Amoul®

T6 Operation Manual Ventilator

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Table of Contents

Product information

Thank you for purchasing the T6 ventilator.

Before using the device, please read and understand contents of this Manual carefully, in order to use this instrument correctly. Please keep this Manual properly after reading and place it in an accessible location.

Product name: ventilator

Model: T6

Production license number: GDFDA Medical Device Production License No.20020533

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

Registrant domicile: A1302, Shenzhen National Engineering Laboratory Building, No.20, Gaoxin South 7th Road, High-Tech Zone Community, Yuehai Street, Nanshan District, Shenzhen

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

Manufacturer address: Floor 3, Building C, Skyworth Innovation Valley #5, No.1 Tangtou Road, Shiyan Street, Bao'an District, Shenzhen

Date of manufacture: see the mainframe

Service life: 8 years

Revision date: 7-2021

Version: H-1.601.00313-A1.0

Notices: This instrument is not designed for household purposes.

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- The relevant electrical equipment meets the national standards;
- The instrument is operated in accordance with the operation instructions.

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- The instrument is repaired or modified by the personnel not authorized by Ambulanc (Shenzhen) Tech. Co., Ltd.;
- The product is not operated correctly according to the Operation Manual.

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Free service scope:

- All devices in line with warranty service regulations of Ambulanc (Shenzhen) Tech. Co., Ltd. can enjoy free service.

Charged service scope:

- Any equipment beyond the scope of warranty service regulations of Ambulanc (Shenzhen) Tech. Co., Ltd. will be charged by Ambulanc for services;
- Within the warranty period, no warranty shall be granted under the following circumstances:

1. Man-made damages;
2. Improper use;
3. Power grid voltage exceeds the specified range of equipment;
4. Irresistible natural disasters;
5. The machine is replaced with the parts and consumables that are not approved by the Ambulanc (Shenzhen) Tech. Co., Ltd., or the machine is repaired by the personnel not authorized by the Ambulanc (Shenzhen) Tech. Co., Ltd.

⚠ Warning:

If the hospital or institution responsible for use of the instrument does not implement a satisfactory repair/maintenance plan, it may result in abnormal instrument failure and may endanger human health.

Guarantee

Manufacturing process and raw materials:

Ambulanc (Shenzhen) Tech. Co., Ltd. guarantees that the instrument in normal use and maintenance state will not appear any manufacturing process and raw materials failure during the warranty period.

After-sales service unit

After-sales service department of Ambulanc (Shenzhen) Tech. Co., Ltd.

Address: Floor 3, Building C, Skyworth Innovation Valley #5, No.1 Tangtou Road, Shiyan Street, Bao'an District, Shenzhen

Postal code: 518108 Toll-free service hotline: 400-9969-120

Tel.: +86-755-26072215 Fax: +86-755-23016012

Website: http://www.ambulgroup.com

E-mail: manager@ambu-lanc.com

Return

Return procedures

Please follow the following steps if you do need to return the goods to Ambulanc (Shenzhen) Tech. Co., Ltd.:

- Obtain the right of return: contact with after-sales service department of Ambulanc (Shenzhen) Tech. Co., Ltd. to inform serial number of Ambulanc product, which has been marked on the outer packing box. If the serial number is not clearly identifiable, the return will not be accepted. Please specify the product model and explain the reason for return.
- Freight: the user shall bear the freight (including customs charges) when the instrument is transported to Ambulanc (Shenzhen) Tech. Co., Ltd. for repair.

Important information

1. After purchase of the product, the customer is fully responsible for maintenance and management of the product.
2. During the warranty period, the following conditions are not covered by the warranty:

- Damage or loss caused by wrong or rough use;
- Damage or loss caused by force majeure, such as fire, earthquake, flood or lightning.
- Damage or loss caused by failure to meet the specified operating conditions of the system, such as insufficient power supply, incorrect installation or non-conforming environmental conditions.
- Damage or loss caused by not operating the system in the area where the system is initially purchased.
- Damage or loss caused by the system which is not purchased from Ambulanc or its authorized dealers or agents.

3. The equipment can be operated by only qualified medical personnel with professional qualification certificate.
4. Software or hardware or any other parts of the product are forbidden to be modified without authorization.
5. Ambulanc shall not be responsible for any problems, damage or loss arising from the reinstallation, modification or repair of the system by the personnel not designated by Ambulanc.
6. This system aims to provide doctors with the auxiliary tools needed for clinical

treatment.

7. The doctors are responsible for the course of treatment. Ambulanc has no responsibility for the course of treatment.
8. Important data shall always be backed up to external storage media, such as clinical records, notebooks, etc.
9. Ambulanc shall not be held responsible for the loss of data stored in the system due to operator error or abnormal circumstances.
10. This Operation Manual contains warnings about potential hazards that can be foreseen. Unstated dangers shall be kept on high alert at all times. Ambulanc shall not be responsible for any damage or loss caused by negligence or disregard of the preventive measures specified in this Operation Manual.
11. This Operation Manual must be handed over in the event of a change in the system administrator.

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1 Safety instructions

Please read these safety instructions carefully. These safety instructions are an integral part of the equipment and must be accessible at all times. For the sake of safety, please note the followings:

The safety instructions are marked in this Operation Manual as follows:

Warning:

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

Notice:

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

Hint:

Information alerts on the contents of this user instruction.

1.1 Overview

Warning:

- A functional check must be performed before using this equipment (see "11 Maintenance and Inspection").
- Follow the instructions in "9 Cleaning and Disinfection" to prevent infection or bacterial infection.
- T6 shall only be used after you are subjected to medical training and technical instructions on ventilator as improper use can cause serious bodily injury.
- Do not leave the patient or the ventilator during ventilation, so as to be able to make a timely response in the event of an emergency (such as deterioration of the patient's condition or machine failure), and to minimize the patient's injury.
- T6 may only be used for the specified purposes (see "2.1 Intended use").
- T6 is strictly prohibited in high-pressure applications (hyperbaric chamber).
- T6 is strictly prohibited in explosive or toxic environments.
- T6 is strictly prohibited in oxygen-rich or flammable environments.
- The device is not intended for use in a magnetic resonance imaging (**MRI**)

environment.

- Use of antistatic or conductive masks or ventilator lines when using high-frequency surgical equipment may cause burns, so do not use antistatic or conductive masks or ventilator lines.
- This equipment cannot be used with nitric oxide.
- This equipment cannot be used with helium or mixtures containing helium.
- In case of respirator failure, if other ventilation methods cannot be applied immediately, it may result in patient death.
- Non-maintenance personnel are prohibited to open the T6 cover to change or modify any external or internal parts of T6.
- To avoid the risk of electric shock, the device can only be connected to a power socket with protective grounding. Do not use a power socket that is not connected with a grounding conductor.
- Do not open the enclosure of the equipment, otherwise there may be a risk of electric shock.
- Maintenance or upgrade of the equipment can only be carried out by the maintenance personnel trained and authorized by the company.
- When used outside the healthcare facility, T6 should be fixed on the road vehicle and operated by EMS personnel with a basic knowledge of mechanical ventilation.

⚠ Notices:

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

- Do not immerse T6 in any liquid. If any liquid gets into the cover, it can cause damage to the device.

1.2 Safe use of oxygen

⚠ Warning:

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

⚠ Notices:

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

1.3 Ventilation/operation

- The patient and ventilator must be observed continuously during ventilation.
- Long-term reliance on T6 for breathing may cause respiratory muscles of the patient to atrophy.
- Ventilation for a long time can dry out the respiratory tract.

- Make sure that the patient breathing tube and inspiratory end are connected smoothly, otherwise the ventilation function of the equipment may be affected.
- The ventilator shall not be placed next to a barrier as this will impede the flow of cold air and cause the device to overheat.

1.4 Patient ventilator line components

⚠ **Warning:**

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

1.5 Software

Extensive quality assurance measures have been taken during development of device software, so the risk arising from software defects is minimal.

Software version:V1.

1.6 Accessories/spare parts

⚠ **Notices:**

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

spare part is used.

1.7 Battery

Warning:

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

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

Notices:

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

1.8 Description of symbols

The symbols used on this device or in this Manual are described in following table.

Symbol	Description	Symbol	Description
	Notice, please refer to attached documents		Refer to the Operation Manual
	Date of manufacture		BF type application part
	Equipotential	IPX3	Protection level
	Do not discard in an ordinary trash bin		Power cord disconnection
	Refer to the manual provided with the device together/Operation Manual		Host switch
	AC power supply		Battery power supply
	Clearing alarms other than Advanced Alarms		Nebulization
	Function menu		Lock/unlock
	Muted alarm		Inspiratory interface
	Expiratory interface		USB port

	Oxygen inlet		Battery capacity state
	Non-invasive		Invasive
	Adult		Pediatric
	Infant		Patient trigger
	The product contains some harmful substances, so it can be safely used within the environment-friendly use period, but it shall be put into the recovery and circulation system after the environment-friendly use period. The product has an environment-friendly service life of 20 years.		
	It is in compliance with the European Union Medical Devices Directive 2007/47/EC, and meets the basic requirements for CE mark in Annex I of the Directive.		

2 Overview

2.1 Intended use

T6 is suitable for providing ventilation assistance and respiratory support to adults, children and infants in and out of the hospital. It is also suitable for all types of ambulance for emergency transport.

The T6 may be operated only if it is securely mounted and fixed or placed on a licensed carrier platform.

Warning:

The ventilator shall not be covered or placed in a position that affects operation and performance of the ventilator.

2.2 Contraindications

The patients with pulmonary bullae, pneumothorax, massive hemoptysis, active tuberculosis, bronchopleural fistula, massive pleural effusion, acute myocardial infarction or other diseases, or the patients who cannot use the ventilator according to clinical experiences.

2.3 Intended operating environment

ICU, EICU, NICU, recovery room, operating room, intra-hospital and out-hospital emergency transport, etc.

2.4 User qualification

The personnel operating T6 must meet the following conditions:

- Has received medical training and technical guidance on the ventilator;
- Has received the training on clinical application of T6 approved by **Ambulanc (Shenzhen) Tech. Co., Ltd.**

Improper use may cause serious injury to personnel (operators and patients).

2.5 Product description

Main components of the T6 ventilator include:

Mainframe (including oxygen line, electronic system, mechanical structure, display,

and carbon dioxide module), trolley, and support arm.

Ambulanc (Shenzhen) Tech. Co., Ltd. has designed all components required for the T6 ventilation system.

2.6 Appearance description

2.6.1 Mainframe - front view

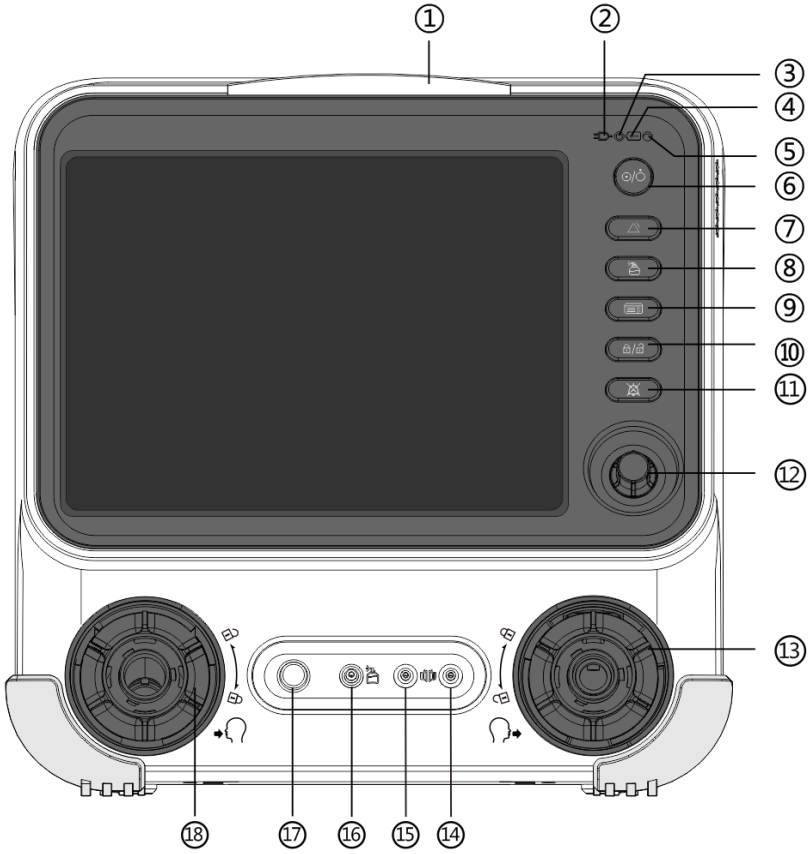


Fig. 1 Mainframe (front view)

Components	Description
1 Alarm light	In the event of an alarm, it turns on in red, flashes in yellow or is always on in yellow to indicate different priority level of the alarm (red=high priority, yellow=medium/low priority level, off=no alarm)
2 External power supply sign	It indicates an external power indicator.
3 External power supply indicator	The indicator will be always on when the power cord is connected. Hint: When the ventilator is switched from the external power supply to internal power supply, the ventilator still

	works normally.
4 Battery sign	It indicates the battery indicator.
5 Battery indicator	The indicator will flash during charging, and will be always on when it is fully charged or during use. Tip: To indicate the ventilator is powered by an internal battery oran external power supply during operation.
6 On/off key	Click this button to turn on the equipment in the Power Off state; click it to turn off the equipment in the Standby state; and press and hold for 3 seconds to force the equipment to turn off in the Power On state.
7 Alarm cancel key	Press this button to clear all alarms other than advanced alarms
8 Nebulization key	Press this key to enable or disenable the nebulization function.
9 Main menu key	To call up the main menu. It contains the "Time", "System", "Calibration", "Alarms", "Records", "About the machine" and other settings. The main menu will be closed when this key is operated again.
10 Screen lock key	It is used to lock the touch screen. If this key is pressed when the touch screen is enabled, the touch screen will be disenabled. On the contrary, the touch screen will be enabled when this key is pressed.
11 Alarm Mute button	This key can be used to disenable the voice alarm function for a period of time (up to 120 seconds); When the alarm is muted, the indicator next to this key will be lit. But the visual alarms (e.g. the warning lights and information bars flash) will not be turned off.
12 Navigation	It is used to operate the display interface, as described below: Press the knob to enter the selected page or select the selected item or save the settings; rotate the knob to adjust the selected item. When it is rotated clockwise, the selected setting parameter will be increased, while when it is rotated anticlockwise,the selected setting parameter will be decreased.
13 Expiratory branch	It is used to connect the expiratory line and is provided with an expiratory valve.

14 External flow sensor interface	External flow sensor interface white tube.
15 External flow sensor interface	External flow sensor interface blue tube.
16 Nebulizer interface	Used to connect the nebulizer.
17 Leak test plug	Used to calibrate compliance
18 Inspiratory branch	Used to connect the inspiratory line.

2.6.2 Mainframe - rear view

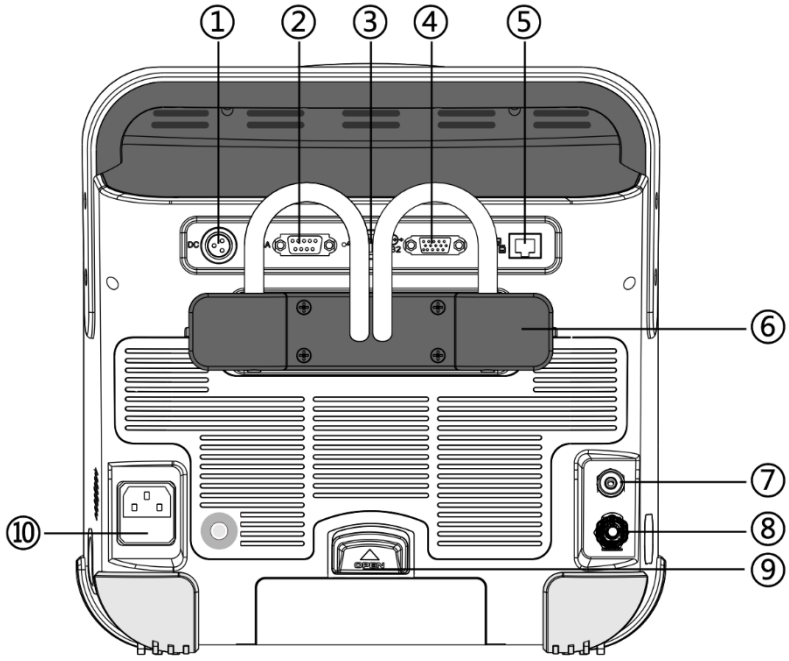


Fig. 2 Mainframe (rear view)

Components	Description
1 DC power input port	Used to connect to the vehicle power supply.
2 VGA port	Output the same VGA video signal as the main monitor display
3 USB port	You can upgrade the respirator software through the USB port, or export configuration information and history data through the USB port (e.g., trend data, logs, etc.)
4 RS232 port	Used to connect to the external calibration equipment,

	or connect to medical grade external equipments.
5 Network port	Support connection to PC for software upgrade.
6 Hook	Hook width: 45mm.
7 Gas supply port(high pressure)	Connect to high pressure gas supply
8 Gas supply port(low pressure)	Connect to low pressure gas supply.
9 Battery latch	Used to remove and replace the rechargeable build-in battery directly below it.
10 AC power input socket	Used to connect to AC power.

2.6.3 Mainframe – right view

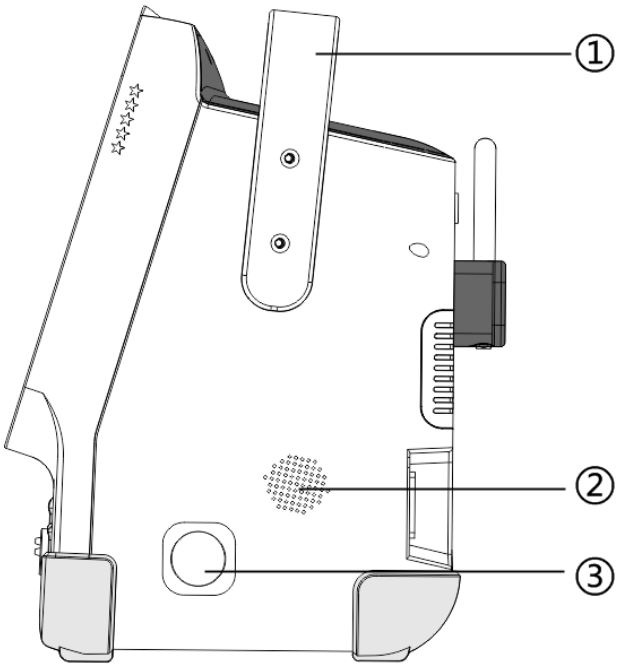


Fig. 3 Mainframe (right view)

Components	Description
1 Handle	Handle height: 27mm.
2 Horn	Speaker of alarms, hints and alarms.
3 Exhalation valve exhaust	Used to discharge gas.

2.6.4 Mainframe - left view

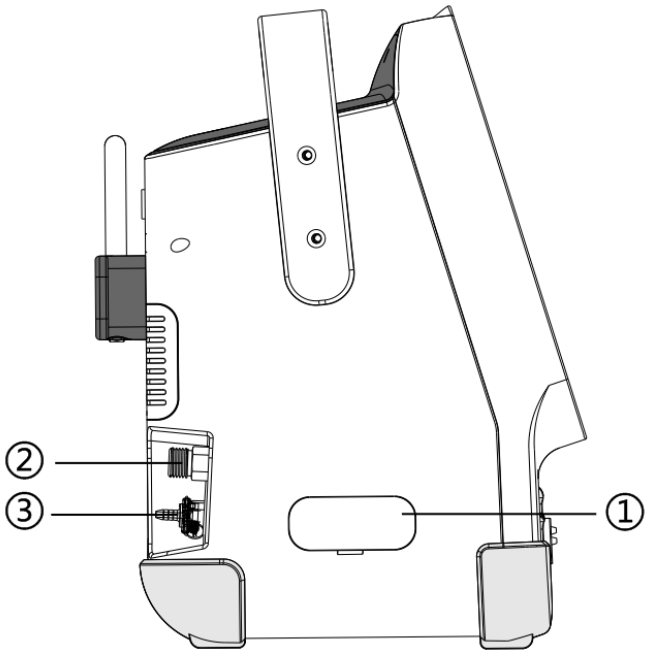


Fig. 4 Mainframe (left view)

Components	Description
1 EtCO2 interface	It is visible after lifting the silicone cover and is used to connect the ETCO2 module.
2 Oxygen source interface (high pressure)	Used to connect the high-pressure oxygen source.
3 Oxygen source interface (low pressure)	Used to connect the low-pressure oxygen source.

2.6.5 T6 component diagram

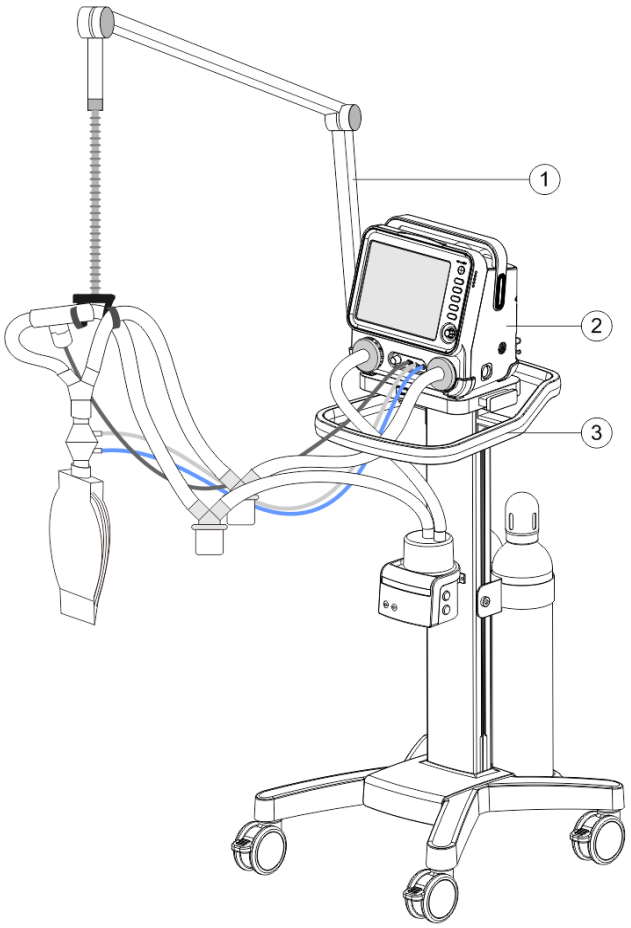


Fig. 5 T6 component diagram

Components	Description
1 Support arm	Used to support and suspend respiratory line of patients.
2 Mainframe	Include the oxygen line, electronic system, mechanical structure, display, and carbon dioxide module.
3 Trolley	Used to support the mainframe, support arm, oxygen cylinder and humidifier, etc.

3 Installation

⚠ **Warning:**

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

3.1 Packing items

T6 ventilator is packed in a single box. Please refer to "12 T6 accessories" for packing items.

3.2 Installation of battery

The battery used in T6 is a rechargeable lithium battery. Push the battery by hand after loading until a “click” indicating that the battery key is reset is heard, in order to ensure that the battery has been installed in place (as shown below).

