Crius V6 Ventilator

Operator’s Manual

Operator’s Manual, the issue date is Aug,2017.

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- All installation operations, expansions, changes, modifications and repairs of this product are conducted by Northern authorized personnel;
- The electrical installation of the relevant room complies with the applicable national and local requirements; and
- The product is used in accordance with the instructions for use.

⚠ WARNING

- **It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.**

NOTE

- **This equipment must be operated by skilled/trained clinical professionals.**

Warranty

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

In accordance with the conditions of storage and use, from the date of the factory 2 years, the ventilator can not work properly, the company free of charge for the user repair, replacement parts or products.

The design life of the ventilator is 10 years (batteries, folding bags and air bags and other accessories are not included).

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- Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.
- Malfunction of the instrument or part whose serial number is not legible enough.
- Others not caused by instrument or part itself.

Customer Service Department

Manufacturer: Shenzhen Northern Meditec Co., Ltd.

Address: Floor 4, Block C, Gold Power Industry Park, julongshan, Grand industrial Zone, Pingshan New District, Shenzhen(518102), P.R.China

Website: www.northernmeditec.com

E-mail Address: info@northernmeditrc.com

Tel: +86 755 29970566

Fax: +86 755 23010276

EC-Representative: Obelis S.A.

Address: Bd. General Wahis 53, 1030 Brussels, Belgium

Website: http://www.obelis.net

E-mail Address: mail@obelis.net

Tel: +32 2732 5954

Fax: +32 2732 6003

Preface

Manual Purpose

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.

Intended Audience

This manual is geared for clinical professionals who are expected to have a working knowledge of medical procedures, practices and terminology as required for monitoring of critically ill patients.

Illustrations

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your ventilator.

Conventions

- Italic text is used in this manual to quote the referenced chapters or sections.
- [ ] is used to enclose screen texts.
- → is used to indicate operational procedures.

Password

A password is required to access different menus within the ventilator.

- Factory Setting: 112358
- Alarm Vol:8888

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FOR YOUR NOTES

Chapter 1 Safety

1.1 Safety Information

 **DANGER**
■ **Indicates an imminent hazard that, if not avoided, will result in death or serious injury.**

 **WARNING**
■ **Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.**

 **CAUTION**
■ **Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury and/or product/property damage.**

NOTE
■ **Provides application tips or other useful information to ensure that you get the most from your product.**

1.1.1 Dangers

There are no dangers that refer to the product in general. Specific "Danger" statements may be given in the respective sections of this manual.

1.1.2 Warnings

⚠WARNING

- **The ventilator must only be operated and used by authorized medical personnel well trained in the use of this product. It must be operated strictly following the Operator's Manual.**
- **Before putting the system into operation, the operator must verify that the equipment, connecting cables and accessories are in correct working order and operating condition.**
- **To avoid the risk of electric shock, this equipment must be connected to a properly installed power outlet with protective earth contacts only. If the installation does not provide for a protective earth conductor, disconnect it from the power line.**
- **Use external power source (AC power or DC power) before the batteries are depleted.**
- **To avoid explosion hazard, do not use the equipment in the presence of flammable anesthetic agent, vapors or liquids. When O2 is used, keep the ventilator away from any fire sources.**
- **Do not place the ventilator adjacent to any barrier, which can prevent cold air from flowing, resulting in equipment over heat.**
- **Do not open the equipment housings. All servicing and future upgrades must be carried out by the personnel trained and authorized by us only.**
- **Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level may result in a hazard to the patient. Remember that alarm settings should be customized according to different patient situations and always keeping the patient under close surveillance is the most reliable way for safe patient monitoring.**
- **The physiological parameters and alarm messages displayed on the screen of the equipment are for doctor's reference only and cannot be directly used as the basis for clinical treatment.**
- **To dispose of the package material, observe the applicable waste control regulations. And keep the package material out of children's reach.**
- **All staff should be aware that disassembling or cleaning some parts of the ventilator can cause risk of infection.**
- **Maintenance menu can only be accessed when the equipment is disconnected from the patient.**
- **Positive pressure ventilation may be accompanied by some side effects such as barotrauma, hypoventilation, hyperventilation, etc.**
- **Using the ventilator in the vicinity of high frequency electrosurgery equipment, defibrillators or short-wave therapy equipment may impair correct functioning of the**

ventilator and endanger the patient.

- **Do not use antistatic or conductive masks or patient tubing. They can cause burns if they are used near high frequency electrosurgery equipment.**
- **Do not use the ventilator in a hyperbaric chamber to avoid potential fire hazard due to an oxygen-enriched environment.**
- **If the equipment internal monitoring system malfunctions, an alternative plan must be available to ensure adequate level of monitoring. The operator of the ventilator must be responsible for patient's proper ventilation and safety under all circumstances.**
- **As required by the relevant rules and regulations, oxygen concentration should be monitored when the equipment is used on the patient. If your ventilator is not configured with such monitoring function or this function is turned off, use a monitor which complies with the requirements of ISO 80601-2-55 for oxygen concentration monitoring.**
- **All analog or digital products connected to this system must be certified to the specified IEC standards (such as IEC 60950 for data processing equipment and IEC 60601-1 for medical electrical equipment). All configurations shall comply with the valid version of IEC 60601-1. The personnel who are responsible for connecting the optional equipment to the I/O signal port shall be responsible for medical system configuration and system compliance with IEC 60601-1 as well.**
- **Do not touch the patient when connecting the peripheral equipment via the I/O signal ports or replacing the oxygen cell, to prevent patient leakage current from exceeding the requirements specified by the standard.**
- **This equipment is not suitable for use in an MRI environment.**
- **When the ventilator's gas supply input system fails or has faults, please contact us immediately for service by specified personnel.**
- **The ventilator shall not be used with helium or mixtures with Helium.**
- **Do not move the ventilator before removing the support arm from it, in order to avoid the ventilator getting tilted during the movement.**
- **Do not block the air intake at the rear of the ventilator.**
- **To prevent interrupted operation of the ventilator due to electromagnetic interference, avoid using the ventilator adjacent to or stack with other device. If adjacent or stacked use is necessary, verify the ventilator's normal operation in the configuration in which it will be used.**
- **To prevent possible personal injury and equipment damage, ensure that the ventilator is secured to the trolley or placed on the safe and smooth surface.**
- **To prevent possible equipment damage, avoid tipping over the ventilator when crossing thresholds.**
- **To prevent possible equipment damage, push the brake down when parking the ventilator.**
- **Avoid the use of polluted air. When the equipment uses air as gas source for ventilation, if the air is polluted, harmful substance may enter the patient tubing**
- **To prevent patient injury caused by equipment malfunction, when the alarm [Technical Error**] occurs, remove the equipment immediately, record failure code, and contact the Customer Service Department.**
- **To prevent possible ventilator malfunction, do not spill liquid onto the ventilator.**
- **A turbine can cause gas to be heated. To reduce the temperature of gas inside the tubing and prevent patient injury accordingly, ensure that the length of patient tubing from the humidifier to Y piece is greater than 1.2m.**
- **The internal electrical power source is to be used if the integrity of the protective earth conductor or the protective grounding system in the installation is in doubt.**

- **Nebulization or humidification can increase the resistance of breathing system filters, and that you need to monitor the filter frequently for increased resistance and blockage.**
- **The ventilation accuracy can be affected by the gas added by use of a nebulizer.**
- **The ventilator shall not be used with nitric oxide.**
- **For non-invasive ventilation, the exhaled volume of the patient can differ from the measured exhaled volume due to leaks around the mask.**
- **Check if the alarm limit settings are appropriate before taking measurement.**
- **When operating the unit with the power supply unit, always connect the unit to an easily accessible outlet so that it can be unplugged quickly in the event of a malfunction.**
- **No modification of this equipment is allowed.**
- **Failure to have an alternative means of ventilation such as a self-inflating, manually-powered resuscitator (as specified in ISO 10651-4) with mask can result in PATIENT death if the VENTILATOR fails.**
- **Stop using the ventilator and contact us immediately when the buzzer sounds.**
- **Under the ambient temperature of 40ºC, the inspiratory pressure of the ventilator exceeds 60 cmH2O, and the maximum temperature on the surface of breathing mask may exceed 41ºC but does not exceed 43ºC**

1.1.3 Cautions

⚠CAUTION

- **The ventilator must be inspected and serviced regularly by trained service personnel.**
- **To ensure patient safety, always prepare resuscitator for use.**
- **Always have a special person attend and monitor the operation of the equipment once the ventilator is connected to the patient.**
- **During the operation of the ventilator, do not disassemble the inspiration safety valve and expiration valve unless in standby status.**
- **To ensure patient safety, use only parts and accessories specified in this manual.**
- **At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products.**
- **Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. For this reason, ensure that all external devices operated in the vicinity of the equipment comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.**
- **This system operates correctly at the electrical interference levels identified in this manual. Higher levels can cause nuisance alarms that may stop mechanical ventilation. Pay attention to false alarms caused by high-intensity electrical fields.**

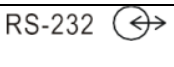
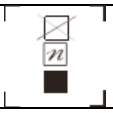
⚠CAUTION

- **Before connecting the equipment to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the equipment's label or specified in this manual.**
- **Always install or carry the equipment properly to avoid damage caused by dropping down, impact, strong vibration or other mechanical force.**
- **To electrically isolate the ventilator circuits from all poles of the supply mains simultaneously, disconnect the mains plug.**
- **To minimize the risk of fire, do not use low-pressure gas tubes that are worn or contaminated with combustible materials like grease or oil.**
- **It is the clinician's responsibility to ensure that all ventilator settings are appropriate.**
- **To prevent possible patient injury, ensure the ventilator is set up for appropriate patient type with the appropriate patient tubing. Ensure the System Check is performed before each patient.**
- **Perform Flow Sensor Calibration before the first use, or when the measured values have deviations.**
- **To prevent possible patient injury, ensure the ventilation parameters are set up properly before ventilating the patient.**
- **To ensure the accuracy of oxygen monitoring, replace an exhausted oxygen cell as soon as possible or use an external monitor that complies with ISO 80601-2-55.**
- **A fan failure could result in oxygen enrichment inside the ventilator and a subsequent fire hazard.**
- **To reduce the risk of explosion, do not burn the O2 cell or force the cell open.**
- **When ventilating with a mask, avoid high airway pressures. High pressures may cause gastric distension.**
- **Peak pressures, exceeding 33 cmH2O, may increase the risk of aspiration due to gastric insufflation. When ventilating with such pressures, consider using an invasive mode.**
- **To reduce the risk of fire, use only tube systems approved for medical purposes and for use with oxygen between the oxygen source and ventilator.**
- **To reduce the risk of fire, ensure adequate ventilation at the rear of the ventilator.**
- **To reduce the risk of fire, switch off the oxygen source when the ventilator is not in a ventilating mode.**
- **Avoid putting the ventilator in the storage environment of more than 50℃ for a long time. Such environment may damage or shorten the battery lives of internal battery and oxygen sensor.**
- **Use the original packing materials to ship the ventilator.**
- **To prevent fire hazard, use only specified fuses or fuses with the same type, rated voltage, and rated current as the existing fuses. When it is necessary to replace fuses, contact the Customer Service Department.**
- **The ventilator is suitable for use within the PATIENT ENVIRONMENT.**
- **Additional MULTIPLE SOCKET- OUTLET or extension cord shall not be connected to the system.**
- **Before moving the ventilator, ensure that the casters and brakes can work properly, and the main unit is locked on the trolley.**

1.1.4 Notes

NOTE
■ **Put the ventilator and its accessories in a location where you can easily see the screen and access the operating controls.** ■ **Keep this manual close to the equipment so that it can be obtained conveniently when needed.** ■ **The software was developed in compliance with IEC 62304. The possibility of hazards arising from software errors is minimized.** ■ **This manual describes all features and options. Your equipment may not have all of them.**

1.2 Equipment Symbols

Symbol	Meaning	Symbol	Meaning
	Notice! Check the documentation		Refer to user manual
	Switch on/off key		Up selection operation key
	Enter key		Down to select the operation key
	Network connector		USB connector
	Ventilator gas outlet		Flow sensor
	Oxygen sensor connector		RS-232 connector
	Expiration connector		Inspiration connector
	AUDIO PAUSED		CO_2 module
	Date of manufacture		Manufacturer
	Serial number	IP21	Degree of protection provided by enclosure
	Protective earth ground		CE mark
	Type BF applied part. Defibrillation-proof protection against electric shock.		MR Unsafe - do not subject to magnetic resonance imaging (MRI)
	The EU Representative Office		Stacking limit by number

	Temperature limitation		Humidity limitation
	Atmospheric pressure limitation		This way up
	Fragile, handle with care		Keep dry
	Recyclable		
	The following definition of the WEEE label applies to EU member states only. This symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased it. * For system products, this label may be attached to the main unit only.		

1.3 Symbols and Abbreviations

1.3.1 Unit

cmH_2O	centimeter of water	mW	milliwatt
hPa	hectopascal	nm	nanometer
A	ampere	ppm	part per million
Ah	ampere hour	s	second
bpm	breaths per minute	V	volt
℃	centigrade	ms	millisecond
cc	cubic centimetre	mV	millivolt
cm	centimeter	L	litre
dB	decibel	lb	pound
℉	fahrenheit	m	meter
g	gram	mAh	milliampere hour
hr	hour	mbar	millibar
Hz	hertz	mg	milligram
inch	inch	min	minute
J	joule	mL	milliliter
k	kilo-	mm	millimeter
kg	kilogram	mmHg	millimeter of mercury
kPa	kilopascal	μA	microampere
VA	volt ampere	μV	microvolt
Ω	ohm	W	watt

1.3.2 Symbols

-	minus
%	percent
/	per；divide；or
～	to
^	power
＋	plus
＝	equal to
＜	less than
＞	greater than
≤	less than or equal to
≥	greater than or equal to
±	plus or minus
*	multiply
©	copyright

1.3.3 Abbreviations

Abbreviations	Meaning
Et CO2	End-tidal Carbon Dioxide
Fi CO2	Fraction of Inspired Carbon Dioxide
FiO2	Inspired Oxygen Concentration
awRR	Air Way Respiration Rate
Paw	Airway Pressure (measured at the patient)
Volume	Gas Volume
Flow	Flow
Ppeak	Peak Pressure,（Pinsp+PEEP）=Ppeak
Pplat	Plateau Pressure
Pmean	Mean Pressure
PEEP	Positive End-Expiratory Pressure
Vte	Expiration tidal Volume
Vte mand	Expiratory Tidal Volume Mandatory
Vte spon	Expiratory Tidal Volume Spontaneous
Vti	Inspiration tidal Volume
Vti mand	Inspiratory Tidal Volume Mandatory
Vti spon	Inspiratory Tidal Volume Spontaneous
MVe	Expiratory minute volume
MVe spon	Expiratory minute volume Spontaneous
MVi	Inspired Minute Volume
MVi mand	Inspiratory Minute Volume Mandatory
MVi spon	Inspiratory Minute Volume Spontaneous
Tinsp	Time of Inspiration
Texp	Time of Expiration
PIF	Patient inspiration flow
PEF	Patient expiration flow
Vt Leak	Leakage tidal Volume
Rtotal	Total Breathing Rate
RR spon	Respiratory Rate Spontaneous
FiO2 Cal	Inspired oxygen calculate
FiO2 Measu	Inspired oxygen measure
Rlung	Lung resistance of the patient
Cdynamic	Dynamic Compliance
RSBI	Rapid Shallow Breath Index
PTP	Pressure time product [mbar·s], measure for the work of breathing (integral of airway pressure below PEEP over time).
Pmax	Maximum pressure (safety systems make sure this pressure can't be exeeded)
Psupp	Pressure Support Level(relative to PEEP/Plow)
Pinsp	Pressure Control Level of Inspiration
Rate	Breathing rate
Tslope	Time of Pressure Rising
MV	Minute Volume

Vt	Tidal Volume
Tpause(%)	Percent of Inspiratory Pause Time
Trigger	Trigger
Exp%	Exhale sensitivity
Phigh	High Pressure
Thigh	Time of High Pressure
Plow	Low Pressure
Tlow	Time of Low Pressure
I:E	Inspiratory Time:Expiratory Time Ratio
RSL	Resuscitation Sensitivity Level
ATC	Automatic intubation compensation
PCVR	Pressure Controlled Volume Regulation, in pressure control modes, adapt the inspiratory pressure setpoint to realize an operator set target volume. A.K.A. as PRVC Pressure Regulated Volume Control
P0.1	100ms Occlusion Pressure
VC-ACV	Volume Controlled – Assist Control Ventilation
PC-ACV	Pressure Controlled – Assist Control Ventilation
PVC-ACV	Pressure Volume Controlled-Assist Control Ventilation
VC-SIMV	Volume Controlled – Synchronized Intermittent Mandatory Ventilation
PC-SIMV	Pressure Controlled – Synchronized Intermittent Mandatory Ventilation
PVC-SIMV	Pressure Volume Controlled – Synchronized Intermittent Mandatory Ventilation
PC-Dual PAP	Pressure Controlled-Duo Positive Airway Pressure
PC-AMV	Pressure Controlled – Assisted Manual Ventilation
PC-APRY	Pressure Controlled – Airway Pressure Release Ventilation
PC-MMV	Pressure Controlled – Mandatory Minute Ventilation
Spn-CPAP	Spontaneous – Continuous Positive Airway Pressure (mode without mandatory
Adu	Adult
Ped	Pediatric
Neo	Infant
IV	Invasive Ventilation
NIV	Non-Invasive Ventilation
O2	Oxygen
Sigh	Sigh

FOR YOUR NOTES

Chapter 2 The Basics

2.1. System Description

2.1.1 Intended Use

This product is intended to provide ventilation assistance and breathing support for adult, paediatric and infant patients.

2.1.2 Contraindications

There are no absolute contraindications for this product. For some special diseases, however, some necessary treatments shall be taken for ventilator mechanical ventilation, or special ventilation modes shall be adopted to prevent possible patient injury.

