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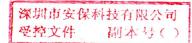
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# **177** User's Manual Emergency and Transport Ventilator



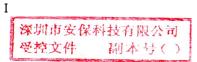
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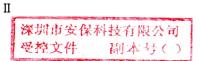
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#### **Product Information**

Thank you for purchasing T7 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 : T7

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

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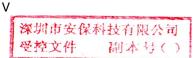
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#### Statement

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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 :

- any component is dismantled, expanded or re-adjusted;
- 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:
- 1. Damage caused by personal fault;
- 2. Improper use;
- 3. Grid voltage beyond the limits;
- 4. Irresistible natural disaster;
- 5. Use of spare part/ consumables not approved or machine service performed by personal not authorized by Ambulanc.



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 Town, Baoan District, Shenzhen 518108, China

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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:



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



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.

# Marning :

- 【After the training】 You can operate T7 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 T7 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.
- T7 can be used for the intended purpose (refer to Section 2.1 Purpose

for more details).

- 【Hyperbaric chamber】 Do not use T7 in hyperbaric application (hyperbaric chamber).
- 【Danger】 Do not use T7 in any explosive or toxic environment.
- [Fire] Do not use T7 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 T7.



- **[**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 T7 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 T7 is used in an uninterrupted way for a long time), please do not use any external power supply; instead, please give priority to power T7 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 T7 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



- 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 T7 alarms in low battery, please make any of the following operations:

- Replace battery by fully charged battery.
- Connect T7 with external T7 power supply.

### Attention :

[Keep battery installation] In order to enable T7 to make sustainable operation, it is advised to always install fully charged battery (even though when T7 is powered by external power supply).

#### 1.9 Symbols that

Description ICONS and symbols

SYMB	OL DESCRIPTION	SYMBO	L DESCRIPTION
Ŵ	Refer to the document		Refer to the document
	attached for more details		attached/manual
$\sim$	Date of production	Ť	BF type applications
IPX4	Waterproof level	X	Do not reject into
		_	dustbin
©/Ô	Main Unit Switch	(((•)))	Non-ionizing radiation
	. Power supply by adapter	<b>(</b> + –)	Power supply by
			battery
	menu	À	Alarm mute
₽\₽	Lock/unlock	CPR	cardiopulmonary
_,_			resuscitation ( CPR )
÷	Air inlet	$\bigcirc$	PEEP control
100%	Battery level indication		Adapter off
	Emergency ventilation		Emergency ventilation
	mode - Infants		mode -Children

**Emergency ventilation** mode - Adults



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#### 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 T7 ventilator is intended to provide continuous ventilation for patients with weight greater than 2kg (infants, children, adults) who require invasive or non-invasive respiratory support, with a tidal volume greater than 20ml. The T7 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.

# Marning :

T7 is suitable for patient' s tidal volume more than 20ml, offering A/C, invasive and noninvasive ventilation support.

# 2.3 Scope of Application

T7 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 T7 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 T7 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

T7 Emergency Ventilator The main composition of

consists of a main unit, respiratory hose and its accessories, and rechargeable lithium battery.

All components necessary for T7 operating as a ventilation system have been designed by Amoul.

### 2.6 Main Unit

T7 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 machine has control modes of volume-controlled ventilation, pressure-controlled ventilation, noninvasive ventilation, advanced ventilation and recovery ventilation.
- This machine has two trigger methods of flow trigger and pressure trigger.
- This equipment provides electronic PEEP function.
- This machine has 17 optional breathing modes (IPPV, V-AC, V-SIMV,

PRVC, PRVC+,PCV, P-AC, P-SIMV, CPAP, CPAP+, BiPPV, BiPPV+, APRV, APRV+, CPR, RSA, HFNC), to adapt to the breathing of patients under different conditions.

- This machine can adjust the oxygen concentration and the adjustable resolution of oxygen concentration is 10%.
- The large 7" screen provided for the equipment displays patient's breathing parameters and pressure curve.

**Oscillogram :** Paw, Flow, Volume and ETCO<sub>2</sub>, respectively (cannot be used until it is connected to ETCO<sub>2</sub> module).

Doughnut : P-V, F-V, P-F, respectively.

- This machine is also equipped with the touch-screen functionality which allows control on the machine by touch.
- This machine has 3 emergency ventilation modes (adults, children and infants) for users to quickly choose in case of emergency.
- This machine can be connected to an external mainstream ETCO<sub>2</sub> module to monitor end-expiratory CO<sub>2</sub> of patients in real time.

# 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 :

high-precision control on positive end-expiratory pressure and continuous positive airway pressure.

• Flow sensor :

monitor the respiratory flow and control the respiratory trigger.

# 2.8 T7 Main Unit instruction

#### 2.8.1 Main Unit-Front View

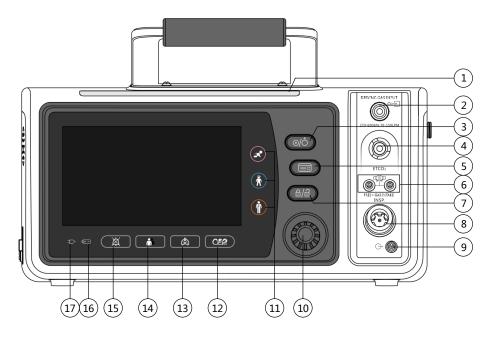
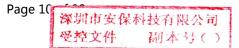


FIGURE 1 Main Unit (Front View)

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 O2 source interface	For connection to O2 source.
3 Start/Shut Down button	Press it to start. ,Long press it for 3 seconds to shut down the equipment.
4 ETCO2 interface	Connecting the ETCO2 module
5 Main menu button	Press it to access main menu, which contains time, system, calibration and record settings and system information.
6 Flow sensor interface	The white interface is on the left while the blue interface is on the right. They are respectively connected to the transparent tube and the blue tube of the flow sensor on the respiratory tube.



7 Screen locking button	It is used to lock the touch screen, and if this button is pressed when the touch screen is activated, the touch screen will be banned from use. Conversely, press this button, and the touch screen will be activated.
8 fresh air outlet	For connection of respiration hose to patient.
9 PEEP air supply port	For connection of white hose in respiration hose loop.
10 Navigation knob	Used to access various operation interfaces as shown below: 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.
11 Indicator light of the emergency ventilation mode	The indicator light will light up when corresponding emergency ventilation mode is currently used.
12 CPR	Is used in cardiopulmonary resuscitation operation procedure in emergency treatment.
13 Ventilation parameter setting button	It is used to quickly enter into or exit from the ventilation parameter setting interface.
14 Emergency mode selection button	It is used to call out the three emergency ventilation modes for further selection. Infants ventilation mode (about 5 kg) Children ventilation mode for (about 25 kg) Adults ventilation mode for (about 50 kg)
15 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.
16 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.
17 Indicator of external power supply	The indicator will be normally on when T7 connects to power adapter. Tips: When the respirator is switched from external power supply to internal power supply, the respirator is still normally working.

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### 2.8.2 Main Unit-Rear View

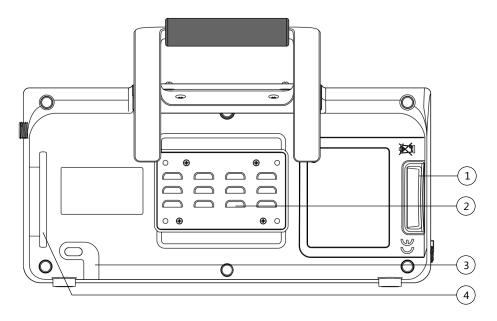
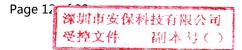


FIGURE 2 Main Unit ( Rear View )

PARTS	DESCRIPTION
1 Rechargeable battery	External 7800mAh high capacity rechargeable battery.
2 Radiating panel	It is used for radiating host, which must not be blocked.
3 Safety valve air outlet	Shall not be blocked.



4 Air intake	Air inlet and safety valve outlet, which shall
	not be blocked.

#### 2.8.3 Main Unit-Left View

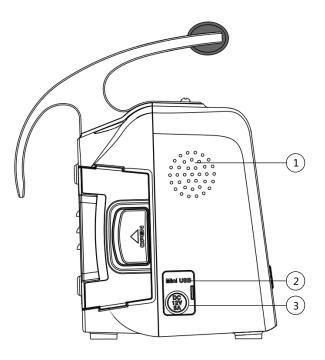
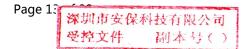


FIGURE 3 Main Unit (Left View)

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.



### 2.8.4 Wain Unit-Right View

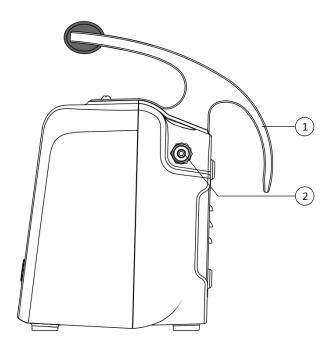


FIGURE 4 Main Unit (Right View)

PARTS	DESCRIPTION		
1 Hook width	36mm.		
2 O2 source interface	For connection to O2 source.		

# **3** Interface description

## 3.1 Main interface components

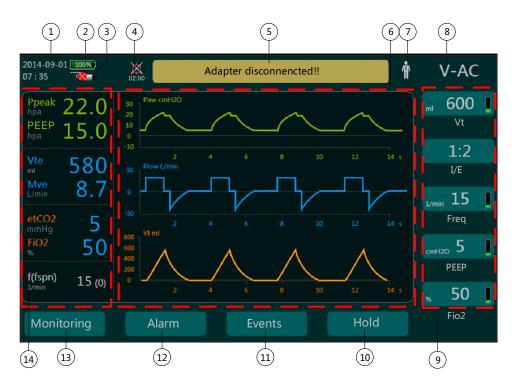


FIGURE 5 Main interface

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 displaying of the current breath parameters through the Oscillogram or Doughnut.

	Oscillogram: Respectively are Paw、Flow、
	Volume、ETCO2 etc. Doughnut: Respectively are P-V、F-V、P-F etc.
7 Emergency ventilation mode icon	Real-time displaying of the current emergency ventilation mode.
8 Ventilation modes	Displays current mode, and enables mode selection page for mode selection.
9 Setting of main ventilation parameters	When selected, the parameter value set in the current mode can be adjusted through the navigation rotary knob.
10 Кеер	Use it to maintain inhalation or exhalation process.
11 Logs	Use it to access system logs.
12 Alarm limit	When selected, the alarm limit interface can be called out.
13 Monitoring	When selected, the monitoring content selecting interface can be called out. Oscillogram, Doughnut, respiratory mechanics, trend graph and son on are optional.
14 Real-time parameter monitoring	It can display the breath parameters of the ventilator obtained by real-time measurement.



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 Alarm	Set alarm volume and mode.
2 System	Set screen brightness, unit, desktop style, waveform style, voice, waveform content and cycle graph content.
3 Time	Set system time in the equipment.
4 Tendency	Set tendency graph or view tendency data and waveform.
5 Maintain	Calibrate the equipment and view equipment version and configuration.
6 Configuration	Configure pressure control and volume control.
7 About Host	View master software version number, control software version number and power board software version number.