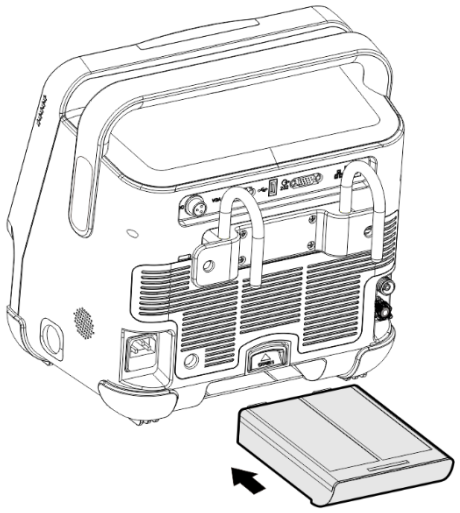


Fig. 6 Installation of battery

3.3 Connection of oxygen source

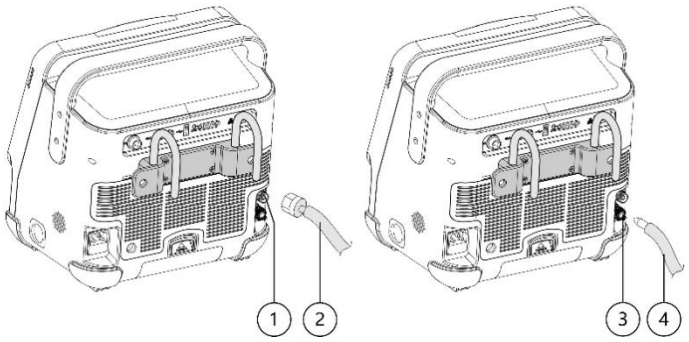


Fig. 7 Oxygen source interface

The ventilator is provided two gas source interfaces, namely the high-pressure oxygen and low-pressure oxygen.

When the ventilator is connected with the high-pressure oxygen gas source, the normal working gas source pressure is 300-600kPa. If pressure of gas source is lower than 300kPa, performance of the ventilator will be affected, or even the ventilation may be disenabled. When pressure of gas source is between 600 and 1,000kPa, performance of the ventilator will be affected, but it will not cause any harm due to the high-pressure gas. The connection steps of high-pressure oxygen gas source are as follows:

1. Check if the sealing ring of the connector is in good condition before connecting the gas source line. If the sealing ring is damaged, the line shall not be used and the sealing ring must be replaced, otherwise it will cause gas leakage.

2. Align the connector and insert it into the high-pressure oxygen gas source inlet on back of the ventilator.

3. Make that the gas source hose is connected to the gas source inlet into place, and tighten the nuts of the hose manually.

When the ventilator is connected to the low-pressure oxygen gas source, supply flow rate of low-pressure oxygen shall not exceed 8L/min. In order to reduce the risk of fire prevention, do not use the low-pressure oxygen gas sources whose output flow rate exceeds 8L/min. The connecting steps of the low-pressure oxygen gas source are as follows:

1. Align the low-pressure oxygen source hose and insert it into the low-pressure oxygen gas source interface.
2. It shows that the gas source hose has been installed in place when a "splat" sound is heard.
3. During removal, the metal dome on the low-pressure oxygen gas source

interface shall be pressed, and then the gas source hose shall be pulled out.

3.4 Power supply connection

The ventilator can be connected to DC power supply and AC power supply.

3.4.1 Connect AC power supply

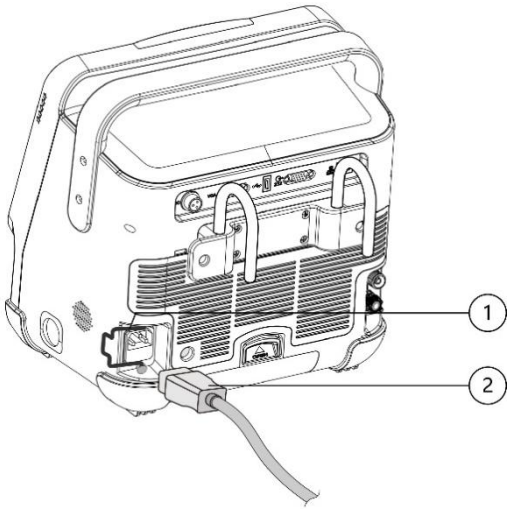


Fig. 8 AC power interface

1. Plug the AC power cord into the AC power socket.
2. Position the power cord retaining plate over the power socket and align it with the screw hole.
3. Tighten the two screws.

3.4.2 Connect DC power supply

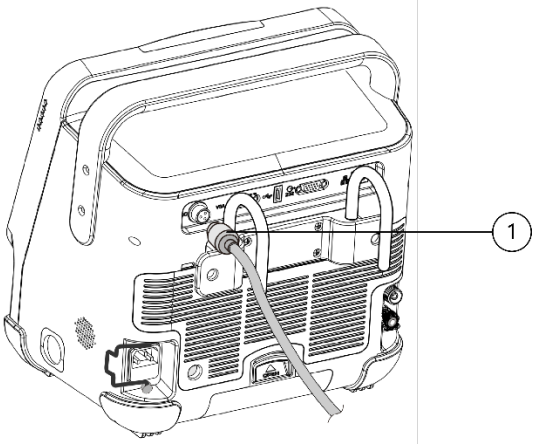


Fig. 9 DC power interface

Insert the DC power cord directly into the DC power input interface, and then rotate clockwise until a "splat" sound is heard which shows that it has been installed in place.

3.5 Install support arm

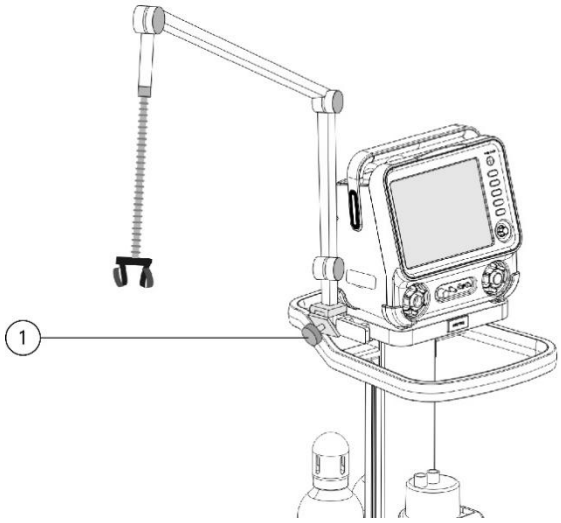


Fig. 10 Support arm installation diagram

1. Loosen knob of the fixing block (① in the figure), and place the fixing block on the handrail on side of the ventilator.
2. Tighten knob of the fixing block.

3.6 Patient respiratory line assembly and its connection

Respiratory line assembly of T6 is divided into repetitive respiratory line assembly and disposable respiratory line assembly. And connection mode of the line is: double-line connection mode. Following steps shall be followed in the connection mode (as shown below):

The respiratory hose and flow sensor in the respiratory hose assembly are connected according to the connection methods as shown in the following figure.

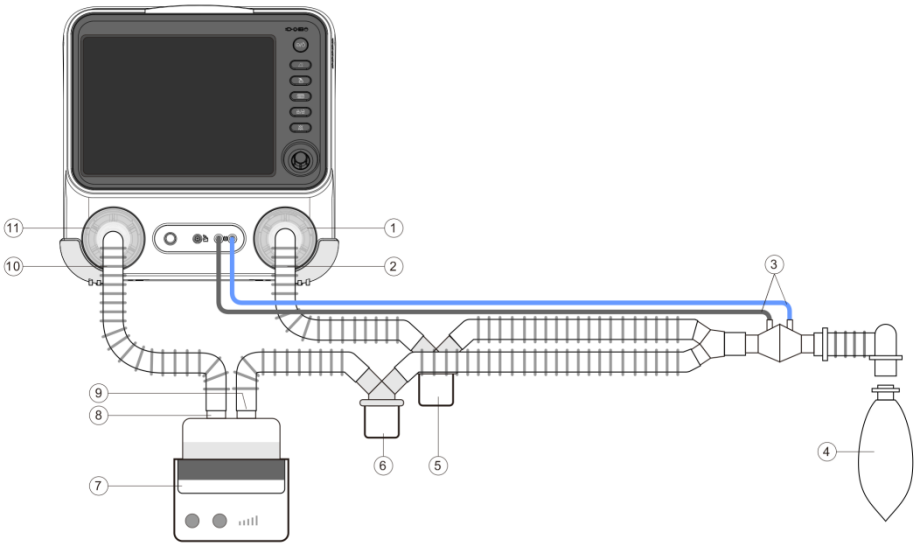


Fig. 11 Connection of double-line accessories

Components	Components
1 Expiratory branch filter	7 Humidifier
2 Expiratory line	8 Humidifier gas inlet
3 Flow sensor	9 Humidifier gas outlet
4 Simulated lung (patient)	10 Inspiratory line
5 Seeper trap in expiratory branch	11 Inspiratory branch filter
6 Seeper trap in inspiratory branch	

Notices:

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

Warning:

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

3.7 Install humidifier

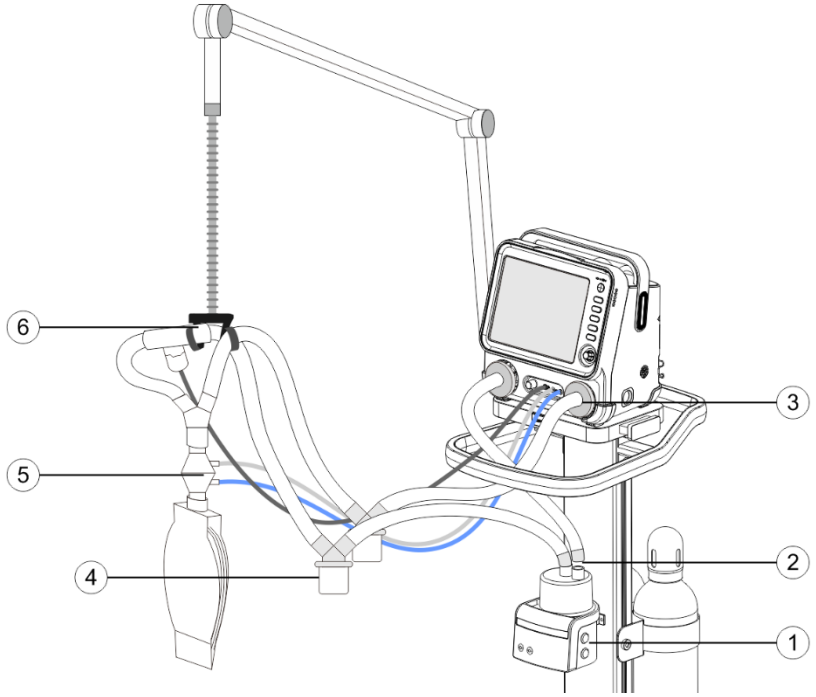


Fig. 12 Humidifier installation diagram

1. Align humidifier pulley with the humidifier support mounting seat and slide into it, and then tighten the screws.
2. Install the filter to the inspiratory and expiratory interface.
3. Connect the filter in inspiratory branch to the humidifier inlet via the line.
4. Connect the humidifier outlet to seeper cup via the line, and then connect the seeper cup to the Y-shaped connector via the line.
5. Connect the filter in expiratory branch to the seeper cup via the line, and then connect the seeper cup to the Y-shaped connector via the line.
6. Place the respiratory line on hook of the support arm.

Parts	Parts
1 Humidifier	2 Humidifier air-intake tube
3 Humidifier exhalation tube	4 Sump tank
5 External flow sensor	6 Nebulizer

3.8 Infant invasive pipeline connection

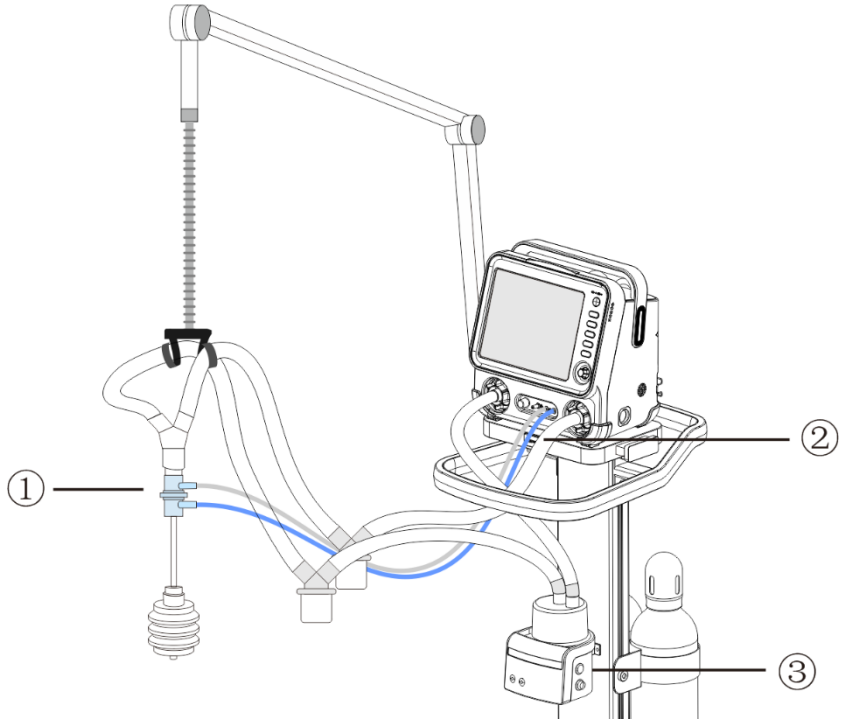


图 3-8 Schematic diagram of infant invasive pipeline connection

parts	parts
①Infant flow sensor	②Expiratory line
③Humidifier	

3.9 Infant noninvasive pipeline connection

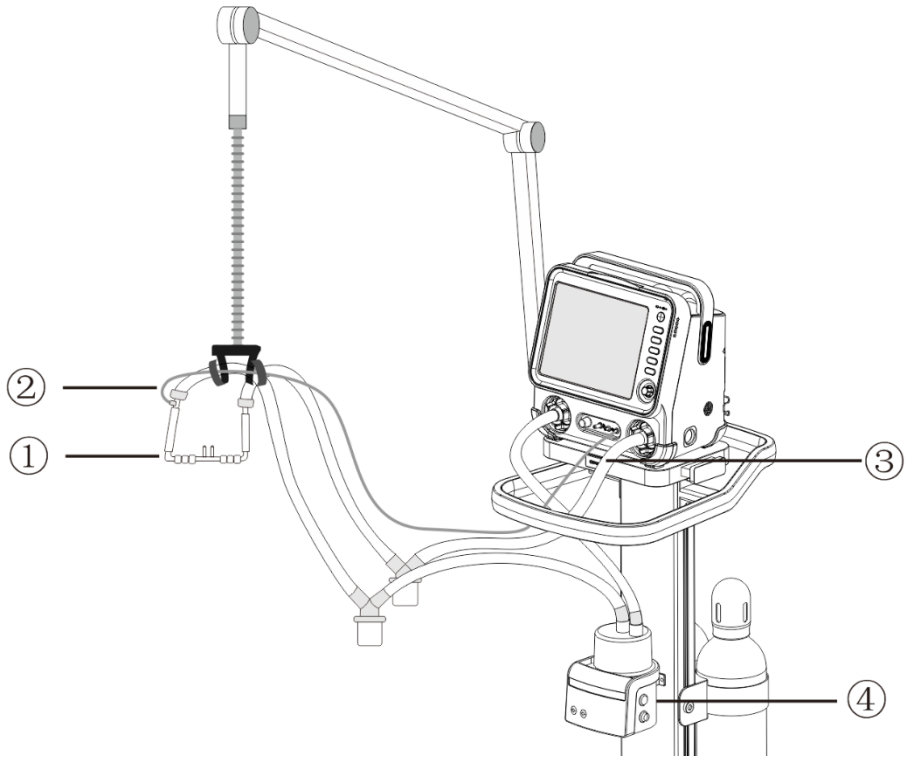


图 3-9 Schematic diagram of noninvasive pipeline connection for infants

parts	parts
①Infant nasal oxygen tube	②pressure pipeline tube
③Expiratory line	④Humidifier

Warning:

Infant patients:

•You can only select CPAP, PCV mode or switch from CPAP, PCV mode to other modes during standby.

•When switching from CPAP, PCV mode to other modes (and vice versa), you must calibrate the pipeline (for pressure pipeline) or flow sensor.

•The infant flow sensor requires that the breathing line can be used in all ventilation modes except CPAP mode and PCV mode. When using CPAP mode and PCV mode, remove the flow sensor and use the pressure monitoring line with breathing line.

3.10 Install nebulization

Nebulization refers to the drug is atomized into aerosol, and inhale by the patient, to achieve the purpose of treatment

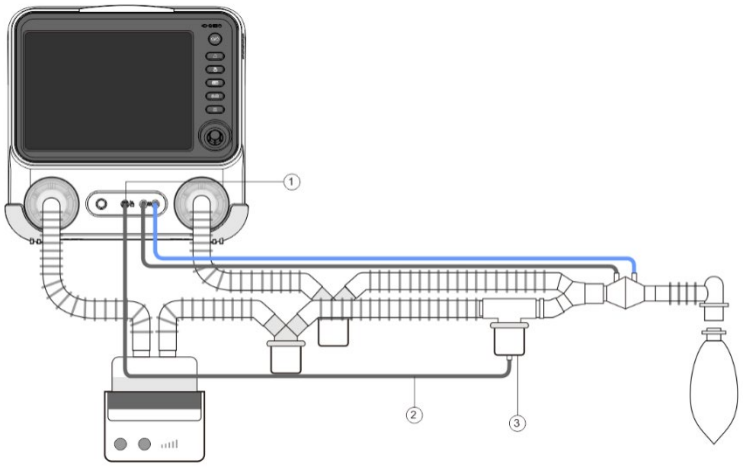


Fig. 13 Nebulizer installation diagram

Parts	Parts
1 Nebulization port	2 Nebulization air-intake tube
3 Pneumatic nebulizer	

3.11 Install EtCO2

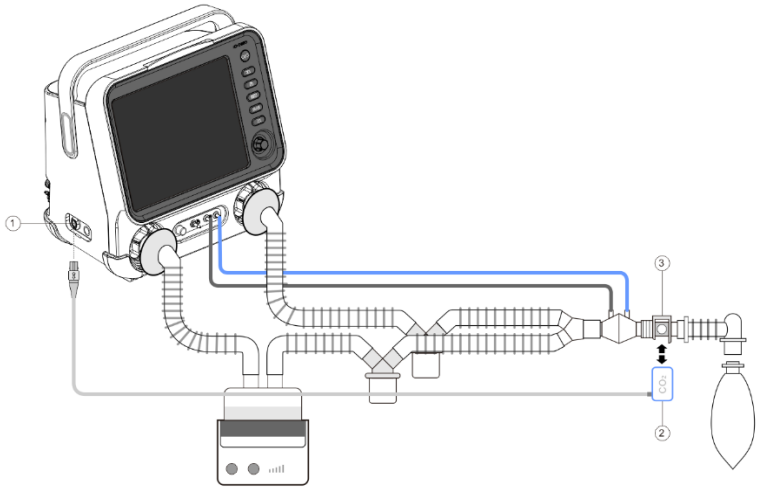


Fig. 14 EtCO2 installation diagram

Parts	Parts
1 CO_2 module port module	2 Mainstream CO2 monitoring
3 CO2 module adapter	

3.12 Patient breathe valve

3.12.1 Patient inspiratory valve

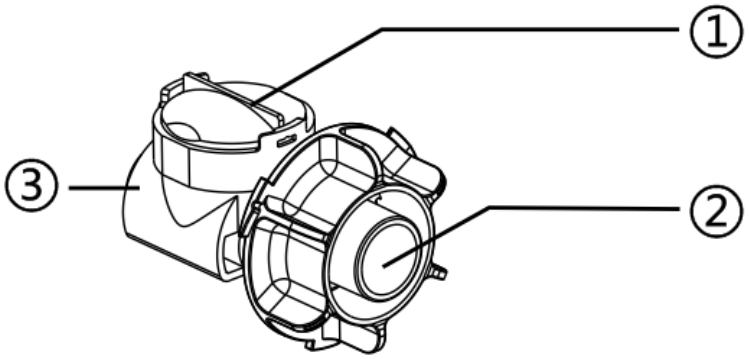


Fig. 15 Patient inspiratory valve

Components	Description
1 Safety valve cover	Can be used to replace diaphragm of the safety valve.
2 Gas outlet	Used to connect to patient inspiratory line, and is provided with a Φ15mm/22mm coaxial interface.
3 Safety valve vent port	It is used for vent of the safety valve, and is strictly forbidden to be blocked.

3.12.2 Patient expiratory valve

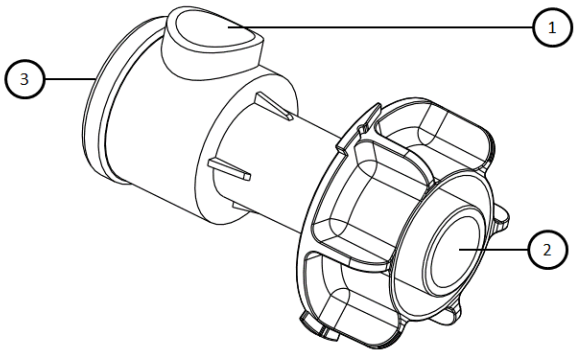


Fig. 16 Patient expiratory valve

Components	Description
1 Gas outlet	It is used as the patient expiratory outlet, and is strictly forbidden to be blocked.