2.1.3 Components

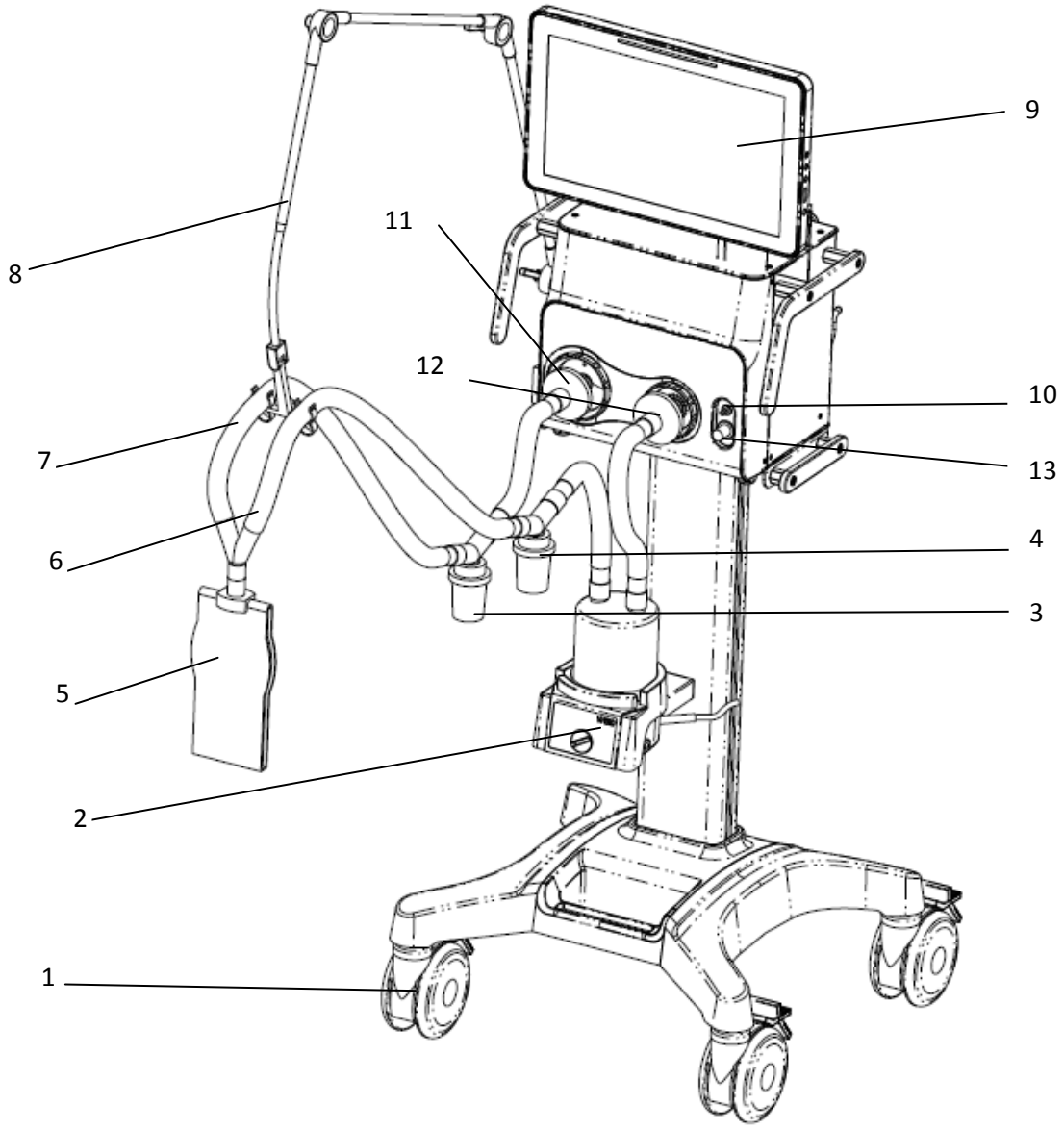
The ventilator consists of a main unit (including pneumatic circuit, electronic system, mechanical structure, software, display, CO_2 module), trolley, and support arm.

Connect the patient to the ventilator via the patient breathing circuit.

The applied part of the ventilator is breathing masks.

2.2. Equipment Appearance

2.2.1 Front View



1. Caster and brake

   The ventilator has four casters and all casters have brakes.

2. Humidifier

3 Expiratory water trap

   Collects condensed water in the expiratory tube.

4. Inspiratory water trap

   Collects condensed water in the inspiratory tube.

5. Test lung

6. Inspiratory tube

7. Expiratory tube

8 Support arm

   Supports and hangs the patient tubing.

9. Display

10. Nebulizer connector Connects the nebulizer.

11. Expiratory filter

    Prevents water and bacteria inside the patient tubing from entering the ventilator's internal pneumatic circuit.

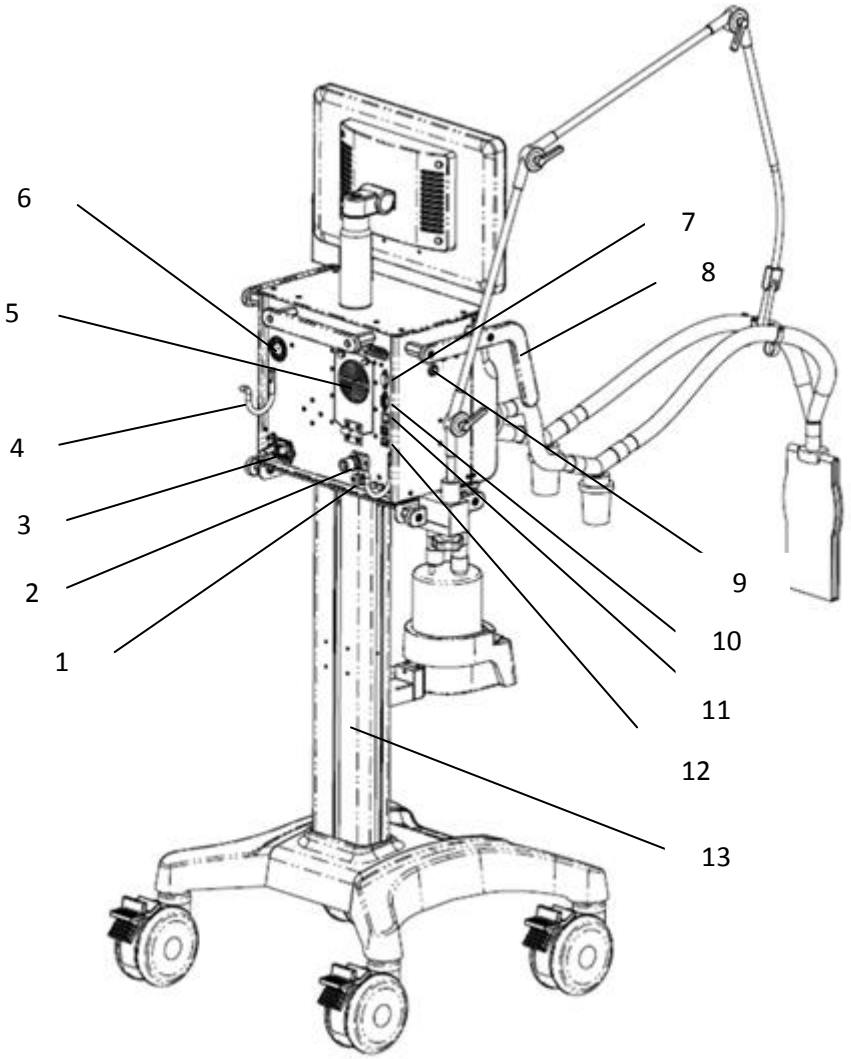
12. Inspiratory filter

    Prevents water and bacteria inside the patient tubing from entering the ventilator's internal pneumatic circuit.

13. Leak test plug

    For System Check or Flow Calibration.

2.2.2 Rear View



1. Inlet of low-pressure O2 supply
2. Inlet of high-pressure O2 supply
3. AC power receptacle
4. Hang the power cord
5. Main unit air inlet grille

   Air intake dust filter and Oxygen sensor.
6. Fan
7. VGA connector

   Outputs VGA video signals with the same contents to the primary display and connects to the external display (supporting display with resolution of 1280*800).
8. Trolley front handle

9. CO2 module

   Mainstream or sidestream CO_2 module for optional configuration. The connector varies depending on the configured module.

10. RS-232 connector

    Connects to the external calibration device for calibrating pressure. An external medical device can be connected via this connector to communicate with the ventilator.

11. Network connector

    A connector which supports connection with a PC to realize software upgrade.

12. USB connector

    Conducts ventilator software upgrade export, configuration transfer between machines of the same type via USB device.

13. Trolley

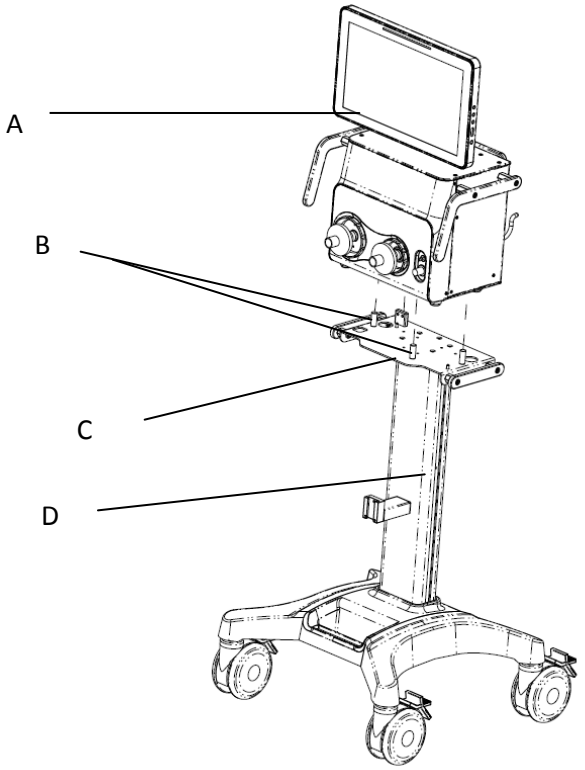
FOR YOUR NOTES

Chapter 3 Installations and Connections

⚠ WARNING

- **Do not use antistatic or conductive masks or patient tubing. They can cause burns if they are used near high frequency electrosurgery equipment.**
- **To ensure optimum performance of the ventilator, re-do System Check each time after accessories or components like patient tubing, humidifier, and filter are replaced.**
- **Adding accessories or other components to the breathing system of the ventilator can increase system inspiratory and expiratory resistance.**

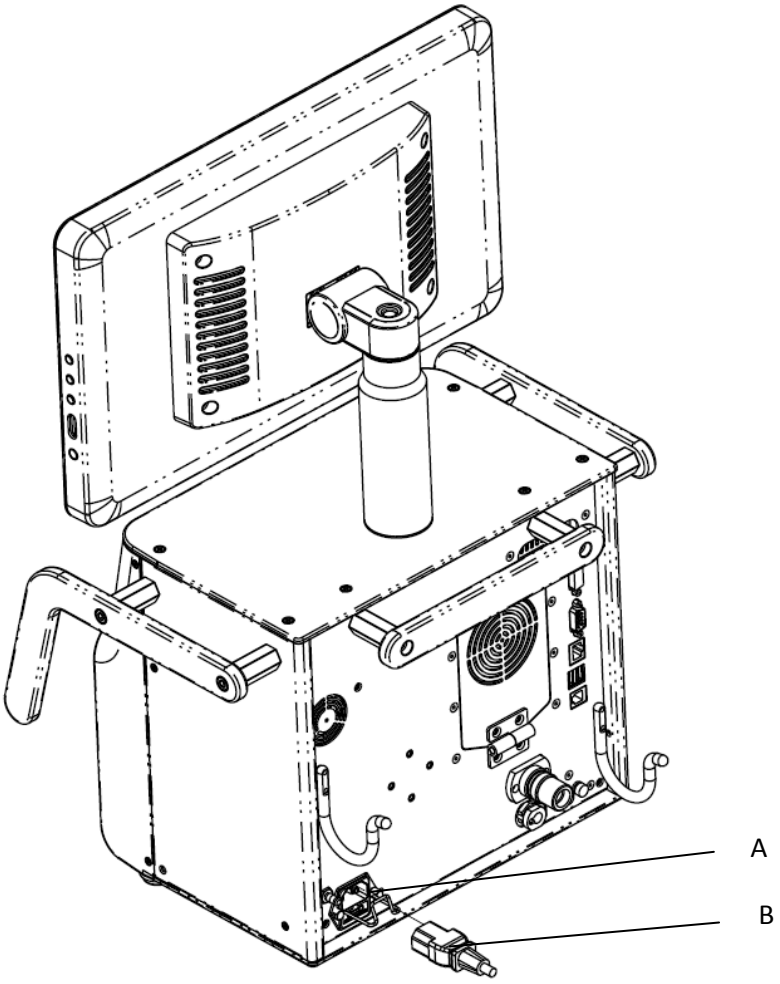
3.1 Install the Main Unit



A. Main unit B. Positioning post C. Trolley unlocking button D. Trolley Align the main unit with the two positioning posts on the trolley and put it onto the trolley in place. To remove the main unit from the trolley, depress the trolley unlocking button and then lift it up with both hands.

3.2 Connect to the Power Supply

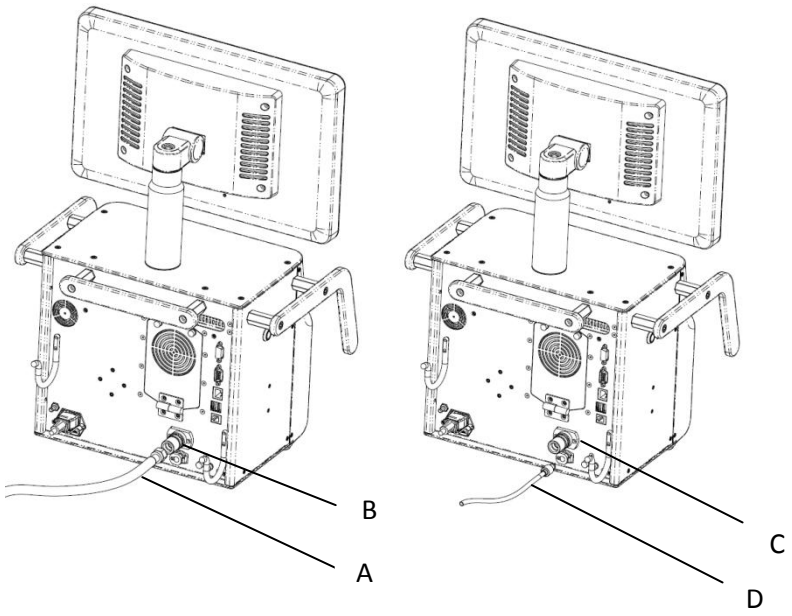
3.2.1 Connect to AC Power



A. AC power receptacle B. AC power cord

1. Insert the AC power cord into the AC power receptacle.

3.3 Connect to the Gas Supply



A. High-pressure O_2 supply connector B. High-pressure O_2 supply hose and fitting
C. Low-pressure O_2 supply connector D. Low-pressure O_2 supply hose

This ventilator provides two types of gas supply connection: high-pressure O_2 and low-pressure O_2.

When the ventilator is connected to high-pressure O_2 supply, the normal working gas supply pressure is 280~600KPa. If gas supply pressure is less than 280KPa, it will compromise the performance of the ventilator and even stop ventilation. If gas supply pressure is within 600~1000KPa, it will compromise the performance of the ventilator but will not cause any hazard due to high-pressure gas. Connect the high-pressure O_2 supply as follows:

1. Check if the sealing ring at the gas supply connection is in good condition before connecting the gas supply hose. If the sealing ring is damaged, do not use the hose. Replace the sealing ring to prevent leakage.
2. Align the connector with and insert it into the inlet of high-pressure O_2 supply at the rear of the ventilator.
3. Ensure that the gas supply hose is properly connected to the gas supply inlet. Tighten the hose nut by hand.

When the ventilator is connected to low-pressure O_2 supply, the flow of low-pressure O_2 supply cannot exceed 15 L/min. To reduce the risk of fire, do not use a low-pressure O_2 supply that delivers a flow greater than 15 L/min. To connect the low-pressure O_2 supply, align the low-pressure O_2 supply hose with and insert it into the low-pressure O_2 supply connector. When a click is heard, it indicates that the gas supply hose is inserted in place. Depress the metal dome on the low-pressure O_2 supply connector to remove the gas supply

hose.

