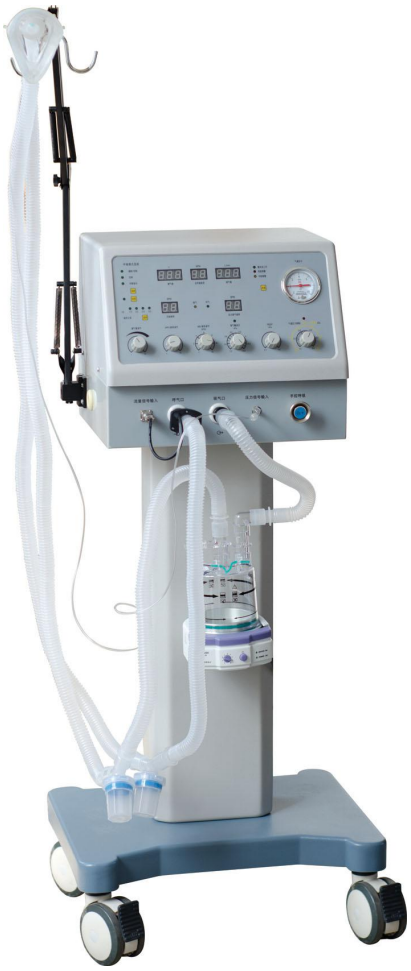
CCV-PA500 Ventilator

USER'S MANUAL



Safety Guide

1. Before operating the ventilator, please read this manual thoroughly, and make sure that all the cautions and instructions are strictly followed.
2. To avoid any unexpected ill effects on patients in case the power is cut off suddenly, make sure the ventilator is equipped with a built-in backup battery before operation.
3. Main power supply to the ventilator should be equipped with a protective ground. If this cannot be ensured, apply the backup battery.
4. DO NOT operate the ventilator under circumstances that contain flammable, explosive or narcotic air, since the unit is not explosion proof. Do not let liquid enter the mechanism since the unit is not waterproof. If there is any liquid splashing on the unit, please wipe it immediately.
5. Before putting the ventilator into use, make sure it has been cleaned thoroughly and disinfected, and each function is in good order. NEVER continue to operate the ventilator which has been detected to be malfunctioning.
6. Before being connected to the windpipe of a patient, the ventilator should be stationed, adjusted and tested on a simulated lung firstly.
7. The electrical wire and breathing tubes should be well laid in order not to interfere with personnel's movements in the sickroom. The airway cannot be under any pressure in case it is out of shape and blocked. Do not move the ventilator casually when it is in use so as to avoid such accidents as the airway or wire falling off and the oxygen cylinder toppling over.
8. There must be qualified medical personnel guarding on the spot during the operation of the ventilator. Pay attention to the working status of ventilator and humidifier, meanwhile, pay attention to the patient's Life Indicator and vigor analyzing data, and adjust the ventilator to the most appropriate status for the patient.
9. Although the ventilator is considered technically mature and highly reliable in design, any instruments have the possibility to malfunction unexpectedly. For the sake of the patient's safety, please do prepare a standby ventilator of good and reliable conditions.

Figure & Type Matter

DANGER：Denotes that it should be alert to high danger.

WARNING：Denotes that it should be alert to moderate danger.

NOTE：Denotes that it should attend slight danger.

The Equipment of Type B.

Check the random file.

CE 1023

Through the CE Certificate.

Contents

1.Overview

1.1Scope of Application and Main Features

The CCV-PA500 ventilator is an electrically controlled pneumatic ventilator integrating such functions as time, volume cycling, pressure limit, etc. It is mainly intended for providing ventilation support to a critically ill patient during the life threatening phase and ensuring the going-through of the dangerous period by the patient and smooth treatment of primary diseases for recovery. Also it provides an alternation in case of irreversible lesions in respiratory muscles or irreversible damage to upper airway to maintain the respiratory function of the patient, and also provides ventilation assistance for the patient during the recovery from a disease or operation. Its main features are as follows:

A.Gas drive and electrical control, time-pressure switching and pressure limit control.

B. A high-brightness LED digital display is used to present the control frequency, tidal volume, throughput, overall respiratory rate, spontaneous breathing frequency, etc.

C.A highly sensitive and responsive pressure sensor and a flow sensor are used to measure, control and display the airway pressure and gas flow rate and the ventilator is equipped with automatic throughput compensation.

D.In case of an abnormality to the ventilator or misoperation, the ventilator can raise a visual-audible alarm to automatically protect itself.

