The tidal volume, I/E and inspired air flow rate for the patient are completely controlled by respirator, which supplies constant inspired air flow rate and all respiratory power.

IPPV, also known as Controlled Mechanical Ventilation (CMV), is a ventilation technology commonly used in clinic applications and mainly for patients without spontaneous breathing. The respirator will provide patient with positive pressure ventilation based on the preset ventilation parameters regardless of the patient's own breathing condition.

**A typical pressure waveform of IPPV is shown below :**

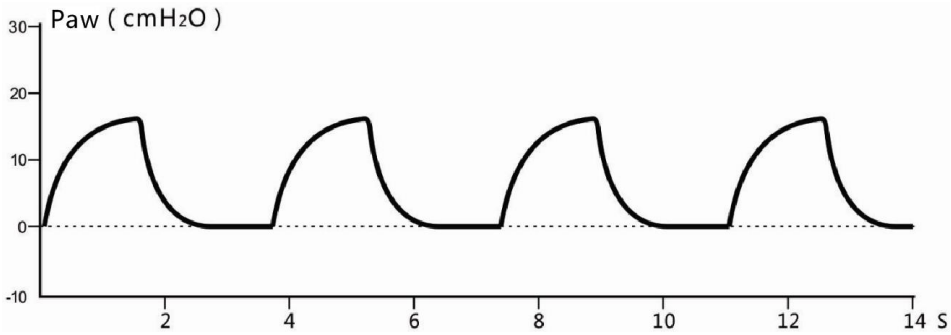



FIGURE 26 IPPV

- **PCV**

In PCV (Pressure Controlled Ventilation), airway pressure and inspiration duration are preset. After inspiration is started, air flow rate is raised quickly to the preset pressure level and then slowed down by the feedback system and maintained at the preset pressure till end of inspiration, and then expiration is started. Each ventilation is of full load based on preset pressure. In PCV, airway pressure falls, and there is no peak pressure, and rare barotrauma, which is beneficial for aeration of pulmonary alveolus, improvement to ventilation-blood stream rate and optimization of air exchange. PCV is primarily used for newborn, infants and patients suffering respiratory insufficiency, severe unbalancing ventilation-blood stream rate resulted from ARDS or COPD, ensures supply of tidal volume even in case of leakage of respiratory hose.

**A typical pressure waveform of PCV is shown below :**

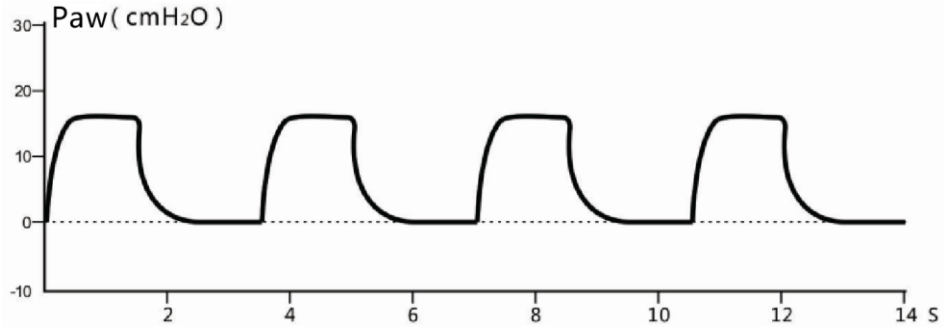



FIGURE 27 PCV

## 5.5.2 V-A/C and P-A/C

- **CV**

In CV (Controlled Ventilation), which is also known as Mandatory Ventilation, respirator provides ventilation at preset frequency, in preset tidal volume or at preset pressure, periodically activates inspiration and switches to expiration, completely in place of patient's independent breathing. The patient's breathing modes (frequency, tidal volume, expiration time and

inspired air flow rate) are completely controlled by respirator, which supplies all respiratory power. CV is classified into Volume Controlled Ventilation (VCV) and Pressure Controlled Ventilation (PCV).

- **AV**

In AV (Assisted Ventilation), which is activated by decrease of airway pressure (pressure trigger) or change in flow rate (flow rate trigger), the respirator conveys air to the patient at preset tidal volume (or Inspiratory pressure), frequency, inspiration duration and expiration duration.

Popularly speaking, in AV, ventilation of respirator is activated by the patient, and ventilation will not be provided unless the patient inhales. Proper parameters should be set for pressure activation or flow rate activation, in the same way as with CV.

- **A/CV**

A/CV (Assisted/Controlled Ventilation) is a combination of CV and AV, during which, when spontaneous breathing is sufficient and at a frequency higher than the preset one, assisted ventilation is applied; when spontaneous breathing is weak and at an actual respiration frequency equal to the preset one, controlled ventilation is enabled. When the patient takes spontaneous breath, mechanical ventilation is started. When spontaneous breathing is unavailable at a time, mechanical ventilation is automatically switched from assisted ventilation to controlled ventilation. A/CV is a type of IPPV.

- **V-A/CV**

V-A/CV (Volume Assisted/Controlled Ventilation) is based on VCV. Synchronous activation is enabled in expiration stage. When the pressure reaches activation pressure, respirator provides one push of VCV at fixed tidal volume in advance.

**A typical pressure waveform of V-A/CV is shown below :**

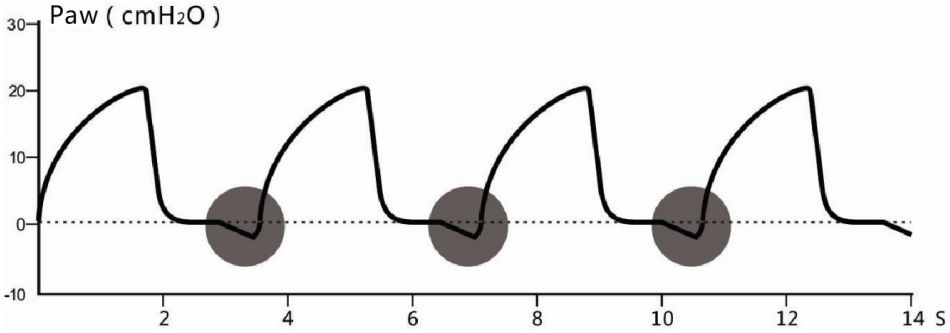



FIGURE 28 V-A/C

- **P-A/CV**

P-A/CV (Pressure Assisted/Controlled Ventilation) is based on VCV. Synchronous trigger is enabled in expiration stage. When the pressure reaches activation pressure, respirator provides one push of PCV at fixed Inspiratory pressure in advance.

**A typical pressure waveform of P-A/CV is shown below :**

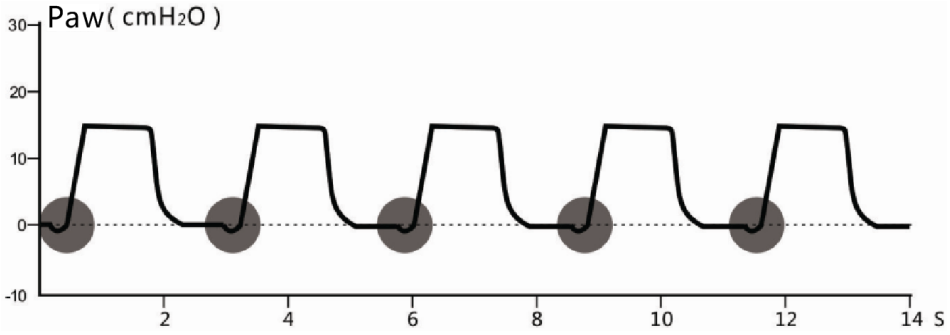



FIGURE 29 P-A/CV

Sign means a deep inhalation at two times of tidal volume based on IPPV once every certain times, which is suitable for patient in long-term need of mechanical ventilation.

**Caution :**

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

## 5.5.3 V-SIMV and P-SIMV

**SIMV**

SIMV (Synchronized Intermittent Mandatory Ventilation) is a ventilation technology combining spontaneous breathing with IPPV, ensuring effective ventilation to the patient, free of patient-ventilator asynchrony. Proper adjustment can be made to SIMV frequency and flow rate to facilitate patient's respiratory function. Clinically SIMV has become a necessity prior to withdrawal of ventilator.