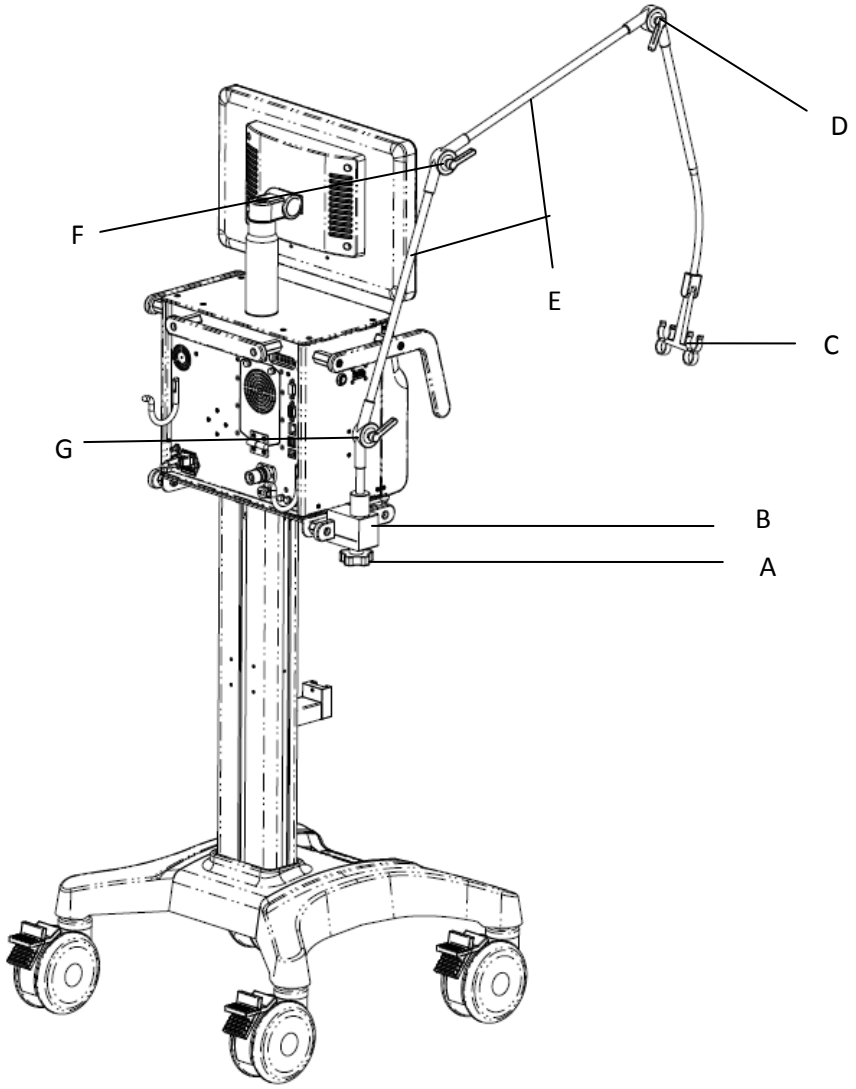
⚠WARNING

- **Inspect the O2 supply connector carefully and ensure there is no leakage. If gas leakage is significant, O2 concentration in the ambient environment will exceed normal O2 concentration in atmosphere, resulting in potentially dangerous O2 enriched environment.**
- **Place the O2 supply hose carefully, avoiding exposure to the environment in which possible damage to the O2 supply hose is easily caused by cut or heating.**
- **To reduce the risk of fire, do not use a low-pressure O2 supply that delivers a flow greater than 15 L/min.**

⚠CAUTION

- **When the ventilator is sourced from an oxygen concentrator, never operate the concentrator with a humidifier. Any humidifier system supplied with the concentrator must be drained or removed before using the ventilator.**
- **The ventilator's oxygen control is not active when low-pressure oxygen is used. To prevent possible patient injury, use low-pressure oxygen only in cases that the**
- **low-pressure supply can provide an adequate level of oxygenation.**
- **Before starting ventilation, ensure the appropriate oxygen source, either**
- **high-pressure oxygen (HPO) or low-pressure oxygen (LPO), was selected during configuration, referring to 5.13 Set O2 Supply Type.**
- **To prevent possible patient injury, ensure that an emergency backup O2 supply (for example, a gas cylinder) is available in case the low-pressure O2 supply fails.**
- **The low-pressure O2 supply hose assembly shall comply with the requirements of ISO 5359.**

3.4 Install the Support Arm



A. Fixing block knob B. Fixing block C. Tube hook

D. Support arm joint E. Support bar F. Support arm joint

G. Support arm joint

1. Loosen the fixing block knob. Place the fixing block onto the handle on the side of the ventilator.
2. Tighten the fixing block knob.

⚠WARNING

- **To prevent possible patient injury due to accidental extubation, check the support arm joints and the connection security as necessary.**

3. Adjust the support arm.
4. Place the patient tubing onto the tube hook.

NOTE

- **Operate support arm joint F or G with both hands as shown below. Operating with a single hand will bring some risks.**
- **The maximum weight of the support arm is 1 kg.**
- **The support arm can be fixed onto the handle on the either side of the ventilator.**

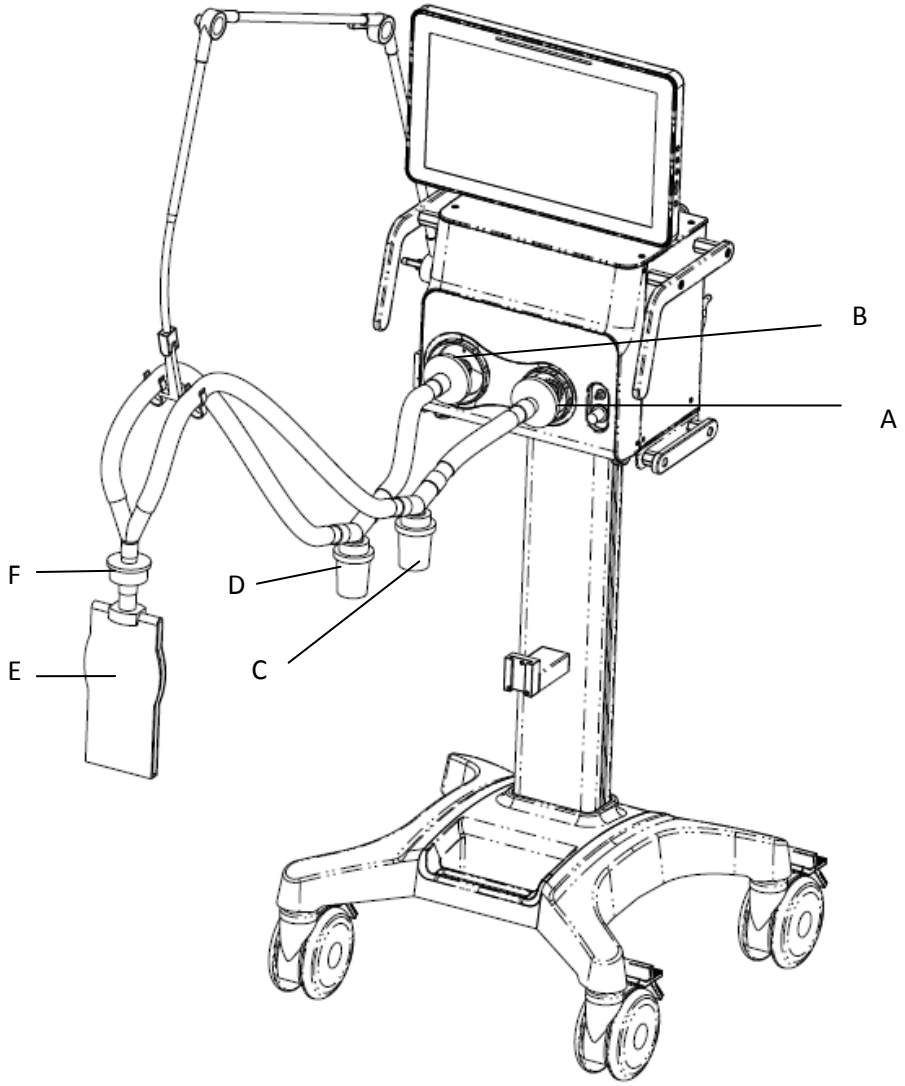
3.5 Install the Patient Tubing

⚠WARNING

- **To minimize the risk of bacterial contamination or physical damage, handle bacteria filters with care.**
- **To prevent patient or ventilator contamination, always use a bacteria filter between the ventilator and the patient inspiratory limb.**

⚠CAUTION

- **The use of an expiratory filter may lead to a significant increase in expiratory resistance. Excessive expiratory resistance may compromise ventilation and increase patient's work of breathing and intrinsic PEEP.**
- **The patient tubing shall comply with the requirements of ISO 5367.**
- **The bacteria filters shall comply with the requirements of ISO 23328-1 and ISO 23328-2.**
- **The Heat & Moisture Exchange (HME) shall comply with the requirements of ISO 9360-1 and ISO 9360-2.**



A. Inspiratory filter B. Expiratory filter C. Inspiratory water trap D. Expiratory water trap

E. Simulation of lung F. Support arm book

Connect the patient to the ventilator via the patient breathing circuit.

1. Mount the filters onto the inspiratory and expiratory ports.
2. Connect the inspiratory filter to the water trap via the tube. Connect the other end of the tube to the Y piece.
3. Connect the expiratory filter to the water trap via the tube. Connect the other end of the tube to the Y piece.
4. Connect the patient side of the Y piece to the HME and then connect the HME to the patient.
5. Place the patient tubing onto the support arm hook.

3.6 Install the Humidifier

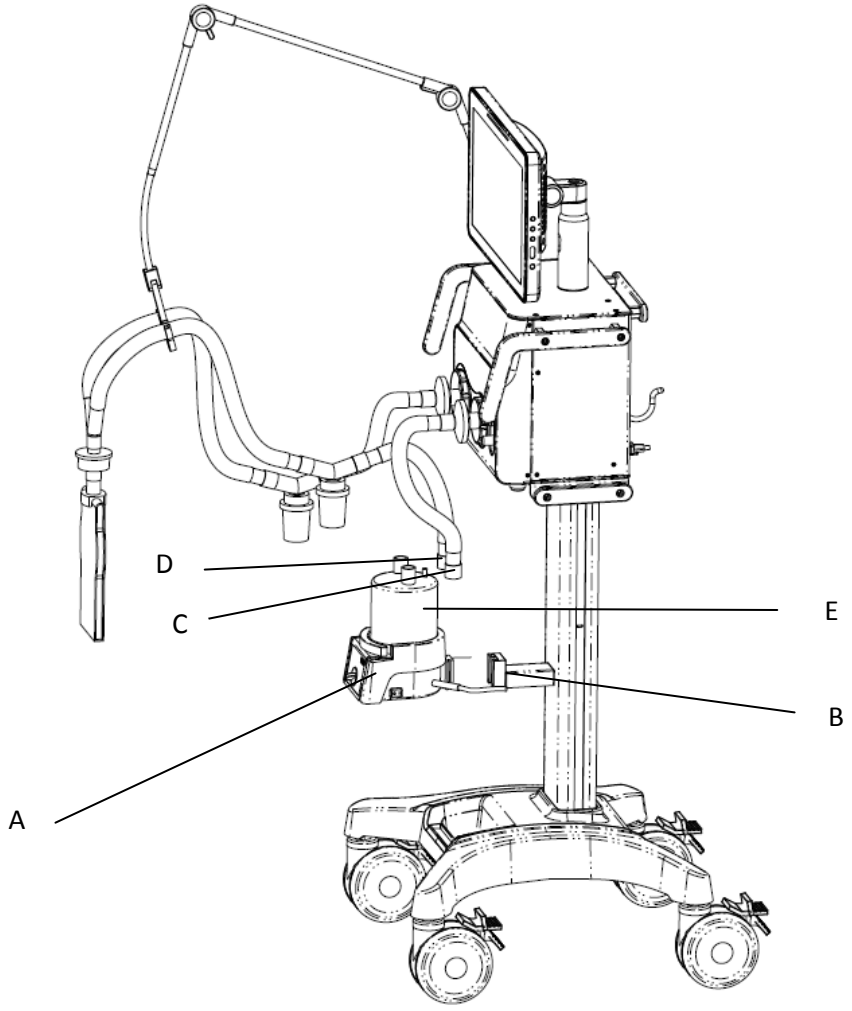
⚠WARNING

- **To prevent possible patient injury and equipment damage, do not turn on the humidifier until the gas flow has started and is regulated.**
- **To prevent possible patient injury and equipment damage, ensure the humidifier is set to appropriate temperature and humidity.**

NOTE

- **The humidifier shall comply with the requirements of ISO 8185. The humidifier assembly and its installation steps described in this section are only for reference.**

3.6.1 Install the Humidifier onto the Ventilator



A. Humidifier B. Humidifier bracket slot C.Humidifier inlet

D.Humidifier outlet E. Humidifier mounting plate

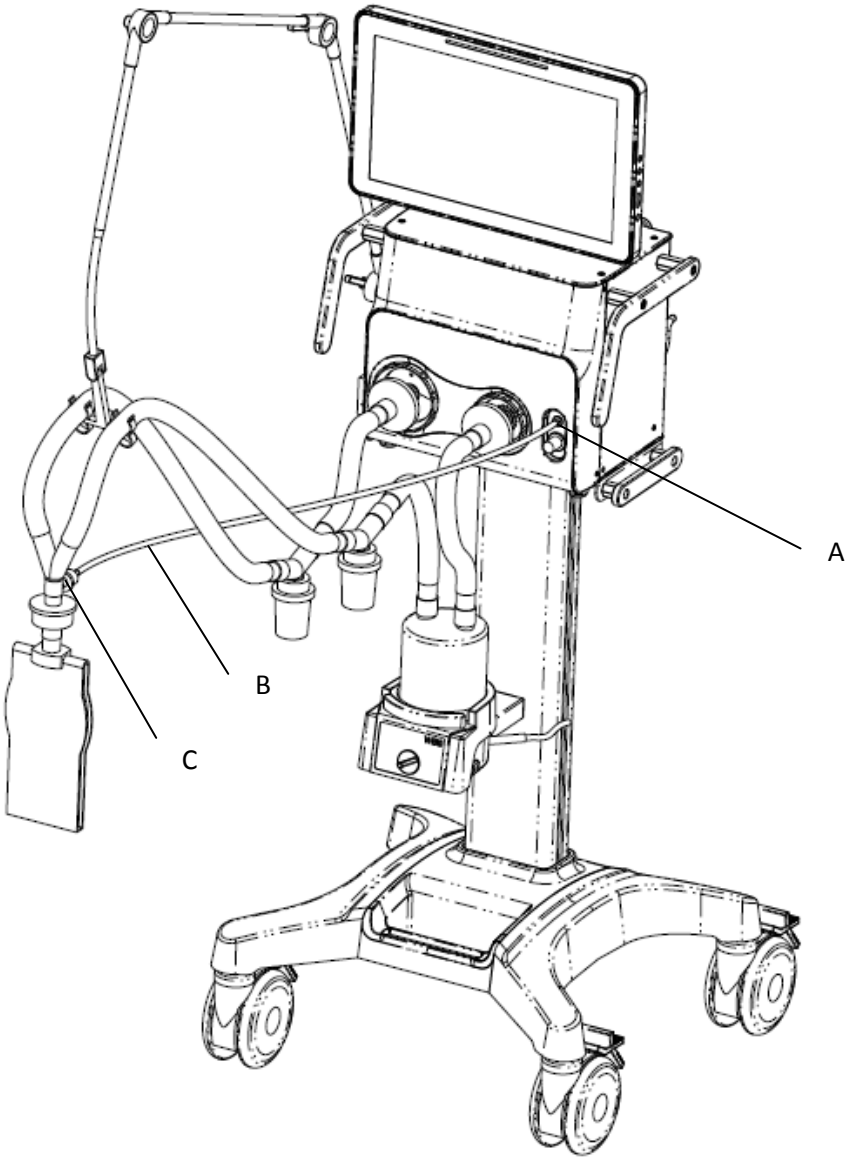
1. Align the humidifier mounting plate and the slot, and slide the humidifier in.
2. Tighten the screw.
3. Mount the filters onto the inspiratory and expiratory ports.
4. Connect the inspiratory filter to the humidifier inlet via the tube.
5. Connect the humidifier outlet to the water trap via the tube. Then, connect the water trap to the Y piece via the tube.
6. Connect the expiratory filter to the water trap via the tube. Then, connect the water trap to the Y piece via the tube.
7. Place the patient tubing onto the support arm hook.

The rated range of the ventilator breathing system (VBS):
Inspiratory and expiratory gas pathway resistance: 0 to 6 cmH_2O/ (L/s) at 60 L/min
VBS compliance: 0 to 5 mL/cmH_2O.

3.7 Install the Nebulizer

NOTE

- **Install the specified nebulizer. The nebulizer assembly and its installation steps described in this section are only for reference. Refer to the nebulizer accompanying directions for use to install and use the nebulizer.**
- **To prevent the expiration valve from sticking due to nebulized medications, use only medications approved for nebulization, and regularly check and clean or replace the expiration valve membrane.**
- **Do not use an expiratory filter or HME in the patient's breathing circuit during nebulization. Nebulization can cause an expiratory side filter to clog, substantially increasing flow resistance and impairing ventilation.**
- **Connect the nebulizer to the inspiratory limb. Connecting the nebulizer between the patient connector and the endotracheal tube increases dead space ventilation.**



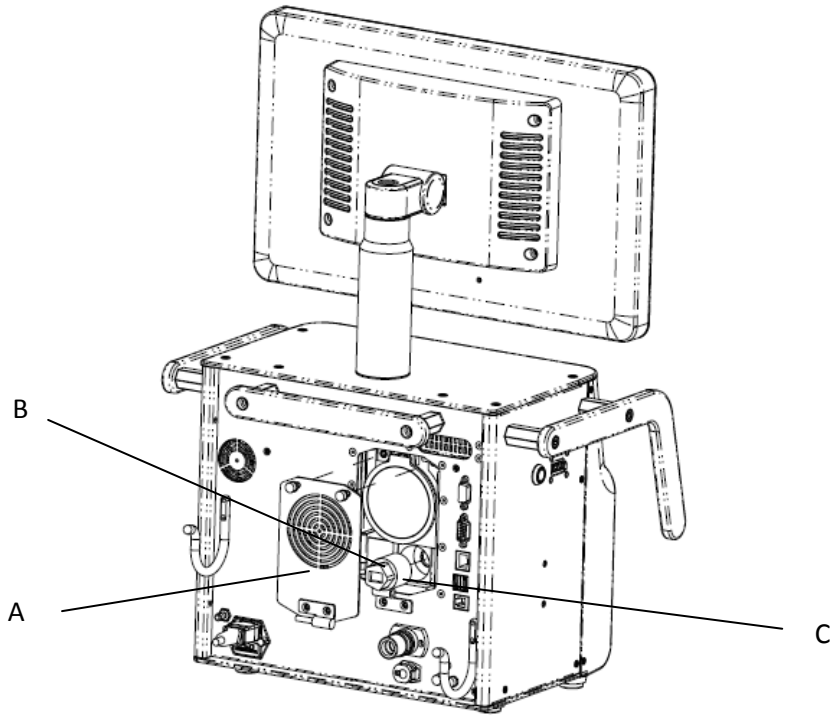
A. Nebulizer connector B.Nebulizer tube C.Nebulizer

1. Connect one end of the nebulizer tube to the nebulizer connector and the other end to the nebulizer.
2. Install the nebulizer to the inspiratory limb via the tube.