1.2 Requirements for Ambient Conditions

The CCV-PA500 ventilator is a mobile medical device as specified in *the Environment Requirements and Test Methods for Medical Electrical Equipment* to operate in Climatic Environment Group II and Mechanical Environment Group II. Its normal operating conditions are as follows:

——Ambient temperature: 10 ～ 40℃, relative humidity: no higher than 80%.

——Atmosphere pressure: 86kPa ～ 106kPa

——Gas source requirement: medical oxygen source with a pressure ranging from 280 to 600kPa and a flow rate of 50L/min (containing no fresh air).

——Power supply requirements: AC 220V±10%, 50±1Hz and 30VA, well grounded.

2.Structural Characteristics and Operating Principles

Driven by compressed medical oxygen, the CCV-PA500 ventilator uses a gas ejector based on Venturi effect to form a mix of medical oxygen and ambient atmosphere which is delivered through the ventilator circuit into the airway in the patient for mechanical ventilation. During such process, a fast solenoid valve, a highly sensitive flow sensor, a pressure sensor and a single-chip microcomputer control system are used to measure, adjust and control such parameters as the ventilation pressure, ventilation time, throughput, etc. to the patient.

This ventilator can display in real time the following important parameters:

——Operating mode and respiratory rate;

——Ventilator control frequency set by medical staff;

——Tidal volume of each breath in the patient;

——Occurrence of spontaneous breath in the patient and spontaneous breathing frequency;

——Expiratory phase and inspiratory phase and actual respiratory rate;

——Minute volume;

——Setting and adjustment of inspiration triggering pressure, PEEP, and highest airway pressure;

——Real-time variation in internal airway pressure.

This ventilator is capable of raising an alarm in case of abnormality. For example, the ventilator can automatically alarm in case of too low airway pressure due to the gas leak in the tube or tube separation. In case of too high tube pressure caused due to the tube blockage, it not only can raise an alarm but also automatically switch to the expiratory phase if the pressure further rises to release the too high pressure.

3.Technical

3.1 main performance

3.1.1 Basic Functions

——Sigh (deep breath);

3.1.2 Ventilation Modes

——SIPPV

——IPPV

——IMV

——SIMV

3.2 Technical Data

—Tidal volume range: no less than 50 to 1200ml, permissible deviation: ±20 %.

——Maximum minute ventilation: ≥ 18 L/min, permissible deviation: ±20 %.

——Oxygen concentration of output gas: <45 %.

——Controlled ventilation (IPPV) frequency range: 6 ～ 60times/min, permissible deviation: ±15 %.

——I:E ratio: 1:1.5, 1:2.0, 1:2.5 and 1:3.0, permissible deviation: ±15%.

——Maximum safety pressure: ≤6.0 KPa

——Settable maximum operating pressure: 5~6.0 KPa (gas source pressure ranging from 280kPa to 600kPa).

——Oxygen consumption: the variation in the gas pressure in the cylinder should be less than or equal to 1.5MPa/h when the ventilator operates on a 12250KPa / 40L medical oxygen cylinder continuously for one hour.

——Inspiration triggering pressure range: －0.4 ～ 1.0 KPa, permissible deviation: ±0.15 KPa

—— Time to switch between controlled and assisted ventilation modes: 6s, permissible deviation: ＋1 s, －2 s.

——Intermittent mandatory ventilation (IMV) frequency range: 1 to 12 times/min, permissible deviation: ±15%.

——PEEP range: no less than 0.1 to 1.0kPa.

——Sigh (deep breath): the inspiration time should be no less than 1.5 times of the original setting.

——Pressure limit range: 1.0~6.0kPa, permissible deviation: ±20 %

——The presentation of the spontaneous breathing frequency, overall respiratory rate and ventilation capacity is refreshed once every minute.

——Continuous operation duration: the ventilator can operate continuously on a 24-hour basis on an AC utility main.

——Main unit net weight: 28kg, dimension (L×W×H): 410×300×1100 (mm).

3.3 Alarm System

The device alarm system provides high level and low level alarms. The principle for monitoring for pressure alarm is that a pressure sensor measures and compares the current ventilator airway pressure with the set value in real time. The principle for monitoring for tidal volume and throughput alarms is that a flow sensor detects and compares the value measured by the ventilator with the set value in real time. The principle for monitoring for oxygen concentration is that a chemical reaction occurs in the oxygen to generate a voltage which will be acquired by the AD of the circuit and converted and such value is compared with the set value in real time. The principle for monitoring for frequency alarm is that the current ventilator operation frequency is calculated and compared with the set value by timing on ventilator CPU. The principle for monitoring for low battery voltage alarm is that the AD of the circuit acquires and detects whether the battery voltage is lower than 10.5V.