#### 3.2.1 Setting Alarm Volume

You can set alarm volume and mode as required (as shown below).

The setting procedure is given below.

- 1. Select <Alarm> button by using the navigation knob to pop up alarm setting window.
- 2. Select the tab which you want to modify by pressing navigation knob or directly clicking on it.
- 3. Modify the selected tab and press navigation knob again to confirm the modification.
- 4. Modify any other setting by repeating Steps 2 and 3.
- 5. Click Save button to apply the modification; Press or touch "X" button, or press Main Menu button to exit from main menu and cancel parameter modification.

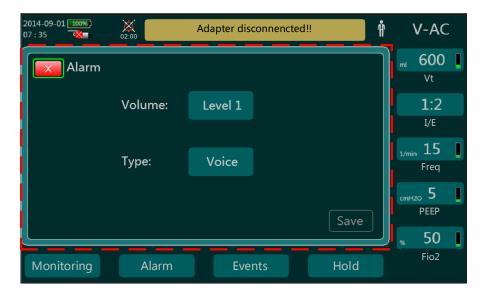


FIGURE 8 Alarm Volume

PARTS	DESCRIPTION
1 Volume	By default three levels are available. The available options are: shut down, Level 1, Level 2, and Level 3.
2 Туре	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).

#### 3.2.2 System Settings

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



FIGURE 9 System Settings

PARTS	DESCRIPTION
1 Brightness	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.
6 Wave Form	P+F+V、P+F+C、P+V+C、P+F。
7 Cycle Graph	(P-V)+(F-V), (P-V)+(P-F), (F-V)+ (P-F).

#### 3.2.3 time setting

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

2014-09-01 07 : 01		00	Adapter	disconner	ncted!!		IPPV
	Time						m 220 ∎ ∨t
	2017		2		21		1:2
	Year		Month		Day		I/E
							1/min 15 🚦
	9		3		38		Freq
	Hour		Minute		Second		<sub>mbar</sub> 5
					Save	•	PEEP
							<sub>%</sub> 40
Moni	toring	Alarm	η [	Events	Hold	I	Fio2

FIGURE 10 Time Settings

#### 3.2.4 Tendency

In main menu page, select <Tendency> button to enter tendency page (as shown below).

In the page you can set tendency chart or view tendency data and waveform.

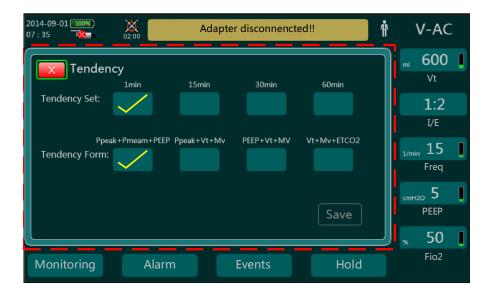


FIGURE 11 Tendency

#### 3.2.5 Maintain

In main menu page, select <Maintenance> button to enter maintenance page to calibrate and configure settings (as shown below).

2014-09-01 100%) X 02:00	Adapter disconnencted!!	∯ V-AC
Maintain		600 ∎ 
	Calibration	1:2
	Config	I/E
	Coning	1/min 15
		стн20 <b>5</b>
Monitoring A	larm Events Hold	Fio2

FIGURE 12 Maintain

PARTS	DESCRIPTION			
1 Calibration	Use it to calibrate air proportional valve 1, oxygen proportional valve 1, patient-side bi-directional film sensor, peep proportional valve, air proportional valve 2, oxygen proportional valve 2.			
2 Configuration	Use it to view or activate equipment configuration.			
Access authorization: When access to the operation interface is				

restricted, the manufacturer or its authorized professionals must enter the password for access.

#### 3.2.6 Configuration

In main menu page, select <Configuration> button to enter configuration page (as shown below).

2014-09-0 07 : 35	1 100%)	02:00	Adapter disconnencted!!				V-AC	
	Config	guration				י	h 600 Vt	
Vc C	onfig:	Ppeak	Pmean	PEEP	Pplat		1:2	
	J	Vti	Vte	Mvi	Mve		I/E	
Pc C	onfig:	$\checkmark$	$\checkmark$			1	<sub>/min</sub> 15 Freq	
							mH20 5	
					Save		PEEP	Π
Monit	toring	Aları	n	Events	Hold		Fio2	-

FIGURE 7 Configuration

#### 3.2.7 About Host

In main menu page, select <About Host> button to view software version (as shown below).



FIGURE 13 About Host

#### 3.3 Alarm Message

The Alarm Prompt button in the main interface shows the current alarm message with the highest priority. If there are multiple alarms, You can access alarm message by pressing alarm indication button in main interface (As shown below).

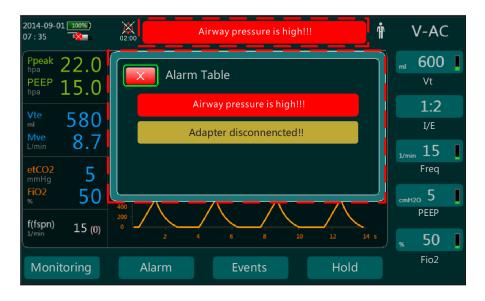


FIGURE 14 Alarm Message

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:

Туре	LCD	LED	Voice alarm	Remark
High-pri	The alarm	The red	1. Five consecutive	The form of
ority	zone in the	light	beep sounds:	voice alarm
alarm	main	blinks	"Beepbeepbee	depends on
	interface	Blinking	pbeep-beep-";	the setting of
	changes to	frequency:	pulse interval time:	alarm type.
	red and	0.5s/time	0.1s 0.1s 0.5s 0.1s ;	See "3.2.2
	shows the		pulse duration:	Data
	correspondi		0.2s; pulse train	Management
	ng alarm		interval time: 7s;	Function,
	text plus !!!		2. Voice prompt	Alarm
				Setting"

#### • Priority :

Medium-	The alarm	The	1. Three	The form of
priority	zone in the	yellow	consecutive beep	voice alarm
alarm	main	light	sounds:	depends on
	interface	blinks	"Beepbeepbee	the setting of
	changes to	Blinking	p"; pulse interval	alarm type.
	red and	frequency:	time:  0.1s 0.1s ;	See "3.2.2
	shows the	2s/time	pulse duration:	Data
	correspondi		0.1s; pulse train	Management
	ng alarm		interval time: 24s;	Function,
	text plus !!		2. Voice prompt	Alarm
				Setting"

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

No.	Name	Level	Condition	Remark
1	High airway	High-level	Airway pressure is	Physiological
	pressure	alarm	above upper threshold	alarm
2	Low airway	High-level	Airway pressure is	Physiological
	pressure	alarm	below lower threshold	alarm
3	High minute ventilation	High-level alarm	Minute ventilation is above upper threshold	Physiological alarm
4	Low minute ventilation	High-level alarm	Minute ventilation is below lower threshold	Physiological alarm
5	Patient apnea	High-level alarm	Patient apnea time is above upper threshold	Physiological alarm
6	Device fault	High-level alarm	The device is faulted	High-level alarm
7	High FiO2	High-level alarm	FiO2 is above upper threshold	Physiological alarm
8	Low FiO2	High-level alarm	FiO2 is below lower threshold	Physiological alarm
9	Breathing hose disconnected	High-level alarm	Breathing hose disconnected	Medium-leve I alarm
10	Check flow sensor	High-level alarm	Flow sensor fault	Medium-leve I alarm
11	High PEEP	High-level alarm	PEEP is above upper threshold	Physiological alarm

12	No gas	High-level	No gas supply	Medium-leve
	supply	alarm	pressure	l alarm
	pressure	alann	pressure	1 alaitti
13		High loval	Gas supply pressure is	Medium-leve
15	High gas	High-level alarm		l alarm
	supply	alarin	above upper threshold	I didffff
1.4	pressure			Dhunialaniaal
14	High EtCO2	High-level	EtCO2 is above upper	Physiological
		alarm	threshold	alarm
15	Low EtCO2	High-level	EtCO2 is below lower	Physiological
		alarm	threshold	alarm
16	Battery level	High-level	Battery level is lower	Technical
	is too low	alarm	than 0%	alarm
17	Insufficient	Medium-	Gas supply pressure is	Technical
	gas supply	level alarm	below lower	alarm
	pressure		threshold	
18	Low Vt	Medium-	Tidal volume is below	Physiological
		level alarm	lower threshold	alarm
19	High	Medium-	Respiratory	Physiological
	respiratory	level alarm	frequency is above	alarm
	frequency		upper threshold	
20	Low	Medium-	Respiratory	Physiological
	respiratory	level alarm	frequency is below	alarm
	frequency		lower threshold	
21	Gas leak	Medium-	Breathing hose leaks	Physiological
		level alarm	_	alarm
22	Low battery	Medium-	Battery level is lower	Technical
		level alarm	than 20%	alarm
23	Adapter	Medium-	The power adapter is	Technical
	disconnected	level alarm	disconnected	alarm
24	Vt is unable	Medium-	Vt is unable to reach	Technical
	to reach	level alarm		alarm
25	Inversion of	Medium-	Inversion of flow	Technical
	flow sensor	level alarm	sensor	alarm
L				

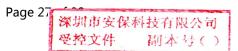
• Voice alarm: In actual sound alarms, either voice alarm or buzzer alarm can be selected.

No.	Voice prompt	Meaning	Level
1	Check the airway to eliminate airway obstruction	High airway pressure	High-level alarm
2	Check the airway to eliminate tube disconnection	Low airway pressure	High-level alarm
3	Check the airway to eliminate excessive ventilation	High minute ventilation	High-level alarm
4	Check the airway to eliminate inadequate ventilation	Low minute ventilation	High-level alarm
5	Check the patient's condition to eliminate apnea of the patient	Patient apnea	High-level alarm
6	Device fault	Device fault	High-level alarm
7	High oxygen percent	High oxygen percent	High-level alarm
8	Low oxygen percent	Low oxygen percent	High-level alarm
9	Breathing hose disconnected	Breathing hose disconnected	High-level alarm
10	Check flow sensor	Check flow sensor	High-level alarm
11	High PEEP	High PEEP	High-level alarm
12	No gas supply pressure	No gas supply pressure	High-level alarm
13	Check the patient's condition to eliminate carbon dioxide retention	High EtCO2	High-level alarm
14	Check the patient's condition to eliminate patient oxygenation	Low EtCO2	High-level alarm
15	Battery level is too low. Please replace the battery	Battery level is too low	High-level alarm

16	Check the gas supply	Insufficient gas	Medium-leve
	condition to eliminate	supply pressure	l alarm
	insufficiency of gas supply		
	pressure		
17	High Vt	High Vt	Medium-leve
			l alarm
18	Check the mask wearing	Low Vt	Medium-leve
	condition to eliminate		l alarm
	ventilation leakage		
19	Check the patient's	High respiratory	Medium-leve
	condition to eliminate rapid	frequency	l alarm
	shallow breathing of the		
	patient		
20	Low respiratory frequency	Low respiratory	Medium-leve
		frequency	l alarm
21	Check the state of	Gas leak	Medium-leve
	connection between tube		l alarm
	and mask		
22	Battery level is too low.	Battery level is too	Medium-leve
	Please charge in time	low	l alarm
23	Device fault. Check the	Adapter	Medium-leve
	power supply condition of	disconnected	l alarm
	the adapter		
24	Vt is unable to reach	Vt is unable to reach	Medium-leve
			l alarm
25	Inversion of flow sensor	Inversion of flow	Medium-leve
		sensor	l alarm

### • Multiple alarms:

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



	priority; the alarm interface shows all alarm messages	2s/time	alarms, alarms will be given according to the medium-priority "beep-beep-beep" alarm type
High- and medium-lev 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: 0.5s/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	When an alarm is triggered, there will	
response	be corresponding LCD, LED and voice	
	responses.	
Alarm	If the alarm condition is false, the	
lifting	alarm will be lifted and alarm	
	response ceased.	
Alarm	Press the Mute key to turn on or off	The alarm muting time
muting	the sound. During the period when	is 120s; after pressing
	an alarm is muted, if a new alarm is	the Mute key, the 120s
	triggered, the alarm sound will be	sound will be turned
	turned on again .	off. If the alarm still
		exists 120s later, the
		sound will be turned
		on again.