3.8 Install the O2 Sensor

⚠CAUTION

- **To reduce the risk of explosion, do not burn the O2 cell or force the cell open.**



A. Main unit air inlet grille B. O_2 sensor C. O_2 sensor connection cable

1. Rotate the O_2 sensor clockwise to install it.
2. Push the O_2 sensor and its fixing seat into the ventilator.
3. Connect the O_2 sensor connection cable.
4. Close the main unit air inltet grille.

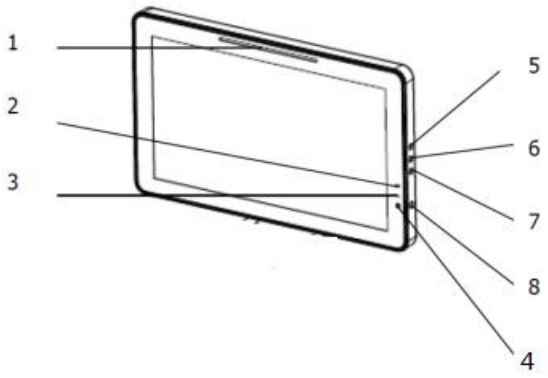
⚠CAUTION

- **Ensure that the gas cylinder is equipped with pressure-reducing valve.**

FOR YOUR NOTES

Chapter 4 User Interface

4.1 Display Controls



The control unit is characterized by a small number of operating elements. Its main elements are:

1. Alarm indicator

   A group of red / yellow color, and includes a translucent lens LED. Provide visual alarm information through different color and different flicker frequency.

2. The battery indicator

   - Bright: battery is charged or fully charged.
   - Bright: In case of shutdown, the AC power is turned on, the AC indicator will light, and the battery will automatically enter the charging state.
   - Extinct: the battery is not installed or the ventilator is not connecting AC.
   - Flash: the ventilator is use battery power supply.

3. AC indicator

   - Nright: ventilator connected alternating current.
   - Extinct: ventilator is not connecting AC.

4. Running indicator

- Bright: start system.
- Extinct: system shutdown

5. Up key

   Alternate user operation key, press this button, the cursor moves upward.

6. Enter key

   Alternate user operation key, press this button for confirmation.

7. Dwon key

   Alternate user operation key, press this key to move the cursor down.

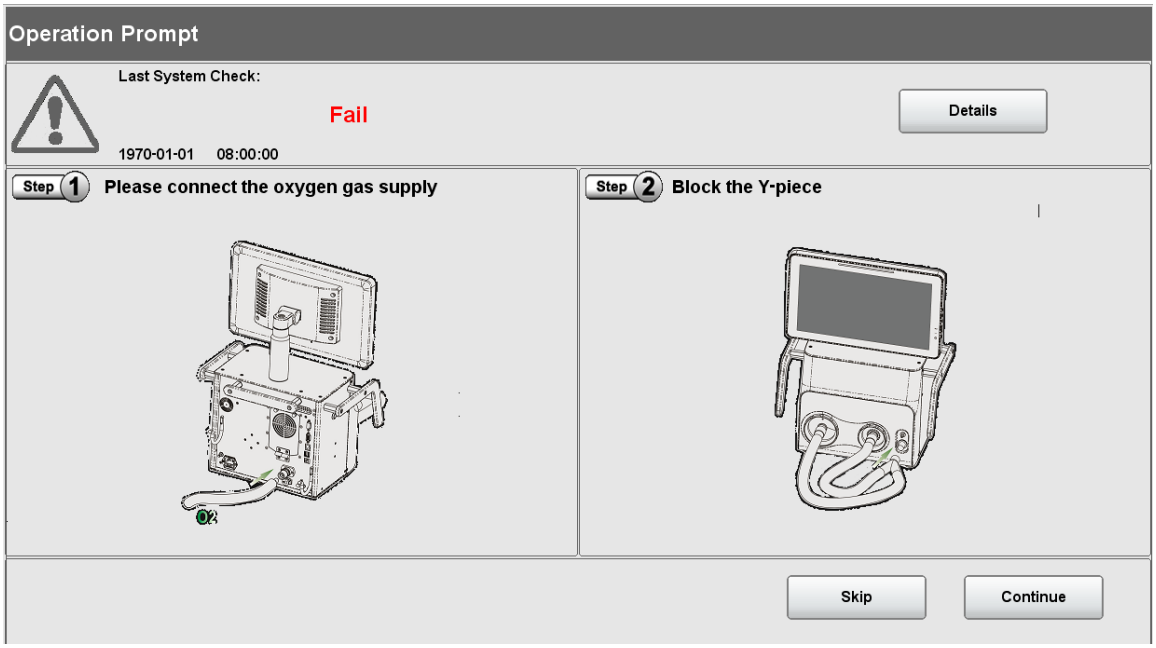
8. System on / off key

   Press this button to start system, long press this button again, pop-up box then select [OK] button, enter the 5S countdown display interface , After countdown system automatically shutdown ; if you choose [Cancel] button, exit interface, return the current state, the system shutdown is not successful.

The ventilator display shows ventilation parameters, pressure/flow/volume waveforms and spirometry loops, etc.

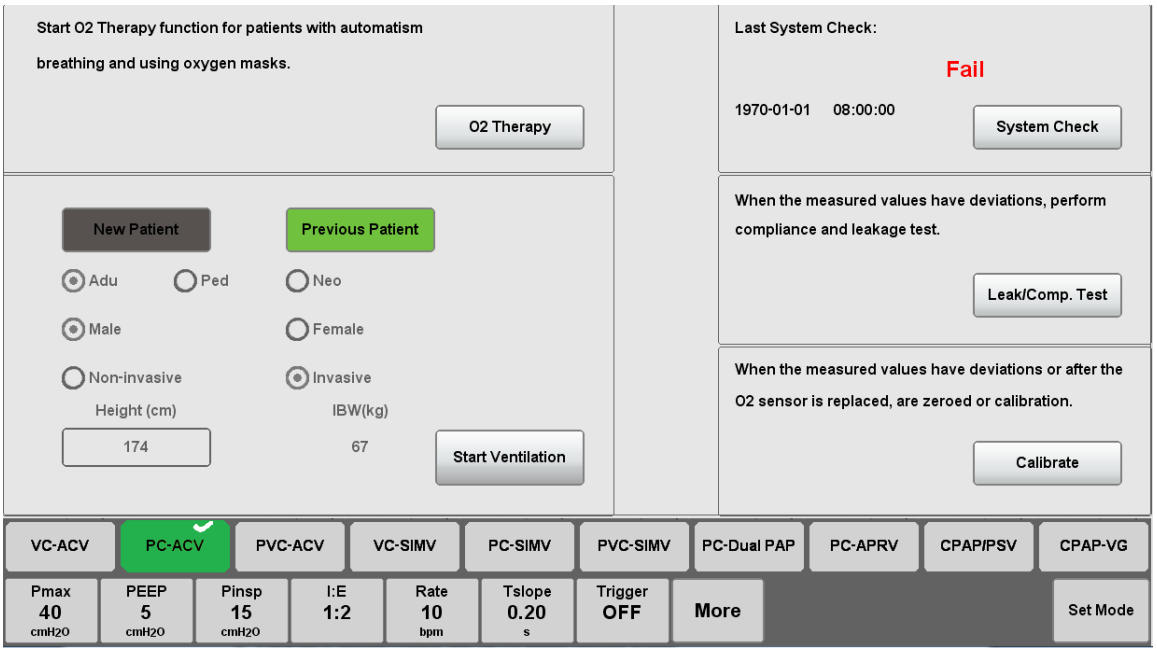
The following is an example of Waveforms screen. Display screen may vary subject to the configurations.

4.2 Syst.Check Screen



1. Click the [Details] button to enter the self-test log log results interface.
2. Click the [Skip] button, jump self-test interface, directly into the standby interface.
3. Click the [Continus] button to enter the self-test function.

4.3 StandBy Screen

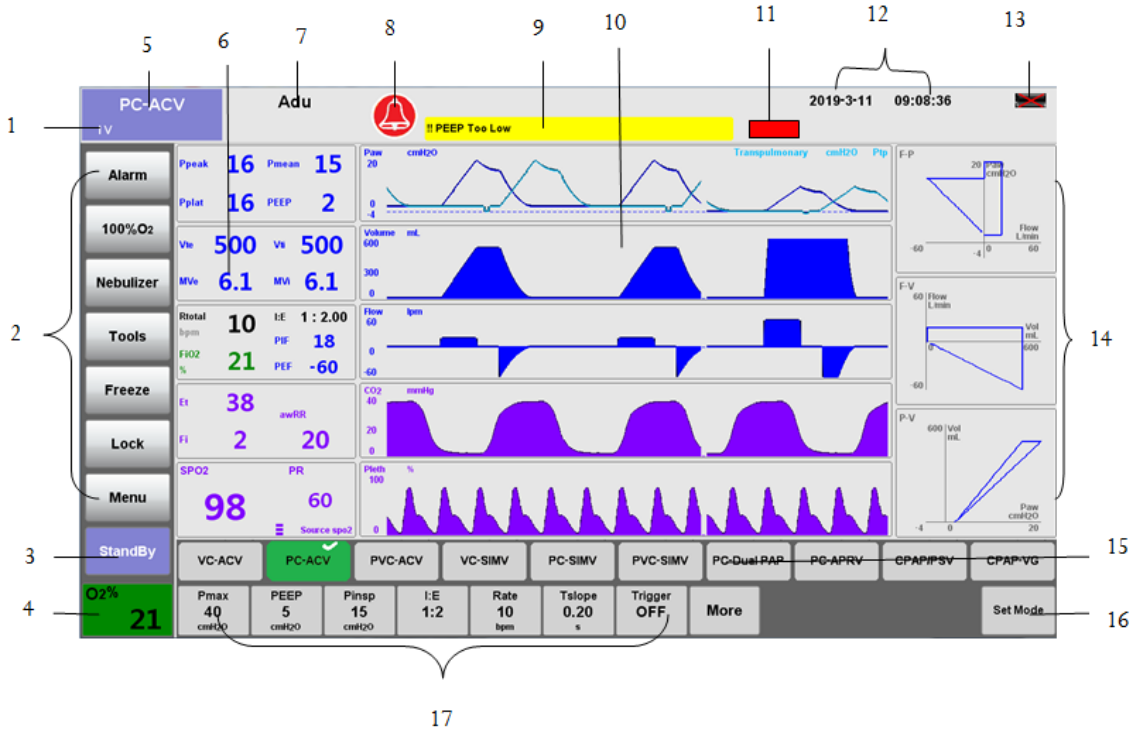


1. Click the [O2 Therapy] button to O2 Therapy ventilation pattern.
2. Patient Type setting

   Click the [New Patient] button, set the patient type, gender, invasive, noninvasive and patient height.

   Click the [Previous Patient] button, displays current patient information and invasive or noninvasive ventilation patterns.
3. Click the [Start Ventilation] button, into the ventilation.
4. Click the [System Check] button, into the system check screen.
5. Click the [Leak/Comp. Test] button, into the leak test screen.
6. Click the [Calibrate] button, into the Zero calibrate、Flow calibrate and O2 sensor calibrate screen.

4.4 User Screen



1. Ventilation type field

   Displays Non-invasive or Invasive ventilation type.

2. Soft key field

   Displays soft keys: Alarm, 100%O2, Nebulizer, Tools, Lock, Freeze,Lock and Menu.

3. StandBy button

   Click to return to the standby interface

4. Oxygen concentration setting button

   Set Oxygen concentration .rang:21~100%

5. Ventilation mode field

   Displays Standby or active ventilation mode and ventilation assist indication.

6. Monitoring parameters field

   Displays monitoring parameters.

7. Patient type icon field

   Indicates current patient type: Adult、Pediatric or Neo.

8. AUDIO PAUSED icon field
9. Physiological alarm field

   Displays the physiological alarm messages. When there are multiple alarm messages, the number of alarms is displayed. In this case, select the alarm message field, and you can view active alarm messages, alarm occurrence time and alarm level on the accessed window.

10. Waveforms field

Displays waveforms：paw、Volume、Flow、CO2、Pleth.

11. Technical alarm field

    Displays the technical alarm messages. When there are multiple alarm messages, the number of alarms is displayed. In this case, select the alarm message field, and you can view active alarm messages, alarm occurrence time and alarm level on the accessed window.

12. System time field

    Displays current system time.

13. Power status icon field

    Displays the status of currently-used power supply.

14. Spirometry loops field

    Displays spirometry loops.

15. Ventilation mode setup field

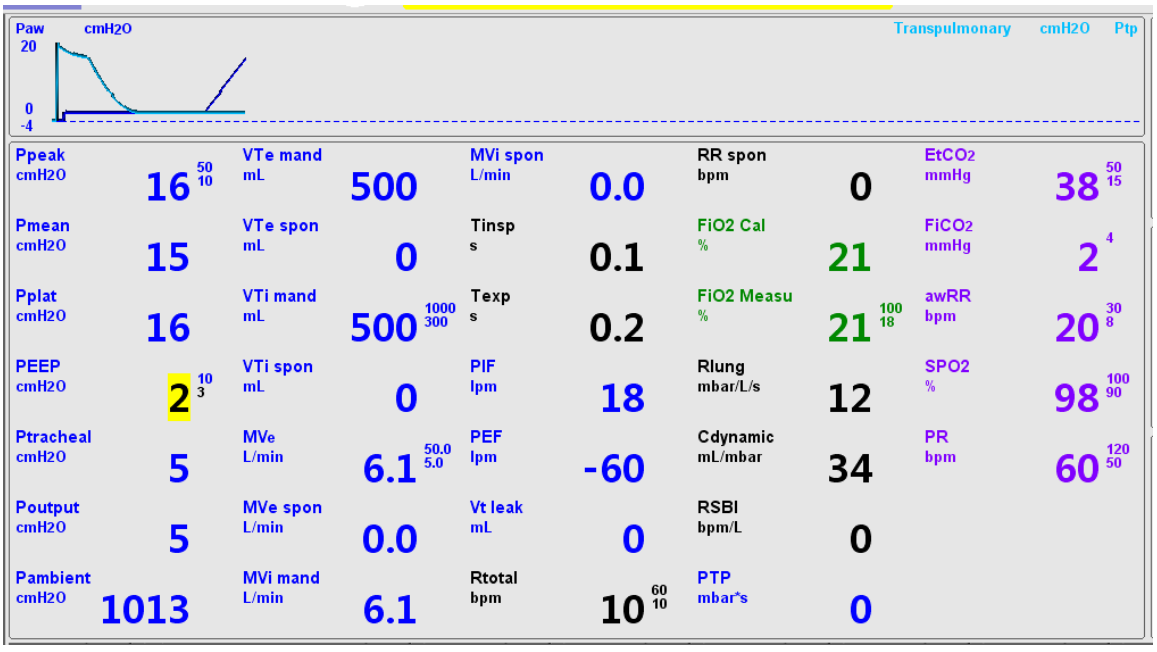
    Displays the keys for setting up ventilation modes.

16. Mode confirm button
17. Parameter setup quick key field

    Displays ventilation setting parameters corresponding to the active ventilation mode.

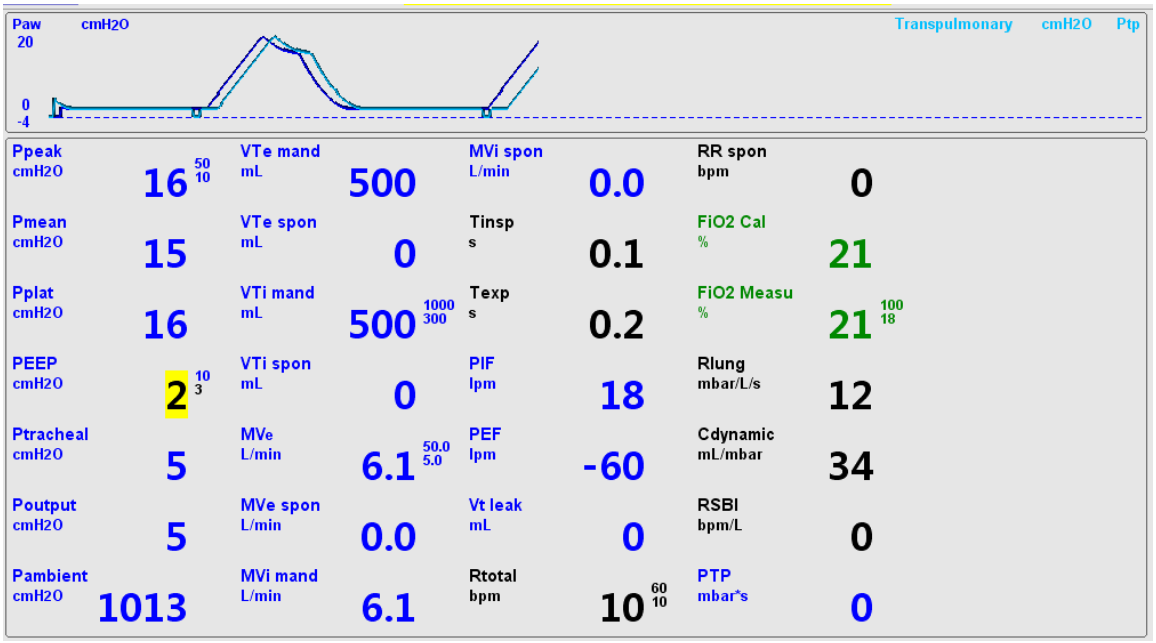
4.5 Measured Values Screen

CO_2 module configured , for ventilation during the click [Menu] ->[Main Menu] interface,select the [System setup]->[setting] layout :select [All Params] to access the screen as shown below.



When the mainstream CO_2 module not configured, select the [Menu] ->[Main Menu] interface ,select the [System setup]->[setting] layout :select [All Params] to access the

screen as shown below.