In V-SIMV (Volume-Constant
Synchronized Intermittent Mandatory Ventilation), within a specific activation window, ventilator detects patient's respiratory effort based on preset trigger sensitivity and immediately gives a push of mandatory ventilation at preset tidal volume so as to synchronize delivery of mandatory ventilation with patient's inhaling effort. During duration of activation window, if patient is capable of activating ventilator, an assisted breath will be given; if not, a push of mandatory ventilation will be provided.

**A typical pressure waveform of V-SIMV is shown below :**

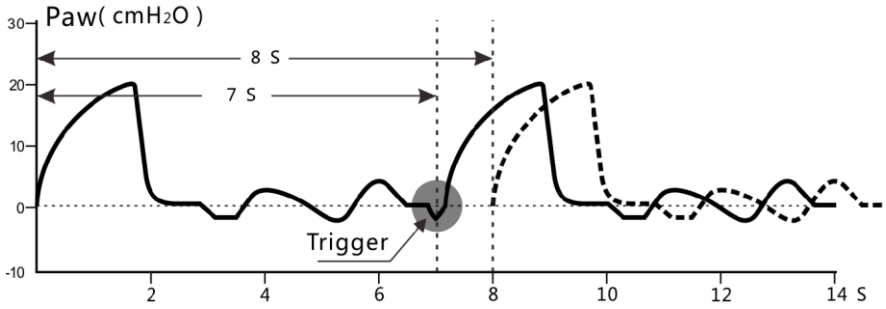



FIGURE 30 V-SIMV

In P-SIMV (Pressure-Constant
Synchronized Intermittent Mandatory Ventilation), within a specific activation window, ventilator detects patient's respiratory effort based on window, ventilator detects patient's respiratory effort based on preset activation sensitivity and immediately gives a push of mandatory ventilation at preset pressure so as to synchronize delivery of mandatory ventilation with patient's inhaling effort. During duration of activation window, if patient is capable of activating ventilator, an assisted breath will be given; if not, a push of mandatory ventilation will be provided.

**A typical pressure waveform of P-SIMV is shown below :**

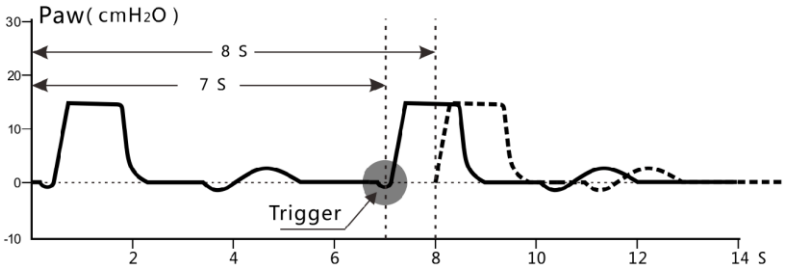



FIGURE 31 P-SIMV

Note: the activation mode in T5 ventilator is pressure activation mode.

## 5.5.4 CPAP

For purpose of CPAP (Continuous Positive Airway Pressure), the ventilator is furnished with a built-in sensitive airway pressure measuring and adjusting system, which adjust positive air flow rate over time and maintain airway pressure substantially at the estimated CPAP. CPAP for intubated patient ranges from 2~5 cmH2O up to 15 cmH2O. CPAP technology can be used only as an assistant breathing means for patients with normal functions of respiratory center and spontaneous breathing, and to exercise respiratory function. CPAP is applicable to hypoxemia mainly resulted from increase of Qsp.

CPAP is a ventilation mode which, based on spontaneous breathing, provide

a proper pressure level to maintain positive pressure within the airway throughout the respiratory cycle.

CPAP provides only a certain constant pressure support, not assistant ventilation function. Patient's respiratory patterns including frequency, amplitude, flow rate and tidal volume are all controlled by himself/herself. Therefore, any patient to whom CPAP is applied must have normal function to drive his/her respiratory center and sufficient capacity of spontaneous breathing.

**A typical pressure waveform of CPAP is shown below :**

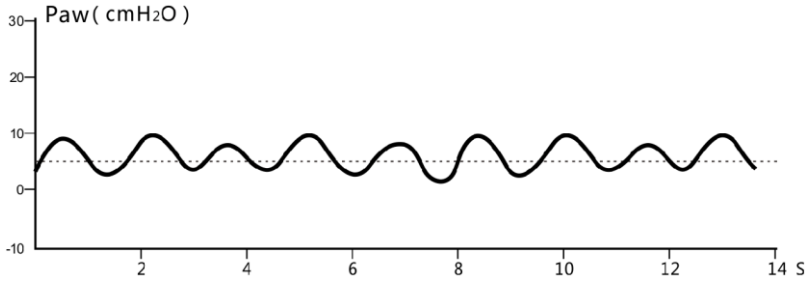



FIGURE 32 CPAP

### 5.5.5 HFNC

HFNC is a high-flow oxygen therapy mode. In this mode, you can adjust the oxygen flow rate and oxygen concentration. This mode is suitable for patients with respiratory failure who have spontaneous breathing.

## 5.6 Execution of Ventilation

### 5.6.1 Intubation

Before connecting cannula to patient breathing valve, the patient will usually be intubated(As shown below).

1. Set proper ventilation mode and related respiration parameters based on patient's condition.
2. Connect patient breathing valve to the connector of tracheal cannula.
3. During ventilation, always keep observing the respiration parameters on the screen, so as to ensure your ventilation mode and parameters as set are suitable to the patient.

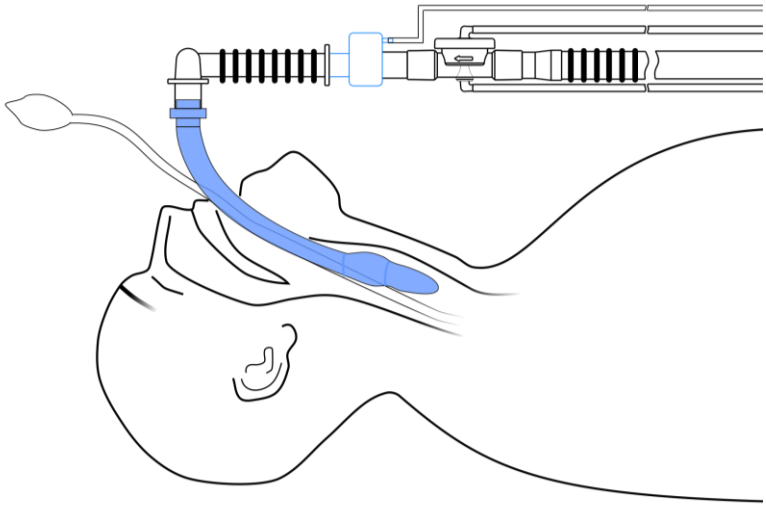


FIGURE 33 Intubation

## 5.6.2 Respiratory mask

1. Connect respiratory mask to patient breathing valve.
2. Place respiratory mask onto patient's nose and mouth.
3. Keep patient's head backwards and make the mask worn closely against the face.
4. Before wearing the mask, keep patient's respiratory tract unblocked.