## 3.4 Review Logs

This system provides the log function. You can click the Log button in the main interface to enter the Log interface to view system logs, (As shown below).



FIGURE 15 Review Logs

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

- Log message structure: time + type + content of message.
- Log time: the time of recording the log.
- Log type: alarm message, user access message, and system operation message. (for the time being only alarm message is available)
- Log message: specific message description.
- Log 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 16 Alarm Limits

PARTS	DESCRIPTION
1 Upper limit of airway pressure	Default: 60 mbar. Adjustable range: 15-70 mbar; step size: 1.
2 Lower limit of airway pressure	Default: 1 mbar. Adjustable range: 0-60 mbar; step size: 1.
3 Upper limit of minute ventilation	Default: 110 L/min. Adjustable range: 1-120 L/min; step size: 1.
4 Lower limit of minute ventilation	Default: 36 L/min. Adjustable range: 0-119 L/min; step size: 1.
5 Upper limit of respiratory frequency	Default: 24 1/min. Adjustable range: 10-125 1/min; step size: 1.
6 Lower limit of respiratory frequency	Default: 20 1/min. Adjustable range: 0-115 1/min; step size: 1.
7 Apnea time	Default: 20s. Adjustable range: 5-60s; step size: 1.
8 Upper limit of Vt	Default: 900 ml. Adjustable range:

50-3000ml; step size: 5.
Default: 300 ml. Adjustable range: 0-2400ml; step size: 5.
Default: 100 %. Adjustable range: 40-100 %; step size: 10.
Default: 0 %. Adjustable range: 18-90 %; step size: 10.
Default: 70 mmHg. Adjustable range: 1-150 mmHg; step size: 1.
Default: 0 mmHg. Adjustable range: 0-149 mmHg; step size: 1.
Range within 20% above/below monitored value.
-

# 4 Installation

### 4.1 Overview

Generally, T7 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 T7 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

T7 Emergency Ventilator is packaged in a single case. For details on packing list, refer to "10. T7 Supplies Configuration".

## 4.3 Install the battery

T7 is furnished with a rechargeable lithium battery. Mount the battery in and press it till it clacks to lock it in place (as shown below).

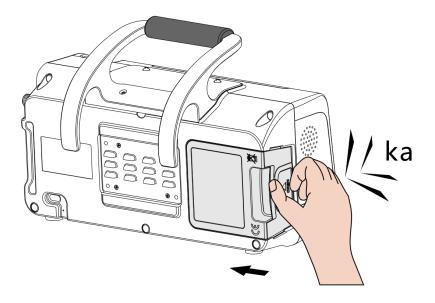


FIGURE 17 Install the battery

# 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 T7 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 T7.
- 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.

# Attention :

- Before connecting the gas supply equipment, please confirm that the patient is not connected with T7.
- Keep any human body away from the valve port to avoid injury caused by any object that may fly out of it!
- 2. Attach the pressure reducing valve onto the cylinder valve, and manually tighten the lock nut.
- 3. Screw the pressure hose with 9/16-18UNF tube connecting nut into the outlet of the pressure reducing valve.
- 4. Connect the other end of the pressure hose to the oxygen port 1 on T7.

## 4.7 Patient Respiratory Hose Assembly and Its

### Connection

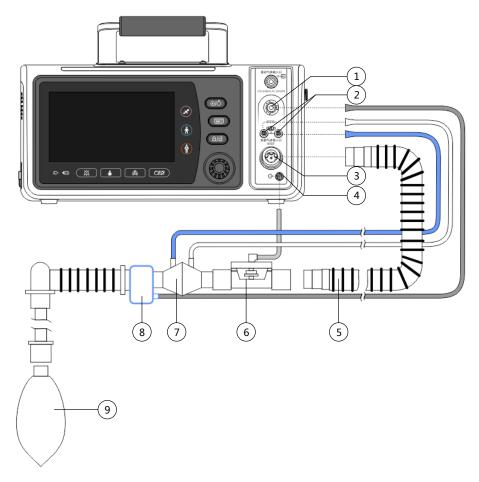
T7 provides a reusable or disposable respiration management assembly. The assembly will be connected to the respirator and related accessories in accordance with the following procedure(As shown below).

1. The breathing hose, patient breathing valve and flow sensor in the respiratory tube components are connected according to the figure below.

# Note :

The monitoring port to which the blue tube is connected should be positioned near the patient side.

- 2. Connect the transparent PU tube of the flow sensor to the white port on the main unit, and the blue PU tube to the blue port.
- 3. Connect the silicone tube of the patient breathing valve to the PEEP gas port on the main unit.
- 4. Insert the breathing hose to the inhalation port. Pay attention not to bend other gas tubes that have been connected.
- 5. As to connection among other fittings and how to connect to a patient, please see the "Diagram of tube fittings connection" below.
- 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 18 Accessories Connection Diagram

PARTS	PARTS
1 ETCO2 port	6 patient Valve
2 Flow sensor port	7 Flow sensor
3 fresh gas intake (to patient)	8 Mainstream CO2 module
	(used in optional
	configuration)
4 PEEP Port	9 simulative lung(patient)
5 Hose	

## 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

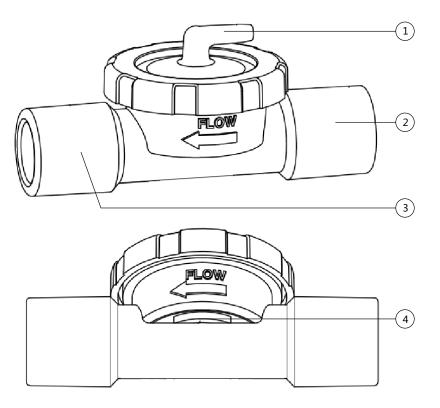


FIGURE 19 Patient Breathing Valve

PARTS	DESCRIPTION
1 PEEP air source port (self-reliant unit)	Connect to PEEP air supply port on main unit, Inner diameter Φ15mm.
2 Gas inlet (from the main u	<b>nit)</b> Φ15mm/22mm coaxial port.
3 Patient connection port (for connection of mask/ cannula)	Connect to the patient, Φ15mm/22mm coaxial port
4 Air outlet	Patient's expired air outlet, which shall not be blocked.

# Marning :

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).

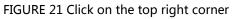
#### Tips :

To calibrate it subsequently, long press <Lock Screen> button upon start-up to enter touch screen calibration page.



FIGURE20 Click on the bottom left corner





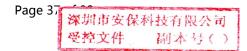




FIGURE 22 Click on any location

### 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.
- 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 T7. 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 23 Startup-Self-Checking

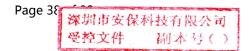




FIGURE 24 Error code

- 5. The main unit can work normally if the main display interface appears on the screen and there is no error message. At this moment, the ventilator will not execute any ventilation mode or ventilation parameters, but only pop up the "Urgent Ventilation Mode Select Box" for your choice.
- You can directly select it; then the ventilator will execute ventilation according to the default ventilation mode and ventilation parameters.
- Or, you can select <Ventilation Mode> and choose the desired ventilation mode in the pop-up drop-down menu. Then, the ventilator will automatically pop up the ventilation parameter setting window. After setting corresponding parameters, tap "Save". The ventilator will execute ventilation.

# The above operations will be described in detail in the subsequent sections.

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



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 Urgent Ventilation Mode

T7 provides 3 ventilation modes with preset respiratory parameters so that it can be used under circumstances requiring urgent ventilation. At any time during ventilation, you can press the <Urgent Ventilation Select Key> to call out the urgent ventilation mode interface, where you can choose from 3 ventilation modes(As shown below).



FIGURE 25 Choose patient type

PARTS	DESCRIPTION
1 Infant mode setting button	Press this button to select the Infant Urgent Ventilation Mode, and to exit the urgent ventilation interface, return to the main interface and switch the icon of urgent mode.
2 Child mode setting button	Press this button to select the Child Urgent Ventilation Mode, and to exit the urgent ventilation interface, return to the main interface and switch the icon of urgent mode.
3 Adult mode setting button	Press this button to select the Adult Urgent Ventilation Mode, and to exit the urgent ventilation interface, return to the main interface and switch the icon of urgent mode.

These three emergency ventilation modes are P-SMIV (for children), V-SMIV (for infant), V-SMIV (for adult), which are suitable respectively to patients of the following types.

- Infant (weight: about 5 kg)
- Child (weight: about 25kg)
- Adult (weight: about 50 kg)

Parameter	Adult	Child	Infant
pmax	30 mbar	25 mbar	20 mbar
I:E	1:1.7	1:1.7	1:1.7
Frequency	12/min	20/min	30/min
Vt	600 ml	250 ml	/
Pinsp	1	/	12 mbar
PEEP	0	0	0
FiO2	100%	100%	100%

### 5.4 Choose Ventilation Mode

T7 provides up to 17 ventilation modes for your choice. The following describes the ventilation modes in detail:

To choose a ventilation mode, you can simply select the <Ventilation Mode> button in the main interface to call out the Ventilation Mode drop-down box, and then choose the desired ventilation mode(As shown below).