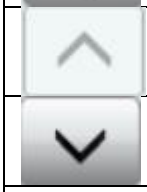
4.6 History Data

Select the [Menu], select the [Data] button to access the window as shown below. You can view tabular trend, graphic trend, and event logbook in the History window.

4.6.1 Tabular Trend

You can view the patient's monitored parameter data and events under the Tabular Trend tab. Trend data displays at one-second intervals by default.

4.6.1.1 Navigating in Tabular Trend

Button	Function
	Moves the cursor one record back/forward from its current position.
	Moves the cursor to the top/bottom parameter from its current position.
	Moves the cursor up/down one page from its current position.
Previous Event	Moves the cursor to the previous event from its current position.
Next Event	Moves the cursor to the next event from its current position.

4.6.1.2 About Tabular Trend

- Tabular Trend displays the time and date on the vertical axis
- Tabular Trend displays the parameter data on the horizontal axis.
- Tabular Trend is not stored when the machine is in standby status.
- The system can display a rolling 24 hours of continuous trend data.

4.6.1.3 Interval

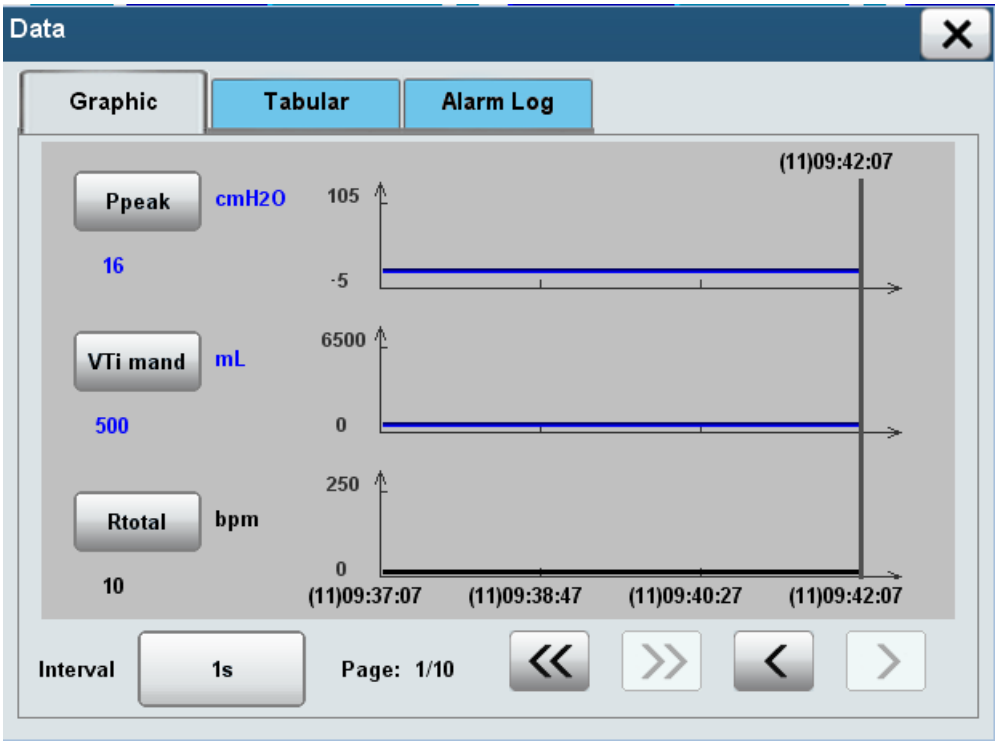
In the Tabular Trend window, you can set [**Interval**] to [1s], [**5s**], [**1min**], [**10min**], [**30min**], and [1h].

4.6.2 Graphic Trend

A trend graph is used to review the trend of parameter values within a specific time period.

The trend is reflected through a curve. Every point on the curve corresponds to the parameter value at a specific time point. When the ventilator is restarted, the trend graph is recorded anew.

Click the bottom [Menu] -> [Data] -> [Graphic], you can enter the trend interface, as shown below:



4.6.2.1 About Graphic Trend

- Graphic Trend displays the time and date on the vertical axis.
- Graphic Trend displays the parameter data on the horizontal axis.
- Graphic Trend is not stored when the machine is in standby status.
- The system can display a rolling 24 hours of continuous trend data.

4.6.2.2 Navigating in Graphic Trend

Button	Function
	Moves the cursor one recorous/next page frd Previom its current position.
	Moves the cursor up/down one parameter from its current position.
	
Previous Event	Moves the cursor to the previous event from its current position.
Next Event	Moves the cursor to the next event from its current position.

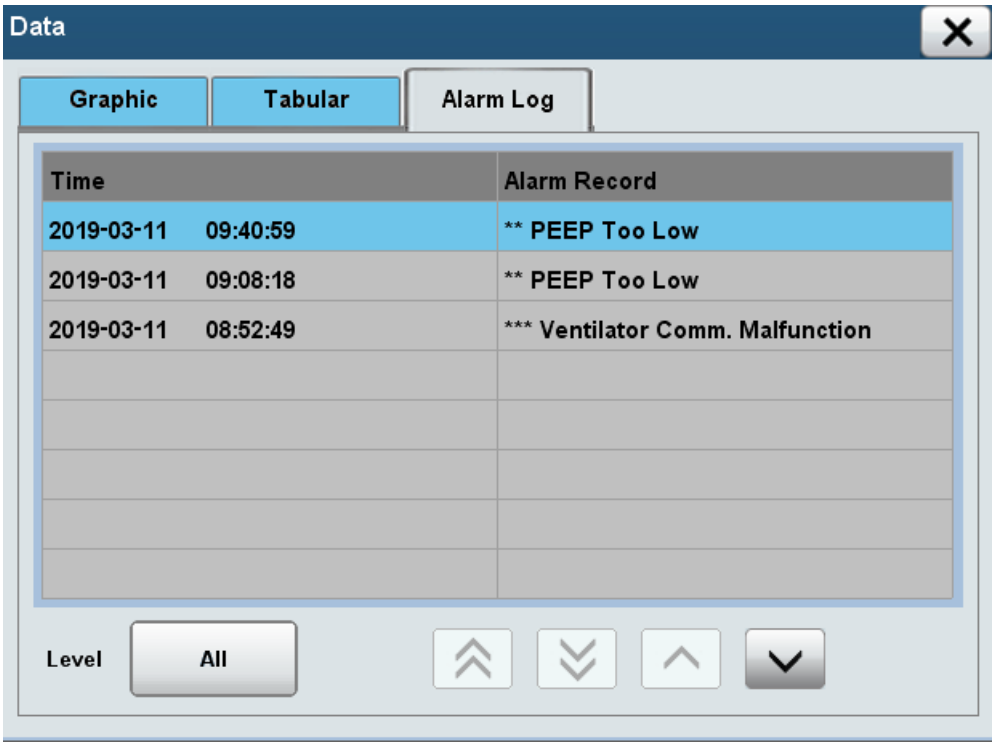
4.6.2.3 Interval

In the Tabular Trend window, you can set [Interval] to [1s], [5s], [1min], [10min], [30min], and [1h].

4.6.3 Event Log

For alarm logbook, the system provides up to 500 events, which are stored in chronological order. When a new event occurs after 500 events are already stored, the new event overwrites the earliest one.

Click the bottom [Menu] -> [Data] -> [Alarm Log], you can enter the trend interface, as shown below:

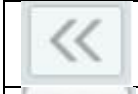
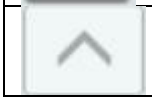


4.6.3.1 About Event Log

- Event Logbook displays the most recent record at the top.
- The system can store up to 5000 records of Event Logbook.

NOTE
■ **The system can store up to 5000 records of Event Logbook. When a new event occurs after 5000 events are already stored, the new event overwrites the earliest one.**

4.6.3.2 Navigating in Event Log

Button	Function
	Moves the cursor one recorous/next page frd Previom its current position.
	
	Moves the cursor up/down one parameter from its current position.

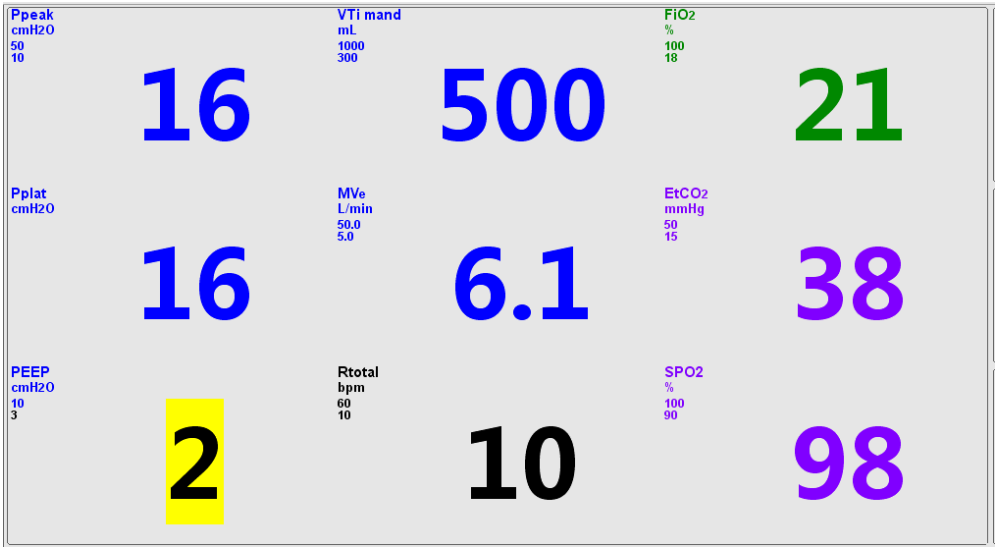
Previous Event	Moves the cursor to the previous event from its current position.
Next Event	Moves the cursor to the next event from its current position.

4.6.3.3 Filter

In the Event Logbook window, you can set [Level] to [High Alarms], [Med Alarms], [Low Alarms] and [All Alarms].

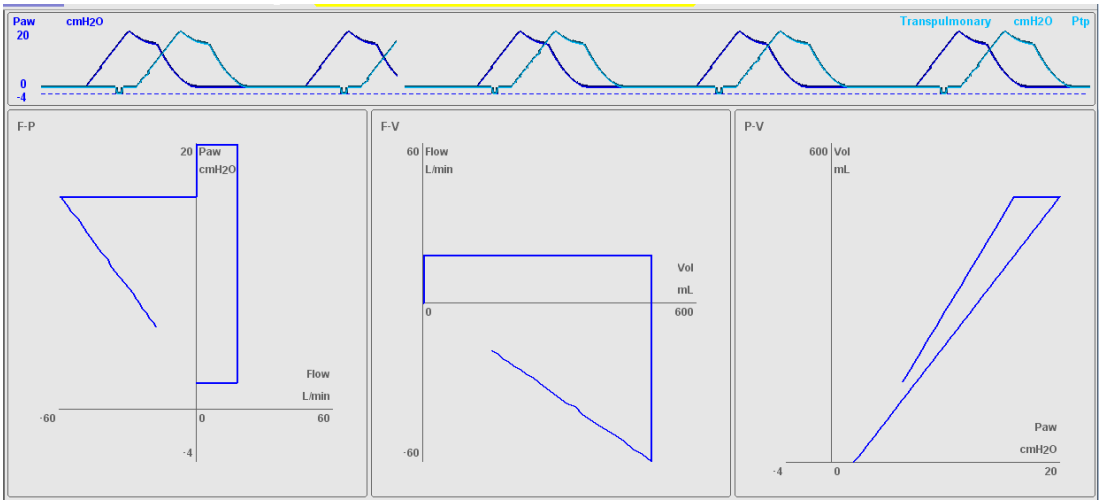
4.7 Big Font Screen

Click the bottom [Menu] -> [System setup] -> [setting], Flayout:select [Big Font], as shown below:



4.8 Big Loop Screen

Click the bottom [Menu] -> [System setup] -> [setting], Flayout: select [Big Loop], as shown below:



4.9 Freeze

The freeze function's feature is that it can pause the real-time refreshing of waveforms and spirometry loops on the screen, so that you can have a close examination of the patient's status within this time period. The reviewed data are waveforms and spirometry loops in the 30 seconds before entering freeze state.

4.8.1 Enter freeze status

During ventilation, press the [Freeze] key and the [Freeze Active. Press the Freeze key to Unfreeze] prompt message is displayed on the screen. The system enters freeze status. All displayed waves and loops are frozen, namely, they are not refreshed. The data in the parameter area are refreshed normally. In freeze status, the user can enter data storage for reviewing historical data

4.8.2 Exit freeze status

In freeze status, press the [Freeze] key to exit freeze status. In freeze status, if no operation is performed on the ventilator for more than three 3 minutes, the system exits freeze status automatically.

4.10 Lock Screen

Press the [Lock] soft key on the main screen to enter locked status, and the [Screen locked. Press the Lock key to unlock screen.] prompt message is displayed. During the period of screen locked, only [], [O2%]Suction, and [unLock] key are enabled. Touch screen, control knob, and other keys are disabled. Press this key a second time to unlock the screen.

FOR YOUR NOTES

Chapter 5 System Settings

5.1 Display Settings

5.1.1 Interface

1. Select [Menu]→[System **Setting**]→[**Setting**].
2. Set [Layout] as required to select the type of interface you want to display.
   - 【Normal】: Display the main interface.
   - 【Big Font】: Display large font interface.
   - [All Params]: display the full parameter monitoring interface.
   - [Big Loop]: Display large loop interface.

5.1.2 Waveforms

1. Select [Menu]→[System **Setting**]→[**Setting**].
2. Select [**Wave mode**] and toggle between [Scan] and [**Fill**].
   - [Scan]: the waveform is displayed as a curved line.
   - [**Fill**]: the waveform is displayed as a filled area.

5.2 Set Unit

5.12.1 Set Pressure Unit

1. Select [Menu]→[System setup]→[Setting].
2. Set [Pressure **Unit**] among [MPa], [PSI], [bar].

5.12.2 Set Paw Unit

1. Select [Menu]→[System setup]→[Setting].
2. Select [**Paw Unit**] among [**cmH_2O**], [K**Pa**], and [**mbar**].

5.3 IBW/Height

1. Select [Menu]→[System setup]→[Setting].
2. Select [IBW/Height] : [IBW] and [Height].
3. VT/IBW.select 6~8mL/Kg.

5.4 Adjust Screen Brightness

1. Select [Menu]→[System setup]→[Setting].
2. Select [**Day**] or [**Night**] to choose the corresponding default screen brightness.
3. On the screen backlight brightness setting, select [Menu] → [System Setup] → [Other].
   - 【Day】: 【Back Light】 defaults to 6, 【Back Light】 range of 0 ~ 9, the user can set the brightness as needed.
   - 【Night】: 【Back Light】 defaults to 3, 【Back Light】 range of 0 ~ 6, the user can set the brightness as needed.

5.5 Set Date and Time

1. Select the system time field on the main screen to pop up time setup menu.
2. Set [**Date**] and [**Time**].
3. Set [**Date Format**] to [**YYYY-MM-DD**], [**MM-DD-YYYY**] or [**DD-MM-YYYY**].
4. Select [**Time Format**] and toggle between [**24 h**] and [**12 h**].

5.6 Adjust Alarm Volume

1. Select [**Menu**]→[**System setup**]→[**Other**].
2. Set[Alarm Vol]rang:1~9.

5.7 Adjust Alarm delay

1. Select [**Menu**]→[**System setup**]→[**Other**].
2. Set[Alarm delay]rang:off,1~8s.

5.8 Screen Calibration

1. Select [**Menu**]→[**System setup**]→[**Other**].
2. Click the **[Cal.Touchscreen]** button to enter the screen calibration interface, click the prompt order, and finally select **[OK]** button.

5.9 Defaults

1. Select [Menu]→ [System setup]→[Other].
2. Set [Defaults] as required to restore the setting alarm delay,alarm vol and backlight to the default values.

5.10 Set Language

1. Select [Menu]→[Factory setting]→enter the required password→[**Setting setup**].

2. Select [**Language**] and select the desired language.
3. Restart the ventilator to activate the selected language.

5.11 Set 100%O2 Active Time

1. Select [Menu]→[Factory setting]→enter the required password→[**Setting setup**].
2. Select [100%O2 Active Time] among 2min and 3min.
   - [2min]:100%O2 straight for 2 minutes.
   - [3min]:100%O2 straight for 3 minutes.

5.12 Set Protect Board Switch

1. Select [Menu]→[Factory setting]→enter the required password→[**Setting setup**].
2. Select [Protect Board Switch] among off and on.
   - [OFF]: Protect board switch stop working.
   - [On]: Protect board switch start working.

5.13 Set Mexico Logo Switch

1. Select [Menu]→[Factory setting]→enter the required password→[**Setting setup**].
2. Select [Mexico Logo Switch] among off and on.
   - [OFF]: Mexico Logo switch stop working.
   - [On]: Mexico Logo switch start working.

5.14 Module setup

5.12.1 Set CO2 module

1. Select [Menu]→[Factory setting]→enter the required password→[Module Type Setup].
2. Select [CO2] and select the desired CO2 type.
3. Restart the ventilator to activate the selected CO2 type.

5.15 Set CO2 Mode

5.14.1 Setting the working status

1. Select [Menu] → [System setup] → [CO2 module].
2. 【Operating Mode】: 【Measure】, 【Standby】, the default is 【Measure】.
   - [Measure]: Module for the measurement state.
   - 【Standby】: The module is pending command status.

5.14.2 Set CO2 Units

1. Select [Menu] → [System setup] → [CO2 module].
2. 【CO_2 Unit】: 【mmHg】, 【Kpa】, 【%】, the default is 【mmHg】.

5.14.3 Set O2 compensation

1. Select [Menu] → [System setup] → [CO2 module].
2. 【O2 Compen】: 【Low】, 【Mid】, 【High】, the default is 【Low】.

5.14.4 Set N2O compensation

1. Select [Menu] → [System setup] → [CO2 module].
2. 【N2O Compen】: 【ON】, 【OFF】, the default is 【Low】.

5.14.5 Set CO2 suffocation

1. Select [Menu] → [System setup] → [CO2 module].
2. 【Apnea Delay】: 【20s】, 【25s】, 【30s】, 【35s】, 【40s】, the default is 【20s】.