A list of alarms is presented as below:

List of Alarms

Alarm Item	Alarm Level	Alarm Condition	Alarm Form
Low gas source pressure	High	The gas source pressure drops to a level below 0.2MPa.	
Upper airway pressure limit		Range: 0.9 ～ 5.4 KP a, permissible deviation: ±20% (90% of set value)	Immediate alarm; “high level alarm” indicator flickers raising an audible alarm.
Continuous positive pressure		The airway pressure exceeds 15hpa.	The maximum delay is no longer than 17s. The “high level alarm” indicator flickers raising an audible alarm.
Low tidal	Medium	Lower than 50ml	The alarm will be raised after one

volume			breathing cycle. The “medium level alarm” indicator flickers raising an audible alarm.
Lower airway pressure limit		The airway pressure drops to 0.5KPa. The permissible deviation is ±0.2 KPa.	The alarm will be raised after a delay of 4 to 15s. The “medium level alarm” indicator flickers raising an audible alarm.
Upper throughput limit		The throughput is higher than 18L/min.	Immediate alarm. The “medium level alarm” indicator flickers raising an audible alarm.
Battery voltage		The battery voltage is lower than 10.5V.	

When the “high and medium level alarm” indicators on the front panel of the ventilator flicker, this indicates that alarms are raised. You can press the Silence key to silence the alarm and press it again to disarm silencing.

If you need to query the alarm information, you can press and hold the Silence key for more than 3s and the ventilator can show the current alarm information on the throughput window. The symbol designation is as follows:

P upper limit upper pressure alarm limit;

P lower limit lower pressure alarm limit;

U upper limit upper throughput alarm limit;

Po low airway pressure alarm;

CP High continuous pressure alarm

12.0 Battery voltage value

You can switch the information of the alarm currently occurring by pressing the Silence key. In case of no alarm, the battery voltage will be directly invoked. After the battery voltage is displayed, press the Silence key again to exit the previous status and display the throughput, or, the system will automatically exit the previous status and display the throughput if you do not press a key within 6s.

3.4 Battery

This ventilator is equipped with an internal backup power supply of the voltage 12V ± 10％, rated capacity 7Ah and maximum current 2A. The fully recharged battery can support the

operation of this ventilator for a duration of no less than 30min. In case of a utility main failure, this ventilator can automatically switch to operate on the internal power supply.

3.5 Operating Noise Level

The noise level when this ventilator normally operates is no higher than 65 dB.

3.6 Safety Requirements

In accordance with the classification requirements in GB 9706.1－2007 Medical Electrical Devices Part 1: General Safety Requirements:

A)By electric shock protection type

——Type I device.

——Internal power supply device.

B）By degree of electric shock protection

——**Type B application**

C)By degree of protection against liquid intrusion

——Common (IPX0)

D)By operating mode

——Continuous operation.

E)This product is not equipped with an application part for protection against defibrillation and discharge effects.

F)This product is not equipped with signal output and input parts.

G)This product is a movable device.

H)This product is not explosive-proof and thus cannot be used in an environment with combustible and explosive anesthetic gases.

4 Installation and Commissioning

Caution: this ventilator should be installed, commissioned, inspected and used by professionals with certain qualifications to avoid unexpected faults or damages.

4.1 Preparations Prior to Installation

Confirm that this ventilator and its fittings are in complete and good condition free from damage during transportation and that contents of the packing box are consistent with the packing list. Keep properly the damping cushions in the packing box for use in another transportation.

Learn how to use the front and rear control panels of this ventilator . Check the position of the pointer of the pressure gauge. If the pointer is not at zero point, then adjust the zero point adjustment screw on the pressure gauge by using a screwdriver.

Check the medical compressed oxygen source and make sure that its pressure ranges from 280 to 600KPa and flow rate is 50L/min. If you supply oxygen with a cylinder, then you also need to check and make sure that the cylinder is sufficient of oxygen, and that the pressure reducer on the cylinder functions well and is correctly installed.

Check and make sure that the single-phase AC power supply used for this ventilator is of the AC 220V±10% voltage and securely grounded for protection and make sure that the emergency battery is already connected correctly.

Before the first use, you need to check whether the corresponding components are washed and disinfected following the method as specified in Section 8 of this user manual.

4.2 Installation and Pre-adjustment of Ventilator

1)Install the ventilator support holder onto the ventilator bracket and mount casters at four corners of the bracket base.

2)Connect the base plate of the ventilator on the support holder of the frame by using screws.

3)Install the battery box on the frame and connect the lead wires of the battery to the terminal screws on the rear panel of the ventilator.