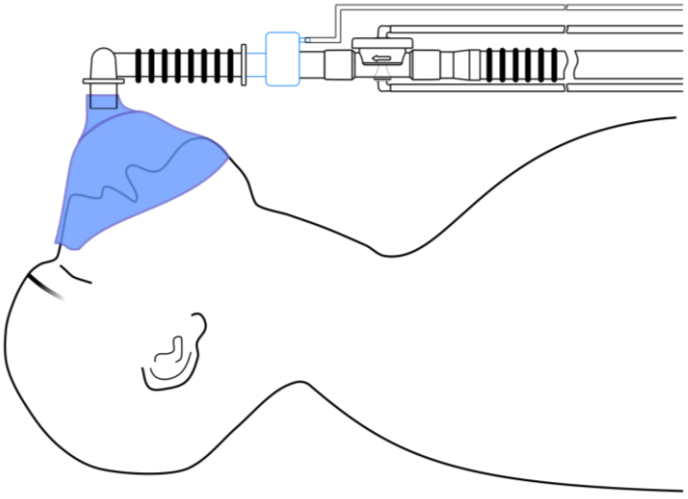


FIGURE 34 Respiratory mask

# 5.7 Monitoring of Respiration

## 5.7.1 Real-Time Ventilation Parameters

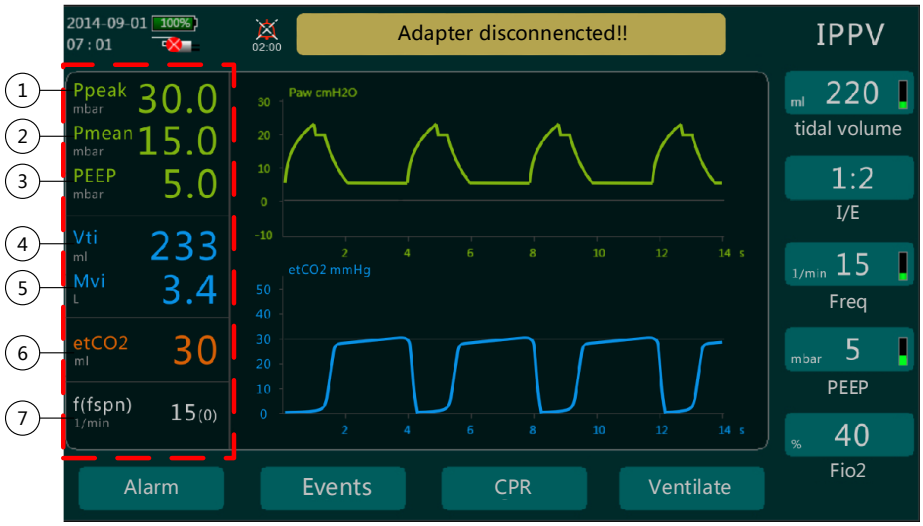



FIGURE 35 Ventilation Parameters

| PARTS | PARTS |
|---|---|
| **1 Airway Peak Pressure** | **5 Ventilation rate** |
| **2 Average airway pressure** | **6 Concentration of carbon dioxide** |
| **3 PEEP** | **7 Respiration frequency** |
| **4 Tidal volume** | |

### 5.7.2 Waveform Diagram

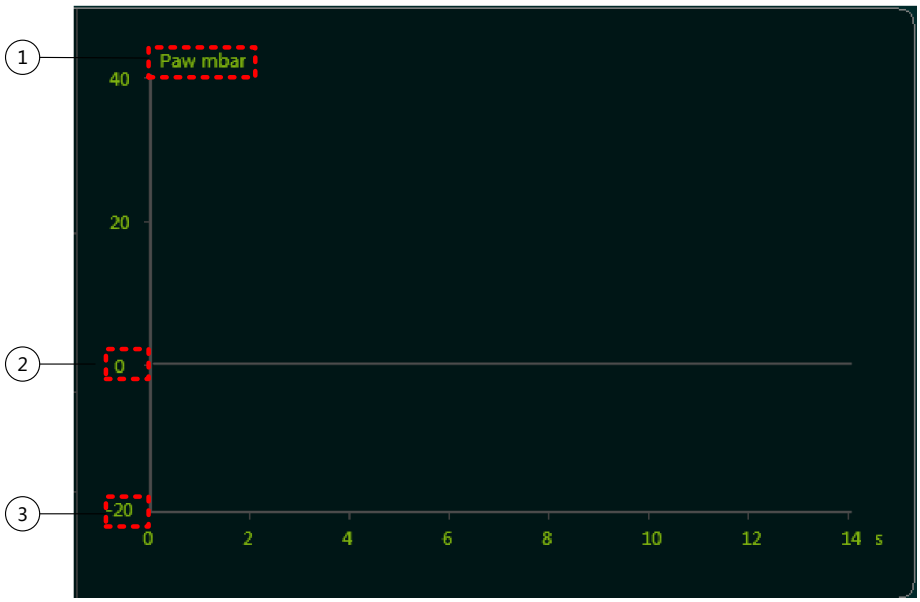



FIGURE 36 Waveform Diagram

| PARTS | PARTS |
|---|---|
| **1 Designation unit** | **3 Time scale** |
| **2 Pressure scale** | |

## 5.8 CPR Ventilation

CPR (Cardiopulmonary Resuscitation) is a procedure used for first-aid treatment. CPR is a first-aid ventilation mode for blood circulation or respiratory arrest and intended to maintain supply to patient's organism and assistance with emission of CO2 from the body. CPR uses volume-constant controlled ventilation. The ventilation rate is set by the user. The preset ventilation rate varies depending on specific type of patient. The vibration frequency varies with operation mode.

The following information are included in CPR procedure:

- **Firstly** :As shown below, click on CPR button in the main interface to open Select Patient Type window with a voice prompt "select patient type".

Three preset tidal volumes correspond to three patient types, as shown below.

| SN | Patient Type | Preset Tidal Volume | Preset Time |
|---|---|---|---|
| 1 | Adults | 600ml | I/E of 1:2, and inspiration time of 1s |
| 2 | Children | 200ml | I/E of 1:2, and inspiration |

| | | | |
|---|---|---|---|
| | | | time of 1s |
| 3 | Infants | 100ml | I/E of 1:2, and inspiration time of 1s |


FIGURE 37 Select patient type

- **Secondly :**As shown below, access operation mode selection window with voice prompt "please select operation mode".

Three press ventilation rates correspond to three operation modes, as shown below.

| SN | Operation Mode | Press Ventilation Rate | Remark |
|---|---|---|---|
| 1 | Single-Person Mode | 30:2 | Not less than 100 presses per minute |
| 2 | Double-Person Mode | 15:2 | |
| 3 | Continuous Mode | Continuous press ventilation | |


FIGURE 38 Selection of Operating Mode

- **Thirdly :** As shown below, start CPR function - first voice prompt "press for 5 cm or more", then "start pressing", and finally alternative voice prompt " metronom with a speed force " and "ventilation".

  Perform pressing in the rhythm of " metronom with a speed force ".

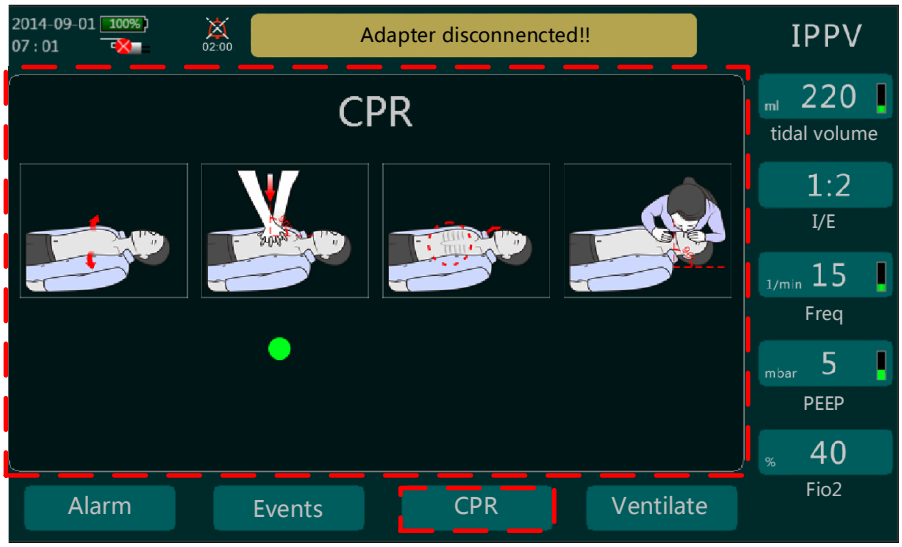



FIGURE 39 CPR

## 5.9 End Ventilation

Long press Start/Shut Down button for about 3 seconds to shut down ventilator(As shown below).