2 Gas inlet	Used to connect to patient expiratory line, and is provided with a Φ15mm/22mm coaxial interface.
3 PEEP valve disc	/

Warning:

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

4 Interface description

4.1 Main interface components

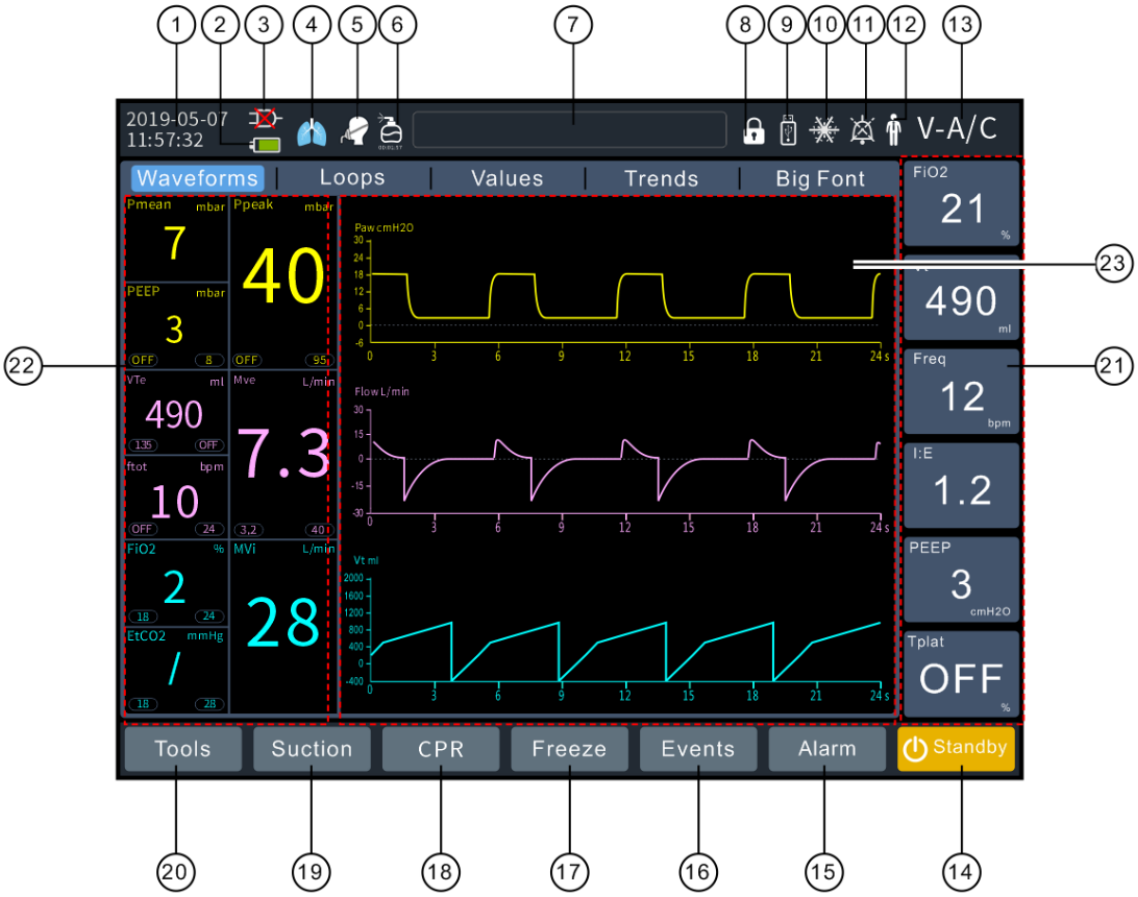


Fig. 17 Main interface

Components	Description
1 System date and time	Display current time and date.
2 Power supply service state	Display battery power and charging status.
3 Adapter state	Show whether the adapter is in place.
4 Patient trigger	Indicate that current respiration is triggered by the patient
5 Invasive/non-invasive	Indicate that current ventilation type (invasive or non-invasive)
6 Nebulization	Indicate whether atomization is currently turned on

7 Alarm/hint message area	Display alarm and message hints.
8 Screen lock	Display locking status of screen
9 USB	Display that the USB is connected now
10 Freezing mode	Show the waveform freeze status.
11 Alarm mute prompt icon	Display current alarm mute state.
12 Patient type icon	Display current patient type (adult/Pediatric).
13 Ventilation mode	Display current mode. After selecting, the mode selection interface can be brought up to re-select the mode.
14 Standby	The standby mode will be entered into after selecting
15 Alarm limit	The alarm limit interface can be brought up after selecting.
16 Log	The current patient log can be viewed after selecting.
17 Freezing	Waveform of current interface can be frozen after selecting.
18 CPR	The operations under CPR mode can be carried out after selecting.
19 Suction	After selection, suction is prompted and the mainframe will automatically carry out oxygen aeration. At this time, suction of the patient can be performed.
20 Tool	A special tool can be opened
21 Parameter setting area	
22 Parameter monitoring area	
23 Waveform area	

⚠ Notices:

All the operations that can be selected or confirmed by touch screen can also be

enabled by the navigation knob, which will not be described below, but is considered to be available by default.

4.2 Waveform interface

Select the [Waveform diagram] button on the main interface screen to open the interface as shown in the figure below

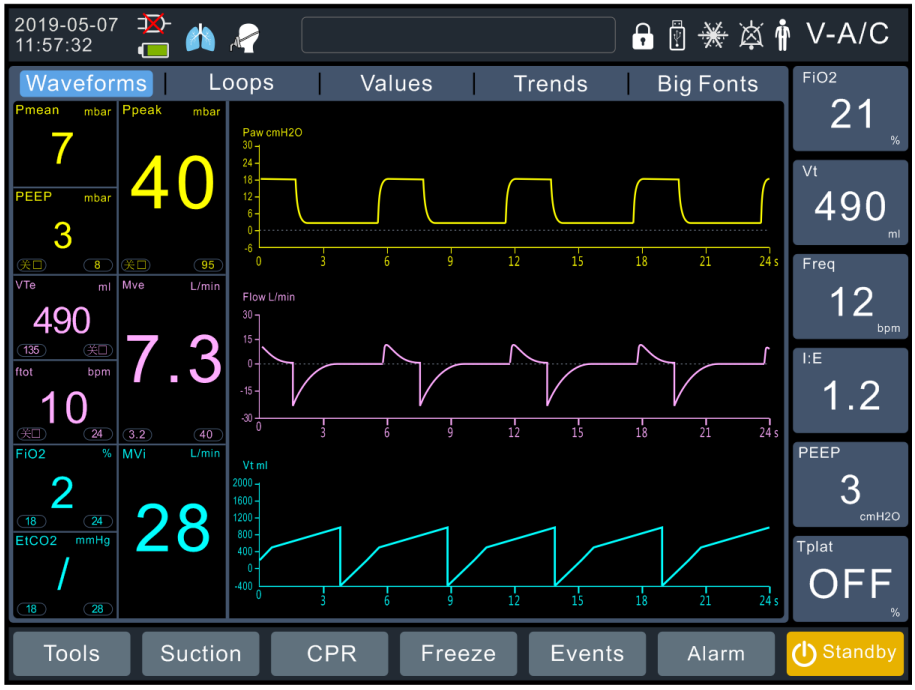


Fig. 18 Waveform interface

4.2.1 Monitor waveform switching

In the main interface, click the waveform to be switched, double click to pop up the switching options, and then select to switch

Fig. 19 Waveform switching

Notices:

In the waveform interface, figureswitching interface, monitoring interface, trend diagram interface and large fonts interface,the waveforms or parameters to be switched can be switched by double click, which will not be descrbed in detail below.

4.3 Loops interface

Select the [Loops] button on the main interface to open the interface as shown in the figure below. This interface can display the combination of 2 loops and 1 waveform on the same screen

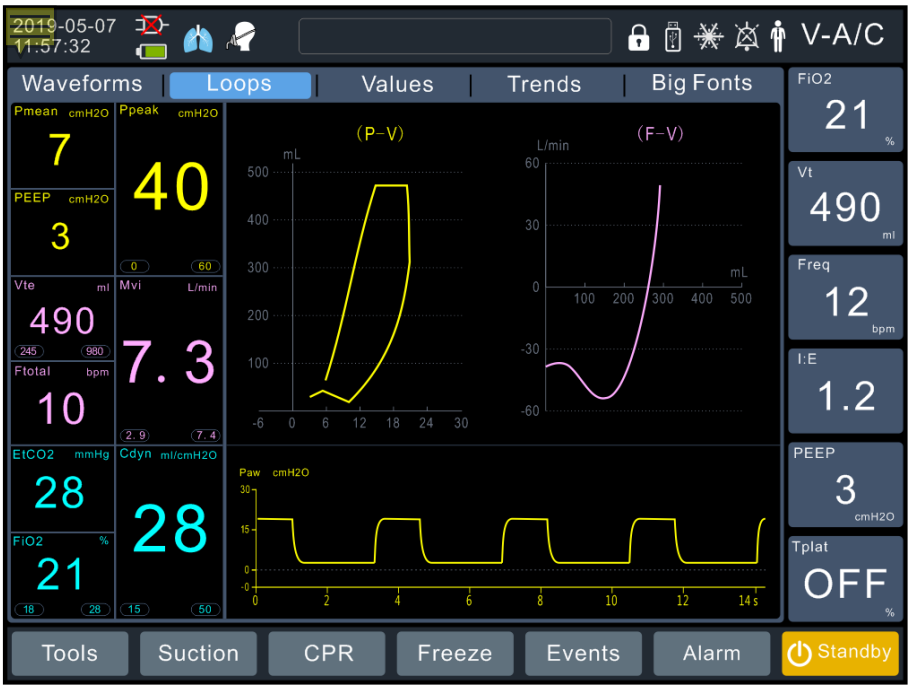


Fig. 20 Loops interface

4.4 Monitoring value interface

Select the [Monitoring value] on the main interface to open the interface as shown in the figure below

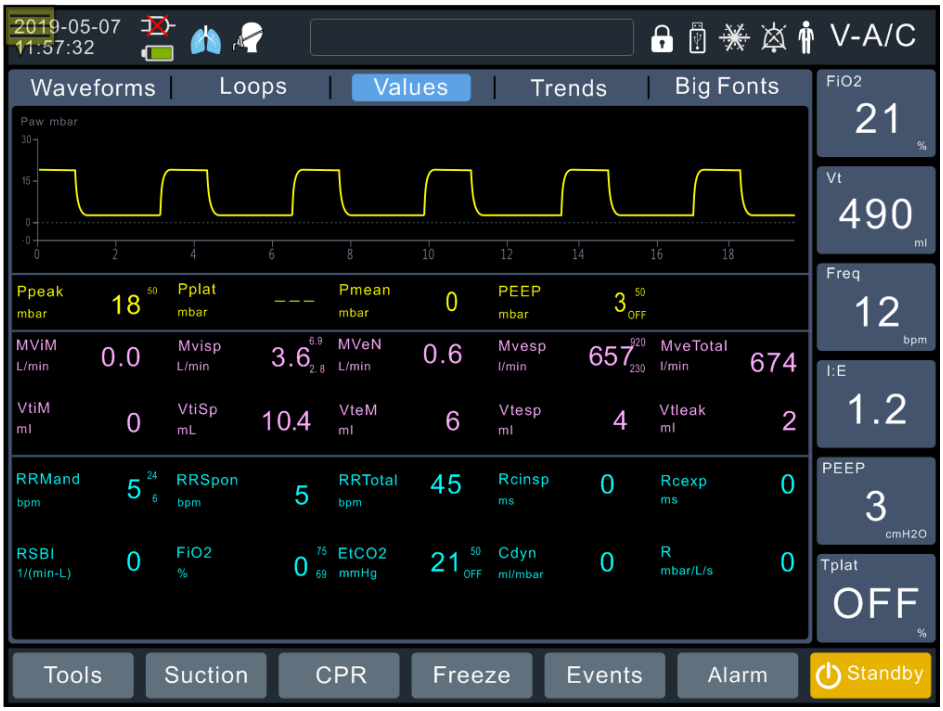


Fig. 21 Monitoring value interface

4.5 Trend diagram interface

In the main interface, select the [Trend diagram] option to pop up the trend setting interface. Enter the trend interface (as shown below).

You can set up the trend diagram or view trend data and trend waveforms in this interface. And view the 5min, 15min, 30min or 60min trend charts. The trend chart can be saved for a maximum of 168 hours.

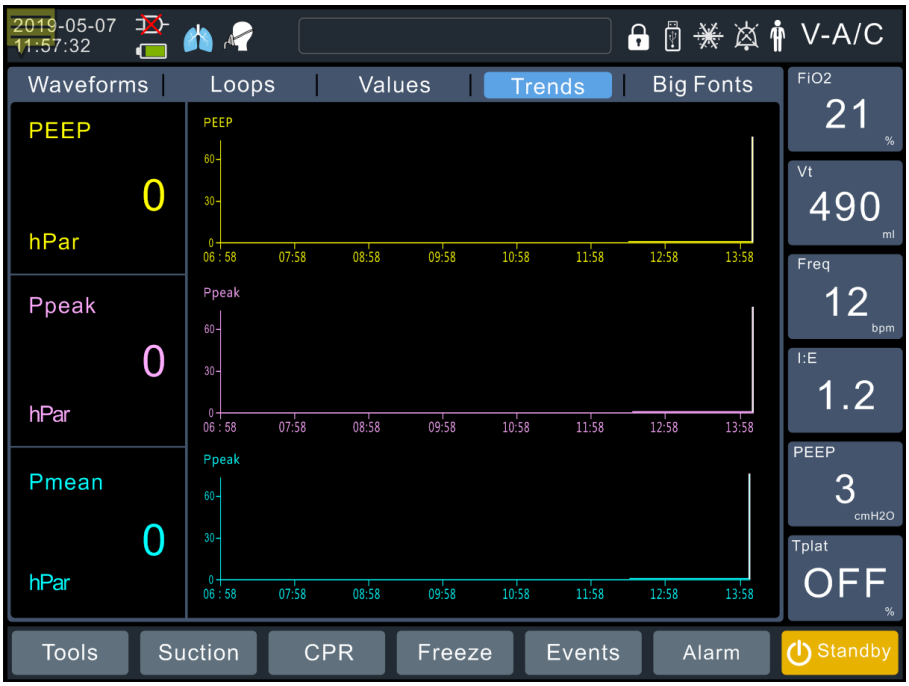


Fig. 22 Trend diagram interface

4.6 Big fonts interface

Select [Big fonts] on the main screen to open the interface as shown in the figure below

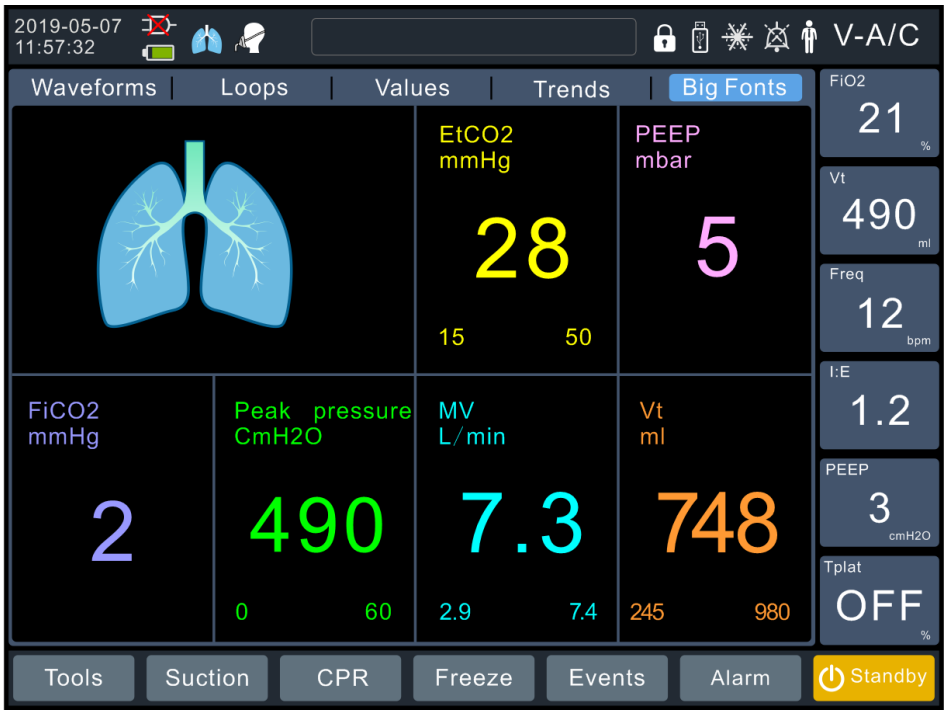


Fig. 23 Big fonts interface

4.7 Freezing

The freezing function is to temporarily stop real-time refresh of waveform and loops data on the screen, so as to review data of patient for a short period of time, and to observe condition of the patient during this period in detail. The data reviewed are the waveforms and loops 30 seconds before entering the freezing state.

When the "Freeze" is pressed again, the freezing state can be cancelled.

4.8 Events

The system has logging function. Users can click the "Events" button in main interface to enter the events interface to view the system events. At present, the system supports storage of up to 5,000 messages. When the maximum number of log messages is reached, the newer event will overwrite the older ones. The following points shall be noted when viewing the logs:

- Events structure: time + type + message.
- Events type: alarm message, user use message, system operation message. (Only the alarm message is provisionally available)
- Events e: specific message description.
- Color of events: red for advanced alarms; yellow for middle-level alarms, and

black for others.

- The events can be viewed by category: display all, alarms, and events.

4.9 Settings

In the main menu, you can optimize settings of the mainframe to adapt to different usage situations. The main menu can be brought up by pressing the [Function menu] soft button on right side of the machine, and then corresponding settings can be made by the navigation knob or touching.

Components	Description
1 System	To set the screen brightness, unit, desktop style, waveform style, voice, waveform content and loops content.
2 General	To set general functions of the device
3 Service	To maintain and calibrate the device
4 About this device	To view main software version number, control software version number and power board software version number of the device

4.9.1 System

In the [System] interface, you can set the system parameters according to your needs (as shown below).

Fig. 24 System settings

Keys	Description
1 Time setting	Year, month, day, hour, minute
2 Language	Chinese (default). Adjustable range: Chinese, English
3 Sound Type	Beep(default)
4 Volume	Level 1 by default. Adjustable level 1-3
5 Luminance	Level 3 (default). Adjustable range: level 1-3
6 style	Night (default). Adjustable range: night, day
7 Waveform	Filling (default). Adjustable range: filling, line
8 Pressure	mbar (default). Adjustable range: mbar, hPa, cmH2O

4.9.2 General

Fig. 25 General setting

Keys	Description
1 Nebu time	1-90 min (adjustable)
2 Hold Time	1-40s (adjustable)
3 Sensor temperature	0-100 (adjustable)
4 Gas	ATPD, STPD, BTPS (adjustable)
5 Humidifying	Artificial nose and humidifier (optional)
6 Oxygen sensor	Indicate whether the oxygen concentration sensor is connected
7 Height/weight	Select to set height/weight
8 I:E/Ti	Select to set inspiration and expiration ratio/inspiratory time
9 Height	Select to set height unit:cm,inch
10 Weight	Select to set weight unit:kg,lb

4.9.3 Service

From [Settings]→[Service], you can enter the Service interface, which contains the user maintenance and manufacturer maintenance function.

1、For user maintenance function, in the standby interface, click [Settings] → [Service] → [User maintenance] (for the maintenance operation, please refer to 11 “Maintenance and inspection”):

- EtCO2 Zeroing (8.4 EtCO2 zeroing)
- Calibrate oxygen concentration sensor (11.6 Oxygen concentration calibration)
- Flow sensor calibration (11.7 Flow sensor calibration)
- Calibration touchscreen （ 11.5 Touch screen calibration ）
- Data export (7.10 Data export)
- Oxygen consumption data (7.9 oxygen consumption)

2、For manufacturer maintenance function, in the standby interface, click [Settings] → [Service] → [Manufacturer maintenance] (this function is temporarily unavailable to users)

4.9.4 About

In the " Settings " → "About", view the software version.

5 Special functions

5.1 Lung recruitment

Lung recruitment maneuver is a pulmonary protective ventilation strategy. The applying of a pressure higher than the normal mean airway pressure and maintaining it for a certain period of time during mechanical ventilation can enable reexpansion of more collapsed alveoli on one hand, and prevent secondary atelectasis caused by small tidal ventilation on the other hand.

1. click [Tools] → [Lung recruitment] in the home screen to open the recruitment tool and set the corresponding parameters.
2. Click [Measure], and the system will perform the recruitment maneuver according to the preset parameters
3. Click [Cancel] to stop the current recruitment maneuver.

⚠Notices：

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

5.2 CPR

CPR (cardiopulmonary resuscitation) mode is a procedure used in first aid. CPR (Cardiopulmonary Resuscitation) is a mode of emergency ventilation for circulatory or respiratory arrest, and is used to maintain oxygen supply to the patient's body tissues and assist the discharge of CO2 inside the body. In CPR mode, constant-volume controlled ventilation is adopted, and three ways of [30:2], [15:2] and [continuous pressing] can be selected for operation. The ventilation volume can be set by users, and the preset volume is different for different patient types.

It mainly includes the following steps:

1. **Step 1**: Select CPR (as shown below)

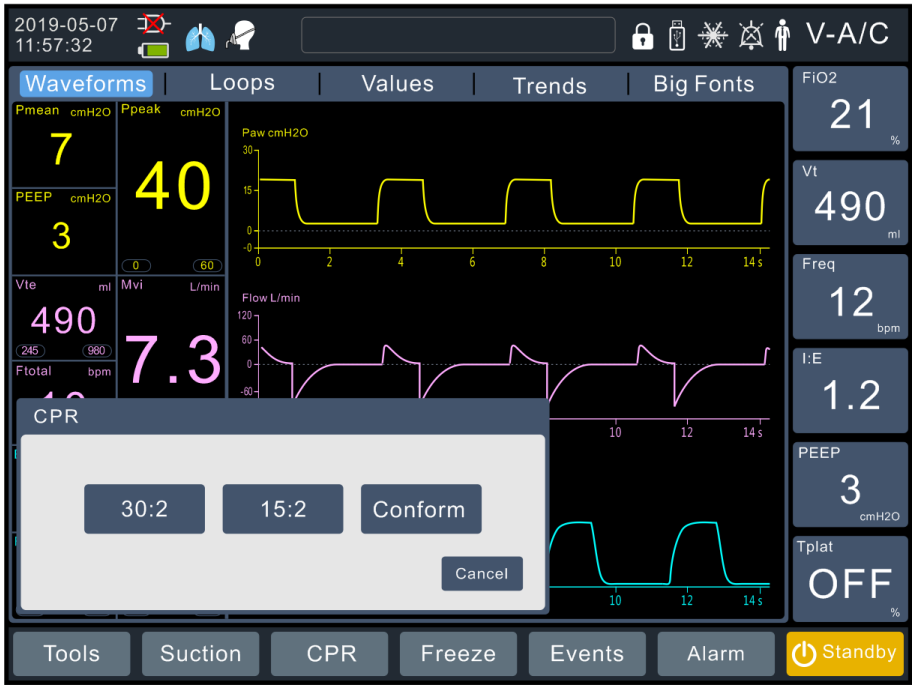


Fig. 26 CPR (select operation mode)

2. **Step 2: Start CPR by following the voice prompts and the "Dong Dong Dong..."beat**

- 30:2: Namely, 30 pressings and 2 default ventilations are given
- 15:2: Namely, 15 pressings and 2 default ventilations are given
- Continuous pressing: that is, pressings are accompanied by default ventilation

Notices：

- It's not available in infant types.

5.3 PEEPi

PEEPi (intrinsic PEEP) refers to the positive end-expiratory alveolar pressure in the absence of extrinsic PEEP

1. Select [Tools] key → [Diagnosis] → [PEEPi].
2. Select the [PEEPI] button to enter the PEEPI measurement interface.
3. After selecting the [Start] button in the opened interface, the system will start the P0.1 measurement.
4. After measurement, the system will display the measurement results. The ventilator is able to display results of the last three measurements.

Notices：

- PEEPi function is not available in CPAP/PSV mode.

- Manual breath, inspiratory hold, and expiratory hold functions cannot be initiated during PEEPi measurements.
- It's not available with HFNC, CPR and infant types.

5.4 P0.1

P0.1 refers to the pressure drop within the first 100ms when the patient begins to breathe autonomously.

1、Select [Tools] key → [Diagnosis] → [P0.1].

2、Select the [P0.1] button to enter the P0.1 measurement interface.

3、After selecting the [Start] button in the opened interface, the system will start the P0.1 measurement.

4、After measurement, the system will display the measurement results. The ventilator is able to display results of the last three measurements.

Notices：

- It's not available in IPPV, PCV, CPAP/PSV, HFNC, CPR and infant types.

5.5 NIF

NIF means the maximum negative pressure generated by the patient breathing spontaneously over a period of time.

1. Select [Tools] button → [Diagnostics] → [NIF].
2. After pressing the [Exp Hold] button, the system will start the measurement.
3. Once you release the [Exp Hold] button or the button is automatically released 15 seconds later, the measurement is completed, and the system will display the measurement results.
4. The respirator can display the results of the last three measurements.

Notices：

- It's not available with HFNC, CPR and infant types.

5.6 Dynamic lung

The amount of light and dark in the lung image indicates the inspiratory and expiratory process. The lung is brighter and larger during inspiratory process. The lung is dark and smaller during expiratoryprocess. Click [Large fonts] on the main interface to see the dynamic lung interface.