4)Connect two gas guiding screw tubes to the inspiration outlet and expiration inlet of the ventilator respectively, connect the other ends of these tubes to a tee tube and connect that tee tube to a test lung.

5)Connect the pressure signal interface on the tee tube to the “pressure signal input interface” on the front panel of the ventilator circuit casing by using a tube.

6)Install the flow sensor between the “expiration screw tube adapter” and screw tube and

connect the output signal wire of the sensor to the “flow signal input interface” on the front panel of the ventilator circuit casing.

7)Turn the “tidal volume adjustment” knob to the middle position.

8)Set the IPPV frequency to 20times/min.

9)Set the “inspiration triggering pressure” to －0.2 kPa.

10)Set the airway pressure limit to 4.0kPa.

11)Connect the medical compressed oxygen source with a pressure ranging from 280 to 600kPa.

12)When the above adjustment is completed, you can connect the power supply of the ventilator.

4.3 Test Operation of Ventilator

After connecting the gas source and power supply of the ventilator and turning on the power to start up the ventilator, you should observe:

1)That the ventilator operates in the ventilation mode in which it is shut down previously.

2)Such parameters as “spontaneous breathing frequency”, “overall respiratory rate”, “throughput”, etc. have to be displayed one minute after the startup as they are refreshed once every minute.

3)The indication of the airway pressure does not exceed 4.0kPa.

4)The expiration indicator and inspiration indicator flicker alternatively and you can hear the close-open sound of the solenoid valve in the ventilator. The frequency at which the solenoid valve closes and opens and the indicators flicker is the indicative value of the “control frequency”. Also, you can see that the height of the water column in the test lung increases and decreases alternatively at the control frequency.

5) The indicative value of the tidal volume on the test lung is substantially the same as that of the “tidal volume” on the ventilator and relative error between both does not exceed ±20 %.

4.4 Inspection and Alarm

——Block the tee tube to increase the pressure in the airway and you should observe that the ventilator generates an audible-visual alarm signal when the airway pressure increases to the upper pressure limit.

——Cut off the oxygen supply from the oxygen cylinder for a normally operating ventilator and you should observe that the airway pressure indication drops. When the airway pressure indication drops to a level below the lower airway pressure limit, after a delay of 5 to 8s the ventilator generates an audible-visual alarm signal.

——A normally operating ventilator will raise a buzzing alarm when the power supply is interrupted.

——The duration of the inspection alarm sound should be no shorter than 120s.

——In case of an alarm, continuously press the jog dial twice and the alarm will be silenced. But, if the fault is not eliminated, the alarm buzz will sound again within a time no longer than 120s.

5 Use and Operation

5.1 Attention for Use

1）Prior to the use of this ventilator, you must check and read its use record and washing and disinfection record and make sure that it is not only in good condition with good performance but also is thoroughly washed and disinfected.

2）Prior to use, you must check and confirm whether the power supply and gas source in the field comply with requirements in accordance with the description in 4.1, and must check whether all functions of the ventilator are normal in accordance with descriptions in 4.3 and 4.4.

3）Prior to use of this ventilator on a patient, you must adjust properly all operating parameters by connecting it to a test lung. For details, see 5.2.

4）Medical staffs must provide field monitoring during the use of this ventilator. While pay attention to the operating status of this ventilator, the monitoring physician must pay attention to the vital signs and blood gas analysis data of the patient and adjust the ventilator to the operating status most adapting to the needs of the patient for optimal medical effect.

5）If oxygen is supplied with an oxygen cylinder, you may use an oxygen pressure reducer. You should adjust the pressure regulation handle to the minimum level position, then turn on the main switch on the oxygen cylinder and then slowly adjust the pressure regulation handle until the desired pressure is reached. Turn off the gas source and then the power to shut down the ventilator.

6）Prior to startup, check the pressures of the air source and oxygen source and they should be stabilized at a level around 0.4MPa.

5.2 Setting of Ventilation Modes

5.2.1Assisted/Controlled" Mode

The "Assisted/Controlled" mode is the default mode in which the ventilator operates when it is started up.

Such mode is mainly intended for patients with no or weak and intermittent spontaneous

breathing. If the patient shows no spontaneous breathing, the respirator provides intermittent positive pressure ventilation of the patient following the set parameters, and this ventilation mode is namely called controlled ventilation mode. When the spontaneous breathing is recovered to a certain extent, the ventilation by the respirator is automatically synchronized with the spontaneous breathing in the patient, and this ventilation mode is namely called assisted ventilation mode. The control ventilation and assisted ventilation modes are switched to each other at an interval of 6s.