**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.

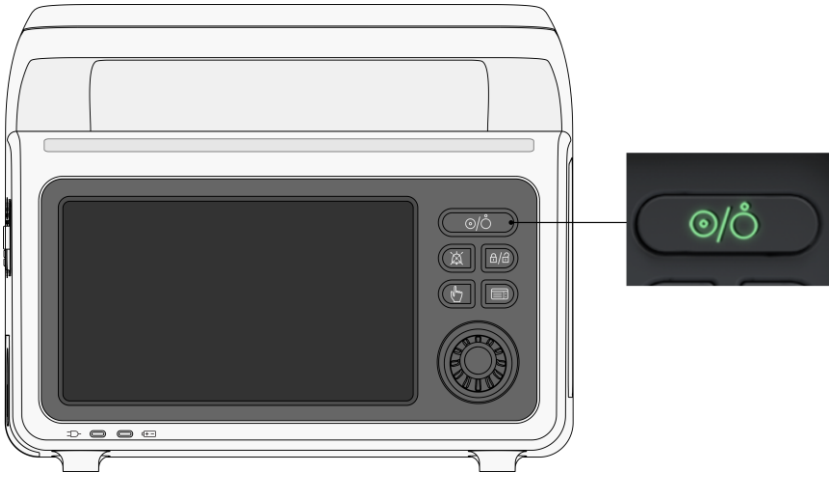


FIGURE 40 Shut down ventilator

# 5.10 Calculation of Storage Capacity/Operation Duration

- **Storage capacity of oxygen cylinder**

Oxygen capacity = cylinder volume × cylinder pressure.

| Example | cylinder volume | X | cylinder pressure | = | oxygen storage capacity |
|---|---|---|---|---|---|
| **1** | 10 L | | 200 Bar | | 2000 L |
| **1** | 10 L | | 100 Bar | | 1000 L |

- **Ventilation Duration**

Tidal Volume VT (L) × Respiration Frequency F (1/min) = Ventilation Rate MV (L/min)

$$\text{Ventilation Duration (min)} = \frac{\text{Oxygen Storage Capacity (L)}}{\text{MV(L/min)}} \times \frac{100\%}{\text{Oxygen Concentration}}$$

- **Example：**

Oxygen Storage Capacity = 1000 L; MV = 11 L / min; oxygen concentration = 100%Calculated as follows：

$$\text{Ventilation Duration (min)} = \frac{1000\ \text{L}}{11\ \text{L/min}} \times \frac{100\%}{100\%} = 91\ \text{min} = 1\ \text{h}\ 31\ \text{min}$$

## 5.11 Alternative Breathing Apparatus

In case of any malfunction in T5 during respiration, use the following alternative breathing apparatus:

- **Respiratory Leather Bag**

1. Remove the patient breathing valve off the cannula or mask.
2. Connect respiratory bag and then perform manual respiration.

- **Failure of Oxygen**

In case of failure of oxygen source for T5, the patient can inhale air through patient breathing valve.

## 5.12 Battery Management

T5 is equipped with a built-in chargeable battery whose working time must not be shorter than 5 hours in standard state.

The built-in battery should be recharged for not less than 8 hours, either independently or by the main unit of T5 ventilator.

**Battery Status Description：**

User can view in the main interface whether the battery is connected, being recharged and the battery level, as detailed below：

| PARTS | DESCRIPTION |
|---|---|
| 1  | indicates that the battery is not connected |
| 2   | indicates a battery level of 20 % |
| 3   | indicates a battery level of 40 % |
| 4   | indicates a battery level of 60 % |
| 5   | indicates a battery level of 80 % |
| 6   | indicates a battery level of 1000 % |

A floating battery level indicates that the battery is being recharged.

If battery indicator LED turns on, it indicates that the battery is connected; the LED going off indicates that the battery is disconnected or run out of; the LED which keeps flashing means that the battery is being recharged.

**⚠ 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.

# 6 Sanitization

T5 and its accessories must be sanitized each time after use to keep them in good condition and avoid cross infection. Each time after sanitation, perform functional inspection (refer to Section 7 - Functional Inspection).

## 6.1 T5 Main Unit

Scrub and clean the host simply by soft cloth wet by common water-soluble sanitizer.

While cleaning, prevent the disinfectant from flowing into the respirator.
Do not clean the surface of machine by organic solvent.

**Caution :**

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

## 6.2 Respiratory Hose Assembly

Any respiratory hose assembly supplied by Amoul shall be sanitized in accordance with the instructions given below. Any respiratory hose assembly supplied by another manufacturer shall be sanitized in accordance with such manufacturer's instructions.

## 6.3 Components and Accessories

The mask and any other rubber components shall be sanitized with approved disinfectant.

1. All interior and exterior surfaces of the components shall be adequately soaked without any air bubble. These components can be sanitized for the maximum duration as instructed by the disinfectant manufacturer.
2. After disinfection, clean the components with distilled water to prevent effect of any residual disinfectant on the machine or patient.
3. Place all rubber components in dry air to dry it naturally.
4. Inspect the mask, and make replacement for any damage.
5. Reusable respiratory hose and rubber pads of patient breathing valve and respiratory mask can be disinfected with high temperature.

## 6.4 Valve Fittings

**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.

## 6.5 Sanitization Methods

Sanitize T5 main unit and its accessories by using the methods as stated below:

| Part | Cleaning | Disinfection | Rinsing in Washer | Sterilization |
|---|---|---|---|---|
| T5 | Use dry or soaked cloth | By wiping | Not permitted | Not permitted |
| PEEP hose | Soaked into warm water mixed with mild domestic detergent | With all interior and exterior surfaces soaked into diluted solution for a sufficiently long time without any air bubble; after disinfection, clean all interior and exterior surfaces with distilled water and then dry it | Not permitted | Not permitted |
| Patient Breathing Valve | | | Rinsing in temperature below 93 °C is permitted (thermal disinfection in automatic cleaning machine) | Sterilized with hot steam in temperature of 134 °C for 5 minutes by using EN 285 compliant equipment |
| Reusable respiratory mask | | | | |
| Reusable respiratory hose | | | | |
| Oxygen valve fittings | Use dry or soaked cloth | By wiping | Not permitted | Not permitted |

# 7 Functional Inspection

User must perform a functional inspection on the equipment prior to use and after disassembly, or once every six months.

**Tips:**

When performing functional inspection on T5, the respiratory hose and patient breathing valve must be connected.

In case that any malfunction or deviation to any set value is found in functional inspection, the ventilator shall not be used until such malfunction is remove in accordance with Section 8 - Trouble Shooting. If such malfunction cannot be removed, contact Amoul or any professional authorized by it for repair.

**The full functional inspection shall include:**

- System Air-Tightness Inspection under 7.2 ;
- Examination of Patient Breathing Valve under 7.3 ;
- Machine Function Inspection under 7.4.

**It is recommended to keep proper inventory of the following spare parts:**

- One-way diaphragm of patient breathing valve

## 7.1 Inspection Cycle

**Prior to each use:**

- Perform a full functional inspection.

**After use or disassembly:**

- Clean, disinfect or sterilize the equipment and its components (refer to Section 6 - Sanitization);
- Examine one-way diaphragm in patient breathing valve (refer to 7.3 - Examination of Patient Breathing Valve). The diaphragm shall not be wrinkled, become sticky or twisted.
- Perform a full functional inspection.

**As long as being idle**

- at least once every six months,Perform a full functional inspection.

## 7.2 Inspect System Air-Tightness

1. 1. Open the oxygen cylinder valve slowly. Check the cylinder pressure on the meter of reducing valve. For example, a reading of 2,00PSI indicates sufficient oxygen storage, while a reading of 1,000PSI indicates that only there is only one half of the full capacity in it. If the pressure reading is less than 725PSI, replace the oxygen cylinder to ensure a ventilation duration of sufficient length.
2. Shut off the oxygen cylinder valve.
3. Observe the reading on the meter of reducing valve for about one minute. If the pointer stays still, it indicates a good air tightness; or otherwise, there is leakage in the cylinder.

**Locate and remove leakage :**

1. Prepare a dose of soap solution with perfume-free soap.
2. Soak all thread joints and hose couplers into the soap solution. The leakage is located at the position where air bubble appears.
3. Discharge the system pressure by shutting off the oxygen cylinder. Start T5 till the reading on cylinder is "0"; and then shut down T5.
4. In case of leakage, replace the damaged component.
5. Inspect air tightness again.
6. If the leakage cannot be removed, an overhaul is necessary.