The dynamic lung state is as follows:

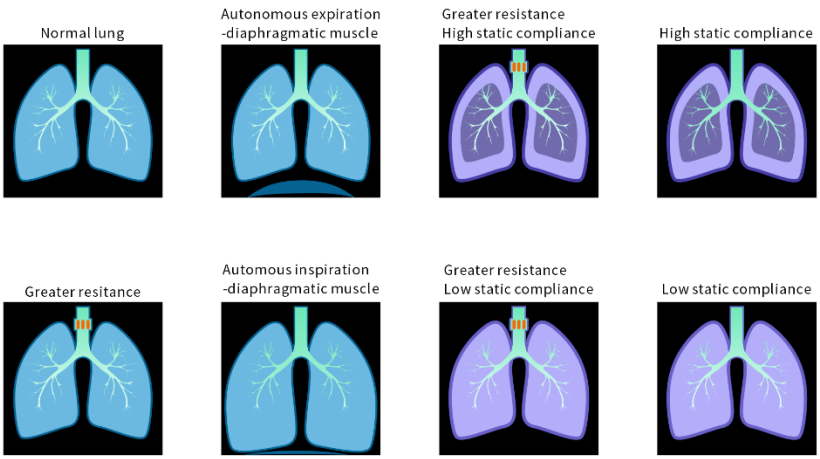


Fig. 27 Dynamic lung

5.7 Sputum Suction

Sputum suction is the process during which respirator is used to assist the user to suck sputum of the patient. The respirator automatically detects the action of the user disconnecting and connecting the patient's tube, applies oxygenated ventilation before and after sputum suction, and block relevant alarms during the process of sputum suction.

1、Click [Sputum Suction] on the home screen, and the respirator will automatically start the oxygenating function for 120s.

2、Once you disconnect the patient's catheter, the system alerts [Patient's catheter disconnected! Please reconnect the patient once suctioning is complete!]

3、Once the operation for the patient is completed, please connect the patient's catheter. When a tube connection is detected, the system will oxygenate and ventilate the patient for 120 seconds.

Notices：

- P0.1, PEEPi, and NIF are not able to be started once the sputum suction is initiated.
- Not available in CPR mode
- 100% pure oxygen is given during the oxygenating stage for the Adult type, and 1.25 times of the current oxygen concentration value is given for the pediatric and infant type.

5.8 Inspiratory holding

Inspiratory holding is the practice of artificially prolonging the patient's inspiratory stage and preventing the patient from expiration for a certain period of time.

1. After selecting the [Tools] key → [Hold] → [Inspiratory hold], and pressing the [Inspiratory hold] key continuously, the ventilator will enable the inspiratory holding function, and the system will prompt [Inspiratory holding is in progress]. After releasing the [Inspiratory hold] key, the ventilator will disenable the inspiratory holding function.
2. The maximum duration of inspiratory holding is 40 seconds. When the [Inspiratory hold] key is pressed for more than 40 seconds, the ventilator will automatically disenable the inspiratory holding function.
3. The maximum duration of inspiratory holding can be set in the [Functions menu] → [General] and [Maximum inspiratory hold] option.
4. During inspiratory holding, the machine will automatically calculate the patient's Pplat and display it in the prompt bar.

Notices: :

- Not available in HFNC, CPR and CPAP mode
- You can not activate Insp Hold function in CPAP/PSV ventilation mode. If apnea ventilation occurs, the Inspiration Hold function is supported.

5.9 Expiratory holding

Expiratory holding is the practice of artificially prolonging the patient's expiratory stage and preventing the patient from inspiration for a certain period of time.

1. After selecting the [Tools] key → [Hold] → [Expiratory hold], and pressing the [Expiratory hold] key continuously, the ventilator will enable the expiratory holding function, and the system will prompt [Expiratory holding is in progress]. After releasing the [Expiratory hold] key, the ventilator will disenable the expiratory holding function. After you release the [Expiratory hold] key, the ventilator will automatically disenable the expiratory holding function.
2. During inspiratory holding, the machine will automatically calculate the patient's PEEPi and display it in the prompt bar.

Notices :

- Not available in HFNC, CPR and CPAP mode
- You can not activate Expiration Hold function in CPAP/PSV ventilation mode.

If apnea ventilation occurs, the Expiration Hold function is supported.

5.10 Manual

After selecting [Tools] key → [Function] and clicking [Manual], the machine will automatically provide one inspiration or respiration in the current ventilation mode.

⚠ Notices:

- Not available in HFNC and CPR mode
- You can not activate Manual Ventilation function in CPAP/PSV ventilation mode. If apnea ventilation occurs, the Manual function is supported.

5.11 Nebulization

Press the [Nebulization] soft key on the right side of the machine to enable the nebulization function

After clicking the [Function menu] → [General] → [Nebulization start time], and selecting the [Save] button after setting, and the ventilator will work according to the set nebulization time. After the nebulization function is enabled, remaining time of this function will be displayed in the system prompt message area.

When the nebulization time is reached or the [Nebulization] key is clicked again, the ventilator will disenable the nebulization function.

⚠ Notices:

- In the presence of aerosol products, EtCO2 cannot be measured. Remove EtCO2 monitoring module before activate the nebulization function. Sampling and monitoring functions on the EtCO2 module are suspended.
- When type of patient is infant, nebulization function is ineffective.
- When the oxygen gas source type is low-pressure oxygen, the nebulization function cannot be enabled.
- Drugs may block expiratory valve and flow sensor during nebulization, because of which inspection and cleaning shall be carried out after nebulization.
- Increased gas from the nebulizer may affect ventilator accuracy.
- Nebulization is not available when inspiratory flow rate is lower than 15 L/min.

5.12 P-V tool

Mechanical ventilation set at optimal PEEP can improve oxygenation, improve alveolar mechanics, and reduce lung injury. The P-V tool is a method to determine the optimal PEEP by drawing a static pressure-volume curve (static P-V ring) and then identifying the characteristic points on the static P-V ring diagram curve. The physician can use this function to determine the optimal PEEP indicated for the patient.

1. Select the [Tools] button → [P-V Tools]
2. Click [Measure], the system will start the measurement according to the preset value
3. At the end of measurement, [Result analysis] will display tidal volume, pressure and static compliance value.
4. Click [History Ring Chart] to check the last four complete measurement records.

⚠ **Notices**：

- It is not available when the patient is pediatric and infant & toddler type.
- It is not available in CPAP/PSV, non-invasive and apnea ventilation modes.
- It is not available during the process of sputum suction and within 1 minute after the process, and not available within 1 minute after the last P-V test

6 Alarm

6.1 Alarm message

The alarm messages with the highest priority at present will be displayed in the alarm prompt bar on the main interface. If there are multiple alarms, you can click the alarm prompt message bar in the main interface, and the alarm message interface will be brought up to view other alarm messages (as shown below).

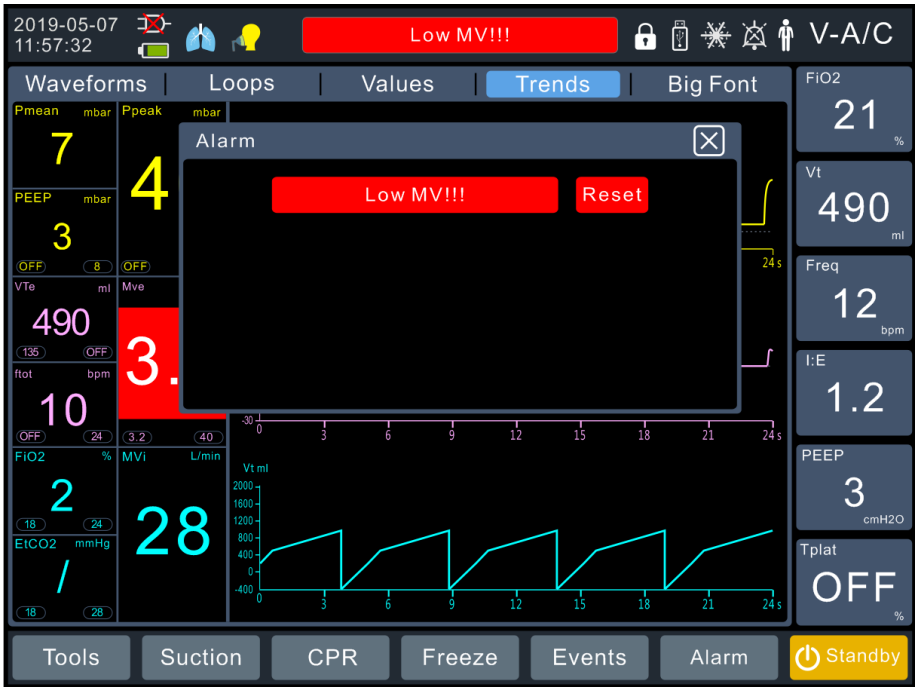


Fig. 28 Alarm prompt

6.2 Alarm priority

Each alarm will correspond to a type of alarm priority, and a variety of alarm phenomena may be produced. It can effectively alert medical staff when any abnormal conditions occur. Exception handling shall be carried out to prevent the occurrence of unexpected events. Description of the alarm function is detailed as follows:

- **Priority:**

Type	LCD	LED	Voice alarm
High-priority alarm	The alarm area on the main interface will turn red and	The red light flashes Flash	1. Five continuous “beep--beep--beep----beep-beep-” sounds will

Type	LCD	LED	Voice alarm
	corresponding alarm texts+ will be displayed!!!	frequency: 0.5s each time.	be heard, the pulse interval is |0.1s|0.1s|0.5s|0.1s|, the duration of pulse is 0.2s, and the interval of pulse group is 7s.
Medium-priority alarms	The alarm area on the main interface will turn red and corresponding alarm texts+ will be displayed!!	The yellow light flashes Flash frequency: 2s each time.	1. Three continuous “beep--beep--beep” sounds will be heard, the pulse interval is |0.1s|0.1s|, the duration of pulse is 0.1s, and the interval of pulse group is 24s.
Low-priority alarms	The alarm area on the main interface will turn yellow and corresponding alarm texts+ will be displayed!	The yellow light is always on	1. A “Beep” sound will be heard every 24s.

6.3 Technical Alarm

Alarm code	Alarm name	Alarm description	Priority
1000	Fault 1000!	Oxygen valve failure	High
1001	Fault 1001!	Turbine failure	High
1002	Fault 1002!	Control valve failure	High
1003	Fault 1003!	Output flow sensor failure	High
1004	Fault 1004!	Air flow sensor failure	High
1005	Fault 1005!	Oxygen flow sensor failure	High
1006	Fault 1006!	Internal flow sensor measurement error	High
1007	Fault 1007!	Output pressure sensor failure	High
1008	Fault 1008!	Input gas temperature sensor failure	High
1009	Fault 1009!	Output gas temperature sensor failure	High

Alarm code	Alarm name	Alarm description	Priority
1010	Fault 1010!	Motor temperature sensor failure	High
1011	Fault 1011!	Motor temperature read failure	High
1012	Fault 1012!	Oxygen supply pressure sensor failure	High
1013	Fault 1013!	Ambient pressure sensor 1 failure	High
1014	Fault 1014!	Ambient pressure sensor 2 failure	High
1015	Fault 1015!	Incorrect ambient pressure measurement	High
1016	Oxygen concentration sensor failure!!!	Oxygen concentration sensor failure	High
1017	Fault 1017!	Safety valve failure	High
1018	Fault 1018!	Patient sensor reading failure	High
1019	Fault 1019!	Ventilation module internal communication failure	High
1020	Fault 1020!	ADC conversion failure	High
1021	Fault 1021!	Module received illegal exception data	High
1022	Oxygen supply pressure is too low!	Air inlet is blocked	High
1023	LPO Error!!!	Oxygen supply pressure> 800 mbar	High
1024	Air inlet flow rate is low!!!	Air inlet is blocked	High
1025	Ventilation module voltage is too low!!!	12 ± 1V <voltage ≤ 20 ± 1V	High
1026	Ventilation module voltage is too low!!!	Voltage <12 ± 1V	High
1027	Motor temperature is too high!!!	70 °C <motor temperature ≤ 100°C	High
1028	Motor temperature is out of range!!!	Motor temperature> 100°C	High
1029	Patient side flow sensor failure!!!	Patient side flow sensor failure	High

Alarm code	Alarm name	Alarm description	Priority
1030	No valid patient flow rate measurement!!!	No valid patient flow rate measurement	High
1031	Patient side pressure sensor failure!!!	Patient side pressure sensor failure	High
1032	No pressure sensor!!!	No pressure sensor	High
1033	Input gas temperature too high!!!	Input gas temperature greater than 50°C	High
1034	Output gas temperature is too high!!!	Output gas temperature is greater than 50°C	High
1035	The catheter is blocked!!!	The catheter is blocked	High
1036	The catheter is blocked!!!	The catheter is blocked	High
1037	The breathing tube is detached!!!	The breathing tube is detached	High
1038	Maximum pressure reached!	Maximum pressure limit reached	Low
1039	PRVC min value reached!	PRVC min value reached	Low
1040	PRVC max value reached!	PRVC max value reached	Low
1041	Emergency pressure released!	Emergency pressure released	Low
1042	Pressure released to PEEP!	Pressure released to PEEP	Low
1043	Pressure released to the environment!	Pressure released to the environment	Low

6.4 Physiological alarm

Alarm code	Alarm name	Alarm description	Priority
2000	Airway pressure is too high!!!	Airway pressure is above upper limit	High
2001	Airway pressure is too low!!!	Airway pressure is below lower limit	High
2002	Minute ventilation volume is too high!!!	Minute ventilation volume is above upper limit	High

Alarm code	Alarm name	Alarm description	Priority
2003	Minute ventilation volume is too low!!!	Minute volume is below lower limit	High
2004	Oxygen concentration is too high!!!	Oxygen concentration is above upper limit	High
2005	Low Oxygen!!!	Oxygen concentration is below lower limit	High
2006	EtCO2 is too high!	EtCO2 is above upper limit	High
2007	EtCO2 is too low!!!	EtCO2 is below lower limit	High
2008	PEEP is too high!!!	PEEP is above upper limit	High
2009	PEEP is too low!	PEEP is below lower limit	Medium
2010	High flow rate!!!	CPAP mode, flow rate is above alarm limit	High
2011	Tidal volume is too high!!	Tidal Volume is above upper limit	Medium
2012	Tidal volume is too low!!	Tidal volume is below lower limit	Medium
2013	Respiratory rate is too high!!	Respiratory rate is above upper limit	Medium
2014	Respiratory rate is too low!!	Respiratory rate is below lower limit	Medium
2015	Patient embarrassed!!!	Patient suffered from embarrassment for a period longer than Suffocation time	High

6.5 Battery alarms

Alarm code	Alarm name	Alarm description	Priority
1044	Battery failure!!!	No output from battery	High
1045	Battery charging fault!!!	Battery can not be recharged	High
1046	Abnormal battery communication!!!	Battery and power board fail to communicate properly	High
1047	Battery is aged!!!	Full charged battery service time is too short	High
1048	Battery not found!!!	Battery not found	High

1049	Low battery!!!	Battery life time ≤ 20 minutes	Medium
1050	About to shut down, so connect to external power supply!!!	Battery life time ≤ 5 minutes	High
1051	High battery temperature, and the system is about to shut down!	High temperature during battery discharge, and the system is about to shut down. (>75 °C)	High
1052	High battery temperature, and please connect to the external power supply!!	High temperature during battery discharge (≥ 65 °C)	Medium
1053	External power supply disconnected!	External power supply disconnected	Low

6.6 Communication Alarms

Alarm code	Alarm name	Alarm description	Priority
3000	Main board communicating with gas module error!!!	Main board communicating with gas module error	High
3001	Main board communicating with power board error!!!	Main board communicating with power board error	High

6.7 Alarm rules

Condition	LED	LCD	Horn alarm
Multiple high-priority alarms are given simultaneously	Only the alarm messages with the highest priority will be displayed in the prompt area; however, all alarm messages are displayed in the alarm	The red light flashes, Flash frequency: 0.5s each time.	If it is a beep alarm, it will be given with high priority in the form of beeps.

Condition	LED	LCD	Horn alarm
	interface.		
Multiple medium-priority alarms are given synchronously	Only the alarm messages with the highest priority will be displayed in the prompt area; however, all alarm messages are displayed in the alarm interface.	The yellow light flashes, flash frequency: 2s each time	If it is a beep alarm, it will be given with medium priority in the form of beeps.
Multi-ple low-priority alarms are given synchronously	Only the alarm messages with the highest priority will be displayed in the prompt area; however, all alarm messages are displayed in the alarm interface.	The yellow light is always on	If it is a beep alarm, it will be givenwith low priority in the form of beeps.
High、medium and low priority alarms are given synchronously	Only the alarm messages with the highest priority will be displayed in the prompt area; however, all alarm messages are displayed in the alarm interface.	The red light flashes, Flash frequency: 0.5s each time.	If it is a beep alarm, it will be given with high priority in the form of beeps.

6.8 Alarm mode

Alarm mute:

- Press the mute button  to turn on or off the sound. If a new alarm is triggered during alarm mute, the voice alarm will be turned on again.
- The duration of alarm mute is 120s; after pressing the alarm mute, the sound will be muted for 120s; and, if the alarm still exists after 120s, it shall be restarted to turn on the sound.

Adjustment of alarm volume:

- Press the [Function menu] soft key, and click [System] → [Volume] to adjust the sound volume from :close , Level 1-3 .

Alarm form:

- Press the [Function menu] soft key, and click [System] →[Sound Type] to select the default beep alarm

Alarm cancellation:

- When the alarm limit is set to [OFF], the system will turn off the physiological alarm of the corresponding parameters. Namely, the text message, visual alarm, audible alarm and parameter flashing of the physiological alarm are all cancelled.

6.9 Setting of alarm limits

Alarm limits can be set according to physiological characteristics of the patient's breathing. The steps are as follows:

1. n the main interface, select [Alarm limits] via the navigation knob.
2. Select the alarm limits that you want to change, and press the navigation knob or directly touch to select.
3. Change the alarm limits selected, and press the navigation key again to determine.
4. Repeat step 2 and 3 to change the alarm limits that you want to change.
5. After the “Save” button is clicked, the changed prameters will become effect

6.10 Alarm parameter range

S/N	Alarm parameter	Alarm range
1	Upper limit of tidal volume	3-3,000mL, closed
2	Lower limit of tidal volume	Closed, 1-2,000mL
3	Upper limit of breath rate	5bpm-155bpm, closed
4	Lower limit of breath rate	Closed, 1bpm-145bpm
5	Upper limit of minute ventilation	0.02L/min ~ 50L/min

S/N	Alarm parameter	Alarm range
6	Lower limit of minute ventilation	0.01L/min ~ 25L/min
7	Upper limit of oxygen concentration	19%~100%
8	Lower limit of oxygen concentration	18%~99%
9	Upper limit of positive end expiratory pressure	1cmH2O-50 cmH2O
10	Lower limit of positive end expiratory pressure	Closed, 1cmH2O-40 cmH2O
11	Upper limit of airway pressure	12cmH_2O ~ 100 cmH_2O
12	Lower limit of airway pressure	Closed, 1cmH_2O-90 cmH_2O
13	Apnea	5s ~ 60s
14	Gas source pressure is insufficient	Pressure of oxygen source is below 250 kPa
15	Gas source failure	Pressure of oxygen source is below 110 kPa
16	Respiratory system integrity alarm	This alarm will be given when the respiratory line and other respiratory accessories are disconnected
17	Upper limit of end-tidal carbon dioxide	1mmHg-150mmHg, closed
18	Lower limit of end-tidal carbon dioxide	Closed, 1mmHg-149mmHg
19	Battery power is low	The device shall work for at least 20min from giving of an alarm to shutdown
20	The battery power is too low	The battery is running low
21	External power supply is disconnected	External power supply is disconnected

7 Operations

7.1 Power-on

Plug the power cord into power outlet. Make sure the external power indicator is on.

1. Press the [ON/OFF] button to turn on T6.
2. At this time, a progress bar indicating that the ventilator is subjected to self-inspection will appear on the screen. After the self-inspection, the main interface will pop up.
3. If self-inspection fails, an error code will be displayed on the screen. At this point, the ventilator cannot be used.

7.2 Self-inspection and calibration

Enter self-inspection mode of the system.

1. After the system is started, calibration interface of the system will be entered automatically, and the machine will automatically carry out gas line self-inspection and gas line calibration.
2. After selecting the [System self-inspection] button on the standby interface, you can enter the system calibration interface.
3. One-key calibration or single calibration is available

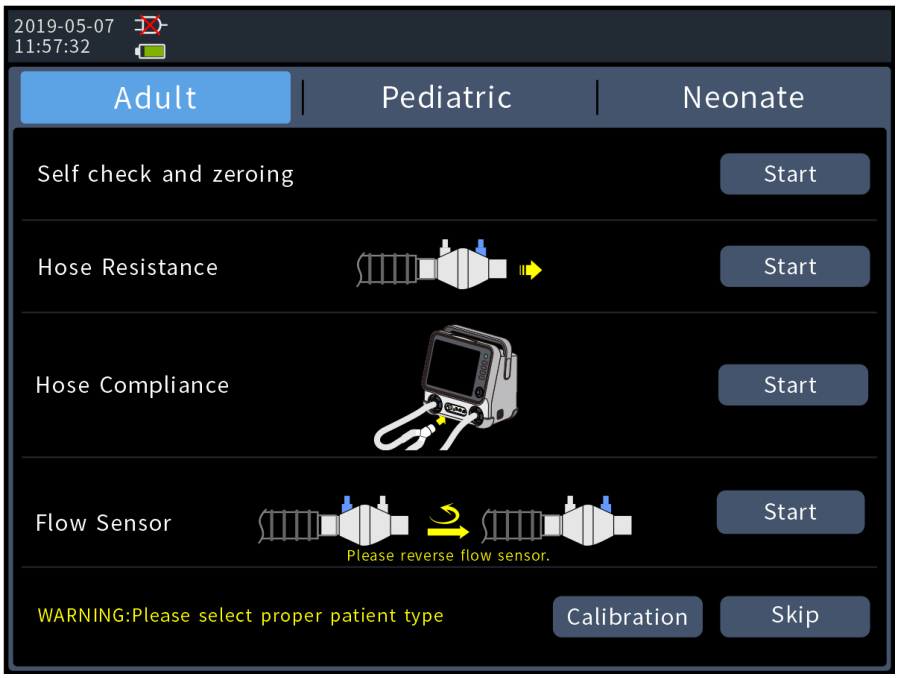


Fig. 29 Startup calibration interface

System calibration includes:

- Gas line zero calibration
- Line resistance calibration
- Line compliance calibration
- Flow sensor calibration

Notices:

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

7.3 Select the patient

System startup calibration interface. In this interface, you can choose the type of patients: adult, pediatric, infant.

Please select the patient after calibration. If you select the [Previous patient], set [Ventilation type] in the menu that is opened, and then select [Start ventilation]. If a [new patient] is selected, set [Gender], [Height]/[Ideal weight], [Ventilation method] (invasive or non-invasive) in the menu that is opened, and then select [Start

ventilation].