5.16 Select mode Calibration

1. Select [Menu]→[Factory setting]→enter the required password→[Calibration].
2. Select [**Calibration mode**] among [O_2 Sensor], [Insp.Press.Value], [PEEP], [Leakage Test] and [Exp.Flow Sensor].

5.17 Set Mode Parameter

5.17.1 Set Pmax

1. Select【VC-ACV】、【PC-ACV】、【PVC-ACV】、【VC-SIMV】、【PC-SIMV】、【PVC-SIMV】、【PC-Dual PAP】、【PC-APRY】、【CPAP/PSV】or 【CPAP-VG】 ->【Pmax】soft key.
2. Popup the prompt setting window,use your finger presss the frame and slide to the right，the value gradually increase；slide to the left，the value gradually reduce；or long press【  】and no release，the value gradually increase；long press【  】and no release，the value gradually reduce；also you can press【  】or【  】release，the value increaseor reduce one step length.Set【Pmax】to the appropriate value.
3. Press【  】to confirm your setting take effect；press【  】cancel setting and not take effect.

5.17.2 Set PEEP

1. Select 【VC-ACV】、【PC-ACV】、【PVC-ACV】、【VC-SIMV】、【PC-SIMV】、【PVC-SIMV】、【PC-Dual PAP】、【PC-APRY】、【CPAP/PSV】or 【CPAP-VG】 ->【PEEP】soft key.

2. Popup the prompt setting window,use your finger presss the frame and slide to the right，the value gradually increase；slide to the left，the value gradually reduce；or long press【  】and no release，the value gradually increase；long press【】and no release，the value gradually reduce；also you can press【  】or【】release，the value increaseor reduce one step length.Set【PEEP】to the appropriate value.

3. Press【  】to confirm your setting take effect；press【  】cancel setting and not take effect.

5.17.3 Set Vt

1. Select【 VC-ACV】、【PVC-ACV】、【VC-SIMV】、【PVC-SIMV】or 【CPAP-VG】 ->【Vt】soft key.

2. Popup the prompt setting window,use your finger presss the frame and slide to the right，the value gradually increase；slide to the left，the value gradually reduce；or long press【  】and no release，the value gradually increase；long press【】and no release，the value gradually reduce；also you can press【  】or【】release，the value increaseor reduce one step length.Set【Tinsp】to the appropriate value.

3. Press【  】to confirm your setting take effect；press【  】cancel setting and not take effect.

5.17.4 Set Psupp

1. Select【VC-SIMV】、【PC-SIMV】、【PVC-SIMV】or 【CPAP/PSV】->【Psupp】soft key.

2. Popup the prompt setting window,use your finger presss the frame and slide to the right，the value gradually increase；slide to the left，the value gradually reduce；or long press【  】and no release，the value gradually increase；long press【】and no release，the value gradually reduce；also you can press【  】or【】release，the value increaseor reduce one step length.Set【Psupp】to the appropriate value.

3. Press【  】to confirm your setting take effect；press【  】cancel setting and not take effect.

5.17.5 Set Pinsp

1. Select【PC-ACV】、【PC-SIMV】or【PC-APRY】->【Pinsp】soft key.

2. Popup the prompt setting window,use your finger presss the frame and slide to the right，the value gradually increase；slide to the left，the value gradually reduce；or long press【 】and no release， the value gradually increase；long press【 】and no release，the value gradually reduce；also you can press【 】or【 】release，the value increaseor reduce one step length.Set【Pinsp】to the appropriate value.

3. Press【 】to confirm your setting take effect； press【 】cancel setting and not take effect.

5.17.6 Set Tinsp

1. Select【VC-SIMV】、【PC-SIMV】、【PVC-SIMV】or【PC-APRY】->【Tinsp】soft key.

2. Popup the prompt setting window,use your finger presss the frame and slide to the right，the value gradually increase；slide to the left，the value gradually reduce；or long press【 】and no release， the value gradually increase；long press【 】and no release，the value gradually reduce；also you can press【 】or【 】release，the value increaseor reduce one step length.Set【Tinsp】to the appropriate value.

3. Press【 】to confirm your setting take effect； press【 】cancel setting and not take effect.

5.17.7 Set Rate

1. Select【VC-ACV】、【PC-ACV】、【PVC-ACV】、【VC-SIMV】、【PC-SIMV】or【PVC-SIMV】->【Rate】soft key.

2. Popup the prompt setting window,use your finger presss the frame and slide to the right，the value gradually increase；slide to the left，the value gradually reduce；or long press【 】and no release， the value gradually increase；long press【 】and no release，the value gradually reduce；also you can press【 】or【 】release，the value increaseor reduce one step length.Set【Rate】to the appropriate value.

3. Press【 】to confirm your setting take effect； press【 】cancel setting and not take effect.

5.17.8 Set Texp

1. Select【PC-APRV】->【Texp】soft key.

2. Popup the prompt setting window,use your finger presss the frame and slide to the right，the value gradually increase；slide to the left，the value gradually reduce；or long press【 】and no release， the value gradually increase；long press【 】and no release，the value gradually reduce；also you can press【 】or【 】release，the

value increaseor reduce one step length.Set【Texp】to the appropriate value.

3. Press【  】to confirm your setting take effect；press【  】cancel setting and not take effect.

5.17.9 Set Trigger

1. Select【VC-ACV】、【PC-ACV】、【PVC-ACV】、【VC-SIMV】、【PC-SIMV】、【PVC-SIMV】、【PC-Dual PAP】、【PC-APRY】、【CPAP/PSV】or 【CPAP-VG】-> 【Trigger】soft key.

2. Popup the prompt setting window,use your finger presss the frame and slide to the right，the value gradually increase；slide to the left，the value gradually reduce；or long press【  】and no release，the value gradually increase；long press【  】and no release，the value gradually reduce；also you can press【  】or【  】release，the value increaseor reduce one step length.Set【Trigger】to the appropriate value.

3. Press【  】to confirm your setting take effect；press【  】cancel setting and not take effect.

5.17.10 Set Tslope

1. Selec【PC-ACV】、【PVC-ACV】、【VC-SIMV】、【PC-SIMV】、【PVC-SIMV】、【PC-Dual PAP】、【PC-APRY】、【CPAP/PSV】or 【CPAP-VG】->【Tslope】soft key.

2. Popup the prompt setting window,use your finger presss the frame and slide to the right，the value gradually increase；slide to the left，the value gradually reduce；or long press【  】and no release，the value gradually increase；long press【  】and no release，the value gradually reduce；also you can press【  】or【  】release，the value increaseor reduce one step length.Set【Tslope】to the appropriate value.

3. Press【  】to confirm your setting take effect；press【  】cancel setting and not take effect.

5.17.11 Set Exp%

1. Select【VC-SIMV】、【PC-SIMV】、【PVC-SIMV】、【PC-Dual PAP】【CPAP/PSV】or 【CPAP-VG】-> 【Exp%】soft key.

2. Popup the prompt setting window,use your finger presss the frame and slide to the right，the value gradually increase；slide to the left，the value gradually reduce；or long press【  】and no release，the value gradually increase；long press【  】and no release，the value gradually reduce；also you can press【  】or【  】release，the value increaseor reduce one step length.Set【Exp%】to the appropriate value.

3. Press【  】to confirm your setting take effect；press【  】cancel setting and not take effect.

5.17.12 Set Tpause

1. Select【VC-ACV】or【VC-SIMV】->【Tpause】soft key.
2. Popup the prompt setting window,use your finger presss the frame and slide to the right，the value gradually increase；slide to the left，the value gradually reduce；or long press【  】and no release，the value gradually increase；long press【  】and no release，the value gradually reduce；also you can press【  】or【】release，the value increaseor reduce one step length.Set【Tpause】to the appropriate value.
3. Press【  】to confirm your setting take effect；press【  】cancel setting and not take effect.

5.17.13 Set I:E

1. Select【VC-ACV】、【PC-ACV】or【PVC-SIMV】->【I:E】soft key.
2. Popup the prompt setting window,use your finger presss the frame and slide to the right，the value gradually increase；slide to the left，the value gradually reduce；or long press【  】and no release，the value gradually increase；long press【  】and no release，the value gradually reduce；also you can press【  】or【】release，the value increaseor reduce one step length.Set【I:E】to the appropriate value.
3. Press【  】to confirm your setting take effect；press【  】cancel setting and not take effect.

5.17.14 Set Phigh

1. Select【PC-Dual PAP】->【Phigh】soft key.
2. Popup the prompt setting window,use your finger presss the frame and slide to the right，the value gradually increase；slide to the left，the value gradually reduce；or long press【  】and no release，the value gradually increase；long press【  】and no release，the value gradually reduce；also you can press【  】or【】release，the value increaseor reduce one step length.Set【Phigh】to the appropriate value.
3. Press【  】to confirm your setting take effect；press【  】cancel setting and not take effect.

5.17.15 Set Plow

1. Select【PC-Dual PAP】->【Plow】soft key.
2. Popup the prompt setting window,use your finger presss the frame and slide to the right，the value gradually increase；slide to the left，the value gradually reduce；or long press【  】and no release，the value gradually increase；long press【】and no release，the value gradually reduce；also you can press【  】or【】release，the value increaseor reduce one step length.Set【Plow】to the appropriate value.
3. Press【  】to confirm your setting take effect；press【  】cancel setting and not take effect.

5.17.16 Set Thigh

1. Select【PC-Dual PAP】->【Phigh】soft key.
2. Popup the prompt setting window,use your finger presss the frame and slide to the right，the value gradually increase；slide to the left，the value gradually reduce；or long press【  】and no release，the value gradually increase；long press【】and no release，the value gradually reduce；also you can press【  】or【】release，the value increaseor reduce one step length.Set 【Thigh】to the appropriate value.
3. Press【  】to confirm your setting take effect；press【  】cancel setting and not take effect.

5.17.17 Set Tlow

1. Select【PC-Dual PAP】->【Tlow】soft key.
2. Popup the prompt setting window,use your finger presss the frame and slide to the right，the value gradually increase；slide to the left，the value gradually reduce；or long press【  】and no release，the value gradually increase；long press【】and no release，the value gradually reduce；also you can press【  】or【】release，the value increaseor reduce one step length.Set【Tlow】to the appropriate value.
3. Press【  】to confirm your setting take effect；press【  】cancel setting and not take effect.

5.18 Manage Default Settings

The ventilator provides the following types of settings:

- Factory default settings, namely, values of factory preset setting items. There are two

groups of default settings, adult and pediatric, based on patient type.

- Current settings. You can change the ventilator's default settings based on the current settings during ventilation and save the changed settings as default settings. There are two groups of default settings, adult and pediatric.
- Recent settings. In actual applications, you may change some settings, which, however, may not be saved as current settings. The ventilator stores these settings in real time. The stored settings are recent settings.

NOTE
■ **Patient type, gender, height, ventilation mode, ventilation parameters, and alarm limit settings can be saved as current settings.**

5.18.1 Restore Factory Default Settings

You can restore factory default settings manually as required, while unit is in standby status.

1. Select [Menu]→[System All Default].
2. Select [System All Default] to restore the defaults to factory defaults. When the ventilator is used on a new patient after powered on, the system loads the factory default settings automatically.

5.19 View System Information

5.19.1 Version Information

Select [Menu]→[System Info] to view the version information of system software.

5.19.2 Configuration Information

Select [Menu]→[Factory setting]→enter the required password→[Module Type Setting] to view the configuration information of the ventilator such as ventilation mode.

5.19.3 Maintenance Information

Select [Menu]→[Factory Info]→enter the required password→[Diagnosis] to view the system total running time, system startup time, CO_2 last calibration time, O_2 sensor last calibration time, flow sensor last calibration time, time left for the next turbine blower maintenance, and time of last maintenance.

FOR YOUR NOTES

Chapter 6 Ventilation

6.1 Turn on the System

1. Insert the power cord into the power receptacle. Ensure the external power indicator light is lit.
2. Press the  key.
3. The alarm indicator light flashes yellow and red once in turn, and then the speaker and the buzzer give a check sound respectively.
4. A start-up screen and start-up check progress bar appear. Then the System Check screen is displayed.

NOTE

- **When the ventilator is started, the system detects whether audible alarm tones and alarm lamp function normally. If yes, the alarm lamp flashes red and yellow successively, and the speaker and the buzzer give check tones. If not, do not use the equipment and contact us immediately.**

6.2 System Check

WARNING

- **To ensure optimum performance of the ventilator, re-do System check each time when accessories or components like patient tubing, humidifier, and filter are replaced**

CAUTION

- **Always run System Check before using the ventilator on a patient. If the ventilator fails any tests, remove it from clinical use. Do not use the ventilator until necessary repairs are completed and all tests have passed.**
- **Before running System Check, disconnect the patient from the equipment and ensure that a backup ventilation mode is available for patient ventilation.**

To enter the System Check screen,

- The System Check screen is accessed automatically after powering on the system.
- On the non-standby screen, select the [**Standby**] button and enter the Standby status after your confirmation. Select the [**System Check**] button in the Standby status to enter the System Check screen.

The system check screen displays the last system check time. Select the [**Details**] button to query the system check information of the ventilator system, including system check items, System Check results, and System Check time.

Connect the gas supply and block the Y piece as illustrated. Then select [**Continue**] to start System Check item by item.

System Check items include:

- Hardware Voltage
- Sensor
- Calibration Date
- Inhale Valve&Exhale Valve
- Blower
- O_2 Valve
- Hardware Comm.
- Compliance

System Check result can be:

- Pass: indicates that check of this item is completed and is passed;
- Fail: indicates that check of this item is completed but is failed;
- Cancel: indicates that check of this item is cancelled;
- O_2 Supply Failure: indicates that O_2 supply is insufficient when O_2 sensor test or O_2 flow sensor test is being carried out;
- Monitoring Off: indicates that sensor monitoring function may not be switched on when O_2 sensor test is being carried out.

During System Check, the system prompts [**Running**] on the right side of the current check item. In this case, if you select [**Skip**], the system stops the check of this item immediately and displays [**Cancel**] as the check result. The check of the next item begins at the same time. If you select [**Stop**], the system stops the check of the current item and also the check of the remaining items immediately, and displays [**Cancel**] as the check result.
When O_2 sensor test fails, the [**O_2 Calibration**] button is displayed. Press this button to open the O_2 calibration menu, and then to calibrate oxygen concentration.
When checks of all items are completed, if you select [**Retry**], the system starts a new round of checking. If you select [**Exit**], the system exits the check and enters Standby status.

6.3 Select Patient

After System Check is completed, select [**Continue**] to enter Standby status. Then select patient. If you select [Previous **Patient**], set ventilation type in the accessed screen, and then select [**StartVentilation**]. If you select [**New Patien**], set gender, [**Height**], ventilation type in the accessed screen, and then select [**Start Ventilation**].

6.4 Ventilation Type

The ventilator provides two ventilation types: invasive and non-invasive.

⚠WARNING

- **Check the alarm limit settings after switching over from NIV to Invasive.**

6.4.1 Invasive Ventilation

Invasive ventilation means to ventilate the patient through manual airway (ET tube or Trach tube). In invasive ventilation, all ventilation modes for adult 、 pediatric and neo patients are enabled.

The leakage compensation in invasive ventilation: The upper limit of the leakage compensation is 80% of the setting TV in volume control ventilation mode. If leakage exists, the ventilator will increase the flow in pressure control ventilation mode for compensation. The maximum flow can reach 210 L/min.

⚠WARNING

- **Incorrect tube type, ID or compensate setting can endanger the patient. Make sure to set them properly.**

⚠CAUTION

- **Do not attempt to use NIV on intubated patients.**

6.4.2 Non-invasive Ventilation (NIV)

NIV means to ventilate the patient by using a nasal mask or facial mask instead of ET tube or Trach tube. In NIV, the enabled ventilation modes include: PC-ACV, PVC-ACV,PC-SIMV,PVC-SIMV,PC-Dual PAP, PC-APRV,CPAP/PSV and CPAP-VG in adult, pediatric and neo patient ranges. The disabled ventilation modes in NIV appear grey. The leakage compensation in non-invasive ventilation: The non-invasive ventilation is enabled only in pressure control ventilation mode. The leakage compensation ability in non-invasive ventilation is consistent with that in invasive ventilation and pressure control

ventilation mode.

⚠ CAUTION

- **Do not use NIV on patients with no or irregular spontaneous breaths. NIV is intended to provide supplemental ventilatory support to patients with regular spontaneous breaths.**
- **Do not attempt to use NIV on intubated patients.**

6.4.3 Set Ventilation Type

To set ventilation type,

1 If the ventilator is in non-standby mode, press the [**Standby**] key and enter Standby status after confirmation.

2. Select [Previous **Patient**], [**New Patient**] in the Standby status.

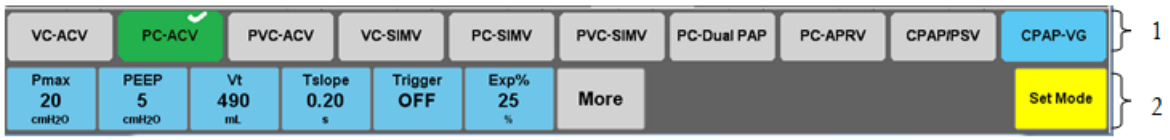
3. Set ventilation type to [**Non-Invasive**] or [**Invasive**] on the accessed screen.