## 7.3 Examine Patient Breathing Valve

1. Disassemble patient breathing valve.
2. Perform visual inspection on the surfaces of all parts and components for any crack or mechanical damage. Any wrinkled, sticky or twisted one-way diaphragms (in number of three) must be replaced. Replacement is unnecessary during inspection, but any wrinkled, sticky or twisted one-way diaphragms must be replaced to prevent potential serious failure.
3. Re-assembly the patient breathing valve.

⚠ **note :**

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

## 7.4 Machine Function Inspection

In addition to the aforesaid inspections, a simple functional inspection shall be carried on by the dedicated medical personnel on the machine in accordance with the following procedure to prevent any malfunction before use for patient.

**Warning :**

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

1. Connect power supply and air supply, and check whether the power supply and air supply operate normally.

2. Start the machine to make it perform self-checking, to mainly inspect whether all sensors operate normally.

3. Perform an asphyxia alarm inspection in accordance with the following steps:

a) Set asphyxia alarm time to 15s.

b) Set respiration mode to CPAP, and start timing; record the time elapsed before asphyxia alarm is triggered, and compare it with the set value. The tested time value should range between 13s and 17s.

4. Check alarm triggered by upper airway pressure limit in accordance with the following steps:

a) Set the ventilator to V-A/C ventilation mode.

b) Set Vt to 600ml, I/E to 1: 2, and frequency to 10.

c) Set Pmax to 20cmH20.

d) Block with hand the connection port of Patient Breathing Valve to generate an airway pressure higher than 20cmH20, and at this moment audible and visual alarm should be triggered by the excessive airway pressure. Release hand, and the alarm should be removed about 10 seconds later.

5. Perform an inspection on respiratory system integrity alarm function in accordance with the following steps:

a) Set the ventilator to V-A/C ventilation mode.

b) Set Vt to 600ml, I/E to 1: 2, frequency to 10, and Pmaxto 30cmH20.

c) With Patient Breathing Valve not connected to model lung, audible and visual alarm should be triggered by such disconnection after two respiratory cycles; and the alarm should be removed after the model lung is connected.

6. Check low battery level alarm function in accordance with the following steps:

During self-checking upon startup, low battery level alarm function can be checked. When oxygen cylinder is opened, If T5 is started and operates normally and no alarm is triggered, it indicates that the battery is at sufficient voltage level.

7. Inspect activation pressure function in accordance with the following steps:

a) Set ventilation mode to V-A/C.

b) Set activation pressure to -3cmH20.

c) Ventilate air through mask; when negative pressure of inspired air reaches 3cmH20, the respirator should ventilate air in.

# 8 Trouble Shooting

If any failure cannot be removed, contact Amoul or any professional authorized by it for repair. Stop using the machine in problem to avoid any potential injury.

## 8.1 Technical Failure

| Failure | Cause | Solution |
|---|---|---|
| T5 fails to start | T5 malfunctions | Contact the manufacturer or your dealer for repair |
| | Battery is exhausted | Recharge battery |
| Significant oxygen loss | Air supply hose leaks | Locate and eliminate leakage |
| T5 cannot be shut down | Improper operation | Long press Start/Shut Down button for 3 seconds or more |
| Power supply LED operates unstably | Power supply plug gets loose | Re-connect power supply |
| Short battery service duration | Battery service life expires | Replace battery with a new one |

## 8.2 Physiological Alarm

| Message | Alarm | Cause | Solution |
|---|---|---|---|
| High ventilation rate per min. | High ventilation rate per min. | Exceed the set upper limit of ventilation rate per min. | Examine the patient's condition<br>Check whether the upper limit is set properly |
| Low ventilation rate per min. | Low ventilation rate per min. | Lower than the set lower limit of ventilation rate per min. | Examine the patient's condition<br>Check whether the lower limit is set properly |
| Asphyxia | Asphyxia | Asphyxia duration exceeds the set value | Examine the patient's condition<br>Check whether the duration value is set properly |
| High airway pressure | High airway pressure | Exceeds the set upper limit | Examine the patient's condition |

| | | | |
|---|---|---|---|
| | | Airway is blocked | Examine the patient's condition |
| | | Respiratory hose is located improperly | Locate respiratory hose properly |
| | | Pmax is set to a too low value | Set Pmax to a proper value |
| | | Respiratory hose is wound | Check patient's position and make correction as necessary |

## 8.3 System Alarm

| Message | Alarm | Cause | Solution |
|---|---|---|---|
| Air source pressure is lower than 2.7 bar | Air source pressure is lower than 2.7 bar | Cylinder valve is not opened or oxygen in the cylinder is exhausted | Open cylinder valve or replace cylinder |
| | | Cylinder is connected improperly | Inspect related connections and make correction as necessary |
| | | Compressed air source is defective | Replace air source |
| | | Ventilator air source hose is wound or pressed | Arrange the air source hose or relieve the hose of any pressure |
| | | Reducing valve is defective | Replace reducing valve |
| Respiratory system is not connected | Respiratory system is not connected | 1. Respiratory hose leaks or falls down.<br>2. Respiratory mask is worn improperly.<br>3. Pressure measuring hose leaks or falls down. | Check the connection |
| | | System failure | Carry on an overhaul |
| Low battery level | Low battery level | Battery level is low | Recharge battery |

## 8.4 Power failure alarm

1.When the adapter and the built-in rechargeable battery are in place at the same time, unplug the adapter and the device will announce the intermediate alarm: "Adapter is

off!!"

2.When only the built-in rechargeable battery is in place, after the device is used for a long time, an intermediate alarm: "Battery power is low", top alarm: "Battery power is too low", and the abnormal power failure alarm function is triggered until the device is completely powered off. (See 8.5).

3.Only when the adapter is in place, disconnect the adapter, the device will be completely powered off, and the abnormal power failure alarm function will be triggered (see 8.5)

(The original configuration parameters of the device have been saved in the device and are not affected by power failure)

## 8.5 Abnormal power failure alarm

T5 has the function of shutdown alarm caused by abnormal power failure of the system

The alarm triggers a buzzer alarm when the host is shut down due to abnormal power failure, and the alarm duration is not less than 15 seconds;

This alarm can be cancelled by clicking the mute button.

# 9 Maintenance

## 9.1 Routine inspection

Safety inspection shall be performed after each overhaul, and T5 shall undergo safety inspection and maintenance regularly.

**After each use :**

Clean and disinfect reusable respiratory hose and patient breathing valve in accordance with relevant instructions in Section 6.

**Once every six months :**

Replace filter element in accordance with 9.4 - Replace Filter Element.

**Annually :**

Clean, disinfect and perform safety inspection on the equipment in accordance with relevant instructions in Section 6. In addition, a general maintenance shall be carried out by the manufacturer or any professionals authorized by it.

**Biennially :**

Oxygen valve fittings (e.g. reducing valve) shall be maintained by the manufacturer or any professionals authorized by it.

## 9.2 Battery

T5 is equipped with a maintenance-free 7.4V rechargeable lithium battery. It is recommended to periodically recharge it to full (once every 6~12 months, depending on service duration) and then exhaust it. Replace battery in accordance with the following procedure (as shown below).

1. Make sure T5 is shut down.
2. Push the clasp in the direction of arrow.
3. Remove the battery off the slot.
4. Push the clasp in the direction of arrow and mount battery into the slot till the clasp is reset in place.