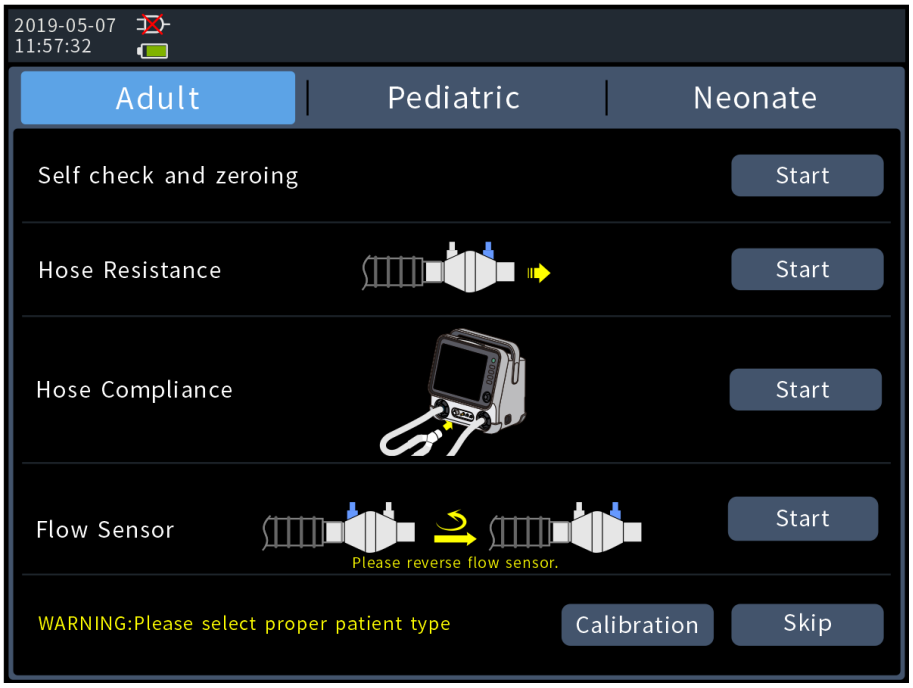


Fig. 30 Patient type selection

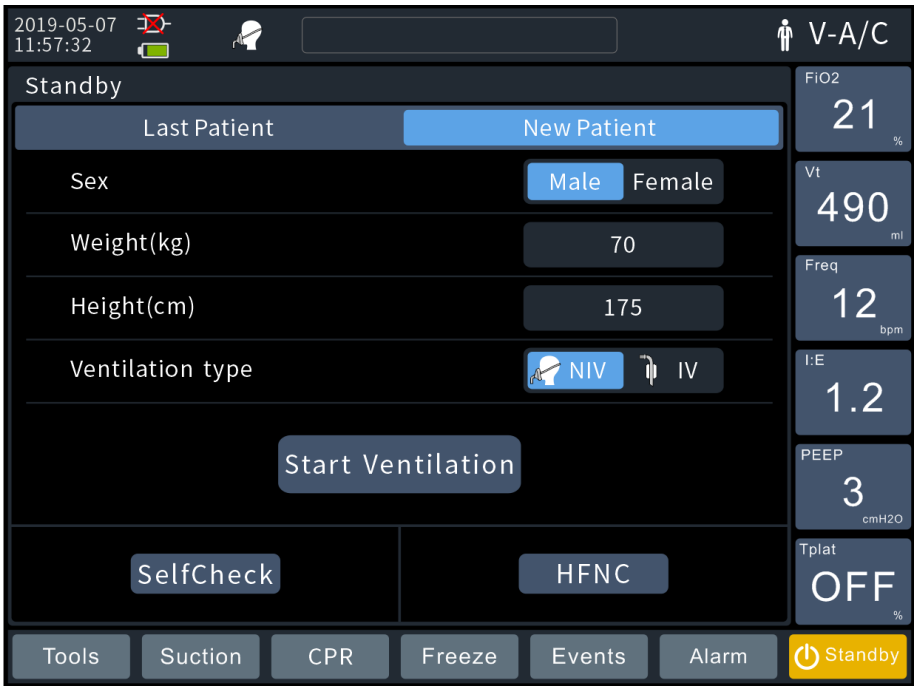


Fig. 31 Patient setting

Notices:

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

7.4 Ventilation type

This ventilator has two ventilation types: invasive ventilation and non-invasive ventilation.

Notices:

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

7.4.1 Invasive ventilation

Invasive ventilation is the ventilation of the patient through connection of artificial airway (endotracheal intubation and tracheotomy). The modes of ventilation that can be initiated with invasive ventilation include: P-A/C, IPPV, PCV, P-A/C, V-SIMV, P-SIMV, PRVC, PRVC -SIMV, APRV, BiPPV, CPAP/PSV ,and under infant types: PCV, P-A/C, PRVC, PRVC-SIMV, P-SIMV, APRV, BiPPV, CPAP/PSV.

Notices:

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

7.4.2 Non-invasive ventilation

Non-invasive ventilation refers to the fact that ventilation of patient is enabled by a nasal mask or respiratory mask without endotracheal intubation or tracheotomy intubation. In non-invasive ventilation mode, the following is available for adult and pediatric types: P-A/C, P-SIMV, APRV, BiPPV, CPAP/PSV, and in infant types: CPAP, PCV.

Notices:

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

7.5 Selection of ventilation mode

For selection of ventilation mode, just select the <Ventilation mode> soft button in main interface to bring up the ventilation mode interface, and then select the ventilation mode required by you (as shown in the figure below).

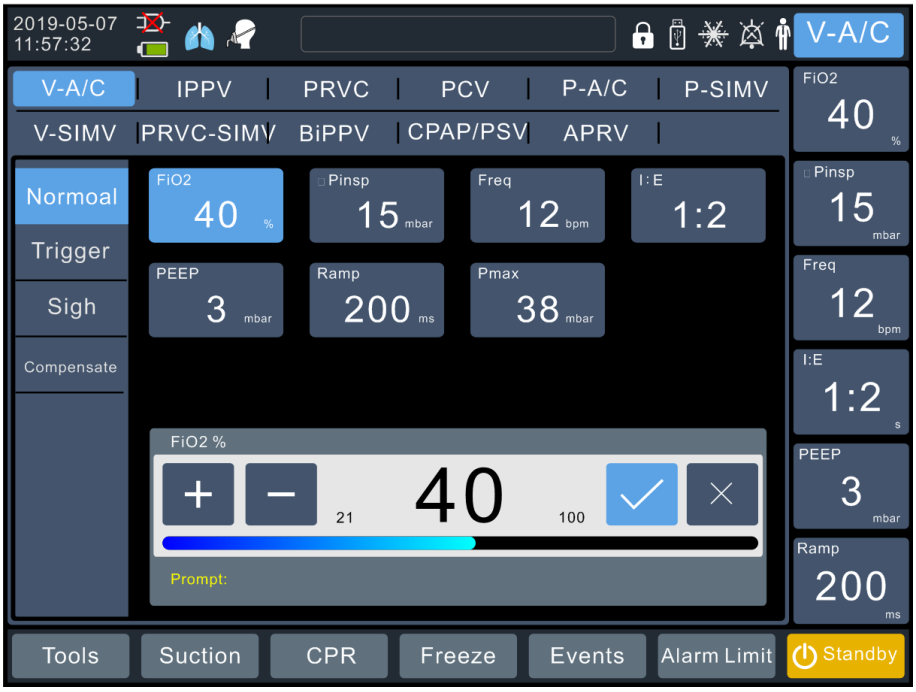


Fig. 32 Ventilation mode selection

7.6 Set ventilation control parameters

7.6.1 Ventilation parameter setting

After selecting the ventilation mode button in upper right corner of the interface in ventilation mode setting area, and the menu that is openeddisplays the ventilation parameters that can be set in this ventilation mode.

1. Select the ventilation parameter keys to be set.
2. Press the main control knob, and then rotate the knob to set the parameters to an appropriate value.
3. Press the main control knob again to confirm the setting, or select [√] to confirm and save, or [×] to cancel the operation
4. Follow the same method to set other parameters that need to be set.
5. After setting the parameters, select the [Save] button.

The quick setting of ventilation parameters is as follows:

1. Select the ventilation parameters to be set in the parameter setting shortcut button area on the right side of the interface.
2. Press the main control knob, and then rotate the knob to set the parameters to an appropriate value.

3. Press the main control knob again to confirm the setting, or select [√] to confirm and save, or [×] to cancel the operation.

4. Follow the same method to set other parameters that need to be set.

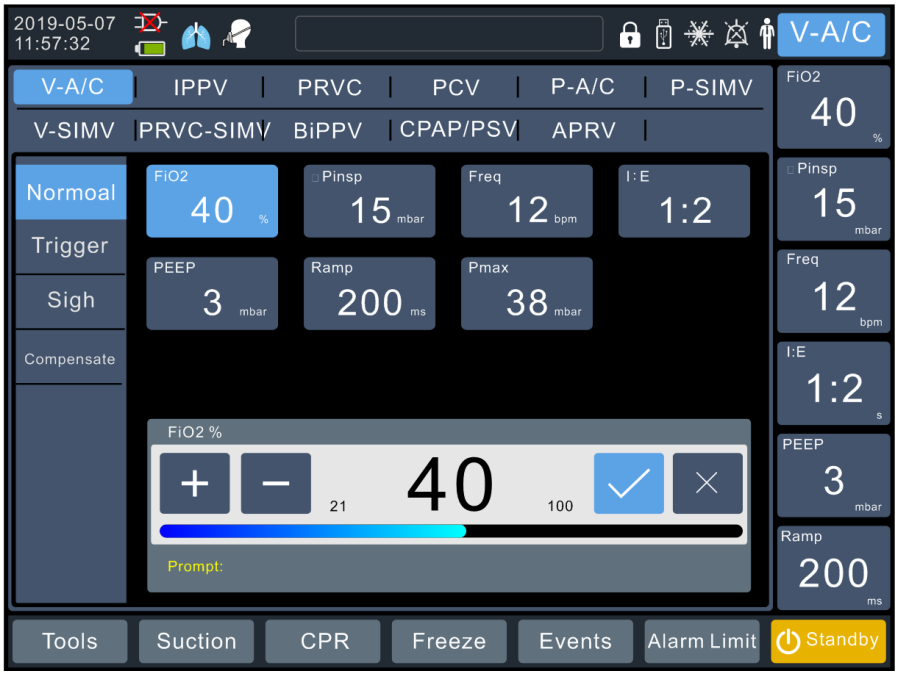


Fig. 33 Ventilation parameter setting

7.6.2 Ventilation parameters in each mode

Ventilation mode	Set parameters
IPPV	Tidal volume/inspiratory time/breath rate/PEEP/oxygen concentration/upper pressure limit/inspiratory pause/sigh
V-A/C	Tidal volume/inspiratory time/breath rate/PEEP/oxygen concentration/sigh/inspiratory trigger mode/inspiratory trigger threshold/upper pressure limit/inspiratory pause/sigh
V-SIMV	Tidal volume/inspiratory pause/inspiration time/inspiratory platform time/SIMV frequency/PEEP/oxygen concentration/sigh/inspiratory trigger mode/inspiratory trigger threshold/expiratory switching sensitivity/trigger window/support pressure/upper pressure limit/sigh
PCV	Inspiratory pressure/inspiratory time/pressure rise time/breath rate/PEEP/oxygen concentration/upper pressure limit/sigh
P-A/C	Inspiratory pressure/inspiratory time/pressure rise

	time/breath rate/PEEP/oxygen concentration/sigh/inspiratory trigger mode/inspiratory trigger threshold/upper pressure limit/sigh
P-SIMV	Inspiratory pressure/inspiratory time/pressure rise time/SIMV frequency/PEEP/oxygen concentration/sigh/inspiratory trigger mode/inspiratory trigger threshold/expiratory switching sensitivity/trigger window/support pressure/upper pressure limit/sigh
APRV	Support pressure/inspiratory trigger mode/inspiratory trigger threshold/expiratory switching sensitivity/PEEP/oxygen concentration/low pressure time/high pressure time/high airway pressure/upper pressure limit/sigh
BiPPV	Support pressure/inspiratory trigger mode/inspiratory trigger threshold/expiratory switching sensitivity/PEEP/oxygen concentration/low pressure time/high pressure time/high airway pressure/upper pressure limit/sigh
CPAP	Support pressure/inspiratory trigger mode/inspiratory trigger threshold/expiratory switching sensitivity/PEEP/oxygen concentration/upper pressure limit
PRVC	Tidal volume/inspiratory time/pressure rise time/breath rate/ /PEEP/ PRVCmax/PRVCmin/oxygen concentration/sigh/inspiratory trigger mode/ PRVC max /PRVC min /inspiratory trigger threshold/expiratory switching sensitivity/upper pressure limit
PRVC-SIMV	Tidal volume/inspiratory time/pressure rise time /SIMV frequency/PEEP/ PRVCmax/PRVCmin/oxygen concentration/sigh/inspiratory trigger mode/ PRVC max/PRVC min /inspiratory trigger threshold/expiratory switching sensitivity/upper pressure limit/sigh
CPAP	PEEP/oxygen concentration/upper pressure limit
CPAP -PC	Inspiratory pressure/inspiratory time/pressure rise time/breath rate/PEEP/oxygen concentration/upper pressure limit
CPR	Tidal volume/oxygen concentration/pause

HFNC	Oxygen therapy flow/oxygen concentration/upper pressure limit

7.6.3 IPPV and PCV

- **Intermittent positive pressure ventilation: IPPV**

During mechanical ventilation of IPPV (Intermittent Positive Pressure Ventilation), the ventilator always provides intermittent positive pressure ventilation. The pressure rises and is positive during inspiration, and the pressure returns to the baseline pressure during expiration. Namely, the patient with apnea or who is not breathing is provided with continuous respiratory support, and each respiration is mandatory. IPPV is a widely used ventilation technique in clinical practices, and is mainly used for the patients without autonomous respiration. Regardless of the condition of the patient's autonomous respiration, the ventilator will provide intermittent positive pressure ventilation to the patient as per the preset ventilation parameters.

Typical pressure waveform of IPPV is as follows:

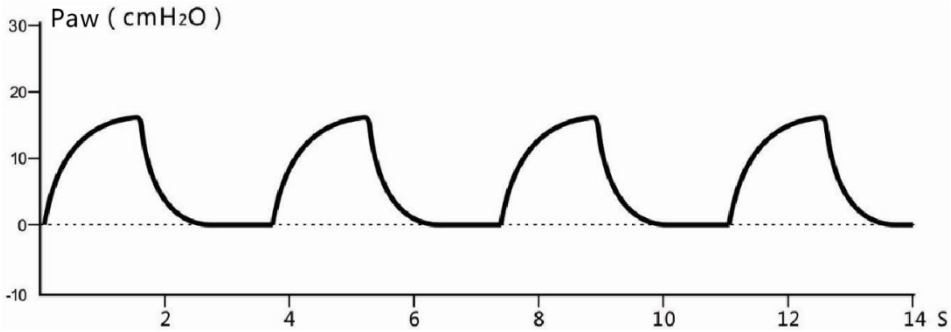


Fig. 34 IPPV typical pressure waveform

- **Pressure controlled ventilation: PCV**

PCV (Pressure Controlled Ventilation) – to preset airway pressure and inspiratory time. After inspiration begins, the gas velocity increases rapidly. After the preset pressure level is reached, the gas velocity is slowed down through the feedback system, and the preset pressure level is maintained until the end of the inspiration, and then the expiration begins. Each time the ventilation is completely carried out with full load at the preset pressure. When PCV is enabled, the airway pressure is reduced, there is no peak pressure, and the occurrence of barometric injury is less. It is beneficial to inflate the alveolar which is not easy to fill, improve the ventilation/blood flow ratio, and the gas exchange is good. PCV is most commonly used in neonates, infants, and the patients with respiratory failure and severe

ventilation/flow ratio imbalance caused by ARDS or COPD. Even when the respiratory line leaks, it can also ensure the supply of tidal volume. PCV shall be used when the gas line leaks.

Typical pressure waveform of PCV is as follows:

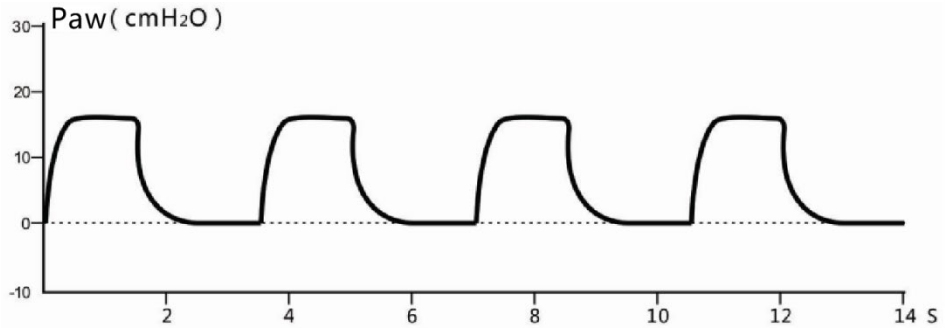


Fig. 35 PCV typical pressure waveform

7.6.4 V-A/C and P-A/C

- **V-A/C**

V-A/C is a volume-controlled ventilation mode based on VCV and supports synchronous triggering during the expiratory stage. When the trigger pressure/flow rate meets the trigger conditions, the ventilator provides once VCV ventilation with fixed tidal volume in advance.

The typical pressure waveform of V-A/C is shown below:

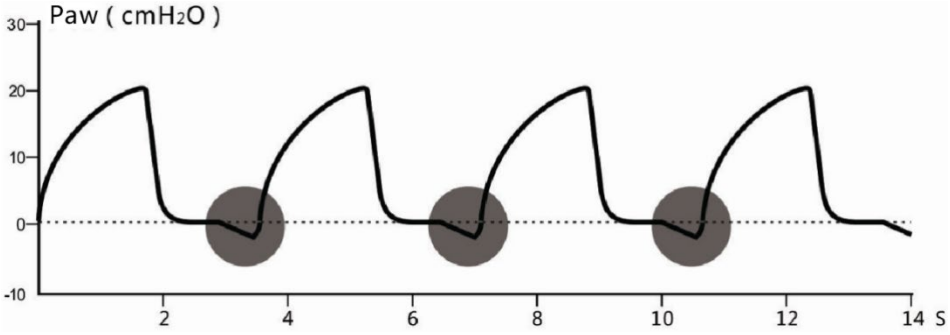


Fig. 36 V-A/C typical pressure waveform

- **P-A/C**

P-A/C is a pressure-controlled ventilation mode based on PCV and supports synchronous triggering during the expiratory stage. When the trigger pressure/flow rate meets the trigger conditions, the ventilator provides once PCV ventilation with fixed inspiratory pressure in advance.

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

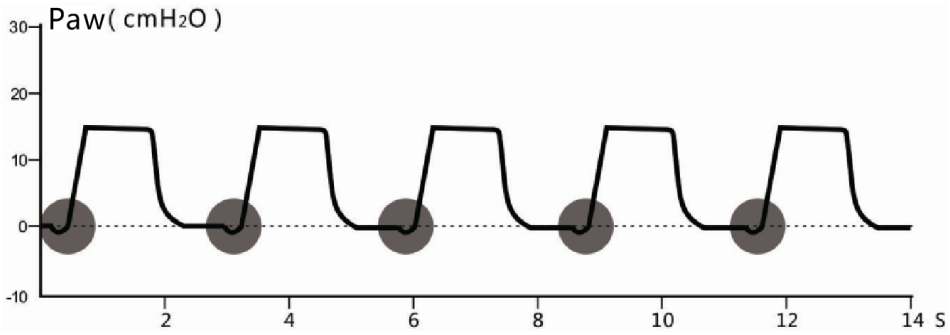


Fig. 37 P-A/C typical pressure waveform

The [Sigh] is a deep inspiration greater than current tidal volume/pressure at every other set ventilation times on the basis of the specified ventilation frequency, and is applicable for the patients who need mechanical ventilation for a long time.

7.6.5 V-SIMV and P-SIMV

Synchronized intermittent mandatory ventilation: SIMV

SIMV (Synchronized Interruptive Mandatory Ventilation) is a ventilation technology organically combining autonomous respiration and IPPV, which ensures effective ventilation of patients, is free of any patient-ventilator asynchrony, appropriately regulates the frequency and volume of SIMV, and is conducive to exercise respiratory function of patients. SIMV has become a clinically necessary technique before weaning from ventilator.

V-SIMV (volume controlled synchronized intermittent mandatory ventilation) refers that the machine provides support pressure in case of a triggering outside the trigger window during mechanical ventilation. In a specific trigger window, the ventilator detects the patient's inspiratory effort according to setting of trigger sensitivity and immediately gives forced ventilation once according to the preset tidal volume, so that supply of the mandatory ventilation is synchronized with the patient's inspiratory force. If the patient is able to trigger the ventilator within the time of trigger window, auxiliary ventilation will be given. If the patient fails to trigger after the trigger window expires, forced ventilation will be given once.

The typical pressure waveform of V-SIMV is shown as follows:

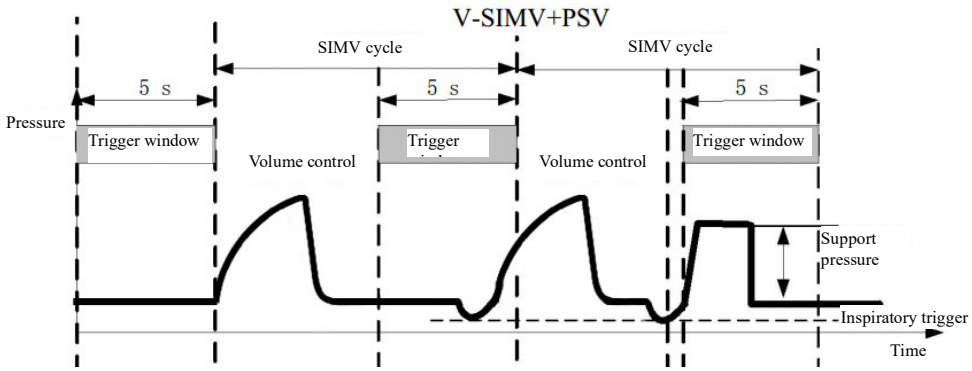


Fig. 38 V-SIMV typical pressure waveform

P-SIMV (pressure-limited synchronized intermittent mandatory ventilation) refers that the machine provides support pressure if the patient is able to trigger the ventilator outside the trigger window during mechanical ventilation. In a specific trigger window, the ventilator detects the patient's inspiratory effort according to setting of trigger sensitivity and immediately gives forced ventilation once according to the preset pressure, so that supply of the mandatory ventilation is synchronized with the patient's inspiratory force. If the patient is able to trigger the ventilator within the time of trigger window, auxiliary ventilation will be given. If the patient fails to trigger after the trigger window expires, forced ventilation will be given once.

The typical pressure waveform of P-SIMV is shown as follows:

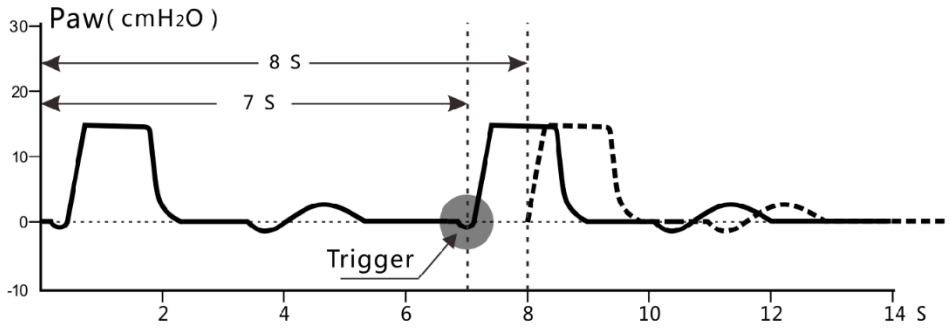


Fig. 39 P-SIMV typical pressure waveform

Warning:

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

7.6.6 CPAP/PSV

Continuous Positive Airway Pressure with Pressure Support

CPAP is a continuous positive airway pressure. The respirator includes a sensitive airway pressure measuring and regulating system, which can regulates the flow

rate of positive airway pressure over time in order to maintain a constant airway pressure at the predicted CPAP level. CPAP is a ventilation mode that provides a certain pressure level under the condition of spontaneous respiration, so that the positive airway pressure is maintained throughout the respiratory cycle. PSV with pressure support means the system activates a pressure support ventilation cycle when the patient's inspiratory effort reaches the preset inspiratory trigger level. The pressure rise time and pressure support level are set by the user. When the inspiration starts, the system will make the patient's airway pressure rise to the preset pressure level according to the preset pressure rise time, and then maintain this pressure level, until the patient's inspiratory flow rate reaches the expiratory trigger level.