Operating parameters should be preset on the test lung following the procedures as follows:

1）Connect the gas source and power and confirm that the ventilator operates in the “Assisted/controlled” mode and the corresponding indicators go on.

2）Adjust the “Adjust IPPV Frequency” knob and the “Control Frequency” digital display will provide the corresponding indication.

3）Select an I:E ratio according to the needs of the patient.

4）Adjust the “Adjust Tidal Volume” knob, observe the “Tidal Volume” indicator and set the tidal volume to the value as needed. For adult patients, make the initial setting based on the value of 10mL per kg of body weight and then fine tune the value according to the actual conditions of the patient.

5）The airway pressure indicator shows the variation in the airway pressure in real time. Carefully adjust the “Airway Pressure Limit” according to the airway pressure peak to set the airway pressure limit to a level slightly higher than the peak pressure.

6） Set the “Inspiration Triggering Pressure”. When the spontaneous breathing in the patient is recovered to a certain extent, the inspiration triggering pressure will provide a ventilation synchronization signal to the respirator. At the same time, each time when the patient takes a breath spontaneously the inspiration triggering pressure indicator flickers once. Generally, the inspiration triggering pressure can be set to be a level 0.1kPa lower than the minimum airway pressure when the patient has no spontaneous breathing.

7） Adjust the “PEEP” knob, observe the minimum airway pressure displayed when expiration ends and judge whether the setting of the PEEP is appropriate or not. The adjustment range is 0.1～1.0 kPa.

8) After selecting the “Sign” button and select this function, the Sigh indicator goes on and the ventilator provides one ventilation at a big tidal volume (no less than 1.5 times of the set value) at an interval of 80 ventilations.

Only upon completion of the above setting can you remove the test lung and connect the ventilator with the patient.

After connecting the ventilator with the airway in the patient, you should carefully observe the symptoms and lung inflation of the patient and further fine adjust the operation status of the respirator according to the monitor instrument and arterial blood and gas analysis data to achieve the optimal ventilation effect.

5.2.2 Controlled” Mode

This mode is only intended for patients with no spontaneous breathing.

Press the “Select Ventilation Mode” key to enable the “Control” indicator to be on and the ventilator enters this operating mode. The “Spontaneous Breathing Frequency” digital display provides no presentation due to the condition that no spontaneous breath is taken and other displays still show the corresponding contents. The setting of the operating parameters in this mode is the same as that in 5.2.1.

In this mode, you can still select (or not select) the PEEP and Sigh functions.

5.2.3 IMV Mode

This ventilation mode is intended for spontaneously breathing patients. It can gradually reduce the patient’s dependency on the ventilator to facilitate weaning of the patient from the ventilator. In this mode, the mandatory ventilation of the patient is performed once at a certain interval. Upon completion of mandatory ventilation, the next mandatory ventilation is performed a certain period of time later. During the interval between two mandatory ventilations, the patient can spontaneously breath at his own breathing rate.

The interval at which the mandatory ventilation occurs depends on the setting of the “IMV” frequency.

1)Press the “Select Ventilation Mode” key to select the “Intermittent Mandatory Ventilation” mode and the corresponding indicator goes on.

2)Adjust such parameters as IPPV frequency, respiratory rate, tidal volume, pressure limit, spontaneous inspiration triggering pressure, etc. to ensure that the optimal respiratory

indexes needed by the patient are reached.

3) You should adjust the “Inspiration Triggering Pressure” knob gradually from “0 kPa” to “-0.4kPa” to exercise and control the patient’s spontaneous breathing efforts and respiratory volume. In this mode, the tidal volume should be adjusted in a finer mode because the tidal volume can change the patient’s respiratory parameters under the impact by the inspiration triggering pressure such as the respiration time, respiratory rate, inspiratory tidal volume and other relevant life index.

4)In this mode, you can still select (or not select) the PEEP and Sigh functions.

5.2.4Manually Controlled Ventilation” Mode

In the event that the AC power supply to the ventilator is down, the ventilator can operate the emergency battery. The output voltage of the battery gradually drops during operation. If such output voltage drops to a level which is insufficient to drive the ventilator to operate, you should replace the battery with one with sufficient power in time. If you cannot replace with a new battery or in an urgent case when you cannot find a new battery, you can apply the “Manually Controlled Ventilation” mode.

Such mode needs to be operated by a physician with rich clinical experiences. That physician should press the “Manually Controlled Ventilation” button at a certain rhythm to simply maintain the respiration of the patient. Each time the physician presses the button the ventilator ventilates the patient once and such parameters as the ventilation time, tidal volume, circuit pressure, etc. are completely manually controlled by the physician.