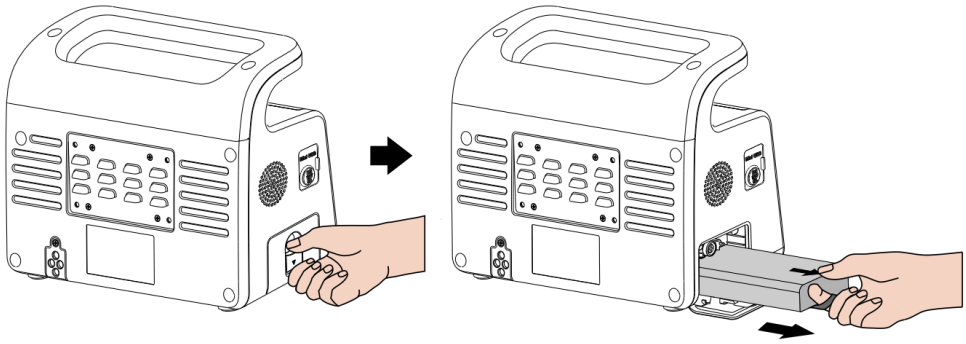


FIGURE 41 Replacement battery

**Warning :**

1. A battery as specified by Amoul 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.

**Tips :**

The battery which T5 is furnished with is subject to no memory effect. Thus you can recharge it whenever possible without impairment of its service life, provided that a battery has its inherent lifespan , such as 2 years or 300 recharging times.

## 9.3 Accessories

For maintenance cycle of T5 accessories and maintenance application, refer to related operating instructions.

Oxygen cylinder must be re-checked pursuant to proper guidelines. Expiration date of oxygen cylinder is indicated on the label attached to it.

## 9.4 Replace Filter

Replace Filter(as shown below) :

1. Unscrew the outlet cover with a screwdriver.
2. Take out the old filter element with tweezers.
3. Clean the filter cartridge with medical cotton ball soaked with alcohol.
4. Re-mount a new filter element into the cartridge with tweezers.
5. Re-mount the cover and tighten the screws.

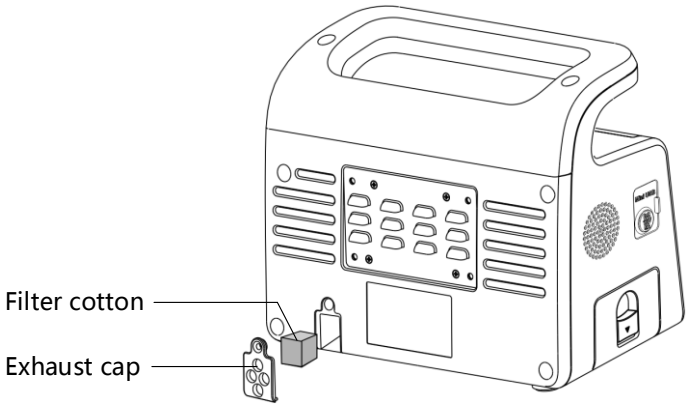



FIGURE 42 Replace Filter

**Warning :**

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

## 9.5 Storage

If T5 is left idle for a long time, it is recommended to take the following measures:

1. Clean and disinfect the equipment (refer to Section 6 - Sanitization).
2. Store T5 in a dry place.
3. The battery can be mounted in the equipment during storage.

**Importan :**

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

## 9.6 Disposal of Waste Equipment

The waste equipment shall be disposed by a certified disposer.

# 10 T5 Supplies Configuration

## 10.1 Standard Components

| SN | Name | Material coding | Unit | Remark |
|---|---|---|---|---|
| 1 | T5 Main Unit | 2.609.00002 | Set | English |
| 2 | Reusable respiratory hose | 2.609.00018 | pcs | |
| 3 | Big hanger for rubber mask | 5.001.00033 | pcs | |
| 4 | Reusable rubber mask (4#) | 5.001.00035 | pcs | |
| 5 | Rubber headgear (for adults) | 5.001.00037 | pcs | |
| 6 | Power adapter | 2.609.00021 | pcs | European Standard |
| 7 | AC power cable | 1.124.00001 | pcs | European Standard |
| 8 | Rechargeable Li Battery | 1.115.00028 | pcs | |
| 9 | Air source hose | 2.601.00046 | PCS | 2m, with a DISS connector at one end and a quick connector at the other end |
| 10 | T5 User's Manual | 1.601.00137 | pcs | English |

## 10.2 Optional Components

| SN | Name | | Material coding | Unit | Remark |
|---|---|---|---|---|---|
| 1 | ETCO2 module 2.609.00017 | Mainstream CO2 module | 5.000.00452 | PCS | |
| | | Adult adapter (disposable) | 5.000.00453 | PCS | |
| | | Newborn adapter (disposable) | 5.000.00454 | PCS | |
| | | Cable fixing slot | 5.000.00457 | PCS | |
| 2 | Single respiratory hose (disposable) | | 2.609.00019 | PCS | |

| | | | | |
|---|---|---|---|---|
| 3 | Splint | 5.000.00168 | PCS | |
| 4 | Bearing system | 2.609.00015 | PCS | |

**Caution :**

The specific configuration shall be subject to the packing list.

## 10.3 Ventilation Mode Configuration List

| SN | Ventilation Mode | Options |
|---|---|---|
| 1 | IPPV | ● |
| 2 | V-A/C | ● |
| 3 | V-SIMV | ● |
| 4 | PCV | ● |
| 5 | P-A/C | ● |
| 6 | P-SIMV | ● |
| 7 | CPAP | ● |
| **SN** | **Other Functions** | **Options** |
| 1 | Manual | ● |
| 2 | HFNC | ● |
| 3 | CPR | ○ |
| Note: ● means standard configuration. ○ means optional configuration. | | |

# 11 Technical Parameters

## 11.1 Medical Devices Management Category

| Medical Devices Management Category | |
|---|---|
| Category | Class-III |

## 11.2 Physical Specifications

| Machine size | |
|---|---|
| size | length：250mm<br>width：200mm<br>height：127mm |
| Weight | 3.4 kg |
| **Display screen** | |
| Types of | TFT color screen |
| size | 7" |
| Resolution | 800 x 480 pixels |
| Features | With resistor type touch screen control |

## 11.3 Environmental specifications

| Operating Environment | |
|---|---|
| Temperature range | -20℃～60℃ |
| Humidity range | 15%～95% |
| Air pressure | 70kPa～110kPa |

## 11.4 Power Specifications

| Power adapter | |
|---|---|
| Input voltage | 100-240V～ |
| Input frequency | 50-60Hz |
| Input Current | 0.7-1.5A |
| **Main unit** | |
| Host input | DC 12V |
| Total power | ≤30VA |

## 11.5 Ventilation mode

| **Ventilation mode** | |
|---|---|
| Volume-control mode | V-A/C、V-SIMV、IPPV |
| Pressure-control mode | P-A/C、P-SIMV、CPAP、PCV |
| Other mode | CPR、Manual、HFNC |

## 11.6 Supply specifications

| **Supply specifications** | |
|---|---|
| Air supply | Medical oxygen |
| Air supply pressure | 2.7～6.0 bar |

## 11.7 Ventilator specifications

| **Patient breathing valve resistance** | |
|---|---|
| Inspiration | ＜6cmH2Oat flow rate of 30、60 L/min时 |
| Expiration | ＜6cmH2Oat flow rate of 30、60 L/min时 |
| Emergency inhaled air inlet | ＜6cmH2Oat flow rate of 15、30 L/min时 |
| **Max. ventilation flow** | |
| Max. ventilation flow | ≥80L/min(@450kPa) |
| **Activation Mode** | |
| Activation Mode | Pressure activation |
| **Control Parameters** | |
| I/E | Adjustable between 9:1 and 1:9 with allowance of ±10% |
| Respiration frequency | 0，1~120bpm with allowance of ±1bpm or ±5%, whichever is the larger |
| Tidal volume | 50~2500mL (ATPD)<br>with allowance of ±30ml or ±15%, whichever is the larger |
| Oxygen flow velocity | 1～80L/min with allowance of ±1L/min or ±15%, whichever is the larger. |
| PEEP/CPAP | 0,3~30cmH20 with allowance of ±2cmH20 or ±10%, whichever is the larger |
| Inspiratory pressure | 5~60cmH20 with allowance of ±2cmH20 or ±10%, whichever is the larger |