The typical pressure waveform of CPAP/PSV is shown below:

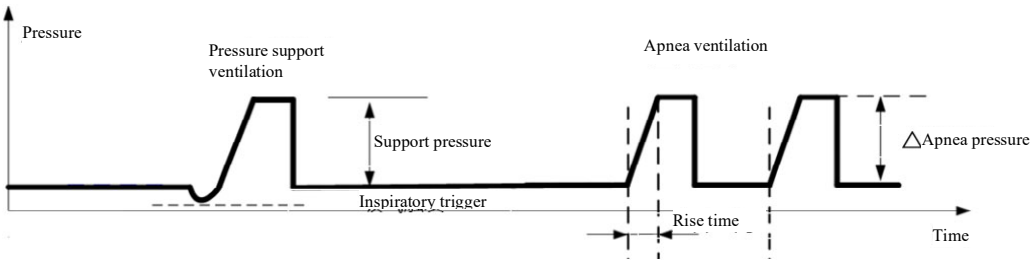


Fig. 40 CPAP/PSV typical pressure waveform

7.6.7 BiPPV

BiPPV, known as the bi-level positive airway pressure, is a procedure in which the ventilator alternately supplies two different levels of positive airway pressure during mechanical ventilation or autonomous respiration. Autonomous respiration of the patient at both of these two pressure levels is available, and support pressures can be set at both high and low pressure stages. The trigger window can be set at both the high and low pressure stages. The low-pressure support ventilation will be supplied for any triggering outside the trigger window in low-pressure stage, while high-pressure gas will be supplied for inspiratory triggering in the trigger window in low-pressure stage. High-pressure support ventilation will be supplied for the inspiratory triggering outside the trigger window in high-pressure stage, while expiration will be changed to during expiratory triggering within the trigger window in high-pressure stage.

Typical pressure waveform of BIPPV:

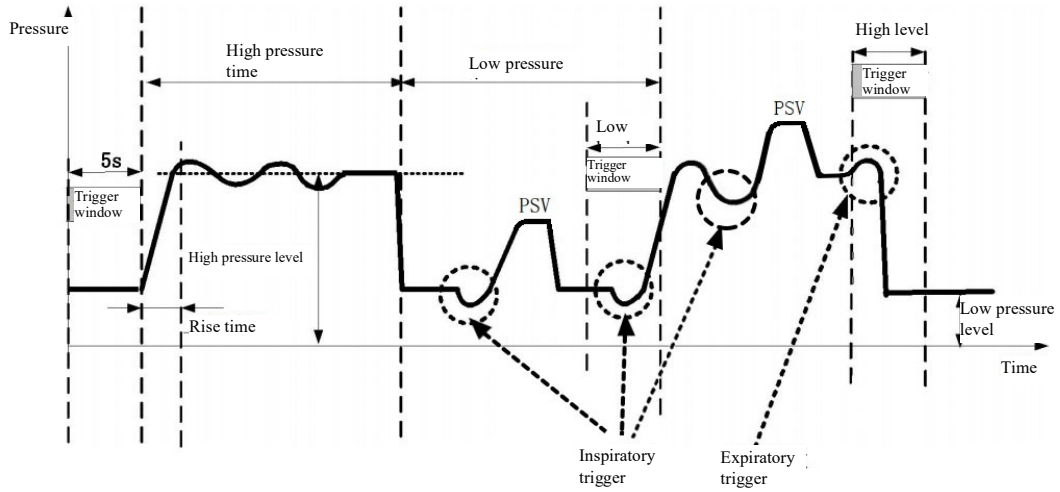


Fig. 41 BIPPV typical pressure waveform

7.6.8 APRV

APRV mode is known as the airway pressure release ventilation mode, which can be viewed as giving periodic and transient airway pressure release in CPAP mode. Autonomous respiration is available at high pressure level, where the support pressure can be set during the high pressure stage, and the time spent in the low pressure release stage shall be less than the high pressure ventilation time.

The typical pressure waveform of APRV:

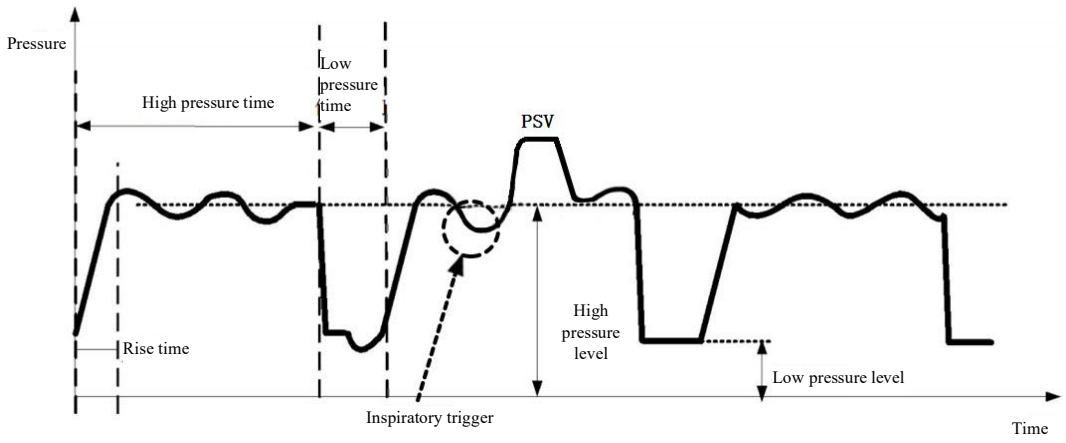


Fig. 42 APRV typical pressure waveform

7.6.9 PRVC

In PRVC mode, volume control is carried out in the manner of pressure-controlled ventilation. In this mode, the pressure level is kept as low as possible during inspiratory stage, while the ventilation control is ensured that the gas supply amount is equal to the preset tidal volume. The pressure control level varies depending on setting size of the tidal volume and resistance compliance of the

patient's lung. After completion of 3-4 times of test ventilation, the machine shall increase the pressure by no more than 3cmH2O each time, the PRVC max and the starting control pressure is PRVC min value + 5 mbar

Typical pressure and flow velocity waveforms controlled by PRVC mode are as shown below:

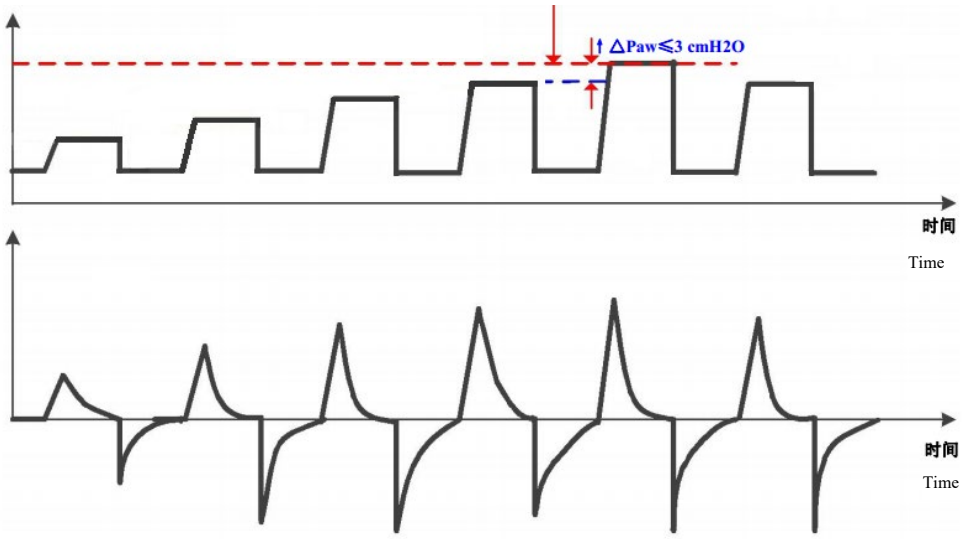


Fig. 43 PRVC mode controlled typical pressure and velocity waveforms

7.6.10 PRVC-SIMV

The PRVC-SIMV mode is known as the pressure-regulated volume control-synchronous intermittent mandatory ventilation mode, and is a ventilation mode that ensures the lowest preset ventilation frequency. The mechanical ventilation mode provided is the volume mode (PRVC mode). The SIMV is triggered within the trigger window to supply the volume control ventilation once. If a trigger window has not been triggered at the end of the trigger window, the volume control ventilation is also provided once. Autonomous or pressure supporte respiration outside the trigger window is carried out.

The typical pressure waveforms controlled by PRVC-SIMV mode are as shown below:

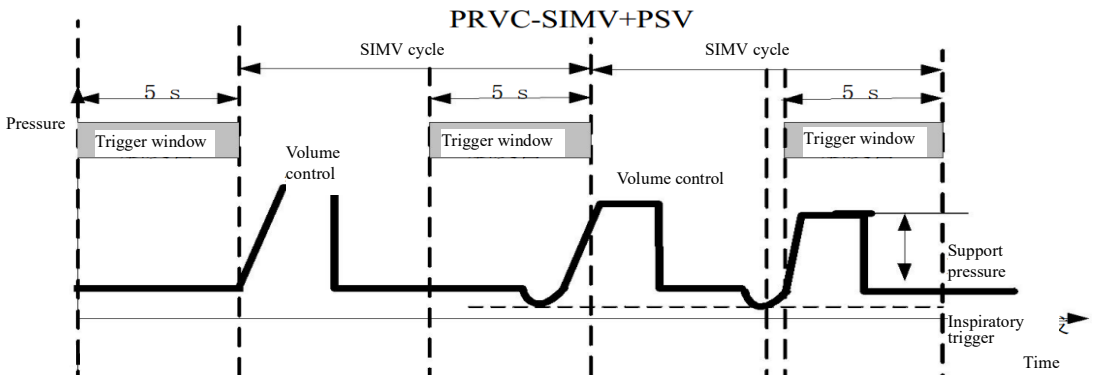


Fig. 44 PRVC-SIMV mode controlled typical pressure waveform

7.6.11 CPAP

CPAP mode is known as the nasal continuous positive airway pressure mode: in this mode, continuous positive airway pressure is provided through the nasal interface (nasal catheter or nasal mask), and respiration frequency and tidal volume of the patient are determined by the patient himself.

The typical pressure and flow velocity waveforms controlled by CPAP mode are as shown below:

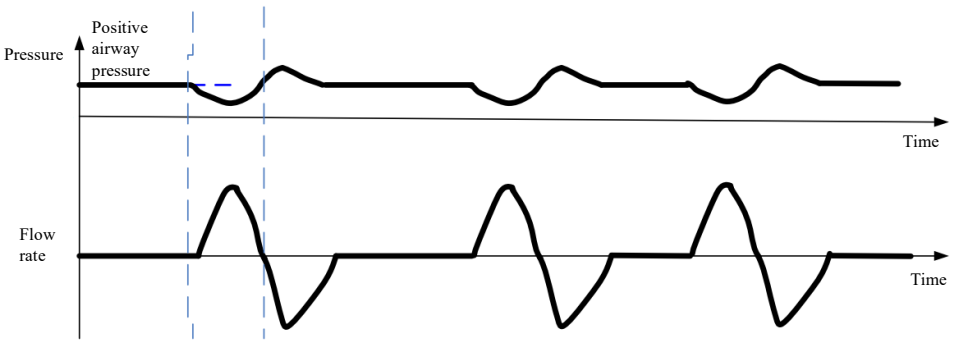


Fig. 45 CPAP mode controlled typical pressure and flow velocity waveform

7.6.12 PCV

The PCV mode is known as the nasal continuous positive airway pressure - pressure control mode: in this mode, gas is supplied to the patient through the nasal interface (nasal catheter or nasal mask), and intermittent, timed, and pressure-controlled respiration with continuous positive airway pressure is provided.

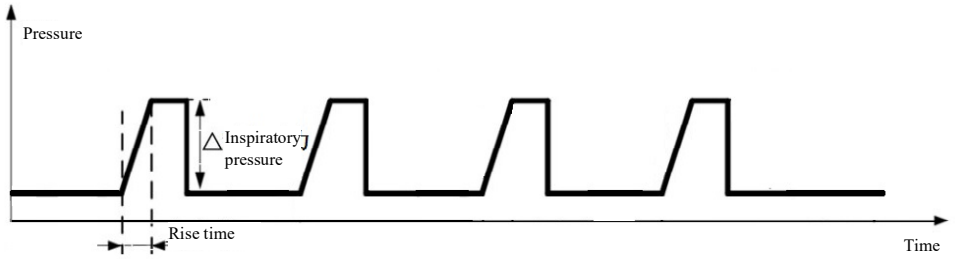


Fig. 46 PCV mode controlled typical pressure waveform

7.6.13 HFNC

HFNC is the high flow oxygen therapy function. This mode is indicated for the patient who has spontaneous respiration. Enter HFNC Mode:

1. Before starting ventilation, click the [HFNC] button in the patient setting screen to start HFNC ventilation and timing. After clicking the [suspend] button, HFNC will suspend ventilation and timing; then after clicking the [Start] button, HFNC will resume ventilation and timing.
2. In other modes, click the [Standby] button to enter the patient setting screen, and click the [HFNC] button to start HFNC ventilation.
3. You can set parameters in HFNC mode: oxygen inhalation flow rate/oxygen concentration/pressure upper limit

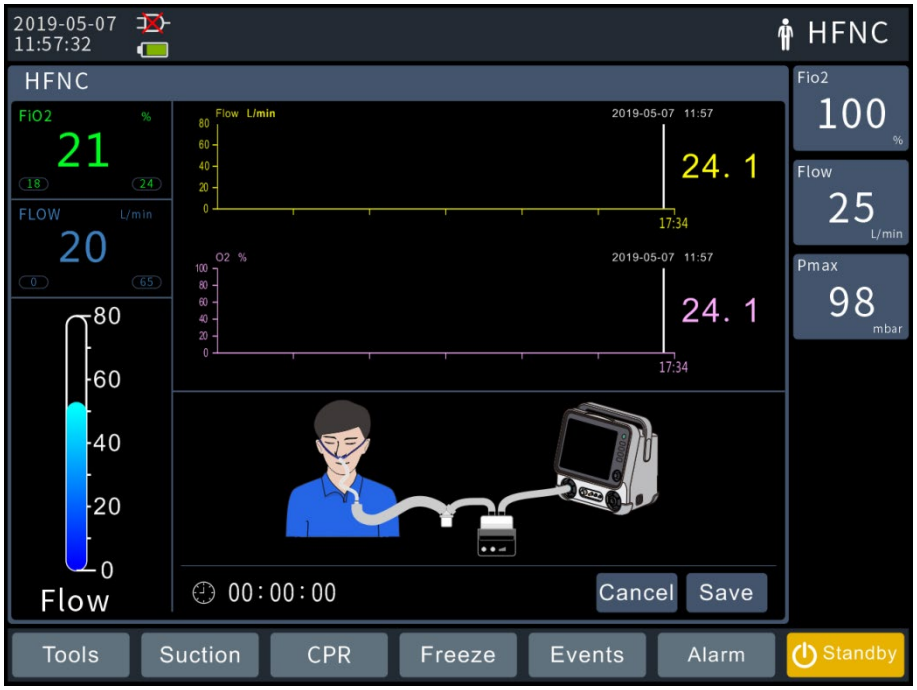


Fig. 47 HFNC interface

Notices:

- HFNC can only be used for the patients with autonomous respiration.

- Patients must be given oxygen therapy under the supervision of medical care professional. If something goes wrong or the patient does not have enough autonomous respiration, the medical care professional can help immediately.
- Only the inhaled oxygen concentration and oxygen flow rate are monitored during oxygen inhalation
- Oxygen shall be inhaled only with an oxygen mask or nasal catheter, not with a NIV mask. Improper use of mask may be dangerous for patients.

7.6.14 Sigh

Sigh function can prevent lung collapse and help reopening of collapsed alveoli. You can activate Sigh function in the current ventilation mode parameter setting screen, and select the Sigh On/Off function.

Sigh function setting:

1、You can activate the pressure sigh function in the Pressure Control mode. Once you activate the Pressure Sigh function, PEEP intermittently increases the preset [Sigh Pressure]. [Sigh Cycle] means the periodic interval of sighing.

2、You can pneumatically activate the tidal volume sigh function in the volume control mode. Once you activate the tidal volume sigh, the preset [Sigh Tidal Volume] will be intermittently provided. [Sigh Cycle] means the periodic interval of sighing.

7.6.15 Apnea ventilation

It is also known as the standby ventilation mode, and is a standby ventilation mode that is enabled when the system detects apnea in the patient. When apnea ventilation is enabled, the pressure control mode or volume control mode can be selected, and apnea ventilation parameters can be set. Apnea ventilation can only be disenabled if autonomous respiration of the patient is detected, the ventilation mode is switched, or the apnea ventilation switch is turned off.

7.6.16 Automatic tube compensation

Automatic tube compensation is to select endotracheal intubation or tracheotomy intubation with different aperture for different users. The ventilator can automatically adjust the gas supply pressure so that the pressure at intubation end is as consistent as possible with setting value of the ventilator pressure.

Once you select the ventilation mode, select [Compensation] → [ATC] in the parameter setting screen. When it is activated, you can perform corresponding

parameter setting. After clicking [Save] button, the system will activate the Cannula Compensation function; after clicking the [Close] button, the system will stop the Automatic tube compensation function during ventilation immediately.

Notices：

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

7.6.17 Compliance compensation

Compliance compensation refers to that the ventilator detects and determines compliance of respiratory line during self-inspection of the machine, and compensates the impact of line compliance in the form of volume during ventilation.

Once you select the ventilation mode, select [Compensation] → [Compliance Compensation] in the parameter setting screen; after clicking [Start], the system will automatically perform the compliance compensation, then after clicking [Close] button, the system will immediately stop the compliance compensation function in the ventilation process

7.7 Standby

Select the [Standby] key and confirm to enter the standby interface

Notices:

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

7.8 End ventilation

Click the [ON/OFF] button in the standby state to turn off the host.

Notices:

The oxygen cylinder shall not be run out completely. It is always necessary to ensure that there is residual gas pressure in the cylinder when you return it to refill,

which will prevent moisture air in the surrounding environment from getting in and causing corrosion.

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

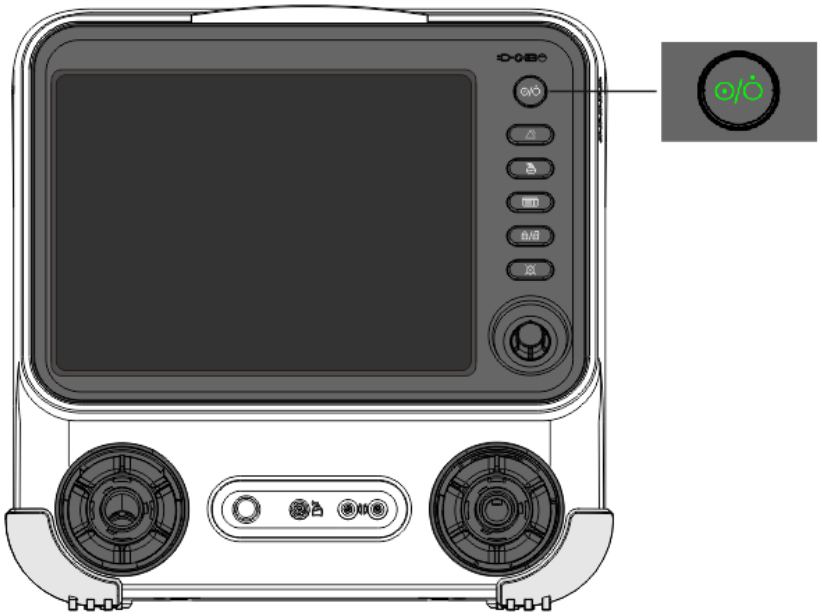


Fig. 48 Shutdown of ventilator

7.9 Oxygen consumption

7.9.1 Oxygen consumption

When connected to high pressure oxygen supply, the machine automatically calculates the oxygen consumption and displays it on the Parameters Monitor screen: O2 con. in L. Oxygen consumption is a cumulative value.

Notices:

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

7.9.2 Oxygen consumption zeroing

1. In Standby screen, click [Zero] in [Function Menu] → [Maintenance] → [User

Maintenance] → [Oxygen Consumption Zeroing],

2. the system will automatically zero the current oxygen consumption and automatically re-accumulate it after it connects to the high pressure oxygen supply next time.

7.10 Data Export

This machine provides the patient data export function, you can use it to export the current patient log information and trend information, etc.

1. Insert the USB drive into the USB port of the respirator.
2. Click [Function Menu] → [Maintenance] → [User Maintenance] → [Data Export] in Standby screen
3. If the export is successful, it will display a successful information, if the export fails, it will display "Export Fails".

⚠ **Notices:**

- To check the export information, please contact our after-sales department.

8 CO_2 monitoring

8.1 Overview

The CO_2 module provided on the ventilator measures CO_2 concentration in patient's respiratory line by the infrared absorption technology. The principle is based on the fact that CO_2 molecules can absorb infrared light energy of a specific wavelength, and the amount of energy absorbed is directly related to the concentration of CO_2. Part of the energy will be absorbed by the CO_2 in the gas when the infrared light emitted by the infrared light source penetrates the gas sample containing CO_2. The remaining infrared light energy is measured by the photoelectric detector on the other side of the infrared light source, and is converted into an electrical signal. The electrical signal is compared with energy of the infrared light source and adjusted to accurately reflect the CO_2 concentration in gas sample.

The CO2 module product is not the only method designed to monitor patients. This device shall always be used in conjunction with other vital signs monitoring devices and/or in conjunction with the individual judgment of a professional to determine the patient's condition. The product is designed for use only by trained and authorized medical professionals.

CO_2 measurement provides:

1. CO_2 waveform.
2. End expiratory CO_2 concentration (ETCO2): concentration of CO_2 measured at the end of the expiratory stage.
3. V-CO_2 curve

Monitored parameters:

- Vdaw: airway dead cavity.
- VDaw/Tve: ratio of airway dead cavity to tidal volume.
- Vtalv: alveolar ventilation volume.
- Valv: minute alveolar ventilation.
- SlopeCO_2: CO_2 rising slope.
- VCO_2: CO_2 emission rate.
- VeCO_2: volume of CO_2 exhaled.

- ViCO2: volume of CO_2 inhaled.

8.2 CO_2 monitoring setting

1. Connect the sensor to CO_2 module.
2. The CO_2 module is the measurement mode by default. After connecting the CO_2 module, the machine will automatically enable CO_2 monitoring.
3. The zeroing calibration operation shall be carried out as described in Section 8.4 (EtCO2 zero calibration).
4. Once you complete zeroing, connect the gas circuit properly.
5. The measurements can be started after confirming airtightness of the gas line.

⚠ Notices:

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

8.3 Measurement influence factors

Accuracy of measurement may be affected by following factors:

- Leakage or internal leakage of sampled gas;
- Mechanical shock;
- Circulating pressure greater than 10 kPa (100 cmH_2O);
- Other sources of interference (if any).