6.5 Ventilation Mode

NOTE

- **The ventilator does not generate subatmospheric airway pressure during exhalation.**
- **The user can set high pressure alarm limit. If the pressure reaches the high pressure alarm limit in the inspiratory phase, the "Paw Too High" high-level alarm is triggered. The ventilator opens the expiration valve and switches to expiratory**
- **phase until the airway pressure reaches the preset PEEP value. If the airway pressure exceeds high pressure alarm limit+5 cmH2O（adjustable pressure limit）, the ventilator opens the safety valve to release pressure, so that the airway pressure**
- **falls to 3 cmH2O for continuous 0.5 s. Make sure to set high pressure alarm limit properly to ensure patient safety.**
- **The PC-ACV and PC-SIMV mode, VT＞50ml, are the recommended ventilation modes and TV tidal volume for use with a closed-suction catheter. And the settings are decided by the operator according to the patient situation.**

6.5.1 Ventilation Mode and Parameter Setup



1. Ventilation mode setup field

Displays all the keys for setting up ventilation modes. The ventilator can be configured with the following ventilation modes:
VC-ACV,PC-ACV,PVC-ACV,VC-SIMV,PC-SIMV,PVC-SIMV,PC-Dual PAP,PC-APRV ,CPAP/PSV and CPAP-VG. Your machine may have different ventilation modes.

2. Parameter setup quick key field

   Displays ventilation setting parameters corresponding to the active ventilation mode.

   Selecting 

displays more ventilation setting parameters. The parameters of sigh function, ATRC function, Apnea Vent and other parameters are also set here. Ventilation parameters vary subject to the ventilation mode.

6.5.2 Apnea Ventilation

Apnea ventilation is a backup ventilation mode initiated when the ventilator detects patient apnea in CPAP/PSV and CPAP-VG modes. Apnea ventilation can exit only under the following circumstances: patient's spontaneous breathing has been detected continuously twice, ventilation mode is switched over, or apnea ventilation is switched off (in SIMV modes).

This ventilator provides one types of apnea ventilation mode: volume-controlled apnea ventilation.

Volume-controlled apnea ventilation means that tidal volume, breathing frequency, and inspiration time in the apnea ventilation cycle can be set in the mode supporting apnea ventilation. After entering apnea ventilation, the ventilator executes PRVC ventilation with the set tidal volume, breathing frequency, and inspiration time in the apnea ventilation cycle (other parameter's setting values are unchanged).

⚠ CAUTION

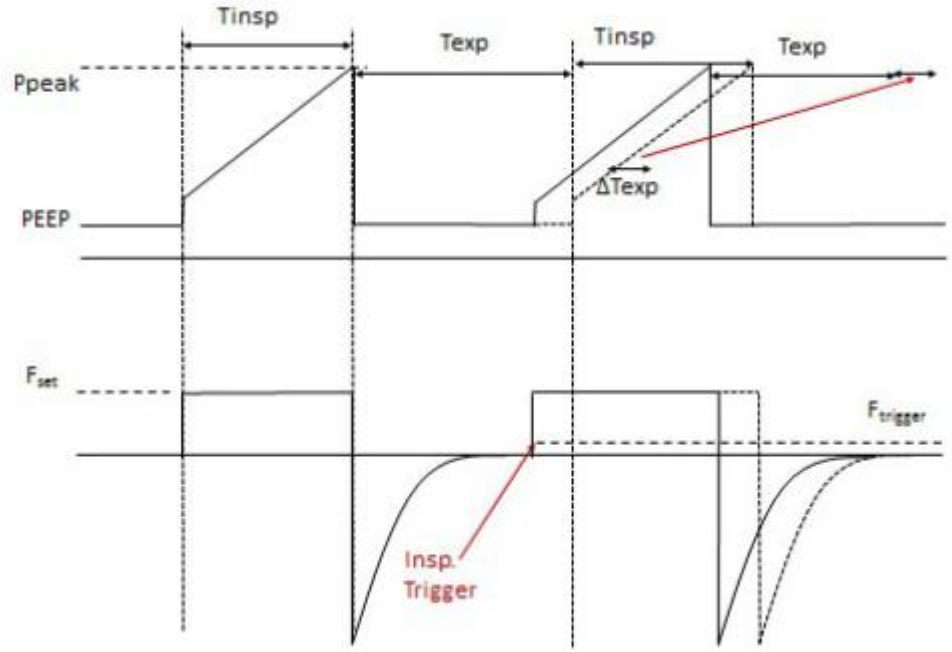
- **You are suggested to initiate apnea ventilation in SIMV mode.**

6.5.3 VC-ACV

VC-ACV (Volume Controlled– Assist Control Ventilation) is a ventilation mode in which the ventilator controls the ventilation, but it can be influenced by the patient. The inspiration is flow controlled until the inspiratory volume is delivered, after this the plateau phase is pressure controlled (maintains inspiratory pressure) and the expiration is pressure controlled (maintains PEEP level). The patient can not breathe spontaneously during inspiration until the plateau phase, because it is flow controlled. During plateau phase and expiration phase spontaneous breathing is possible.

The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, when the patient does not breathe spontaneously. However, during expiration an inspiration can be triggered by the patient. This can lead to an increase of the breathing frequency or respiratory

rate(RR).



In VC-ACV mode, you need to set the following ventilation parameters:

1. [Pmax]: Can prevent high airway pressure caused by patient
2. [PEEP]: Positive end-expiratory pressure
3. [Vt]: Tidal volume
4. [I:E]: Inspiration tiem
5. [Rate]: Breathing frequency
6. [Tpause]: Percent of inspiratory pause time
7. [Trigger]: Inspiration trigger level
8. [O_2%]: Oxygen concentration.

In VC-ACV mode, you can set the following sigh function parameters as required:

1. [**Sigh**]: Switch for turning on sigh function
2. [**Interval**]: Number of sigh cycles
3. [Delta VT]: Tidal volume of sigh cycles

In VC-ACV mode, you can set the following ATRC function parameters as required in Invasive ventilation (this function is applied to all Invasive modes and the description is not repeated in the other ventilation modes section in this manual.):

1. [**Disable ATRC**]: Switch off ATRC function
2. [**ET Tube**]: Endotracheal tube
3. [**Trach Tube**]: Tracheal tube
4. [**Tube I.D.**]: Diameter of tube
5. [**Compensate**]: Compensate portion
6. [**Expiration**]: Compensate of expiration

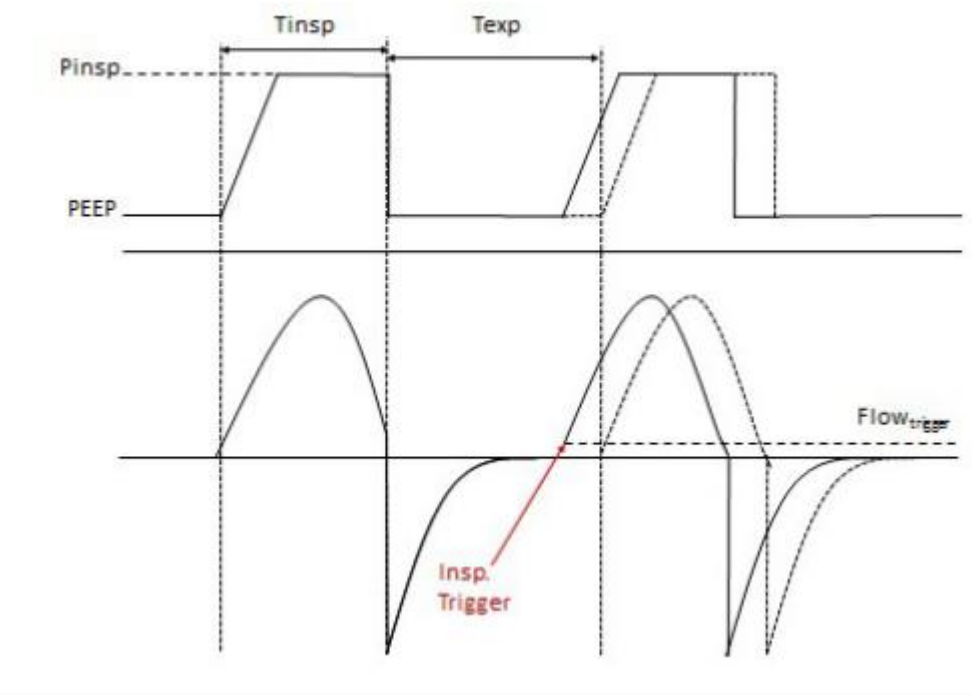
In VC-ACV mode,you can set the other function parameters as required in Invasive ventilation (this function is applied to all Invasive modes and the description is not repeated in the other ventilation modes section in this manual.):

1. [Compliance Compensate]
2. [Exp.Speed]

6.5.4 PC-ACV

PC-ACV (Pressure Controlled– Assist Control Ventilation) is a ventilation mode in which the ventilator controls the ventilation, but it can be influenced by the patient. The inspiration and expiration are pressure controlled. The patient can breathe spontaneously during inspiration and expiration.

The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, when the patient does not breathe spontaneously. However, during expiration an inspiration can be triggered by the patient. This can lead to an increase of the breathing frequency or respiratory rate(RR).



In PC-ACV mode, you need to set the following basic ventilation parameters:

1. [Pmax]: Can prevent high airway pressure caused by patient
2. [PEEP]: Positive end-expiratory pressure
3. [Pinsp]: Inspiration pressure
4. [I:E]: Inspiration time
5. [Rate]: Breathing frequency
6. [Tslope]: Time of pressure rising
7. [Trigger]: Inspiration trigger level
8. [O_2%]: Oxygen concentration

In PC-ACV mode, you can set the following sigh function parameters as required:

1. [**Sigh**]: Switch for turning on sigh function
2. [**Interval**]: Number of sigh cycles
3. [**Delta Pinsp**]: Pinsp added in sigh cycle

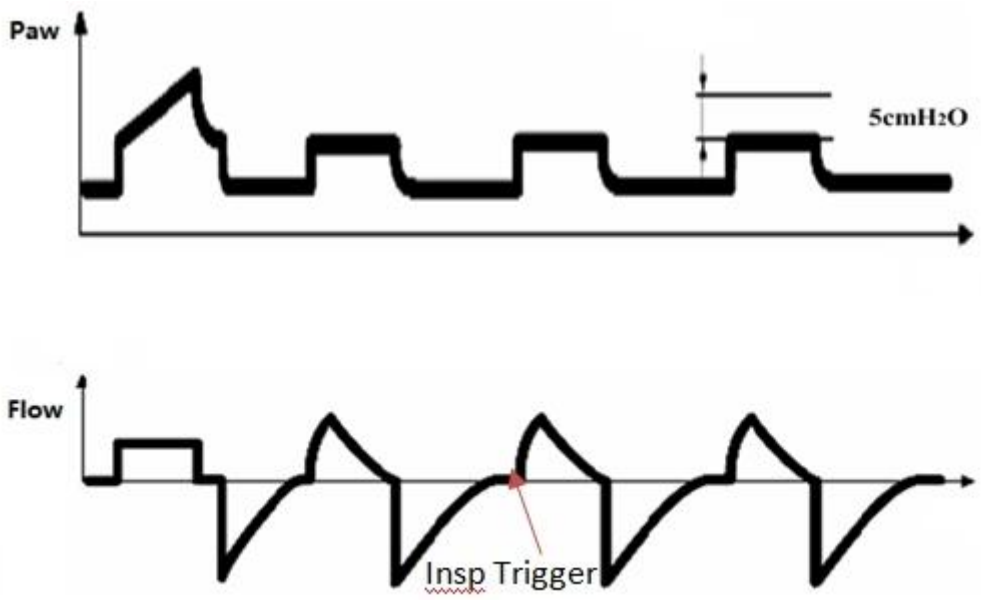
6.5.5 PVC-ACV

PVC-A/C is pressure- regulated volume /control ventilation mode. It implements delivering set tidal volume by the way of pressure control ventilation. In PRVC, a relatively low pressure level is held as much as possible during the inspiratory phase, and the gas volume delivered is

guaranteed to be equal to the preset tidal volume. Ppeak will vary according to the tidal volume setting and the resistance and compliance of the patient's lungs. Pressure adjustment increase of the ventilator cannot exceed 10 cmH2O for the first 3 cycles, and cannot exceed 3 cmH2O for each of the following cycles. The maximum pressure cannot exceed the pressure alarm high limit-5 cmH2O.

The first PRVC delivered is experimental ventilation mode. And the gas delivery pressure of the first cycle is 10 cmH2O+PEEP for the purpose of calculating compliance and resistance of the system and patient's lungs, and calculating pressure level based on the patient's condition. This pressure level will then be used as a regulating object for tidal volume control in the following ventilation cycles. During the expiratory phase, synchronization trigger is supported. Namely, when the ventilator detects patient inspiratory effort, it delivers next mechanical ventilation breath immediately.

The following figure shows typical waveforms in PVC-A/C mode.



In PC-ACV mode, you need to set the following basic ventilation parameters:

1. [Pmax]: Can prevent high airway pressure caused by patient
2. [PEEP]: Positive end-expiratory pressure
3. [Vt]: Tidal Volume
4. [I:E]: Inspiration time
5. [Rate]:
6. [Tsope] : Breathing frequency

7. [Trigger]: Inspiration trigger level
8. [O_2%]: Oxygen concentration

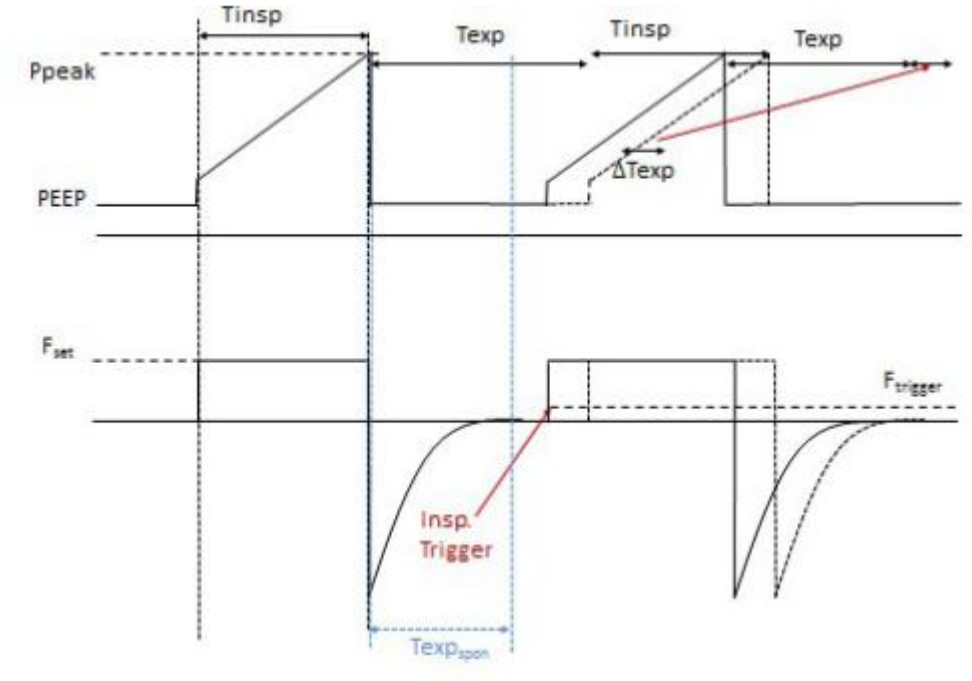
In PC-ACV mode, you can set the following sigh function parameters as required:

1. [**Sigh**]: Switch for turning on sigh function
2. [**Interval**]: Number of sigh cycles
3. [**Delta Pinsp**]: Pinsp added in sigh cycle

6.5.6 VC-SIMV

VC-SIMV (Volume Controlled–Synchronized Intermittent Mandatory Ventilation) is a ventilation mode in which the ventilator controls the ventilation, but it can be influenced by the patient. The inspiration is flow controlled until the inspiratory volume is delivered, after this the plateau phase is pressure controlled (maintains inspiratory pressure) and the expiration is pressure controlled (maintains PEEP level). The patient cannot breathe spontaneously during inspiration until the plateau phase, because it is flow controlled. During plateau phase and expiration phase spontaneous breathing is possible.

The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, when the patient does not breathe spontaneously. However, during expiration an inspiration can be triggered by the patient, during a trigger window. This window starts after the time set by Texpspon has elapsed. The period the inspiration is started earlier is compensated in the next expiration. This prevents an increase of the average respiratory rate(RR). The expiration time can differ due to previous triggering.



In VC-SIMV mode, you need to set the following basic ventilation parameters:

1. [Pmax]: Can prevent high airway pressure caused by patient
2. [PEEP]: Positive end-expiratory pressure
3. [Psupp]: Pressure support leve
4. [Vt]: Tidal Volume
5. [Tinsp]: Inspiration time
6. [Rate]: Breathing frequency
7. [Tslope] Inspiration trigger level
8. [Trigger]: Expiration trigger level
9. [Exp%]: Percent of inspiratory pause time
10. [Tpause]: Oxygen concentration
11. [O_2%]:

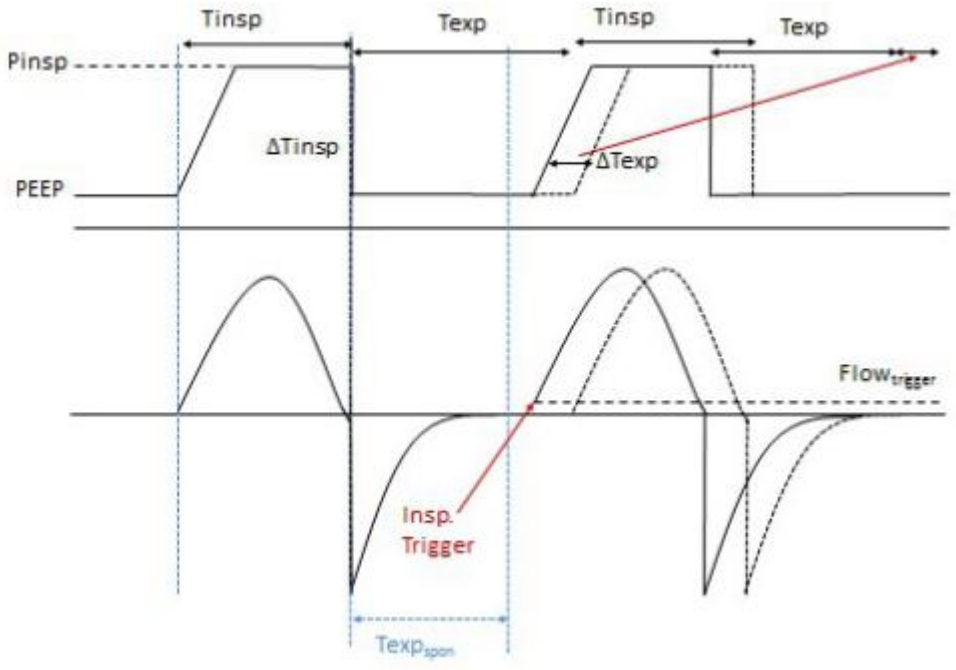
In VC-ACV mode, you can set the following sigh function parameters as required:

1. [**Sigh**]: Switch for turning on sigh function
2. [**Interval**]: Number of sigh cycles
3. [**Delta VT**]: Tidal volume of sigh cycles

6.5.7 PC-SIMV

PC-SIMV (Pressure Controlled–Synchronized Intermittent Mandatory Ventilation)is a ventilation mode in which the ventilator controls the ventilation, but it can be influenced by the patient. The inspiration and expiration are pressure controlled. The patient can breathe spontaneously during inspiration and expiration.