When pressing the button, the physician must pay close attention to the lung inflation of the patient and indication on the airway pressure gauge. The ventilator uses an pneumatic pressure gauge and such gauge will not be affected in case of a sudden power supply failure.

5.3 Use of Humidifier

The humidifier is not a standard accessory of this ventilator and the user needs to optionally purchase it according to actual requirements.

For a patient using an artificial airway or using a ventilator for a long time, a humidifier

should be connected in series on the ventilation tube to increase the temperature and humidity of the mixed gas. The internal water temperature of the humidifier should be carefully adjusted according to the patient's needs. Generally, the water temperature of the humidifier should ensure that the temperature of the gas inhaled by the patient ranges from 32℃ to 35℃ and does not exceed 40℃. Although the humidity is higher if the temperature is higher, a too high temperature will cause adverse reactions to the patient and respiratory tract burn to occur in severe cases.

During the use of the humidifier, you should also always pay attention to the outlet temperature and water volume in the humidifier to prevent dry burning.

5.4 Operation Time Extension Upon Power Failure

This ventilator is capable of extending the operation time in case of power failure: when the AC power supply is down, the ventilator will automatically switch to operate on the battery. At this time, the "Operation on Battery" indicator goes on. After the AC power supply is resumed, the ventilator will automatically switch to operate on AC power supply, the "Operation on Battery" indicator goes out and the ventilator power circuit charges the battery in a trickle manner.

What needs to be noted is that the battery has limited capacity and can be only used as emergency battery. If you need to have the ventilator operate on the battery for a long time, you must select one with large capacity (battery pack).

For the further description of the use and maintenance of the battery, please refer to Section 9.2 of this user manual.

5.5 Shutdown Operations

When the patient's various vital indexes comply with the shutdown requirements, you can wean the ventilator.

Before weaning the ventilator, you should remove the tee tube connected with the patient and observe the spontaneous breathing by the patient. Only after the spontaneous breathing is completely recovered can you remove the mask or extract the endotracheal tube and then shut down the ventilator. You must not shut down the ventilator and then remove the tee tube.

The ventilator should be immediately washed and disinfected after it is used and then should be necessarily serviced and maintained.

6.Troubleshooting

Symptom	Possible Cause	Solution
Ventilator tidal volume is not stable or displayed	Flow sensor is interfered by strong light	Avoid impellers in the flow sensor from direct strong light
	Flow sensor is in poor contact	Re-connect the flow sensor or replace the plug
	Ventilation circuit connection is incorrect	Re-connect the ventilation circuit
	Ventilation circuit leaks and the patient shows oxygen deficit	Check whether the humidifier is tightened and whether the ventilation circuit leaks
	Water vapor exists in the impellers	Remove, wash and air dry impellers
	Air source pressure is too low	Pressurize the compressed air source and ensure the air source pressure ranges from 0.35 to 0.5MPa
	PEEP setting is inappropriate	Set a correct PEEP
	Inspiration triggering pressure setting is inappropriate	Set a correct inspiration triggering pressure
	Inspiration plateau setting is inappropriate	Set a correct inspiration plateau
	Flow sensor is damaged	Replace the flow sensor
Indication from the oxygen pressure gauge or laughing pressure gauge is inaccurate	Input air source pressure is too low	Adjust the air source pressure
	Respiratory circuit leaks	Check the circuit connector and re-install, and replace the leaking cannula.
	Internal pressure regulator valve is in malfunction	Re-adjust the pressure regulator valve or replace
The machine operating frequency is too fast	The frequency setting is too high or the inspiration triggering pressure is inappropriately set	Adjust the operating frequency to the correct level and set the inspiration triggering pressure to be negative
Lower tidal volume limit alarm	Tidal volume is set to be too low	Set the tidal volume to the appropriate range.
Upper tidal volume limit alarm	Tidal volume is set to be too high	Set the tidal volume to the appropriate range.
The ventilator airway	The tidal volume and I:E ratio are not properly adjusted.	Adjust the I:E ratio and tidal volume