8.4 EtCO2 zero calibration

In order to ensure accuracy of monitored parameters, zero calibration of the module shall be carried out before CO_2 monitoring. The steps of zero calibration are as follows:

1. Connect CO_2 monitoring module correctly, and click the [Function menu] soft key → [Maintenance] → [User maintenance] → [EtCO2 zero calibration] → [Start]
2. If the zero calibration passes, the system will display a prompt message: [Pass]. Otherwise, [Zero calibration fails] will be displayed and zero calibration shall be carried out again at this time.

9 Cleaning and disinfection

The T6 mainframe and its accessories must be cleaned and disinfected after each use to keep it in a good standby state, in order to avoid cross-infection. Functional inspection shall be carried out after each cleaning and disinfection (see the "10 Maintenance and inspection" section).

9.1 T6 mainframe

The mainframe shall be simply wiped and cleaned with a piece of soft rag wetted with water-soluble disinfectant.

When cleaning the ventilator, make sure to prevent the disinfectant from entering inside of the ventilator. Surface of the machine shall not be cleaned with any organic solvents.

The whole machine can be sterilized by ultraviolet light with the irradiation disinfection duration of 1 hour.

⚠ **Notices:**

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

9.2 Respiratory line components

If the respiratory line assembly is supplied by **Ambulanc (Shenzhen) Tech. Co., Ltd.**, please follow the instructions described below. If it is purchased separately from another manufacturer, cleaning and disinfection shall be carried out by referring to the instructions provided by the manufacturer.

9.3 Parts and accessories

The mask and all silicone parts must be cleaned and disinfected with disinfectant:

1. All surfaces inside and outside the parts must be wetted and free of any air bubbles. The parts can be disinfected for the longest time specified by the supplier of the disinfectant used.
2. Parts shall be cleaned with distilled water after disinfection, so as to prevent disinfectant residues from causing problems to the machine or the patient.

3. All silicone parts shall be placed in dry air and allowed to dry naturally.
4. The mask shall be checked. If any part is damaged, please replace it immediately.
5. The silicone pads of reusable respiratory hoses, patient respiratory valves, and respiratory masks can also be disinfected with high temperature.

9.4 Valve accessories

⚠ **Warning:**

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

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

9.5 Handling method

Parts	Cleaning	Disinfection	Rinsing in a washer	Sterilization
T6	Use a piece of dry or wetted wiping rag	Wipe to disinfect	Not allowed	Not allowed
Patient breather valve	In warm water with mild household detergent	Immerse in a diluted solution until all surfaces are wetted inside and outside without any	Rinsing shall be carried out below 93°C (heat disinfection in automatic	Boiled water steaming
Reusable respiratory mask				The hot steam sterilization shall be

Reusable respiratory hose		bubbles. The immersion time shall be sufficient. Inside and outside of all parts shall be thoroughly rinsed with distilled water after disinfection, and then left them to dry	cleaning machine)	conducted at 134°C by using a device specified in EN 285 for a retention time of 5 minutes.
Oxygen valve accessories	Use a piece of dry or wetted wiping rag	Wipe to disinfect	Not allowed	Not allowed

Cleaning and disinfection solution can be used	
Medical alcohol(75%)	Disinfectant
Isopropyl alcohol	Disinfectant
glutaraldehyde	Disinfectant
Phthalaldehyde disinfectant	Disinfectant
Soap water(pH from 7.0 to 10.5)	Detergent
clean water	Detergent

10 Faults and troubleshooting methods

If any fault occurs and cannot be removed, please contact the manufacturer, **Ambulanc (Shenzhen) Tech. Co., Ltd**., or the dealer authorized by **Ambulanc (Shenzhen) Tech. Co., Ltd.** It is prohibited to continue using the machine, so as to avoid unnecessary injuries.

10.1 Technical faults

Faults	Causes	Remedies
T6 cannot be started	T6 fails	Hand it over to the manufacturer or seller for repair
	The battery runs out	Recharge the battery
Obvious oxygen loss	The gas supply line leaks	Identify and correct gas leakage points
T6 cannot be shut down	Operation is w0rong	Press and hold the "ON/OFF" key for at least 3 seconds
The power indicator flashes on and off	The power plug is loose	Reconnect firmly
The working time is shortwhen the battery is used to supply power	Service life of battery expires	Use a new battery

10.2 Physiological alarm

Messages	Alarm	Causes	Remedies
Minute ventilation is high	Minute ventilation is high	The set upper limit of minute ventilation is exceeded	Check condition of the patient Check if the set upper limit is reasonable
Minute ventilation is	Minute ventilation is	It is below the set lower limit of	Check condition of the

low	low	minute ventilation	patient Check if the set lower limit is reasonable
Embarrassment	Embarrassment	The respiratory distress time exceeds the set time value	Check condition of the patient Check that the set time value is reasonable
Airway pressure is high	Airway pressure is high	The set upper limit is exceeded	Check condition of the patient
		Airway obstruction	Check condition of the patient
		Respiratory hose is misplaced	Put the respiratory hose in place
		Pmax is set too low	Correct Pmax
		Respiratory hose is twisted	Check position of patient and move to an appropriate position if necessary

10.3 System alarms

Messages	Alarm	Causes	Remedies
The gas source pressure is less than 2.5bar	The gas source pressure is less than 2.5 bar	The cylinder is not opened, or the gas in the cylinder runs out	Open the oxygen cylinder or replace with a full cylinder
		The cylinder is not properly connected	Check the connections and connect the unconnected parts
		The compressed gas source is defective	Replace with a gas source which is in good conditions
		Gas supply	Tidy the ventilator gas

		connection line of ventilator is twisted or compressed	connection line or remove the items compressing the ventilator gas connection line
		The pressure reducing valve is defective	Replace the pressure reducing valve
The respiratory system is not connected	The respiratory system is not connected	1. The respiratory hose leaks/slides off. 2. The respiratory mask is not properly worn. 3. The pressure measurement hose leaks/slides off.	Check the connections
		The system fails	Repair
Low battery level	Low battery level	The battery power is too low	Recharge the battery

10.4 Abnormal power failure alarms

T6 has the function of system shutdown alarm caused by abnormal power failure.

The alarm will be triggered when the mainframe is shut down due to the power failure caused by any abnormality, and the alarm duration is not less than 15 seconds;

This alarm can be cancelled by clicking the lock screen key.

11 Maintenance and inspection

11.1 Routine inspections

Before each use:

- Functional inspection shall be carried out once.

After each use:

- The reusable respiratory hoses and patient respiratory valves must be cleaned and disinfected once according to the instructions for use in Chapter 6.

After each use or removal:

- The device and its components shall be cleaned, disinfected or sterilized (see "9 Cleaning and disinfection");

It should be remembered to carry out safety inspection after each overhaul, and T6 must be regularly inspected and repaired for safety.

Every six months:

- The filter cotton must be replaced. Please refer to "11.13 Replacement of filter cotton" for the replacement method.

Every two years:

- The device must be cleaned, disinfected and inspected for safety in accordance with the instructions for use in Chapter 6. In addition, it should be maintained by the manufacturer or its authorized professionals.

Every three years:

- The oxygen valve accessories (e.g., pressure reducing valve) shall be repaired by the manufacturer or its authorized professional.

If it is not used during this period:

- The functional inspection shall be carried out at intervals not exceeding six months

11.2 Check gas tightness of the system

1. Please open valve of the oxygen cylinder slowly. The cylinder pressure can now be checked on pressure gauge of the pressure reducing valve. For example, a 2,000 psi reading means the cylinder is full, and a 1,000 psi reading

means the cylinder is only half full. For example, when the pressure is less than 725psi, the oxygen cylinder shall be replaced in time to ensure sufficient working time.

2. Reclose valve of the oxygen cylinder.
3. The gauge pointer on the pressure reducing valve shall be observed for approximately one minute. If position of the pointer remains the same, the system is air-tight. If the pointer drops continuously, there is a leak.

Exclude the causes of leakage:

1. Prepare the solution of soapy water from fragrance-free soap.
2. Wet all threaded connectors and hose fittings with this solution. The place where bubbles appear is the leakage point.
3. Relieve pressure from the system: for this, it is necessary to close the oxygen cylinder. Turn on T6 for a while until reading of pressure gauge of the oxygen cylinder is "0". Then turn T6 off again.
4. If there is any leakage, replace the damaged parts.
5. Then check the air tightness again.
6. If the causes of leak cannot be identified, it must be repaired.

11.3 Check patient respiratory valve

1. Open the patient respiratory valve.
2. Visually check all parts for cracks or other mechanical damages on their surfaces. The one-way diaphragms (two in total) that have become corrugated, twisted and sticky must be replaced. The one-way diaphragms do not need to be replaced during inspection. However, the one-way diaphragms that have become corrugated, twisted and sticky must be replaced, or they may cause serious failure.
3. Reinstall the patient respiratory valve.

Notices:

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

11.4 Functional inspection of machine

In addition to the above inspections, before the ventilator is used by the patient, the

ventilator shall also be powered on to operate by the medical staff who is specially responsible for management of the machine to conduct simple functional inspection and confirm that the machine is free from failure before it is connected to the patient for use.

The steps for functional inspection are as follows:

Warning:

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

1. Connect the power supply and gas source, and check whether the power supply and gas source are normal.
2. Power-on self-inspection. After the ventilator is started, the system will start the power-on self-inspection. It is mainly to check if each sensor works normally.
3. Inspection of respiratory distress alarm. The specific steps are as follows:

a) Set the alarm time of respiratory distress to 15s.

b) Set the respiratory mode as CPAP/PSV, count time at the same, record the time when the ventilator gives a respiratory distress alarm, and compare it with the set value. The test time value shall be 13s-17s.

4. Inspection of airway pressure upper limit alarm function. The specific steps are as follows:

a) The ventilator is set to V-A/C ventilation mode.

b) VT is set to 600ml, I:E is set to 1:2, and FREQ is set to 10.

c) Pmax is set to 20mbar.

d) When the patient's gas vent of the patient's expiratory valve is blocked by hand until the airway pressure is higher than 20cmH2O, an audible and visual alarm of high airway pressure shall be generated. The alarm shall be cancelled about 10S after releasing the hand.

5. Inspection of respiratory system integrity alarm function. The specific steps are as follows:

a) The ventilator is set to A/C ventilation mode.

b) VT is set to 600ml, I:E is set to 1:2, FREQ is set to 10, and PMAX is set to 30mbar.

c) If patient end of the line is not connected to the simulated lung, the system shall generate an audible and visual (unconnection) alarm after two respiratory cycles. When the simulated lung is connected, the alarm shall be

cancelled.

6. Inspection of low battery power alarm function. The specific steps are as follows:

When T6 is connected for self-inspection, the low battery power alarm will be inspected sautomatically. If T6 works normally and no alarm is given after the T6 is powered on when the oxygen cylinder is opened, it shows that the voltage is normal.

7. Trigger pressure function test. The specific steps are as follows:

a) The ventilation mode is set to CPAP/PSV ventilation mode, and CPAP pressure is set to 0.

b) The trigger pressure is set to -3mbar.

c) Inhale through the mask. The ventilator shall supply gas when the inspiratory negative pressure reaches to -3mbar, and will stop supplying gas when the support pressure reaches to the target pressure. Wait for next triggering of ventilation.

11.5 Touch screen calibration

When the touch screen does not work correctly, the user can calibrate the touch screen as follows:

Enter the standby mode, click the [Function menu] soft key to enter [Maintenance] → [User maintenance] → [Touch screen calibration]; complete calibration of the first point in the lower left corner and the second point in the upper right corner successively to complete calibration of the touch screen. Oxygen concentration calibration

11.6 Calibrate oxygen concentration sensor

Oxygen concentration calibration shall be carried out when oxygen concentration monitoring value error is large or after replacing the oxygen sensor. Oxygen concentration can be calibrated according to following steps:

1. Ensure that the high-pressure oxygen source is connected.
2. Enter the standby mode, click the [Function menu] soft key to enter [Maintenance] → [User maintenance] → [Oxygen concentration calibration] → [Start]
3. If the calibration successes, the system will display a prompt message:

[Calibration is successful]. Otherwise, it shows that the calibration failed, and it needs to be recalibration at this time.

⚠ Notices：

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

11.7 Flow sensor calibration

Calibration of flow sensor shall be carried out when error of flow monitoring value is large or the flow sensor is replaced. Calibration of flow sensor can be performed according to the following steps:

1. Connect respiratory line and flow sensor
2. After starting the machine, enter the calibration interface, firstly connect the flow sensor reversely according to prompts on the interface, click the [Start] key on right side of the [Flow sensor], then connect the flow sensor positively according to prompts on the interface, and click the [Start] key on right side of the [Flow sensor] again
3. If the calibration successes, the system will display a prompt message: [Calibration is successful]. Otherwise, it shows that the calibration failed, and it needs to be recalibration at this time.

11.8 Line compliance

Compliance calibration of the line shall be carried out when replacing the respiratory line and the external accessories related to the connection between the ventilator and respiratory line. Calibration of line compliance can be performed according to the following steps:

1. Connect the respiratory line
2. After starting the machine, enter the calibration interface and insert the Y-shaped connector into the leak detection plug according to the prompts on the interface, so that the respiratory line is air-tight.
3. From the standby interface, select [System calibration] → [Line compliance] → [Start] key
4. If the calibration successes, the system will display a prompt message: [Calibration is successful]. Otherwise, it shows that the calibration failed, and it needs to be recalibration at this time.

11.9 Line resistance

Resistance of the line shall be calibrated when replacing the respiratory line and the external accessories related to the connection between the ventilator and respiratory line. Calibration of line resistance can be performed according to the following steps:

1. Connect the respiratory line
2. From the standby interface, select [System calibration] → [Line resistance] → [Start] key
3. If the calibration successes, the system will display a prompt message: [Calibration is successful]. Otherwise, it shows that the calibration failed, and it needs to be recalibration at this time.

11.10 Gas line zero calibration

From the standby interface, select [System calibration] → [Gas line zero calibration] → [Start]

If the zero calibration successes, the system will display a prompt message: [Done]. Otherwise, [Fail] will be displayed and zero calibration shall be carried out again at this time.

⚠ Notices:

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

11.11 Gas line self-inspection

From the standby interface, select [System calibration] → [Gas line self-inspection] → [Start]

If the self-inspection passes, the system will display a prompt message: [Pass]. Otherwise, [Fail] will be displayed and self-inspection shall be carried out again at this time.

11.12 Battery management

The T6 is equipped with a rechargeable lithium-ion battery, which is powered by a built-in battery through the T6 mainframe. The charging time shall not be less than 8 hours, and the working time under standard conditions shall not be less than 6 hours after full charging. It is recommended to charge it fully at intervals (every

6-12 months, depending on how long it is used) before running it down completely.

11.12.1 Battery inspection

Following steps shall be referred to when inspecting the battery performance:

1. Disconnect the ventilator from the patient and close the ventilator.
2. Connect the ventilator to the external power supply, and charge the battery continuously for more than 10 hours.
3. Disconnect the external power supply and use the battery to power the ventilator until the ventilator is turned off.
4. Duration of battery power supply reflects performance of the battery.

If power supply duration of the battery is significantly lower than the time stated in the specification, consider replacing the battery or contacting the maintenance personnel.

11.12.2 Battery storage

When the battery is stored, make sure that electrodes of the battery do not come into contact with any metal objects. If long-term storage of the battery is necessary, it shall be kept in a cool environment and the make sure that power of the battery is kept at 40% to 60%. Storing the battery in a cool environment can slow down aging of the battery. Ideally, the battery shall be stored in a cool environment at 15 °C (60 °F). The battery shall not be stored in an environment outside the range of -20℃ (-4℉) to 60℃ (140℉).

If the ventilator will not be used for a long period of time, the battery shall be taken out, or the battery will be over-discharged and the charging time will be significantly prolonged. The stored battery shall be charged incompletely every 2 months to maintain a power of 40%-60%. The battery shall be fully charged before use.

11.12.3 Battery replacement

1. Make sure the T6 mainframe is in shutdown state;
2. Open the battery lock in the direction of the arrow (see Fig. 57);
3. Remove the dead battery from battery case (see Fig. 58);
4. When installing a fully charged battery, push the battery by hand after loading until a “click” indicating that the battery key is reset is heard, in order to ensure that the battery has been installed in place.

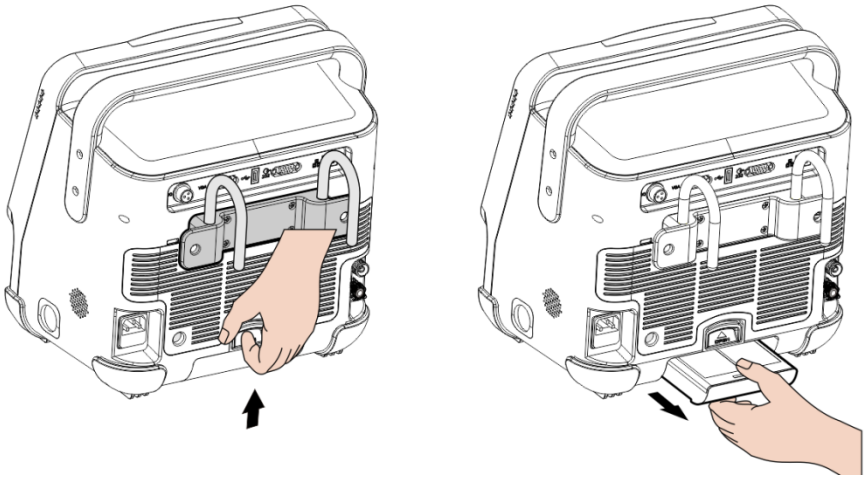


Fig. 49 Opening the battery lock and taking out the battery

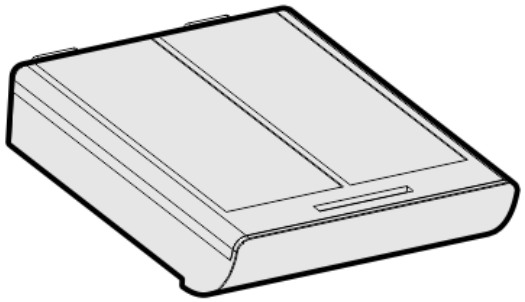


Fig. 50 Placement with a new battery

11.12.4 Battery status description

The user can view whether the battery is connected, whether the battery is charging, the battery power and other information in the interface. Status of the battery is described as follows:

Components	Description
1 	The battery is not connected
2 	20% power
3 	40% power
4 	60% power
5 	80% power
6 	100% power

Fig. 51 Battery status

If the battery indicator flashes, it indicates that the battery is charging. The battery indicator is always on, indicating that the battery has been connected; the battery indicator is off, indicating that the battery is not connected or the battery runs out; and, the battery indicator flashes, indicating that the battery is charging.

Warning:

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

1. The battery specified by Ambulanc (Shenzhen) Tech. Co., Ltd. must be used, or the machine may not work normally.
2. The battery life is about 10,000 hours.
3. Short-circuit of battery is prohibited;
4. Never heat or burn the battery;
5. Avoid using the battery near any heat sources;
6. Never wet the battery;
7. Avoid charging in the vicinity of fire or in direct sunlight;
8. Use a special charger and charge properly;
9. Do not mix with other batteries;
10. Keep the battery away from children;
11. Do not connect with the charger for a long period of time;
12. The leaky battery shall not be kept close to the fire;
13. Avoid using the battery in strong sunlight.

11.13 Accessories

For maintenance interval and maintenance application of each accessory of T6, please refer to operating instructions of each accessory.

Oxygen cylinders must be rechecked in accordance with the proper rules. Expiration date of the oxygen cylinder can be found on the label attached to the cylinder.

11.14 Replacement of filter cotton

Steps to replace filter cotton (as shown below):

1. Open the rear cover ②;
2. Take out the old filter cotton ①;

3. Wipe the filter chamber clean with a medical cotton ball wetted with alcohol;
4. Put the new filter cotton into the filter cartridge.

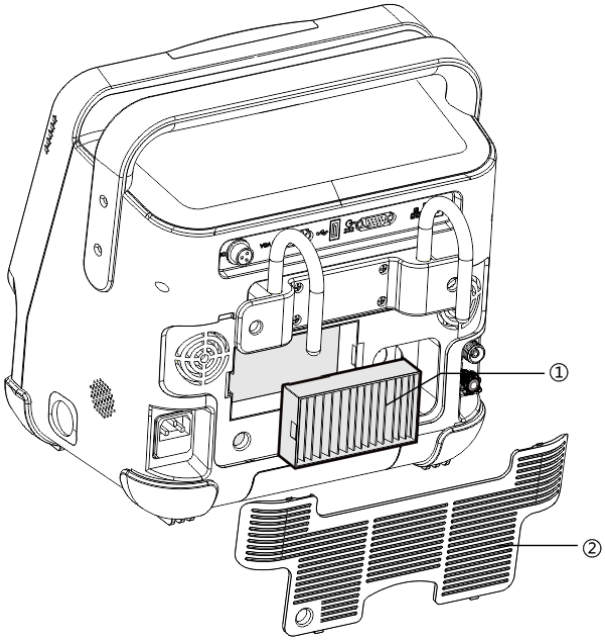


Fig. 52 Replacement of filter cotton

Warning:

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

11.15 Storage

If T6 is not used for a long period of time, following measures are recommended:

1. Clean and disinfect (see Section 6 "Cleaning and disinfection").
2. Store in a dry place.
3. The battery can be retained in the device during long-term storage.

Important:

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

11.16 Disposal of abandoned device

The abandoned device shall be sent to a qualified waste electrical appliance disposer for disposal.