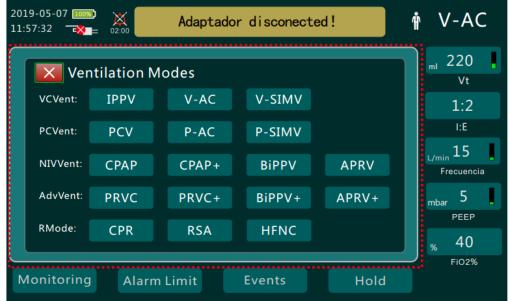


图 26 Choose Ventilation Mode

PARTS	DESCRIPTION	
1 IPPV	Intermittent positive pressure ventilation.	
2 V-AC	Assist-control ventilation in volume control mode.	
3 V-SIMV	Synchronized intermittent mandatory ventilation in volume control mode.	
4 PCV	Pressure controlled ventilation.	
5 P-AC	Assist-control ventilation in pressure control Mode.	
6 P-SIMV	Synchronized intermittent mandatory ventilation in pressure control mode.	
7 CPAP	Continuous positive airway pressure Ventilation.	
8 CPAP+	Continuous positive airway pressure ventilation with pressure support.	
9 BiPPV	Biphasic positive airway pressure / bilevel positive airway pressure ventilation.	
10 BiPPV+	Biphasic positive airway pressure / bilevel positive airway pressure ventilation with pressure support.	
11 APRV	Airway pressure release ventilation	
12 APRV+	Airway pressure release ventilation with pressure support	
13 PRVC	Ventilation in pressure-regulated volume control mode	
14 PRVC+	Ventilation in pressure-regulated volume control mode with pressure support	
15 CPR	Cardiopulmonary resuscitation	
16 RSA	Rapid sequence airway intubation	
17 HFNC	High flow oxygen therapy	

# 5.5 Set Ventilation Control Parameters

### 5.5.1 Set Ventilation Parameters

You can set the ventilation control parameters according to the physiological characteristics of the patient's breath. Here are the setting steps:

- 1. Press the <Main Menu Key> or touch the <Menu> button in the main interface to call out the main menu.
- 2. Use the navigation knob to select the <Ventilation> button; press the navigation knob to select it or directly touch the <Ventilation> button; then the ventilation setting interface will pop up.
- 3. Change the ventilation parameter value selected; press the navigation knob again for confirmation.
- 4. Repeat Steps 2 and 3 to change the parameter limits you want to change.
- 5. Select or touch the "x" button or press the <Main Menu Key> once again to exit the main menu.

You can set the following parameters (different ventilation parameters can be set under different ventilation modes):



FIGURE 27 Set Ventilation Parameters

You can set the following parameters (different ventilation parameters can be set under different ventilation modes):

Name	Adjustable range	
Oxygen percent	40~100%; step size: 10.	
Tidal volume	20~2500ml; minimum step size: 5.	
Inspiratory time	/	
I:E ratio	Default:1:1.7. Adjustable range: (1 : 59) ~ (1 : 99); minimum step size: 0.1.	
Respiratory rate	0 , 1~120bpm; minimum step size: 1.	
Trigger mode	OFF, Flow Trigger, Pressure Trigger	
Flow trigger	1~15L/min; step size: 1.	
Pressure trigger	-20 ~ +20 mbar; step size: 1.	
PEEP	0~30 mbar; step size: 1.	
Sigh period	50~100; step size: 10.	
Pinsp	3~60 mbar; step size: 1.	
Pressure rise time	0.1~2s; step size: 0.1.	
Expiratory trigger threshold	5~80%; step size: 5.	
Pressure support	0 , 3~35 mbar; step size: 1.	
Trigger window threshold	5~80%; step size: 5.	
High pressure time	0.2~60s; minimum step size: 0.1.	
Inspiratory pause time ratio	0~80%; step size: 5.	

Ventilation mode Parameter linkage relationship

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Target Parameter	Linkage parameters	Interdependence	
V <sub>T</sub>	Finsp	$Finsp = V_T / (T_i^* (1-T_p))$	
I:E VT	T <sub>i</sub>	$T_i = 60/Freq* (T_i/(T_i+T_e))$	
1.1.2 V 1	Finsp	$Finsp = V_T / (T_i^* (1-T_p))$	
Finsp	VT	$V_T = Finsp^* (T_i^* (1-T_p))$	
	Finsp	$Finsp = V_T / (T_i^* (1-T_p))$	
$T_i$	I:E	I:E VT = $T_i$ : (60/Freq- $T_i$ )	
	Ramp	$Ramp \le T_i$	
Ramp	T <sub>i</sub>	$T_i \ge Ramp$	
Tplat	Finsp	$Finsp = V_T / (T_i^* (1-Tplat))$	
Erog/E	Ti	$T_i = 60/Freq^* (T_i/(T_i+T_e))$	
Freq/F <sub>apnea</sub>	Finsp	$Finsp = V_T / (T_i^* (1-Tplat))$	
CPAP/PEEP	Pinsp	$P_{insp} > CPAP/PEEP+3cmH2O$	
P <sub>trg</sub>	CPAP/PEEP	$CPAP/PEEP < P_{trg}$	
P <sub>Supp</sub>	CPAP/PEEP	$P_{Supp}$ +CPAP/PEEP < Pmax-10cmH2O (V-SIMV)	
	CPAP/PEEP	$Pmax-10cmH2O > P_{insp}$	
$P_{insp}/P_{apnea}/P_{High}$	Pmax		

### 5.5.2 Setting of Key Ventilation Parameters

To facilitate operation and view, 5 key ventilation parameters are designed on the right side of the main interface(As shown below).

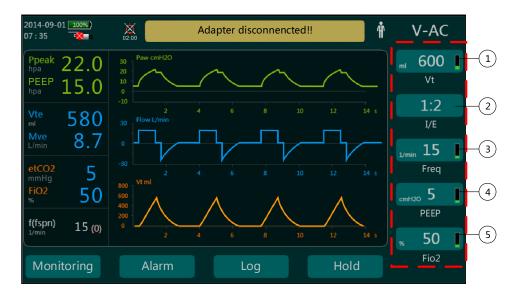


FIGURE 28 Setting of Key Ventilation Parameters

PARTS	PARTS	
1 Inspiratory pressure (tidal volume in volume control mode)		
2 I:E ratio	4 PEEP (or CPAP)	
3 Respiratory frequency	5 Oxygen percent	

### 5.5.3 Ventilation Parameters in Different Modes

Ventilation mode	Set parameters	
IPPV	Tidal volume / I:E ratio / Inspiratory flow rate / Inspiratory time / Inspiratory plateau time / Respiratory frequency / (CPAP/PEEP) / Oxygen percent	
V-A/C	Tidal volume / I:E ratio / Inspiratory flow rate / Inspiratory time / Inspiratory plateau time / Respiratory frequency / (CPAP/PEEP) / Oxygen percent / Sigh / Inspiratory trigger mode / Inspiratory trigger threshold	
V-SIMV	Tidal volume / I:E ratio / Inspiratory flow rate / Inspiratory time / Inspiratory plateau time / SIMV frequency / (CPAP/PEEP) / Oxygen percent / Sigh / Inspiratory trigger mode / Inspiratory trigger threshold / Expiratory switching sensitivity / Trigger window / Pressure support	
PRVC	Tidal volume / I:E ratio / Inspiratory time / Pressure rise time / Respiratory frequency / (CPAP/PEEP) / Oxygen percent	
PRVC+	Tidal volume / I:E ratio / Inspiratory time / Pressure rise time / Respiratory frequency / (CPAP/PEEP) / Oxygen percent / Sigh / Inspiratory trigger mode / Inspiratory trigger threshold / Expiratory switching sensitivity	
PCV	Inspiratory pressure / I:E ratio / Inspiratory time / Pressure rise time / Respiratory frequency / (CPAP/PEEP) / Oxygen percent	
P-A/C	Inspiratory pressure / I:E ratio / Inspiratory time / Pressure rise time / Respiratory frequency / (CPAP/PEEP) / Oxygen percent / Sigh / Inspiratory trigger mode / Inspiratory trigger threshold	
P-SIMV	Inspiratory pressure / I:E ratio / Inspiratory time / Pressure rise time / SIMV frequency / (CPAP/PEEP) / Oxygen percent / Sigh / Inspiratory trigger mode / Inspiratory trigger threshold / Expiratory switching sensitivity / Trigger window	

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	/ Pressure support		
CPAP	(CPAP/PEEP) / Oxygen percent		
CPAP+	Pressure support / Inspiratory trigger mode / Inspiratory		
	trigger threshold / Expiratory switching sensitivity /		
	(CPAP/PEEP) / Oxygen percent		
BiPPV	(CPAP/PEEP)/ Oxygen percent / Low pressure time / High pressure time / High airway pressure		
BiPPV+	Pressure support / Inspiratory trigger mode / Inspiratory trigger threshold / Expiratory switching sensitivity / (CPAP/PEEP) / Oxygen percent / Low pressure time / High pressure time / High airway pressure		
APRV	(CPAP/PEEP)/ Oxygen percent / Low pressure time / High pressure time / High airway pressure		
APRV+	Pressure support / Inspiratory trigger mode / Inspiratory trigger threshold / Expiratory switching sensitivity / (CPAP/PEEP) / Oxygen percent / Low pressure time / High pressure time / High airway pressure		
CPR	Tidal volume / Oxygen percent / Pause		
RSA	Displayed parameters: RSA stage / Oxygen uptake flow / Tidal volume / Gas supply frequency (Manual / Slow / Normal / Fast) / Preset mode		
	Oxygen uptake stage control parameter: Oxygen uptake flow		
	Intubation confirmation stage control parameters: Tidal volume / Gas supply frequency		
HFNC	Oxygen uptake flow / Oxygen percent		

# 5.6 Details on Ventilation Modes

T7 allows different ventilation modes based on patient's condition.

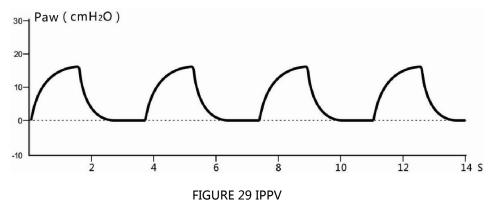
Remarks: The following modes(V-SIMV、P-SIMV、CPAP+、APRV+、BIPPV+、PRVC+) all have Pressure support(PSV) function, you can set support in these modes Some modes are not explained in detail , see the following modes for details.

### 5.6.1 IPPV and PVC

#### • Intermittent positive pressure ventilation: IPPV

During mechanical ventilation in IPPV (intermittent positive pressure ventilation) mode, the ventilator always intermittently gives positive pressure ventilation; during inspiration, the pressure rises, which is positive pressure; during expiration, the pressure returns to baseline pressure. It provides continuous respiratory support to a child patient with apnea or no breathing; every breath is compulsory. T7 supports volume controlled IPPV, which means the ventilator delivers gas of preset tidal volume to a child patient at a constant flow rate and the preset respiratory frequency within the preset inspiratory time. Such ventilation mode ensures that the patient can get a stable tidal volume, but the pressure is variable. Poor compliance or high airway resistance will result in high peak inspiratory pressure, while good compliance or low airway resistance will lead to low peak inspiratory pressure. The patient's tidal volume, I:E ratio and inspiratory flow rate are completely controlled by the ventilator; the inspiratory flow is fixed; the ventilator provides all work of breathing.

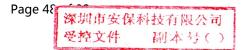
IPPV is also known as controlled mechanical ventilation (CMV). It is a ventilation technique widely used in clinical applications, mainly applying to patients with no spontaneous respiration. The ventilator provides intermittent positive pressure ventilation to the patient according to the preset ventilation parameters, despite the patient's condition of spontaneous respiration.