pressure alarm and airway pressure limits icons are highlighted and the upper airway pressure limit alarm continues to be on	The upper pressure limit is not	Adjust the upper pressure limit
	The patient's spontaneous breathing conflicts with the mechanical ventilation	Set a correct the inspiration triggering pressure
	The patient suffers tracheospasm or airway resistance is increased by secreta	Sputum suction of the patient is recommended and expectorant should be used
The ventilator airway pressure alarm icon is highlighted and the airway pressure lower limit alarm continues to be on.	The tidal volume value is set to be too small.	Adjust the tidal volume
	The pressure of the oxygen cylinder or central oxygen supply is insufficient	Set a correct lower pressure limit
	The pressure of the oxygen cylinder or central oxygen supply is insufficient	Replace the oxygen cylinder or increase the air source pressure
	The oxygen cylinder reducer or oxygen conveyance circuit is in malfunction	Replace the oxygen cylinder, reducer and oxygen conveyance circuit.
	Pressure signal tube is separated or water is accumulated in the tube	Re-connect the signal tube or drain the water
Continuous audible alarm	The battery power is exhausted or battery is damaged after the AC power supply is down.	Replace with battery with sufficient capacity
Black screen of ventilator	Inverter is damaged	Replace the inverter
	LCD screen is damaged	Replace the LCD screen
Blank screen of ventilator	LCD screen wires are in poor contact	Re-connect LCD screen wires
	Control block is damaged	Replace the control block
Rapid oxygen supply valve does not provide gas	The spring of the rapid oxygen supply valve is snapped and the seal ring is dry or valve contains sundries.	Adjust or replace spring and apply Vaseline to the seal ring and clear sundries.
Rapid oxygen supply valve outputs gas all the time	Seal ring is aged or rapid oxygen supply valve cannot retract after being pressed	Re-adjust, install or replace it
Humidifier	AC power is not connected	Re-connect the AC power

cannot work	Fuse is burnt out	Replace the fuse
Humidifier is heating all the time	Heating rod is damaged	Replace the heating rod
Battery works when the grid power is normal	AC power plug is not connected	Connect the power plug
	Fuse is burnt out	Replace the fuse
	Junction panel or power cord is damaged	Replace junction panel or power cord

7.Safety Protection and Accident Handling

7.1 Sealing Performance of Respiratory System

Adjust the tidal volume of the ventilator to 500mL, I:E ratio to 1:2, ventilation frequency to 20 and upper pressure limit to 4kPa. Block the patient end of the tee tube. Under this condition, the upper airway pressure limit alarm should occur each time when the ventilator provides ventilation; otherwise, the respiratory system has leakage.

In case of leakage, you should replace gas circuit components one by one to eliminate faults and identify the damaged components.

If the problem cannot be solved after these measures are taken, please notify Puao Medical and its authorized service agency to handle this

7.2 Safety Valve Release Pressure

The safety valve release pressure has been set to be within the range from 5.5 to 6kPa before leaving factory.

Remove the power plug of the ventilator from the AC power outlet, open the ventilator and expose the safety valve on the ventilation circuit, and seal the patient end of the tee tube and inlet and outlet on the ventilator back panel. Press and hold the Manually Controlled Ventilation button and observe the airway pressure gauge. When the pressure gauge indication should range from 5.5 to 6kPa, the safety valve begins to release gas. If the pressure gauge indication is too high or low when the safety valve operates, please contact Puao Medical or its authorized service agency for adjustment and repair.

7.3 Humidifier

During the use of the humidifier, you should pay attention to observing the temperature of the output gas and water volume in the humidifier. If the patient inhales gas with too high temperature, adverse reactions will occur and even respiratory tract burn will be caused. If the water volume is insufficient, then the humidifier may be burnt out.

7.4 Ventilation Circuit

If the humidifier is used for a long time, water will be accumulated in the ventilation circuit. Such water should be removed in time.

7.5 Fuse

The fuse of the ventilator (fuse tube) is installed on the rear panel.
If the “Operate on Battery” indicator goes on (indicating that the ventilator is powered by the battery) and the power grid is not down, then we can judge that the fuse is burnt out. You must replace the fuse following the procedures as below.
1)Do not turn the power switch of the ventilator in operation. You can simply extract the plug of the ventilator from the power outlet and the ventilator automatically switches to operate on the battery and then replace the fuse.

2) Screw off the cover of the fuse seat by using a screwdriver and replace the fuse.
3)Fuse tube specification: 1A glass casing fuse tube of Φ5×20 mm dimension.

7.6 Improper Operations and Consequence Handling

Improper operations on the ventilator include:
1. Adjust the tidal volume to a too high level, adjust the airway pressure limit knob to a too great extent (which can cause barotrauma to the patient).
2. Adjust the tidal volume to a too low level and adjust the airway pressure limit knob to a too small extent (which can cause oxygen deficit to the patient due to the hypoventilation). The above mentioned two cases can be corrected by adjusting the corresponding knobs.
3. Use a power supply which is not grounded and this may cause the machine to carry static electricity and cause electric shock to the patient or operator. The solution is to use a grounded power supply.