12 T6 accessories

S/N	Name/model	Function	Manufacturer	Remarks
1	Mainstream carbon dioxide module M401B	Support CO2 gas monitoring	Witleaf	Purchased part

Notices:

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

13 Product specifications

13.1 Safety specifications

Medical device management category	
Category	Category III medical devices
Electric shock protection type	Category I device, including internal power supply
Electric shock protection class	Defibrillation-proof BF type
Operating mode	Continuous operation
Degree of safety for flammable anesthetic gas	It shall not be used in the presence of flammable anesthetic gas mixed with air or with oxygen or nitrous oxide
Liquid entering protection grade	IP43
Installation and use classification	Mobile equipment

13.2 Physical specifications

Overall dimensions	
Assembling dimensions	Trolley: L*W*H 600mm*500mm*1,030mm Mainframe: L*W*H 305mm*210mm*300mm
Weight (including battery)	6.2 kg
Display screen	
Type	Color screen TFT
Size	10.4 in.
Resolution	1024 * 768 pixels
Function	With touch screen

Interface	
Network interface	Support to connect to PC for software upgrade function
USB interface	Software of the ventilator can be upgraded via the USB port, configuration information and historical data (e.g., trend data, logs, etc.) can also be exported via the USB port, and configuration can be transferred between the machines with the same model via the USB flash disk.
RS-232 interface	It can be connected to medical grade external devices for communication between the ventilator and these external devices.
VGA interface	Output the VGA video signal with the same content as the main display, used to connect the external display (support 1280*800 resolution display)

13.3 Environmental specifications

	Temperature	Air pressure	Relative humidity
Working	-10℃-50°C	62kPa ~ 110kPa	10%~95%
Storage	-20°C - 60°C (oxygen battery: -20°C - 50°C)	50kPa ~ 110kPa	10%-95% (non-condensation)

13.4 Power supply specifications

External AC power supply	
Input voltage	AC 100-240V
Input frequency	50/60Hz
Input current	<2A
External DC power supply	
Input voltage	DC 12V
Total power	≤140VA

Battery in mainframe	
Battery type	Lithium-ion battery
Battery capacity	9600mAh
Rated battery voltage	DC 14.8V
Minimum power supply time	6h (a new fully charged battery operated in standard operating conditions)

13.5 Gas supply specifications

Gas supply specifications	
Gas supply	Medical oxygen
High-pressure gas source pressure	3.0-6.0 bar
High-pressure pipe input connector	DISS connector
Low-pressure gas source pressure	The flow rate is not greater than 8L/min
Low-pressure pipe input connector	CPC quick connector
Inspiratory module	
Peak flow rate	≥200L/min
Nebulizer interface	Outer diameter 6.5mm
Inspiratory branch external interface	Outer diameter 22mm
Expiratory module	
Expiratory branch external interface	Outer diameter 22mm
Resistance	
Inspiratory resistance	No more than 6 cmH2O (adult) at a flow rate of 60 L/min; No more than 6 cmH2O (pediatric) at a flow rate of 30 L/min;

	No more than 6 cmH2O (infant) at a flow rate of 5 L/min;
Expiratory pressure	No more than 6 cmH2O (adult) at a flow rate of 60 L/min; No more than 6 cmH2O (pediatric) at a flow rate of 30 L/min; No more than 6 cmH2O (infant) at a flow rate of 5 L/min;
Trigger mode	
Trigger mode	Pressure trigger, flow trigger
Mechanical safety valve	
Mechanical safety valve	≤ 110 cmH2O

13.6 Parameter specification

Control parameters	Range	Accuracy
Respiratory rate	Infant: 0,1 ~ 150bpm Adult/Pediatric: 0,1 ~ 100bpm	Error: ±1bpm (0-100bpm); ±5% of set value (above 100bpm)
Inspiratory time	0.20-10S	Error: ±0.1s or ±10% of the set value, whichever is greater
Tidal volume	Adult: 100 ~ 2000mL Pediatric: 20 ~ 300mL Infant: 2 ~ 100mL	± (10 mL + 10% of the setting value) (pediatric/adult mode); ± (1.5 mL + 15% of the setting value) (infant mode); ;
Oxygen concentration	21%-100%	± (3 vol.%+ 1% of set value) While 500ml, 21%-90% response time : 140s; While 150ml, 21%-90% response time : 160s; While 30ml, 21%-90% response time : 220s

Inspiratory pressure	1-90cmH_2O	± (0.9 cmH2O + 10% of the setting value
I:E	4：1～1：10	2:1～1:4：±10% of set value； Others：±15% of set value
Upper pressure limit	10-100 cmH_2O	± (2cmH_2O+ 5% of set value)
Pressure trigger	-20～-0.5 cmH_2O	± (0.4 cmH2O + 10% of the setting value)
Positive end expiratory pressure	0-40cmH_2O	± (0.9cmH2O + 5% of the setting value)
Pressure support	Closed, 1-90cmH_2O	± (0.9cmH2O + 5% of the setting value
Flow trigger	Infant:0.2 ~ 5.0L/min Adult/Pediatric:0.5~20.0L/min	± (0.1 L/min + 10% of the setting value) (infant mode); ± (0.4 L/min + 10% of the setting value) (adult/pediatric mode)
Pressure rise time	60ms-2000ms	± (0.05s + 20% of the setting value)
Sensitivity of expiratory trigger	5%-85 %	± 5% (absolute error
Oxygen therapy flow	Adult: 2 ~ 65 L/min Pediatric: 2 ~ 25 L/min infant: 2～ 20 L/min	± 2 L/min or ± 15%, whichever is greater
High-level pressure	1-90cmH_2O	± (2cmH_2O+ 5% of set value)
Low-level pressure	0-40cmH_2O	± (2cmH_2O+ 5% of set value)
High-level pressure time	0.2-30s	Error: ±0.1s or ±10% of the set value, whichever is greater
Low-level pressure time	0.2-30s	Error: ±0.1s or ±10% of the set value, whichever is greater

Apnea	5-60s	Error: ±0.1s or ±10% of the set value, whichever is greater
Inspiratory pause	0%-60%	
Monitored parameters		
Respiratory rate	0 ~ 250bpm	±2bpm or ±5% of actual reading, whichever is greater
Inspiratory tidal volume	0-3,000ml	± (2mL+ 15% of actual reading) (infant mode); ± (3mL+ 15% of actual reading) (pediatric mode); ±15% of actual reading (adult mode)
Expiratory tidal volume	0-3,000ml	± (2mL+ 15% of actual reading) (infant mode); ± (3mL+ 15% of actual reading) (pediatric mode); ±15% of actual reading (adult mode)
Minute volume	0-100L/min	± (0.4L/min+15% of actual reading)
I:E	150:1-1:150	2:1 ~ 1:4：±10% of set value； Others：±15% of set value
Oxygen concentration	21%-100%	± (2.5 vol.%+2.5% of actual reading)
Airway pressure	0-105cmH_2O	± (2cmH_2O+4% of actual reading)
I:E	299:1-1:299	
Positive end expiratory pressure	0-100	± (2cmH_2O+4% of actual reading)
Resistance	5 to 300	
Time constant	50-1000	
Closure pressure(P0.1)	-105-5	±1-25% of the actual reading
Rapid-shallow-breathing index	0-10000	±10 of actual reading)
Compliance	0.5-100	

⚠ Notices:

- Failure may occur when the ventilator operates beyond the range specified by the manufacturer. Please ensure that the ventilator works under the specified working conditions, so as to maintain stable operation.
- The system overall response time of CO2 concentration is 1 sencond.
- The system response time for oxygen concentration is 3 minutes.
- The response time from10% to 90% for oxygen concentration is 3 minutes.
- When working pressure of the ventilator exceeds the range specified by the manufacturer, performance of the ventilator will be greatly deviated. If the working pressure is too high, the internal sensors may be damaged. Please ensure that working pressure of the ventilator is within the specified range, so as to maintain stable operation.
- When the storage condition exceeds the working condition, the storage state turns into the use state should be placed in the standard environment for more than 8 hours.

13.7 CO_2 specifications

Mainstream CO2 module	
Measuring range: 0-150 mmHg	
Accuracy	(0-40 mmHg) ±2mmHg
	(41-70 mmHg) ±5% of actual reading
	(71-100 mmHg) ±8% of actual reading
	(101-150 mmHg) ±10% of actual reading
Mainstream CO2 alarm limit specification	
Upper limit of ETCO2: 1mmHg-150mmHg, closed	
Lower limit of EtCO2: closed, 1mmHg-149mmHg	

13.8 Gas line diagram

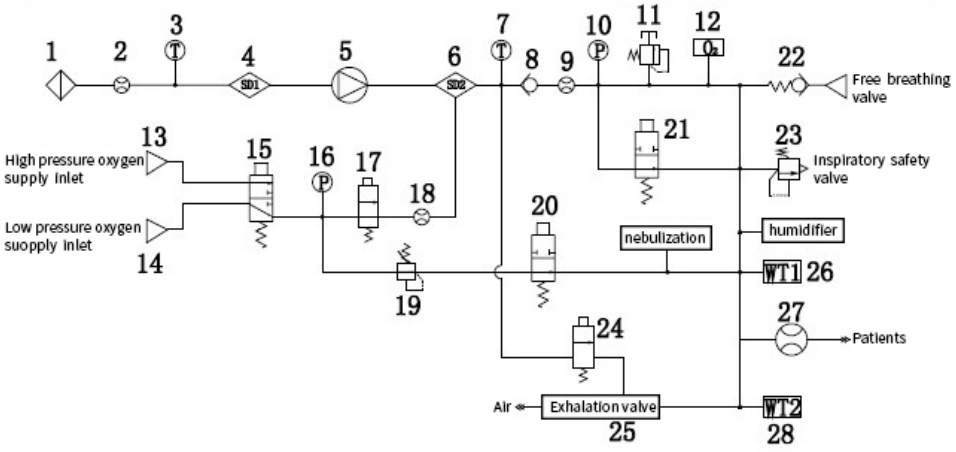


Fig. 53 T6 product structure diagram

13.9 Parts list

Symbol	NAME	Symbol	NAME
1	Air filter cartridge	2	Air inlet flow sensor
3	Temperature sensor	4	Primary acoustic box
5	Turbine	6	Secondary acoustic box
7	Temperature sensor	8	Check valve
9	Fresh gas flow sensor	10	Fresh gas pressure sensor
11	Pressure relief valve	12	Oxygen concentration sensor
13	High pressure oxygen supply inlet	14	Low pressure oxygen supply inlet
15	Oxygen supply control valve	16	Oxygen supply pressure sensor
17	Proportional valve	18	Oxygen flow sensor
19	Pressure relief valve	20	Nebulization control valve
21	Proportional valve	22	Free breathing valve
23	Inspiratory safety valve	24	Proportional valve
25	Exhalation valve	26	Sump tank 1
27	Proximal flow sensor	28	Sump tank 2

13.10 Principle Description

There are two kinds of oxygen supplies, including high pressure oxygen supply and low pressure oxygen supply: high pressure oxygen is connected via high pressure oxygen inlet 13; and low pressure oxygen is connected via low pressure oxygen inlet 14. Select one oxygen supply type: High pressure oxygen supply or low pressure oxygen supply. The oxygen supply enters the secondary acoustic mixing box through the proportional valve 17 and flow sensor 18. Another gas circuit passes through the pressure relief valve 19 and nebulization control valve 20, and connects to the nebulization port. The gas is provided to nebulizate the patient as required.

The air passes through the air filter 1 and the flow sensor 2, and enter the primary acoustic mixing box; with the action of turbine 5, it's then sucked into the secondary acoustic mixing box 6 to mix with oxygen. The fully mixed gas flows through the check valve 8 and flow sensor 9, humidificated by the humidifier, and then enter the patient's lungs.

The flow rate of the exhaled gas at the patient side is monitored by the flow sensor 27, and flow into the exhalation valve 25, with one end of the valve is connected with the gas circuit. The positive end-expiratory pressure is controlled and adjusted by the proportion valve 24.

When the airway pressure exceeds the limiting value of host, the inspiratory safety valve 23 opens; when the airway pressure exceeds a certain threshold value (11KPa), the pressure relief valve 11 opens and connects with atmosphere.

Oxygen concentration sensor 12 is used to measure the oxygen concentration of gas delivered to the patient. 22 is the free breathing valve. When the main unit fails to provide gas, the patient inhales air through 22.

14 EMC

14.1 Electromagnetic radiation declaration

Notices:

- The T6 ventilator complies with the EMC requirements in Chapter 36 of YY 0505, GB 9706.28, YY 0601 and YY 0600.3.
- Users shall install and use according to the EMC information described in the documents provided with the machine together.
- Portable and mobile RF communication equipment may affect performance of T6 ventilator, so strong electromagnetic interference shall be avoided during using, such as closing to mobile phones, microwave ovens, etc.;
- The guidelines and manufacturer's statements are detailed in the annexes.

Warnings:

- The T6 ventilator shall not be used near or stacked with other devices. If it must be used near or stacked with any other devices, it shall be observed to verify its normal operation in the configuration it is used in.
- In addition to the cables sold by manufacturer of the T6 Ventilator as spare parts for internal components, use of the accessories and cables other than those specified may result in increased emission or reduced immunity of the T6 ventilator.

Name	Cable length (m)	Shielded or not
POWER CORD	1.5	NO
CARBON DIOXIDE LINE	2.5	NO
GROUNDING WIRE	2.5	NO

Electromagnetic radiation declaration
The T6 ventilator can be used in following specific electromagnetic environments, and users shall ensure to use the device in following specified electromagnetic environments.

Radiation test	Compliance test	Electromagnetic environment guidance
Radio-frequency radiation (CISPR 11) (GB4824)	1 set	The respirator only uses RF energy when it performs its internal function. It has extremely low RF emission, which is unlikely to causes any electromagnetic interference to any nearby electronic equipment.
Radio-frequency radiation (CISPR 11) (GB4824)	Category B	
Harmonic radiation (GB 17625.1)	Category A	
Voltage fluctuation and scintillation emission (GB 17625.2)	Conform	

14.2 Battery immunity declaration - requirements for all devices and systems

Electromagnetic immunity declaration - requirements for all devices and systems			
The T6 ventilator can be used in following specific electromagnetic environments, and users shall ensure to use the device in following specified electromagnetic environments.			
Immunity category	YY0505 test level	Coincidence zhuyilevel	Electromagnetic environment guidance
Electrostatic discharge (ESD) (GB/T 17626.2)	Contact discharge: ±6kV Air discharge: ±8kV	Contact discharge: ±8kV Air discharge: ±15kV	The floor shall be of wood, concrete or ceramic material. If the floor is paved with composite material, the relative humidity shall be at least

			30%.
Electrical fast transient burst (GB/T 17626.4)	For power cord: ± 2kV For long I/O cables: ±1kV	For power cord: ± 2kV	The power supply shall have a class that is at least as high as that of a typical commercial or medical environment.
Surge (GB/T 17626.5)	Differential mode: ±1kV Common mode: ±2kV	Differential mode: ±1kV Common mode: ±2kV	
Power frequency magnetic field (50/60Hz) (GB/T 17626.8)	3A/m	3A/m 50/60Hz	The power frequency magnetic field shall have the level characteristics of power frequency magnetic field at a typical location in a typical commercial or medical environment.
Voltage drop, short interruption, and voltage variation (GB/T 17626.11)	< 5%U_T (> 95% drop, U_T), 0.5 cycles;	< 5%U_T (> 95% drop, U_T), 0.5 cycles;	The power supply shall have a class that is at least as high as that of a typical commercial or medical environment. It is recommended to use the uninterruptible power supply, so as to ensure that the product can continue to operate during AC
	<40%U_T (60% drop, U_T), 5 cycles;	<40%U_T (60% drop, U_T), 5 cycles;	
	70%U_T (30% drop, U_T), 25 cycles; <5% U_T (>95% drop, U_T), 5s;	70%U_T (30% drop, U_T), 25 cycles; <5% U_T (>95% drop, U_T), 5s;	

			power supply interruption.

14.3 Guidelines and manufacturer's statement - electromagnetic immunity

Guidelines and manufacturer's statement - electromagnetic immunity			
The T6 ventilator is intended to be used in the electromagnetic environment specified below and the purchaser or user shall ensure that it is used in this electromagnetic environment			
Immunity test	**IEC 60601 test level**	**Coincidence level**	**Electromagnetic environment guidance**
Radio-frequency conduction GB/T 17626.6 Radio-frequency radiation GB/T 17626.3	3V (effective value)150 kHz-80 MHz(Except ISM frequency band [a]) 10V (effective value)150kHz-80 MHz(ISM frequency band [a]) 10V/m80 MHz ~ 2.5 GHz	3V (effective value) 10V (effective value) 30V/m	The portable and mobile RF communication devices shall be used at a distance not less than the recommended isolation distance from any part of the T6 ventilator (including cables). The distance is calculated by a formula corresponding to the transmitter frequency. Recommended isolation distance: $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$ $d = \left[\frac{12}{V2}\right]\sqrt{P}$ $d = \left[\frac{12}{E1}\right]\sqrt{P}$ 80 MHz~800 MHz $d = \left[\frac{23}{E1}\right]\sqrt{P}$ 800 MHz~2.5 GHz **Wherein:** —The maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W);

			d - Recommended isolation distance, in meters (m)[b]. The field intensity of a fixed radio frequency transmitter is determined by surveying the electromagnetic field c, but d in each frequency range shall be lower than the coincidence level. Interference may occur near devices marł  h the following symbols.

Note 1:

The formula of higher frequency band is used at the 80MHz and 800MHz frequency points.

Note 2:

These guidelines may not be applicable to all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and the human bodies.

[a]The ISM frequency bands between 150kHz and 80MHz are 6.765MHz-6.795MHz, 13.553MHz-13.567MHz, 26.957MHz-27.283MHz and 40.66MHz-40.70MHz.

[b]The coincidence levels in the ISM frequency band of 150kHz-80MHz and in the frequency range of 80MHz-2.5GHz are used to reduce the possibility of interference caused by mobile/portable communication devices being accidentally brought into the patient area. For this purpose, an additional factor of 10/3 is used to calculate the recommended isolation distances for transmitters within these frequency ranges.

[c] The field intensity of fixed transmitters is theoretically unpredictable, such as base stations for wireless (cellular/cordless) telephones and terrestrial mobile radios,

amateur radios, AM and FM radio broadcasts, and television broadcasts. In order to evaluate electromagnetic environment of the fixed radio frequency transmitter, survey of the electromagnetic field shall be taken into consideration. If the measured field intensity at the location of the T6 ventilator is higher than the applicable RF coincidence level mentioned above, the T6 ventilator shall be observed to verify its normal operation. If any abnormal performance is observed, supplementary measures may be necessary, for example reorienting or positioning the T6 ventilator.

[d] The field intensity in the whole frequency range of 150kHz-80MHz shall be less than 3V/m.

14.4 Recommended isolation distance

Recommended isolation distance between portable and mobile radiofrequency communication device and T6 ventilator				
The T6 ventilator is intended to be used in an electromagnetic environment in which the radiofrequency radiation disturbance is controlled. The purchaser or user, depending on the maximum rated power output of the communication device, can prevent EMI by maintaining the minimum distance between portable and mobile RF communication device (transmitter) and T6 ventilator as recommended below.				
The maximum rated output power of the transmitter W	Isolation distance for different frequencies of the transmitter/m			
	150kHz-80MHz (Except ISM frequency bands) *d =*	150kHz-80MHz (ISM frequency bands) *d =*	80 MHz - 800 MHz *d =*	800 MHz - 2.5 GHz *d=*
0.01	0.12	0.12	0.04	0.08
0.1	0.38	0.38	0.12	0.24
1	1.2	1.20	0.4	0.8
10	3.8	3.80	1.2	2.4
100	12.00	12.00	3.8	7.7
For the maximum rated output power of the transmitter not listed in the table above, the				

recommended isolation distance d (in meters (m)) can be determined by the formula in the frequency bar of corresponding transmitter. The P here is the maximum rated output power of the transmitter, in watts (W), provided by the transmitter manufacturer.

Note 1:

The formula of higher frequency band is used at the 80MHz and 800MHz frequency points.

Note 2:

The ISM frequency 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:

The additional factor 10/3 is used to calculate the recommended isolation distance for the transmitter with 150kHz-80MHz ISM frequency band and 80MHz-2.5GHz frequency range, in order to reduce the possibility of interference caused by the fact that the portable/mobile RF communication device is accidentally brought into the patient area.

Note 4:

These guidelines may not be applicable to all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and the human bodies.

14.5 Patient physiological signal information of T6

Patient physiological signal information of T6
The minimum respiration frequency of the T6 ventilator is 5bpm.
Warnings: **Operating a device or system below the minimum amplitude or the minimum value described above may result in inaccurate results.**

14.6 Basic EMC performance of T6 ventilator

Basic EMC performance of T6 ventilator	
The T6 ventilator can work normally according to the parameter settings. For details, please see Chapter 11 of the Manual. The alarms can be given according to real-time monitoring on status of the T6 ventilator. Accuracy of following parameters can be ensured in the EMC environment declared for the T6 ventilator:	
Tidal volume	300-2,000ml (adjustable, error: ±0.1S) or ±10% of set

	value
Inspiratory time	0.20-10S (adjustable), error: ±0.1S or ±10% of set value, whichever is greater
Breath rate	5-40bpm (adjustable), error: ±1bpm

15 Product warranty

1. For the product quality problems occurred during normal operation and use according to the product instructions within two years from the date of purchase, **Ambulanc (Shenzhen) Tech. Co., Ltd**. can carry out maintenance free of charge. If the warranty period indicated on the product is less than two years, the warranty will expire at the end of the expiration date indicated on the package or in the Operation Manual.
2. A purchase certificate indicating the seller and the date of purchase must be provided when warranty is requested.
3. Warranty is not granted for the followings:

- Violation of the Operation manual
- Operation is wrong
- Improper use or disposal
- Repair of the device by unauthorized personnel
- Force majeure, e.g. lightning, etc.
- Transport damage caused by improper packing during returned delivery
- No maintenance was done
- Wear caused by overuse, or normal wear. Examples of such components are:
- Filter
- Battery
- Disposable items and so on.
- The spare parts used are not geninue.

4. As long as the damages caused by defects are not caused by intentional misconduct or gross negligence, or when any minor negligence leads to physical or life injury, **Ambulanc (Shenzhen) Tech. Co., Ltd**. shall not be responsible for it.
5. **Ambulanc (Shenzhen) Tech. Co., Ltd.** is not responsible for any problems that occur during use of the product after service life of the product expires.
6. **Ambulanc (Shenzhen) Tech. Co., Ltd.** reserves the right, at its own discretion, to exclude defects, provide goods without defects or reduce the purchase price as appropriate.
7. If the warranty claim is rejected, we do not bear the cost of round-trip

transportation.

8. The statutory warranty requirements are not affected by this.

16 Classification description of toxic and harmful substances

Name and content of toxic and harmful substances or elements							
Part name		Cadmium (Cd)	Mercury (Hg)	Lead (Pb)	Hexavalent chromium Cr(VI)	Polybrominated biphenyls (PBB)	Polybrominated diphenyl ethers (PBDE)
Display screen		×	×	×	×	×	×
Lithium battery		×	×	×	×	×	×
Packing materials		○	×	×	○	×	×
Mainframe	PCBA	○	○	×	○	○	○
	Internal connecting line	○	○	○	○	○	○
	Machined parts	○	○	○	×	○	○
Machine casing	Keys	○	○	○	○	○	○
	Label	○	○	○	○	○	○
	Front cover	○	○	○	○	○	○
	Rear cover	○	○	○	○	○	○
Accessories	Oxygen pipe	○	○	○	○	○	○
	Mask	○	○	○	○	○	○
	Oxygen source hose	○	○	○	○	○	○

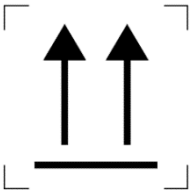
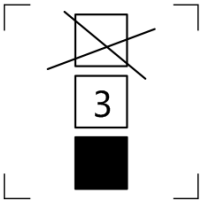
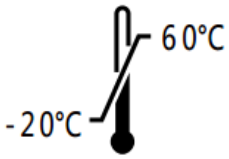
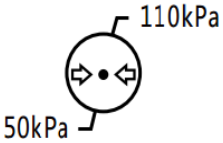
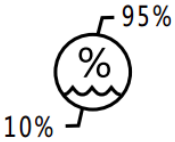
	assembly						
	Gas pocket	○	○	○	○	○	○
	Power cord	○	○	○	○	○	○
	Connector	○	○	○	×	○	○
	Flow sensor	○	○	○	○	○	○
	Oxygen sensor	○	○	×	○	○	○
	CO_2 monitor	○	○	×	○	○	○

×: It means that content of the harmful substance or element in at least one homogeneous material of the component exceeds the limit requirements specified in SJ/T11363-2006.

○: It means that content of the harmful substance or element in at least all the homogeneous materials of the component is within the limit requirements specified in SJ/T11363-2006.

17 Storage and transportation

The packaged products are allowed to be transported by road, air or rail. Shock and violent vibration shall be prevented during transportation. See the description in the table below:

Graphic symbols	Description	Graphic symbols	Description
	This side up		Handle with care
	Keep dry		Stacking layer limit: 3
	Temperature limit: -20℃-60℃		
	Pressure range: 50KPa-110KPa		
	Humidity range: 10%-95% (non-condensation)		

Warning:

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

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