| | |
|---|---|
| Conveyed oxygen concentration | 40%、100%，±10%（v/v） |
| Airway pressure limits | 15~70cmH20 with allowance of ±2cmH20 or ±10%, whichever is the larger |
| Activation pressure | -20~20cmH20 with allowance of ±1cmH20 or ±10%, whichever is the larger |
| Pressure support | 0, 3～35cmH2O, tolerance: ±2cmH2O or ±10%, whichever is the larger. |
| Pause time ratio | 0～80 %, tolerance: ±10% |
| Pressure rise time | Slow/normal/fast |
| **Monitoring Parameter** | |
| Tidal volume | 0~3000ml with allowance of ±30ml or ±15%, whichever is the larger |
| Oxygen flow velocity | 0～80L/min, with allowance of ±1L/min or ±15%, whichever is the larger. |
| Ventilation rate per min. | 0~80L/min. with allowance of ±0.5L/min or ±15%, whichever is the larger |
| Respiration frequency | 0 ~120bpm with allowance of ±1bpm or ±5%, whichever is the larger |
| Airway pressure monitoring | -20~100cmH20 with allowance of ±2cmH20 or ±10%, whichever is the larger |
| End-expiratory carbon dioxide concentration | 0～150mmHg<br>error:<br>(0～40 mmHg) ±2mmHg<br>(41～70 mmHg) ±5%<br>(71～100 mmHg) ±8%<br>(101～150 mmHg) ±10% |
| **Mechanical safety valve** | |
| Mechanical safety valve | ≤ 100 cmH2O |
| **connecting pipe joint specifications** | |
| Ventilator air source connecting pipe joint specification | Germany type quick connector<br>Quick plug male head：Parker Φ6mm 21SFTF06MXN<br>Quick plug female head：Parker G1/8 21KAAW10MPN<br>The maximum working pressure: 35 bar |
| **Respiratory hose connector specifications** | |
| Respiratory hose connector | Interior φ15mm/exterior φ22mm |
| **Conversion** | |

| | |
|---|---|
| 1bar | ≈ 100kPa |
| 1cmH2O | ≈ 100Pa |

**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.

## 11.8 T5 Product Structure Diagram

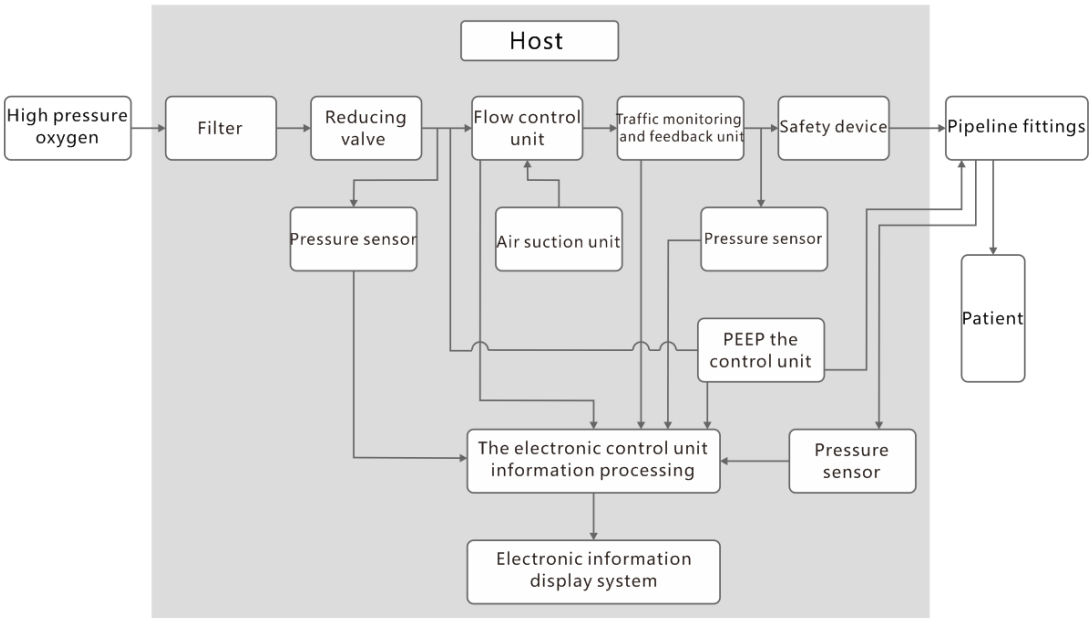



FIGURE 43 T5 Product Structure Diagram

## 11.9 Available Minimum Oxygen Concentration

The oxygen concentration as indicated here is a calculated value, not based on oxygen concentration FiO2 measured with oxygen concentration sensor, but based on the flow rate of inhaled air and output air sum as measured.

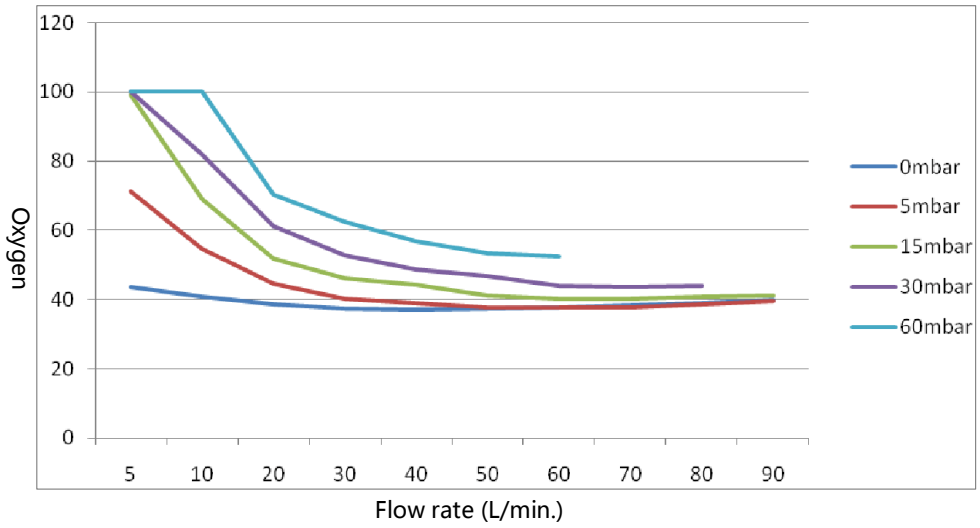



FIGURE 44 Minimum Oxygen Concentration

# 12 EMC

## 12.1 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) (GB4824) | 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) (GB4824) | Category B | T5 is applicable in all facilities, including domestic and public LV power supply network directly connected to house. |
| Harmonic wave radiation (GB 17625.1) | Category A | |
| Voltage fluctuation and flicker emission (GB 17625.2) | Acceptable | |

## 12.2 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 (GB/T 17626.2) | Contact discharge: ±8kV Air discharge: ±15kV | Contact discharge: ±8kV Air discharge: ±15kV | The ground shall be of wood, concrete or ceramics. In case of composite |

| | | | |
|---|---|---|---|
| | | | paving material, the relative humidity shall be at least 30%. |
| EFT (GB/T 17626.4) | To power cable: ±2kV<br>To long I/O cable: ±1kV | To power cable: ±2kV<br>To long I/O cable: ±1kV | Power supply grade shall be minimally the grade for typical commercial or medical environment. |
| Surging (GB/T 17626.5) | DM: ±1kV<br>CM: ±2kV | DM: ±1kV<br>CM: ±2kV | |
| Power frequency magnetic field (50/60Hz) (GB/T 17626.8) | 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 (GB/T 17626.11) | ＜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 power outage. |
| | 40%UT(60% fall, UT), 5 cycles; | 40%UT(60% fall, UT), 5 cycles; | |
| | 70%U T (30% fall, U T ), 25 cycles;<br>＜5% UT(＞95% fall, UT), 5s; | 70%U T (30% fall, U T ), 25 cycles;<br>＜5% UT(＞95% fall, UT), 5s; | |

# 12.3 Guide and Manufacturer Statement – EMI

| **Guide and Manufacturer Statement - EMI** | | | |
|---|---|---|---|
| T5 Emergency 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 GB/T 17626.6 | 3 V (effective value) 150 kHz~80 MHz (except ISM bandsa) | 3V (effective value) | Any portable or mobile radio frequency communication equipment shall not be used in a distance closer to any part of T5 Emergency Ventilator (including cable) than as recommended. Such distance is determined based on a formula related to transmitter frequency.<br>Recommended Distance<br>$d = \left[\frac{3.5}{V1}\right]\sqrt{P}$<br>$d = \left[\frac{12}{V2}\right]\sqrt{P}$<br>$d = \left[\frac{12}{E1}\right]\sqrt{P}$ 80 MHz~800 MHz<br>$d = \left[\frac{23}{E1}\right]\sqrt{P}$ 800 MHz~2.5 GHz<br>**where,**<br>$P$ : the maximum rated output power (in Watt) of transmitter provided by its manufacturer;<br>$d$: the recommended distance (in meter)[b].<br>The field strength of fixed radio frequency transmitter is determined based on the survey at EMI location[c], and each frequency range should be lower than Compliance Level[d].<br>**Interference may occurs near the equipment attached with the following signs.** |
| Radio frequency radiation GB/T 17626.3 | 10V (effective value) 150kHz~80MHz (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 Ventilator is located is higher than the aforesaid applicable radio frequency compliance level, then T5 Emergency 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 Ventilator.

d) Throughout the frequency range of 150kHz~80MHz, the field strength should be lower than 3V/m.