8.Washing and Disinfection of Ventilator

8.1Washing and Disinfection Procedures

The ventilator in use should be routinely disinfected, which means that you should replace the respiratory cannula of the patient with a new or disinfected tube and wash and

disinfect. Also, you can alternately use two ventilators.

After the patient does not use the ventilator, you should ultimately disinfect it: thoroughly wash and disinfect the ventilator and then install it for reuse. The ventilator which is not used for a long time must be washed and disinfected before it is reused.
Work records for the washing and disinfection should be kept for archiving and query.

8.2 Important Points of Washing and Disinfection

Important points to be washed and disinfected include screwed ventilation tube, mask, flow sensor impellers connected on the expiration tube, etc.

8.3 Washing Method

1.Washing of ventilator inlet filter screen: flush the filter screen by using clean water to remove thoroughly the dust attached to the screen. Then swing the screen to get rid of the water and put it to the original position. The ventilator should be usually replaced and washed once every 24 hours.
2.Washing of screwed ventilation tube, mask and flow sensor impellers: remove thoroughly dirt on the internal wall of the circuit by using neutral washing fluid. Pay special attention to clearing sputum scab, bloodstain, oil stain and other dirt residues in the tube. Then wipe and wash them clean by using clean water.
3.Cleaning of ventilator: wipe off the dirt and dust falling on the ventilator casing and caster supports by using a soft cloth dipped with warm water or neutral washing fluid and then dry by wiping with dry cloth. Intrusion of any liquid into the machine is not allowed during the cleaning process.

8.4 Disinfection Methods

Method I: Soak such items as respiratory circuit, mask, etc. which have been washed clean in a disinfectant for 30 to 60min (note that the silicone product is easily damaged if it is soaked in the disinfectant for a too long time). Common disinfectants include bromogeramine, peracetic acid, 84 Disinfectant, etc. Flush the disinfectants inside and outside the circuit off by using sterilizing salt water or distilled water and hang them to air dry.
Method II: Disinfect such items as respiratory circuit, mask, etc. which have been washed clean in the ethylene oxide disinfection box.

9.Care and Maintenance

9.1 Care and Maintenance of Ventilator

You must not use a functionally faulty device. You should ensure that any maintenance service of this ventilator is completed by Puao Medical or its authorized agency. Upon completion of maintenance, you must check that various performances of this ventilator are consistent with the description in this user manual.

This ventilator must be thoroughly cleaned and disinfected once every six months by specially designated personnel. Maintenance records should be archived. You must thoroughly check its performances before restarting up it when it has been used for more than six months.

The “troubleshooting” methods provided in this user manual are basic methods for solving faults of the ventilator. If faults cannot be still eliminated by using such methods or faults occur repeatedly, then you should notify Puao Medical or its authorized service agency for repair.

9.2 Care and Maintenance of Battery

After use, you should charge the battery in time at an interval no longer than 12h. The charging current must comply with the requirements in the Instructions for Use of the battery.

If the battery has not been discharged for 6 consecutive months, one treatment charge and discharge maintenance operation must be performed on it, which means that you should have the ventilator operate on the battery until the battery cannot continue to drive the ventilator. Then sufficiently charge the battery.

You should not place the battery close to a heat source (such as a heating radiator) and under direct strong sunlight. You should not put any object on the battery box to prevent battery temperature from being too high which will cause it to be damaged. The battery box surface should be kept clean. In case of liquid falling down on the battery box, you should immediately wipe it off and make sure that the liquid is not splashed onto the battery; otherwise, you should wipe the battery clean.

The battery must be kept vertical during transportation and use. Keeping its top down or it horizontal is strictly prohibited. You should avoid strong vibration.

10.Transportation and Storage

10.1Transportation Conditions

——The original packing box and damping cushion of the ventilator should be used as specified.

——Standardize the transportation based on the indications and symbols on the packaging box. These indications and symbols are:

——Do Not Turn Over

——Handle with Care

——Keep dry

——The packaging box must be protected by cover in case of open air transportation to protect from sunlight and rain wetting or intensive vibration. It is strictly prohibited to keep top down and throw it.

10.2 Storage Conditions

——Ambient temperature: －10 ～ 40 ℃;

——Relative humidity: no higher than 90 %

——Atmospheric pressure: 86 kPa ～ 106 kPa.

——It should be stored in a room without corrosive gas and well ventilated.

11.Others

The pressure reducer used on the oxygen cylinder and humidifier for warming and humidifying the output gas of the ventilator are not standard configuration of the ventilator and need to be otherwise purchased.

You are welcomed to make consultation by call and letter, and when necessary we can provide further technical data.