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

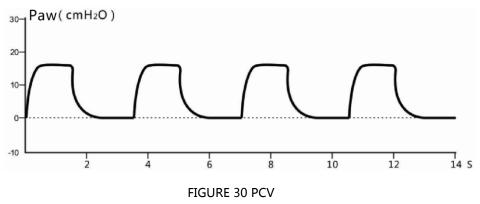
• Pressure controlled ventilation: PCV

Airway pressure and inspiratory time are preset for PCV (pressure controlled ventilation). Upon start of inspiration, the gas flow velocity increases rapidly; when the preset pressure level is reached, the gas flow velocity is reduced



through the feedback system; the preset pressure level is maintained till the end of inspiration; then expiration starts. Every ventilation is performed at full load completely according to the preset pressure. When PCV is used, the airway pressure decreases and there is no peak pressure and little barotrauma, which is good for inflation of alveoli featuring difficult filling, improves the ventilation-perfusion ratio and provides good gas exchange. PCV usually applies to neonates, infants and patients with respiratory failure caused by ARDS or COPD or with serious imbalance in ventilation-perfusion ratio. It can ensure the supply of tidal volume even when the breathing hose leaks. PCV should be selected in case of gas tube leakage.





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

#### • Controlled ventilation: CV

CV (controlled ventilation) is also known as mandatory ventilation. The ventilator executes ventilation at the preset frequency, regularly triggers inspiration and switches to expiration, and delivers the preset tidal volume or executes ventilation at the preset pressure; this means the ventilator completely replaces the patient's spontaneous respiration. The patient's respiratory mode (respiratory frequency, tidal volume, I:E time ratio and inspiratory flow rate) is completely controlled by the ventilator which also provides all work of breathing. Volume controlled ventilation (VCV) and pressure controlled ventilation (PCV) are available for selection.

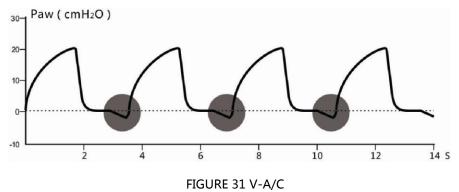
### Assisted ventilation: AV

AV (assisted ventilation) is triggered relying on the decrease of airway pressure (Pressure Trigger) or the change of flow rate (Flow Trigger) when the patient breathes in with force. After triggering, the ventilator delivers gas to the patient according to the preset tidal volume (or inspiratory pressure), frequency, inspiratory and expiratory time. Plainly speaking, gas supply by the ventilator is triggered by the patient; if the patient does not breathe in, the ventilator will not supply gas. It is patient-triggered; the parameter should be set to Flow Trigger or Pressure Trigger. Control and switch parameters are set in the same way as that for controlled ventilation.

• V-A/C

V-A/C is a volume controlled ventilation mode with VCV as the basic ventilation mode. At the expiration stage, it supports synchronous trigger; when the trigger pressure is reached, the ventilator will provide a VCV with fixed tidal volume in advance.

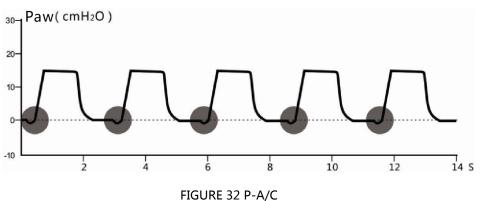




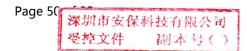
#### • P-A/C

P-A/C is a pressure controlled ventilation mode with PCV as the basic ventilation mode. At the expiration stage, it supports synchronous trigger; when the trigger pressure is reached, the ventilator will provide a PCV with fixed inspiratory pressure in advance.

#### A typical pressure waveform of P-A/C is shown below :



[Sigh] means a deep inspiration about twice the tidal volume will be performed every time the designed number of ventilations is reached, based on the specified ventilation frequency. It applies to patients requiring



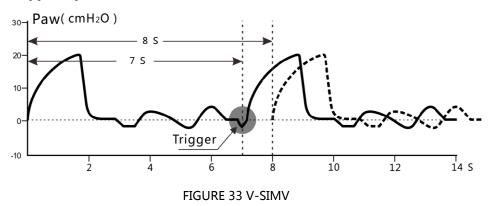
long-term mechanical ventilation.

### 5.6.3 V-SIMV and P-SIMV

#### Synchronized intermittent mandatory ventilation: SIMV

SIMV (synchronized intermittent mandatory ventilation) is a ventilation technique organically combining spontaneous respiration and IPPV, which ensures effective ventilation of the patient. There is no patient-ventilator asynchrony. Appropriate adjustment of the frequency and amount of SIMV will be good for the patient to exercise his/her respiratory function. Clinically, SIMV has become a necessary technique before ventilator weaning.

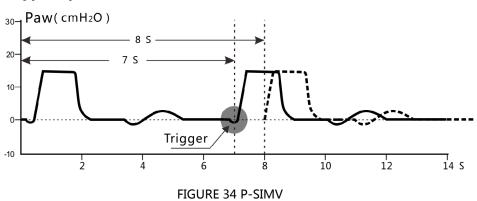
In V-SIMV (volume-limited synchronized intermittent mandatory ventilation) mode, the ventilator, during mechanical ventilation and within the specific trigger window, detects a child patient's inspiratory effort according to the trigger sensitivity, and immediately gives a mandatory ventilation at the preset tidal volume to enable synchronization between the delivery of mandatory ventilation and the patient's inspiratory effort. Within the trigger window period, if the patient is able to trigger the ventilator, an assisted ventilation will be given; if the patient still cannot successfully trigger the ventilator after the trigger window period, a mandatory ventilation will be given.





#### In P-SIMV (pressure-limited

synchronized intermittent mandatory ventilation) mode, the ventilator, during mechanical ventilation and within the specific trigger window, detects a child patient's inspiratory effort according to the trigger sensitivity, and immediately gives a mandatory ventilation at the preset tidal volume to enable synchronization between the delivery of mandatory ventilation and the patient's inspiratory effort. Within the trigger window period, if the patient is able to trigger the ventilator, an assisted ventilation will be given; if the patient still cannot successfully trigger the ventilator after the trigger window period, a mandatory ventilation will be given.



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

# WARNING :

When this mode is chosen, if the patient's condition is worsened, sudden stop of spontaneous respiration may result in hypoventilation or anoxia.

### 5.6.4 CPAP

For CPAP (continuous positive airway pressure), the ventilator is built in with a sensitive airway pressure measurement and adjustment system, which adjusts the positive pressure gas flow rate over time and maintains a constant airway pressure basically at the CPAP level.

CPAP is a ventilation mode that provides certain pressure level under the condition of spontaneous respiration to keep positive airway pressure in the whole respiratory cycle.

CPAP only provides certain constant pressure support, without assisted ventilation function. A patient's respiratory pattern, such as respiratory frequency, respiratory amplitude, respiratory flow rate and tidal volume, is completely controlled by the patient him/herself. Therefore, any patient using CPAP must have strong spontaneous respiration capability. When the patient exhibits apnea, T7 will automatically activate the backup ventilation mode.

A typical pressure waveform of CPAP is shown below :

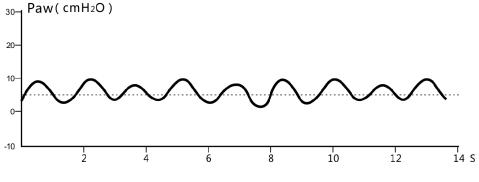


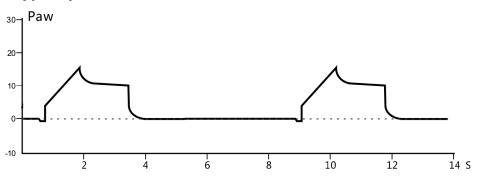
FIGURE 35 CPAP

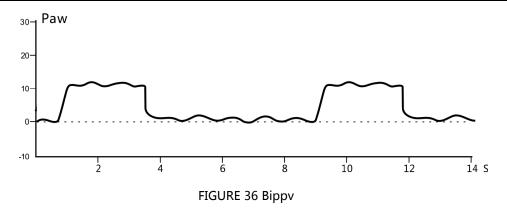
[Apnea Ventilation] : Also known as backup ventilation mode, which is activated when the system detects patient apnea in CPAP/BiLevel mode. In fact, it is a pressure controlled mode, a special P-A/C mode (I:E ratio is fixed to 1:2 and cannot be changed). Apnea Ventilation can be switched to a new ventilation mode only when a new ventilation mode command is received.

### 5.6.5 BiPPV/APRV

BiPPV stands for bilevel positive airway pressure ventilation. In this mode, the ventilator, during mechanical ventilation or spontaneous respiration, alternately gives two different levels of positive airway pressure; the patient can have spontaneous respiration at both pressure levels, and pressure support can be set at the low pressure stage. APRV is short for airway pressure release ventilation. It is similar to BiPPV, with the only difference that the duration of low pressure relief stage in APRV mode is shorter than the duration of high pressure ventilation.

#### A typical pressure waveform of BiPPV is shown below :

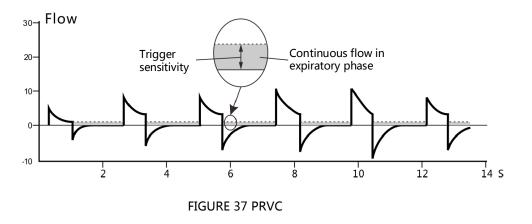




### 5.6.6 PRVC

PRVC mode implements volume control according to the pressure controlled ventilation mode. In this mode, low pressure level is maintained as much as possible at the inspiration stage; meanwhile, ventilation control with the gas supply volume equivalent to the preset tidal volume. The pressure control level changes with the setting of tidal volume and the change in resistance and compliance of the patient's lung. Every time the pressure is regulated, the increment will not exceed 3cmH2O; the maximum pressure will not exceed the upper limit of pressure alarm.

The initial ventilation in PRVC mode is trial ventilation, with the aim to calculate the compliance and resistance of the system and the patient's lung and then calculate the pressure level based on the patient's condition. In the subsequent ventilation period, this pressure level will be taken as the regulated object to control the tidal volume.



#### A typical pressure waveform of PRVC is shown below :

### 5.6.7 CPR

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** : Select CPR (as shown below), and a voice prompt "select operation mode" is given.

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

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

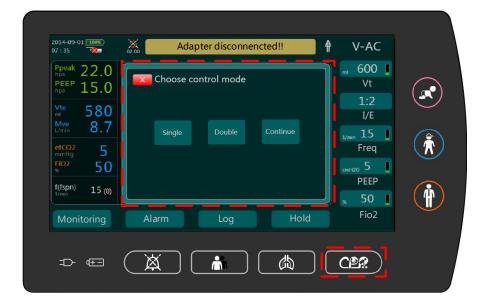


FIGURE 38 CPR(Choose control mode)

• **Secondly**: 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 ".





### 5.6.8 RSA

RSA is short for rapid sequence airway intubation. In this mode, support for the ventilation function is provided at each stage according to the conventional process of rapid sequence airway intubation. RSA consists of three stages: pre-oxygenation, tracheal cannula confirmation, and intubated ventilation.

- Pre-oxygenation stage: Provide a settable oxygen flow rate to completely replace the nitrogen of functional residual capacity, so as to buffer anoxia in apnea during intubation.
- Tracheal cannula confirmation stage: Provide support to the doctor in tracheal cannula confirmation at the set gas supply volume and the set or manual frequency.
- Intubated ventilation: Provide continuous ventilation assurance for the intubated patient according to the preset intubated ventilation mode.