## 12.4 Recommended isolation distance

| **Recommended distance between portable and mobile RF communication equipment and T5 Emergency Ventilator** | | | | |
|---|---|---|---|---|
| T5 Emergency 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 Ventilator as recommended below. | | | | |
| Max. Output | Distance (m) for Transmitters of Various Frequencies | | | |
| | 150 kHz~80 | 150 kHz~80 | 80 MHz ~ | 800 |

| Power of Transmitter (W) | MHz (except ISM bands) d = $1.17\sqrt{P}$ | MHz (ISM bands) d = $1.2\sqrt{P}$ | 800 MHz d = $0.4\sqrt{P}$ | 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.

## 12.5 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 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.**

## 12.6 Basic EMC Properties of T5 Emergency Ventilator

| **Basic EMC Properties of T5 Emergency Ventilator** | |
|---|---|
| T5 Emergency 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 Ventilator, and ensure accuracy of the following parameters in EMC environment instructed for T5 Emergency Ventilator. | |
| I/E | Adjustable between 9:1 and 1:9 with allowance of ±15% |
| Ventilation rate per min. (MV) | 1~45L/min. with allowance of ±0.5L/min or ±20%, whichever is the larger |
| Airway pressure monitoring | -20~100cmH20 with allowance of ±2cmH20 or ±15%, whichever is the larger |
| Activation pressure | -20~20cmH20 with allowance of ±1cmH20 or ±15%, whichever is the larger |
| **Parameters of EMC Cable Material** | |
| Adapter input power cable | 0.8±0.01m |
| Adapter output power cable | 1.45+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.

# 13 Warranty

1. Within two years of purchase, any quality defect occurring in proper operation pursuant to this manual will be subject to Amoul's repair service free of charge. If the shelf life as labeled on the product is less than two years, this warranty will become invalid with expiration of such shelf life.
2. Upon request for repair service, a certificate of purchase attached with name of the seller and date of purchase must be provided.
3. This warranty becomes invalid in one of the following cases:

- Failure to observe related instructions
- Improper operation
- Improper use or handling
- Repair on the equipment by any unauthorized personnel
- Occurrence of force majeure, such as lightning stroke
- Damage during delivery to the manufacture resulted from improper packaging
- Poor maintenance
- Wear resulted from excessive use or normal wear; parts to which this item is applicable include:
- Filter
- Battery
- disposable article
- use of any spare part other than recommended.

4. Amoul will not be responsible for any damage not resulted from intentional or gross negligence and body injury caused by minor fault.
5. Amoul will take no responsibility for any problem arising after service life of this product has expired.
6. Amoul reserves the right to remove any defect, supply deficiency-free goods or properly reduce purchase price at its own discretion.
7. In case that any request for repair service is rejected, the freight shall not be at Amoul's cost.
8. Any statutory warranty shall be exempt of the aforesaid restrictions.

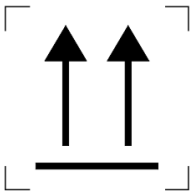
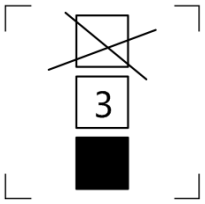
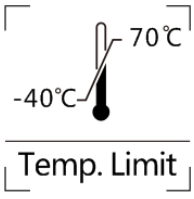
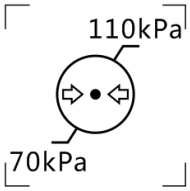
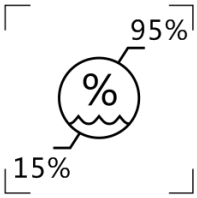
# 14 Classification of Toxic/Harmful Substances

| Name & Content of Toxic/Harmful Substances | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Name of Part** | | **Cadmium (Cd)** | **Mercury (Hg)** | **Lead (Pb)** | **Hexavalent Chrome (Cr-VI)** | **PBB** | **PBDE** |
| Display Screen | | × | × | × | × | × | × |
| Lithium Battery | | × | × | × | × | × | × |
| Main Unit of Anaesthesia Breathing System | | ○ | ○ | × | × | ○ | ○ |
| Packing Material | | ○ | × | × | ○ | × | × |
| Main Unit | PCBA | ○ | ○ | × | ○ | ○ | ○ |
| | Interior Connecting Wires | ○ | ○ | ○ | ○ | ○ | ○ |
| | Machined Parts | ○ | ○ | ○ | × | ○ | ○ |
| Enclosure | Button | ○ | ○ | ○ | ○ | ○ | ○ |
| | Label | ○ | ○ | ○ | ○ | ○ | ○ |
| | Front Cover | ○ | ○ | ○ | ○ | ○ | ○ |
| | Rear Cover | ○ | ○ | ○ | ○ | ○ | ○ |
| Accessories | Air Hose | ○ | ○ | ○ | ○ | ○ | ○ |
| | Mask | ○ | ○ | ○ | ○ | ○ | ○ |
| | Corrugated Tube Assembly | ○ | ○ | ○ | ○ | ○ | ○ |
| | Air Source Hose Assembly | ○ | ○ | ○ | ○ | ○ | ○ |
| | Reservoir Bag | ○ | ○ | ○ | ○ | ○ | ○ |
| | Power Cable | ○ | ○ | ○ | ○ | ○ | ○ |
| | Connectors | ○ | ○ | ○ | × | ○ | ○ |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Vaporizer | ○ | ○ | × | ○ | ○ | ○ |
| | Jinn Bottle | ○ | ○ | ○ | ○ | ○ | ○ |
| | Steel Cylinder | ○ | × | × | ○ | ○ | ○ |
| | Flow Rate Sensor | ○ | ○ | ○ | ○ | ○ | ○ |
| | Oxygen Sensor | ○ | ○ | × | ○ | ○ | ○ |
| | CO2 Monitor | ○ | ○ | × | ○ | ○ | ○ |
| ×：means that content of the harmful substance or element in at least one homogeneous material composing related part exceeds the limit as stipulated in SJ/T11363-2006.<br>○：means that the content of the harmful substance or element in all homogeneous material composing related part is within the limit as stipulated in SJ/T11363-2006. | | | | | | | |

# 15 Storage and Transport

The packaged product can be transported on road, by air or by train. Impact, extreme vibration and humidity shall be prevented during transportation.

| Graphics | DESCRIPTION | Graphics | DESCRIPTION |
|---|---|---|---|
|  | This way up |  | Handle with care |
|  | Keep dry |   | Stacking limit：3 |
|   | Temp.Limit：-40~70℃ | | |
|   | Pressure range：70kPa~110kPa | | |
|   | Humidity range：15%~95% Non-condensing | | |

**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.

# 16 Transient operating conditions

the Ventilator shall comply with its specifications and all the requirements of IEC60601-1-12 when operated in NORMAL USE for a period not less than 20 min under the following environmental operating conditions:

– a temperature range of - 20 °C to + 50 °C;

– a relative humidity range of 15 % to 90 %, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa.

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