After setting the RSA mode, first set the RSA parameters(As shown below).

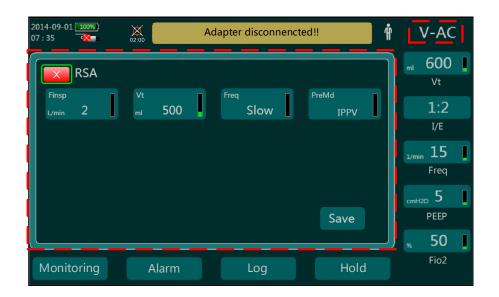
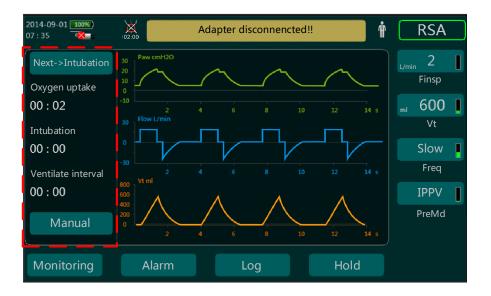


FIGURE 40 RSA

After parameter setting, enter the first stage of RSA, i.e., the pre-oxygenation stage, and meanwhile start oxygen uptake timing, as shown in the figure below :





When the pre-oxygenation stage is finished, tap the "Next->Intubation" button to enter the second stage of RSA, i.e., the tracheal cannula confirmation stage, and meanwhile start intubation timing. At this stage, if the respiratory frequency is set to manual frequency, you can tap the Manual button in the interface to enable manual ventilation, as shown in the figure below :





When the tracheal cannula confirmation is finished, tap the "Next->PreMode" button to enter the third stage of RSA, i.e., the intubated ventilation stage. The intubated ventilation mode is determined by setting the PreMode. Currently three intubated ventilation modes are available: IPPV, V-A/C and V-SIMV.

### 5.6.9 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. The HFNC mode interface is as follows :



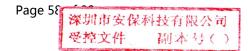


FIGURE 43 HFNC

# 5.7 Execution of Ventilation

### 5.7.1 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.

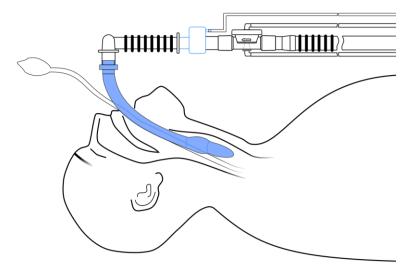


FIGURE 44 Intubation

### 5.7.2 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.

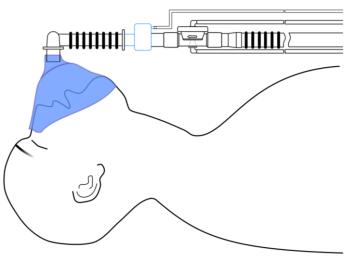


FIGURE 45 Respiratory mask

## 5.8 Monitoring of Respiration

### 5.8.1 Real-Time Ventilation Parameters

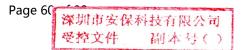


FIGURE 46 Ventilation Parameters

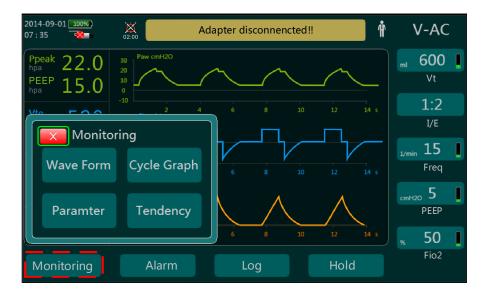
PARTS	PARTS	
1 Peak airway pressure	5 Carbon dioxide percent	
2 PEEP	6 Oxygen percent	
3 Tidal volume	7 Respiration frequency	
4 Ventilation volume		

### 5.8.2 Monitoring Types

During respiration, the patient must be monitored continuously. This



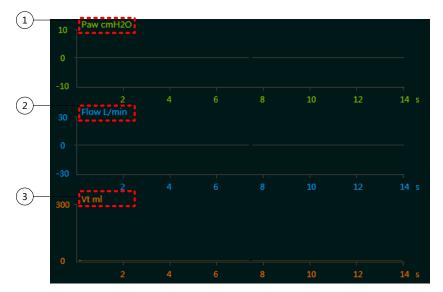
ventilator provides several comprehensive monitoring modes for your choice. You can tap the <Monitoring> button in the main interface to call out the select box. Options include Waveform, Cycle Graph, Parameter, Tendency, etc (As shown below).



#### FIGURE 47 Monitoring

The default type is Waveform, which requires no activation. As for other types, their activation state varies with the selected configuration of the ventilator. How to activate will be described in "5.6.3 Software Configuration".

### 5.8.3 Waveform Diagram



• Waveform interface (P+F+V):

FIGURE 48 Waveform interface (P+F+V)

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#### PARTS

PARTS

1 Pressure waveform

3 Volume waveform

#### 2 Flow waveform

• Waveform interface (P+F+C):

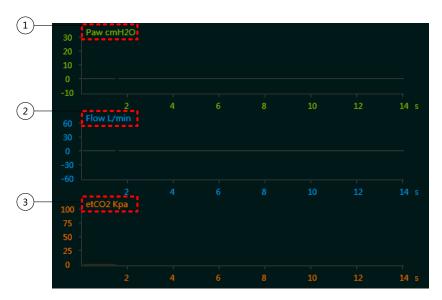


FIGURE 49 Waveform interface (P+F+C)

PARTS	PARTS
1 Pressure waveform	3 Carbon dioxide waveform

#### 2 Flow waveform

• Waveform interface (P+V+C):

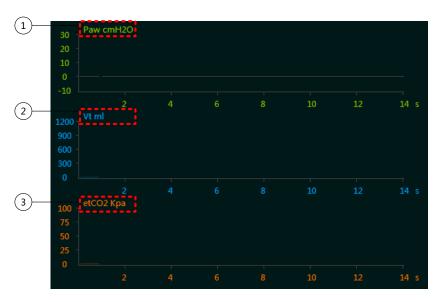


FIGURE 50 Waveform interface (P+V+C)

PARTS	PARTS
1 Pressure waveform	3 Carbon dioxide waveform

#### 2 Volume waveform

• Waveform interface (P+F):

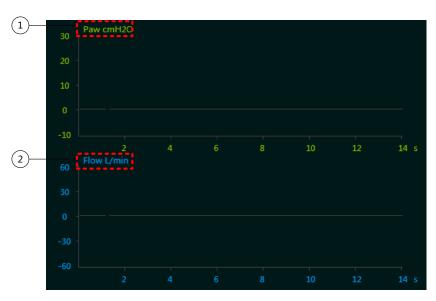


FIGURE 51 Waveform interface (P+F)

PARTS	PARTS
1 Pressure waveform	2 Flow waveform

## 5.8.4 Cycle Graph

• Respiratory cycle graph interface (P-V+F-V):

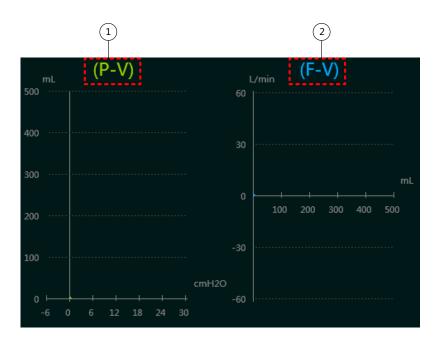


FIGURE 52 Waveform interface(P-V+F-V)

PARTS	PARTS
1 Pressure-volume cycle graph	2 Flow-volume cycle graph

• Respiratory cycle graph interface ( P-V+P-F ):

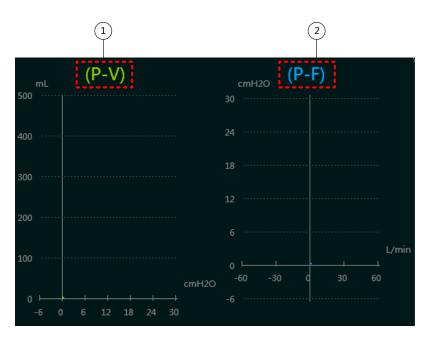
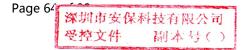


FIGURE 53 Waveform interface(P-V+P-F)

PARTS	PARTS	
1 Pressure-volume cycle graph	2 Pressure -flow cycle graph	



• Respiratory cycle graph interface (F-V+P-F):

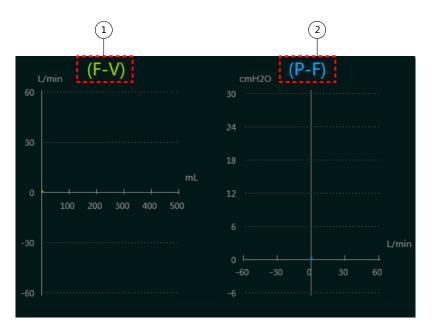


FIGURE 54 Waveform interface(F-V+P-F)

PARTS	PARTS
1 Flow-volume cycle graph	2 Pressure-flow cycle graph

## 5.8.5 Respiratory Mechanics Monitoring Parameters



FIGURE 55 Parameters

PARTS	PARTS
1 Dynamic compliance	9 Expiratory minute

	ventilation		
2 Peak airway pressure	10 Inspiratory minute ventilation		
3 Static compliance	11 Peak expiratory flow rate		
4 Plateau pressure	12 Work of breathing		
5 Airway resistance	13 Peak inspiratory flow rate		
6 PEEP/CPAP	14 Rapid shallow breathing index		
7 Mean airway pressure	15 Moisture volume during		
	the 1st second of expiration		
8 Pressure 0.1 s after the start of inspiration	16 I:E ratio		

## 5.8.6 Tendency Chart



FIGURE 56 Tendency Chart

PARTS	PARTS
1 Freeze button	3 Tendency data

2 Tendency waveform

## 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.

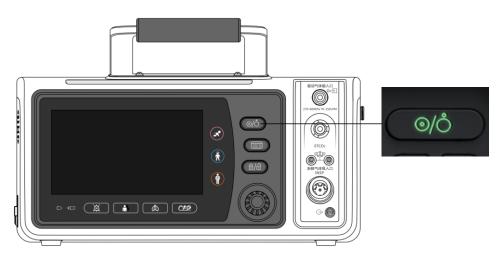


FIGURE 57 Shut down ventilator

# 5.10 Calculation of Storage Capacity/Operation

## Duration

### • Storage capacity of oxygen cylinder

Oxygen capacity = cylinder volume × cylinder pressure.

Example	cylinder volume	х	cylinder pressure =	oxygen storage capacity
1	10 L		200 Bar	2000 L
1	10 L		100 Bar	1000 L



#### • Time of Breathing Work

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

Ventilation Duration (min) =	Oxygen Storage Capacity ( L )	100%
	MV(L / min)	Oxygen Concentration

#### • Example :

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

Ventilation Duration ( min ) =	1000 L		100%	- 01 min -1 h 21 min
		_^_		= 91 mm =1 m 91 mm
	11 L/min		100%	

## 5.11 Spare Breathing Apparatus

In case of any malfunction in T7 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 T7, the patient can inhale air through patient breathing valve.

### 5.12 Battery Management

T7 has a built-in rechargeable battery which allows at least 10h of operation in normal status.

The built-in battery can be charged separately and also allows voltage supply by the main unit of T7. The charging time should be no less than 8h.

The built-in standby battery is activated when the built-in battery needs replacement in the power-on state and no power adapter is available for power supply. It can supply voltage to T7 for at least 20min, and the charging time should be no less than 1h.

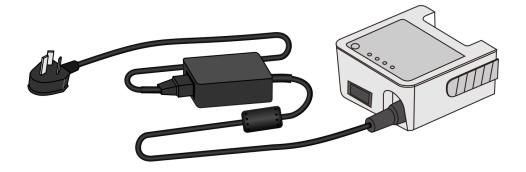


FIGURE 58 Battery

#### **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 20%	indicates a battery level of 20 %
3 40%	indicates a battery level of 40 %
4 60%	indicates a battery level of 60 %
5 80%	indicates a battery level of 80 %
6 100%)	indicates a battery level of 100 %

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

T7 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 T7 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.

When disinfect the whole machine with ultraviolet light, the disinfection time is one hour.

# A Caution :

- 1. Do not fumigate the whole unit with acidum peraceticum or methanal.
- 2. The sanitizer shall be prepared in accordance with the instruction manual provided by the manufacturer.

# 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.

Reusable respiratory hose and rubber pads of patient breathing valve and respiratory mask can be disinfected with high temperature.

# 6.4 Valve Fittings

# Warning :

Do not soak any valve fitting into any disinfectant or other liquid. Disinfect the valve fittings only by wiping with soft cloth. Do not fill any liquid into reducing valve, or otherwise explosion may occur.

Disinfect reducing valve and related oxygen cylinder only by using dry or wet clean cloth.

# 6.5 Sanitization Methods

Sanitize T7 main unit and its accessories by using the methods as stated below:

Part	Cleaning	Disinfection	Rinsing in Washer	Sterilization
T7	Use dry or soaked	By wiping	Not permitted	Not permitted
	cloth			
PEEP hose	Soaked	With all interior	Not permitted	Not
	into warm	and exterior	<u> </u>	permitted
Patient	water	surfaces soaked	Rinsing in	Sterilized
Breathing	mixed	into diluted	temperature	with hot
Valve	with mild	solution for a	below 93 °C is	steam in
Reusable	domestic	sufficiently long	permitted	temperature
respiratory	detergent	time without	(thermal	of 134 °C for
mask		any air bubble;	disinfection in	5 minutes
Reusable		after	automatic	by using EN
respiratory		disinfection,	cleaning	285
hose		clean all interior	machine)	compliant
		and exterior		equipment
		surfaces with		
		distilled water		
		and then dry it		
Oxygen	Use dry or	By wiping	Not permitted	Not
valve	soaked			permitted
fittings	cloth			

# 7 Functional Inspection

Functional inspection shall be performed on the equipment before using it or after dismantling it, or after it has been left idle for more than six months.

### Tips:

When performing functional inspection on T7, the respiratory hose and patient breathing valve must be connected.

When any failure or deviation to set value is found, stop using T7 until related problem is removed.

First remove the fault in accordance with Section 8 - Trouble Shooting. If such malfunction cannot be removed, contact Ambulanc 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:

- Spare sealing materials for device connection;
- 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 T7 till the reading on cylinder is "0"; and then shut down T7.
- 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.

# Marning :

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 the time of respiratory distress alarm as 15s..
- b) Set respiratory mode to CPAP,CPAP+. Record the time when ventilator gives out respiratory distress alarm and compare it with the set value. This alarming time shall be within 13s to 17s.
- 4. Check alarm triggered by upper airway pressure limit in accordance with the following steps:
- a) Set the ventilator to V-AC ventilation mode.
- b) Set Vt to 600ml, I/E to 1: 2, and frequency to 10.
- c) Set Pmax to 20cmH20.
- d) Block the connector of the patient breathing valve with hand to make airway pressure higher than 20mbar, in the condition of which the system shall give out sound and light alarm indicating that airway pressure is high. About 10s after removing the hand, the alarm shall stop.
- 5. Perform an inspection on respiratory system integrity alarm function in accordance with the following steps:
- a) Set the ventilator to A-C ventilation mode.
- b) Set Vt as 600ml, I:E as 1:2, Freq as 10 and Pmax as 30mbar.
- c) The system shall give out "Not Connected" sound and light alarm after2 respiratory cycles if the patient breathing valve is not connected tosimulated lung. The alarm shall stop after a simulated 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 T7 is started and operates normally and no alarm is triggered, it indicates that the battery is at sufficient voltage level.

- 7. Check trigger pressure as below:
- a) Set ventilation mode to CPAP+ ventilation mode, and CPAP pressure as
   0.
- b) Set activation pressure to -3mbar.
- c) Ventilate air through mask; when negative pressure of inspired air reaches -3mbar, the respirator should ventilate air in; when airway pressure reaches the target pressure, delivery of ventilation should be ceased till next ventilation is activated.

# 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
T7 fails to start	T7 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
T7 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	High	Exceed the set	Examine the patient's
ventilation	ventilation	upper limit of	condition
rate per	rate per	ventilation rate per	Check whether the
min.	min.	min.	upper limit is set
			properly
Low	Low	Lower than the set	Examine the patient's
ventilation	ventilation	lower limit of	condition
rate per	rate per	ventilation rate per	Check whether the
min.	min.	min.	lower limit is set
			properly
Asphyxia	Asphyxia	Asphyxia duration	Examine the patient's
		exceeds the set	condition
		value	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 too low	Reset Pmax
		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 Compressed air source is defective	Inspect related connections and make correction as necessary Replace air source
		Ventilator air source hose is wound or pressed Reducing valve is defective	Arrange the air source hose or relieve the hose of any pressure Replace reducing valve
Respiratory system is not connected	Respiratory system is not connected	<ol> <li>Respiratory hose leaks or falls down.</li> <li>Respiratory mask is worn improperly.</li> <li>Pressure measuring hose leaks or falls down.</li> </ol>	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. Built-in rechargeable battery Built-in standby battery (internal device of the device, not unplugged) when in place; Unplug the built-in rechargeable battery, the device reports the advanced alarm " battery power is too low!!&quot ;

3. Adapter built-in standby battery (internal device of the device, not unplugged) when in place; Unplug the adapter, the device announces the intermediate alarm "Adapter falls off!! "And advanced alarm" the battery is too low!!"

4. 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)

5. 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 Outage Alarm

T7 can alarm shutdown caused by the system' s abnormal outage.

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 removed by single clicking on <Lock Screen> button.

# 9 Maintenance

## 9.1 Routine inspection

Safety inspection shall be performed after each overhaul, and T7 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

The battery provided for T7 is rechargeable lithium battery. It is recommended that the battery be fully charged at a certain interval (per 6-12 months, depending on usage time) and then exhaust it. It is very convenient to change the battery. Following is the change steps (see figure below).

- 1. Make sure that T7 is in off status;
- 2. Press the battery buckle in the direction of arrow;
- 3. Take the exhausted battery from the battery jar;
- 4. Insert the fully-charged battery in the jar in proper direction until the battery buckle gives out a clicking sound.

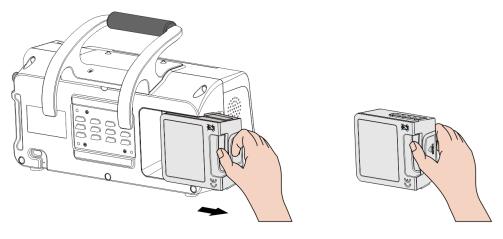


FIGURE 59 Replacement battery

## 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 T7 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

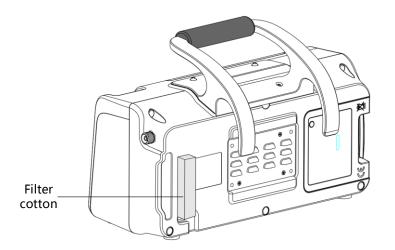
For maintenance cycle of T7 accessories and maintenance application, refer to related operating instructions.

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. Take the used filter cotton out with a tweezer.
- 2. Wipe the filter cartridge with medical cotton ball soaked with alcohol.
- 3. Put new filter cotton in the filter cartridge with a tweezer.





# 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 T7 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 T7 in a dry place.
- 3. The battery can be left in the device for a long time.

## 🕂 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 T7 Supplies Configuration**

## **10.1 Standard Configuration of Main Unit and**

## Accessories

SN	Name	Material coding	Unit	Remark
1	T7 host	2.603.00025	PCS	English
2	Single respiratory hose (repetitive)	2.603.00031	PCS	
3	Flow Rate Sensor (for Adult)	5.000.00254	PCS	
4	Large hook of silicon mask	5.001.00033	PCS	
5	Repetitive silicon mark for adult purpose	5.001.00035	PCS	
6	Adult headgear	5.001.00037	PCS	
7	Power adapter	2.609.00021	PCS	European Standard
8	Power line	1.124.00001	PCS	European Standard
9	Battery	2.603.00029	PCS	English
10	Air source hose	2.601.00046	PCS	2m, with a DISS connector at one end and a quick connector at the other end
11	T7 User's Manual	1.601.00131	PCS	English

# **10.2 Optional Configuration of Accessories**

SN	Name		Material coding	Unit	Remark
1	ETCO2	Mainstream	5.000.00452	PCS	
	module	CO2 module			
	2.609.00	Adult adapter	5.000.00453	PCS	
	017	(disposable)			
		Newborn	5.000.00454	PCS	

		adapter (disposable)			
		Cable fixing slot	5.000.00457	PCS	
2	Single respiratory hose (disposable)		2.603.00030	PCS	
3	Splint		5.000.00168	PCS	
4	Bearing system		2.603.00032	PCS	
5	I-Type First-Aid Kit		2.601.00029	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	СРАР	•	
8	CPAP +	0	
9	BiPPV	0	
10	APRV	0	
11	PRVC	0	
12	PRVC+	0	
13	BiPPV+	0	
14	APRV+	0	
SN	Other Functions	Options	
1	CPR	0	
2	RSA	0	
3	HFNC	0	
Note: $\bullet$ means standard configuration. $\circ$ 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 : 580mm		
	width : 375mm		
	height : 270mm		
Weight	5.1 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°C ~ 60°C	
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	≤50VA		

## **11.5 Ventilation mode**

Ventilation mode		
Volume-control mode	IPPV , V-AC , V-SIMV	
Pressure-control mode	PCV , P-AC , P-SIMV	
Noninvasive-ventilation mode	CPAP , CPAP+ , BiPPV , APRV , HFNC	
Advanced-ventilation mode	PRVC , PRVC+ , BiPPV+ , APRV+	
Resuscitation mode	CPR , RSA	

# **11.6 Supply specifications**

Supply specifications		
Air supply	Medical oxygen	
Air supply pressure	2.7 ~ 6.0 bar	

# **11.7 Ventilator specifications**

Resistance of patien	t breathing valve		
Inspiration	< 6mbar , when the flow rate is 30, 60 L/min		
Expiration	< 6mbar , when the flow rate is 30, 60 L/min		
Emergency air intake	< 6mbar , when the flow rate is 15, 30 L/min		
Maximum minute ve	entilation		
Maximum minute ventilation	≥150L/min(@450kPa)		
Trigger mode			
Trigger mode	Pressure Trigger, Flow Trigger		
Control parameters			
I:E ratio	Adjustable between 59:1 and 1:99; error: ±15%		
Respiratory frequency	0 , 1 ~ 120bpm; error: ±1bpm or ±15%, whichever is bigger		
Tidal volume	20~ 2500mL (ATPD) Error: ±15ml or ±15%, whichever is bigger		
PEEP/CPAP	0~30mbar; error: ±2mbar or ±15%, whichever is bigger		
Inspiratory pressure	$3\sim$ 60mbar; error: ±2mbar or ±15%, whichever is bigger		

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Oxygen percent in gas delivered	40%~100% , ±10% ( v/v )		
Limited airway	15~70mbar; error: ±2mbar or ±15%, whichever is		
pressure	bigger		
Trigger pressure	-20~20mbar; error: ±1mbar or ±15%, whichever is		
	bigger		
Droccura cupport	0, 3 ~ 35cmH2O, tolerance: ±2cmH2O or ±10%,		
Pressure support			
Activation flow rate	whichever is the larger.		
Activation flow rate	$1 \sim 15L/min$ , tolerance: $\pm 1L/min$ or $\pm 15\%$ ,		
	whichever is the larger.		
Pause time ratio	0~80 %, tolerance: ±10%		
Pressure rise time	$0.1 \sim 2s$ , tolerance: $\pm 0.2s$ or $\pm 20\%$ , whichever is the larger.		
Expiration activation	5 ~ 80 %, tolerance: ±15%		
sensitivity			
Oxygen flow	$0 \sim 80L/min$ , tolerance: $\pm 1L/min$ or $\pm 15\%$ ,		
velocity	whichever is the larger.		
Monitoring paramet			
Tidal volume	0~3000ml; error: ±15ml or ±15%, whichever is		
	bigger		
Minute ventilation	0~120L/min; error: ±0.5L/min or ±15%, whichever		
	is bigger		
Respiratory	0~120bpm; error: ±1bpm or ±5%, whichever is		
frequency	bigger		
Airway pressure	-20~100mbar; error: ±2mbar or ±10%, whichever is		
monitoring	bigger		
EtCO2 percent	0~150mmHg		
	error:		
	(0~40 mmHg) ±2mmHg		
	(41 ~ 70 mmHg)±5%		
	(71~100 mmHg) ±8%		
	(101 ~ 150 mmHg) ±10%		
Mechanical safety va	<u> </u>		
Mechanical safety	≤ 100 cmH2O		
valve			
connecting pipe join	t specifications		
	•		
Specification of gas	German-type quick connector		
connection tube			
connector of the			
ventilator			
Respiratory hose cor	nnector specifications		

Breathing hose connector	Inner diameter Φ15mm / outer diameter Φ22mm		
Compliance of respiratory system			
Compliance of respiratory system	100 ml/ cmH2O		
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.
- 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 T7 Product Structure Diagram

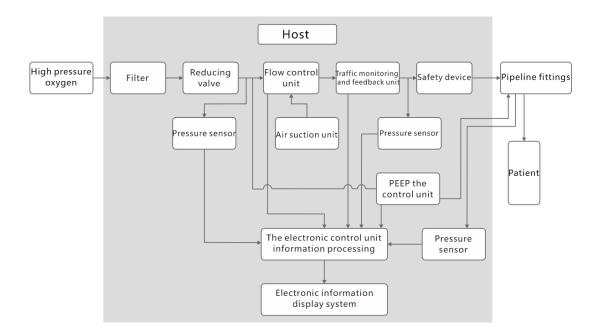


FIGURE 61 T7 Product Structure Diagram

# **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.

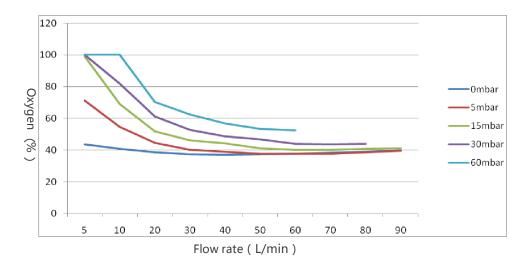


FIGURE 62 Minimum Oxygen Concentration

# **12 EMC**

## 12.1 EMR Statement

EMR Statement				
T7 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	T7 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	T7 is suitable for all facilities that are not directly connected to		
Harmonic wave radiation (GB 17625.1)	Category A	the public low-voltage power supply grid of domestic		
Voltage fluctuation and flicker emission (GB 17625.2)	Acceptable	residence.		

## **12.2 EMI Statement - Requirements for All**

## **Equipment and Systems**

### EMI Statement - Requirements for All Equipment and Systems

T7 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	Compliance	EMR Environment
	Testing Grade	Grade	Guide
ESD	Contact	Contact	The ground shall be of
(GB/T 17626.2)	discharge:	discharge:	wood, concrete or
	±8kV	±8kV	ceramics. In case of
	Air discharge:	Air discharge:	composite paving
	±15kV	±15kV	material, the relative
			humidity shall be at

			1
			least 30%.
EFT (GB/T 17626.4)	To power cable: ±2kV To long I/O cable: ±1kV	To power cable: ±2kV 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 CM: ±2kV	DM: ±1kV 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	< 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
17626.11)	40%UT(60% fall, UT), 5 cycles;	40%UT(60% fall, UT), 5 cycles;	recommended to use UPS to ensure continuous operation of this product even in case of AC power
	70%UT (30% fall, UT ), 25 cycles; < 5% UT( > 95% fall, UT), 5s;	70%UT (30% fall, UT ), 25 cycles; < 5% UT( > 95% fall, UT), 5s;	outage.

# 12.3 EMC Guidance and Manufacturer's

# **Declarations**— Electromagnetic Immunity

EMC Guidance and Manufacturer's Declarations— Electromagnetic Immunity				
T7 transport ventilator is intended for use in electromagnetic environment specified below. The customer or user of T7 transport ventilator should assure that it is used in such environment.				
EMI TestIEC 60601ComplianceElectromagneticTest LevelLevelenvironment—guidance				

Radio frequency transmission GB/T 17626.6 Radio frequency radiation GB/T 17626.3	3 V (effective value) 150 kHz~80 MHz (except ISM bandsa) 10V (effective value) 150kHz~80 MHz (ISM banda) 10V/m 80 MHz ~ 2.5 GHz	3V (effective value) 10V (effective value) 30V/m	Any portable or mobile radio frequency communication equipment shall not be used in a distance closer to any part of T7 Emergency Ventilator (including cable) than as recommended. Such distance is determined based on a formula related to transmitter frequency. Recommended Distance $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$ $d = \left[\frac{12}{V2}\right]\sqrt{P}$ $d = \left[\frac{12}{V2}\right]\sqrt{P} \ 80 \text{ MHz} \sim 800 \text{ MHz}$ $d = \left[\frac{23}{E1}\right]\sqrt{P} \ 800 \text{ MHz} \sim 2.5 \text{ GHz}$ $where,$ $P : \text{the maximum rated}$ output power (in Watt) of transmitter provided by its manufacturer; <i>d</i> : the recommended distance (in meter) <sup>b</sup> . The field strength of fixed radio frequency transmitter is determined based on the survey at EMI location <sup>c</sup> , and each frequency range should be lower than
			The field strength of fixed radio frequency transmitter is determined based on the survey at EMI location <sup>c</sup> , and each frequency range
Note 1 :			Interference may occurs near the equipment attached with the following signs.

### 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 T7 Emergency Ventilator is located is higher than the aforesaid applicable radio frequency compliance level, then T7 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 T7 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 T7 Emergency Ventilator

T7 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 T7 Emergency Ventilator as recommended below.

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

# Caution :

- EMC of the location where this environment is mounted and used shall be adequately take into consideration in accordance with the said guidelines.
- As for other devices on or near the product, even if they comply with the emission requirements of CISPR, they may interfere with the product. Therefore, you should verify whether the machine can work normally before using it for patients.
- 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		Cadm ium (Cd)	Mer cury (Hg)	Lead (Pb)	Hexavalent Chrome (Cr-VI)	PBB	PBDE
Display Screen		×	×	×	×	×	×
Lithium Battery		×	×	×	×	×	×
Main Unit of Anaesthesia		0	0	×	×	0	0
	ng System						
	Material	0	×	×	0	×	×
Main	РСВА	0	0	×	0	0	0
Unit	Interior Connecting Wires	0	0	0	0	0	0
	Machined Parts	0	0	0	×	0	0
Enclos ure	Button	0	0	0	0	0	0
	Label	0	0	0	0	0	0
	Front Cover	0	0	0	0	0	0
	Rear Cover	0	0	0	0	0	0
Acces	Air Hose	0	0	0	0	0	0
sories	Mask	0	0	0	0	0	0
	Corrugated Tube Assembly	0	0	0	0	0	0
	Air Source Hose Assembly	0	0	0	0	0	0
	Reservoir Bag	0	0	0	0	0	0
	Power Cable	0	0	0	0	0	0

H-1.601. 00131-B3.0

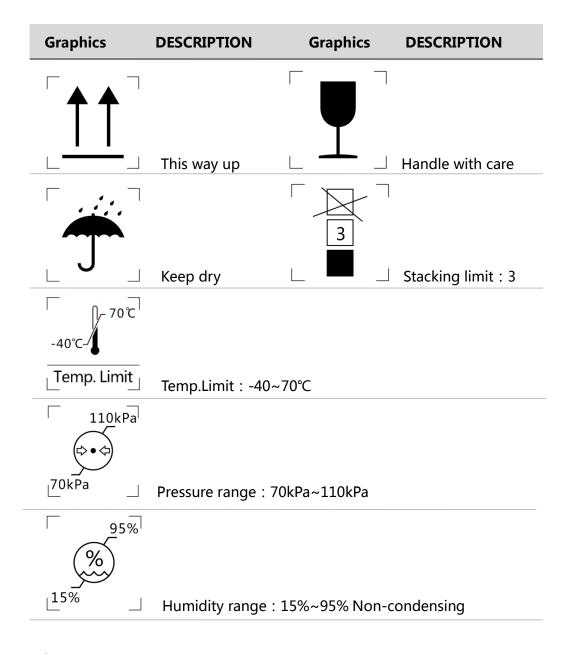
Connectors	0	0	0	×	0	0
Vaporizer	0	0	×	0	0	0
Jinn Bottle	0	0	0	0	0	0
Steel	0	×	x	0	0	0
Cylinder						
Flow Rate	0	0	0	0	0	0
Sensor						
Oxygen	0	0	×	0	0	0
Sensor						
CO2	0	0	×	0	0	0
Monitor						

× : 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.

 $\circ$  : 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.



# Marning :

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.

深圳市安保利	科技有限公司
受控文件	剧本号()

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