The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, when the patient does not breathe spontaneously. However, during expiration an inspiration can be triggered by the patient, during a trigger window. This window starts after the time set by Texpspon has elapsed. The period the inspiration is started earlier is compensated in the next expiration. This prevents an increase of the average respiratory rate (RR). The expiration time can differ due to previous triggering.



In PC-SIMV mode, you need to set the following basic ventilation parameters:

1. [Pmax]: Can prevent high airway pressure caused by patient
2. [PEEP]: Positive end-expiratory pressure
3. [Psupp]: Pressure support leve
4. [Pinsp]: Inspiration pressure leve
5. [Tinsp]: Inspiration time
6. [Rate]: Breathing frequency
7. [Tslope]
8. [Trigger]: Inspiration trigger level
9. [Exp%]: Expiration trigger level
10. [$_{O2}$%]: Oxygen concentration

In PC-ACV mode, you can set the following sigh function parameters as required:

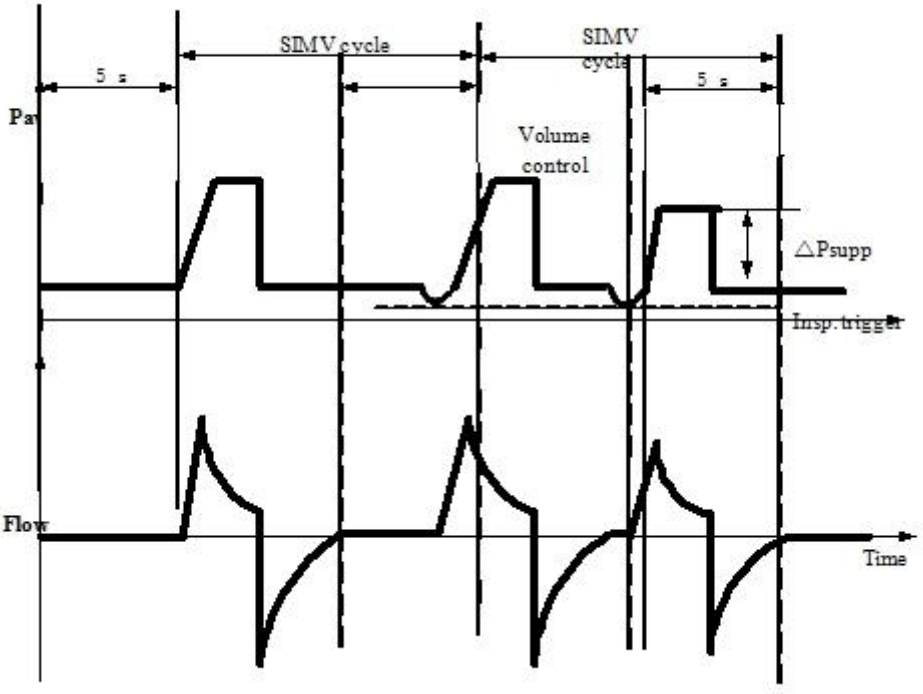
1. [**Sigh**]: Switch for turning on sigh function
2. [**Interval**]: Number of sigh cycles
3. [**Delta Pinsp**]: Inspiration pressure of sigh cycles

6.5.8 PVC-SIMV

PVC-SIMV is volume-synchronized intermittent mandatory ventilation mode. It provides the minimum number of mandatory breaths based on the preset intermittent mandatory ventilation frequency. The provided mechanical ventilation mode is volume mode (PRVC mode). If patient triggers within the trigger window, ventilator delivers mandatory PRVC breath once. Mandatory

PRVC breath is also delivered once if it is not triggered at the end of trigger window.
Spontaneous breathing or pressure support breathing is supported outside the trigger window.

The following figure shows typical waveforms in PRVC -SIMV+PSV mode.



In PVC-SIMV mode, you need to set the following basic ventilation parameters:

1. [Pmax]: Can prevent high airway pressure caused by patient
2. [PEEP]: Positive end-expiratory pressure
3. [Psupp]: Pressure support leve
4. [Vt]: Inspiration pressure leve
5. [Tinsp]: Inspiration time
6. [Rate]: Breathing frequency
7. [Trigger]: Inspiration trigger level
8. [Exp%]: Expiration trigger level
9. [Tslope]: Time of pressure rising
10. [O_2%]: Oxygen concentration

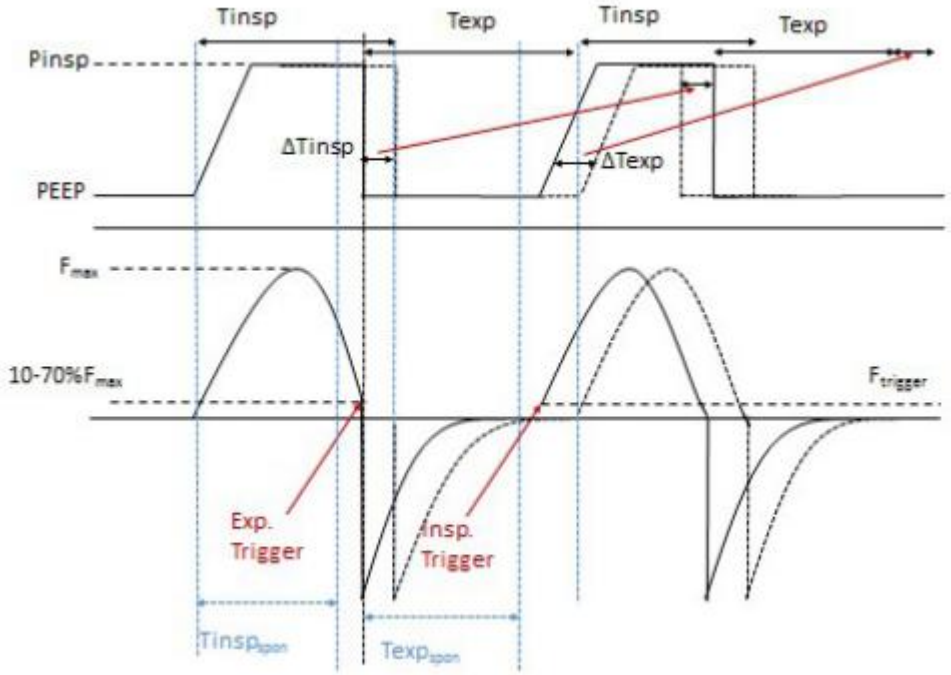
In PVC-ACV mode, you can set the following sigh function parameters as required:

1. [**Sigh**]: Switch for turning on sigh function
2. [**Interval**]: Number of sigh cycles
3. [**Delta Pinsp**]: Inspiration pressure of sigh cycles

6.5.9 PC-Dual PAP

PC-DualPAP (Pressure Controlled– Synchronized Intermittent Mandatory Ventilation Dual PAP)is a ventilation mode in which the ventilator controls the ventilation, but it can be influenced by the patient. It is also known as PC-BIPAP, DuoPAPorBiLevel ventilation. The inspiration and expiration are pressure controlled. The patient can breathe spontaneously during inspiration and expiration.

The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, when the patient does not breathe spontaneously. However, during expiration an inspiration can be triggered by the patient, during a trigger window. This window starts after the time set by Texpspon has elapsed. The period the inspiration is started earlier is compensated in the next expiration. During inspiration an expiration can be triggered by the patient, during a trigger window. This window starts after the time set by Tinspspon has elapsed. The period he expiration is started earlier is compensated in the next expiration. This prevents an increase of the average respiratory rate(RR). The expiration time can differ due to previous triggering.



In PC-DualPAP mode, you need to set the following basic ventilation parameters:

1. [Pmax]: Can prevent high airway pressure caused by patient
2. [Phigh]: Positive end-expiratory pressure
3. [Thigh]: High pressure
4. [Plow]: Time of high pressure
5. [Tlow]: Low pressure
6. [Psupp]: Pressure support level

7. [Trigger]: Inspiration trigger level
8. [Exp%]: Expiration trigger level
9. [Tslope]: Time of pressure rising
10. [O_2%]: Oxygen concentration

In PC-Dual PAP mode, you can set the following apnea vent function parameters as required:

1. [Apnea Vent]: Switch for turning on apnea vent function
2. [Apnea Vt]: Tidal volume in apnea ventilation
3. [Apnea Rate]: Frequency of apnea ventilation
4. [Apnea Tinsp]: Inspiration time of apnea ventilation

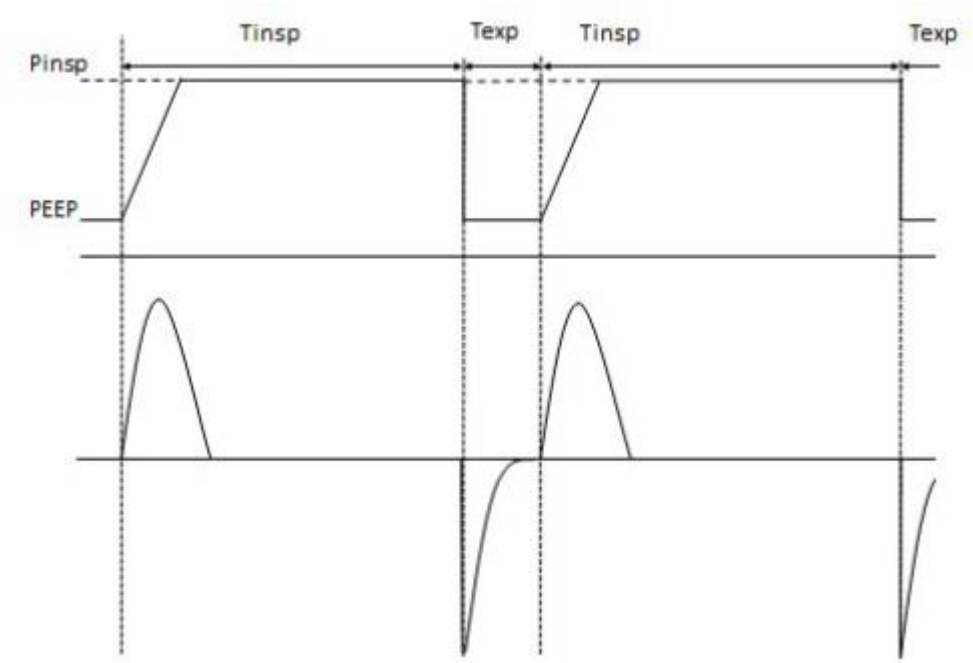
In PPC-Dual PAP mode, you can set the following sigh function parameters as required:

1. [**Sigh**]: Switch for turning on sigh function
2. [**Interval**]: Number of sigh cycles
3. [**Delta Pinsp**]: Inspiration pressure of sigh cycles

6.5.10 PC-APRV

PC-APRV (Pressure Controlled– Airway Pressure Release Ventilation)is a ventilation mode in which the ventilator fully controls the ventilation. The inspiration and expiration are pressure controlled. The inspiration time is much longer than the expiration time. The patient can breathe spontaneously during inspiration. In general the expiration time is too short to breath spontaneously. PC-APRV can be seen as breathing on a high CPAP level, with mandatory short expirations induced by the ventilator in order to support CO2 elimination. The alter nation between the two pressure levels is machine-triggered and time cycled.

The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time.They are not triggered by the patient. The patient can breathe spontaneously, but this does not influence the cycling of the breathing phases.



In PC-APRV mode, you need to set the following basic ventilation parameters:

1. [Pmax]: Can prevent high airway pressure caused by patient
2. [PEEP]: Positive end-expiratory pressure
3. [Pinsp]: Inspiration pressure leve
4. [Tinsp]: Inspiration time
5. [Texp]: Expiration time
6. [Trigger]: Inspiration trigger level
7. [Tslope]: Time of pressure rising
8. [O_2%]: Oxygen concentration

In PC-APRV mode, you can set the following apnea vent function parameters as required:

1. [Apnea Vent]: Switch for turning on apnea vent function
2. [Apnea Vt]: Tidal volume in apnea ventilation
3. [Apnea Rate]: Frequency of apnea ventilation
4. [Apnea Tinsp]: Inspiration time of apnea ventilation

In PPC-APRV mode, you can set the following sigh function parameters as required:

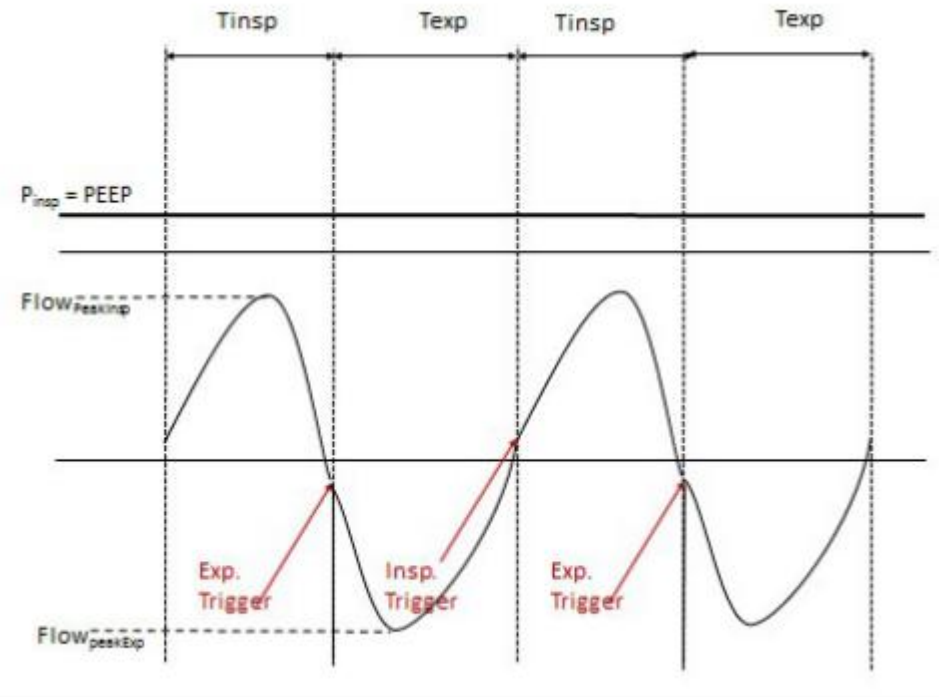
1. [**Sigh**]: Switch for turning on sigh function
2. [**Interval**]: Number of sigh cycles
3. [**Delta Pinsp**]: Inspiration pressure of sigh cycles

6.5.11 CPAP/PSV

CPAP/PSV (Continuous positive pressure ventilation pressure supports ventilation

) is a ventilation mode in which the patient breathes spontaneously. This is possible because it is a pressure controlled mode. In CPAP/PSV, with no options activated, the ventilator does not deliver any mandatory or triggered breaths.

The spontaneous breathing phases (inspiration and expiration) are detected with by using inspiratory and expiratory phase recognition, using a flow level detector.



In Spn-CPAP mode, you need to set the following basic ventilation parameters:

1. [Pmax]: Can prevent high airway pressure caused by patient
2. [PEEP]: Positive end-expiratory pressure
3. [Psupp]: Pressure support leve
4. [Tslope] Time of pressure rising
5. [Trigger]: Inspiration trigger level
6. [Exp%]: Expiration trigger level
7. [O_2%]: Oxygen concentration

In PC-APRV mode, you can set the following apnea vent function parameters as required:

1. [Apnea Vent]: Switch for turning on apnea vent function
2. [Apnea Vt]: Tidal volume in apnea ventilation
3. [Apnea Rate]: Frequency of apnea ventilation
4. [Apnea Tinsp]: Inspiration time of apnea ventilation

6.5.12 CPAP-VG

6.6 Set Alarm Limits

You can set the alarm limits for Paw、PEEP、MVe、Rtotal、VTi mand、FiO2 and Tapnea by pressing the [Alarm] key and selecting alarm limits in the accessed menu. You can set $EtCO_2$ alarm limits if your ventilator is configured with CO_2 module. You can also set alarm volume . For details, refer to ***10 Alarms***.

6.7 Start Ventilation

⚠WARNING

- **Before using the ventilator on the patient, check that the oxygen concentration in the delivered gas is consistent with the setting value.**
- **Adopt manual ventilation immediately if the ventilator malfunctions and cannot continue ventilating the patient.**

Select [**Start Ventilation**] in Standby status, and the system begins to ventilate the patient according to your settings.

6.8 Ventilation Parameters

⚠WARNING

- **As required by the relevant rules and regulations, oxygen concentration shall be monitored when the equipment is used on the patient. If your ventilator is not configured with such monitoring function or this function is switched off, use a monitor which complies with ISO 80601-2-55 for oxygen concentration monitoring.**

NOTE

- **All the parameter values are calculated based on the real-time flow and pressure waveform data. For real-time flow and pressure data, low pass filter is adopted at original sampling rate of 1KHz and cutoff frequency of 20Hz.**
- **Tidal volume and minute volume displayed on the ventilator are in the BTPS condition.**

Setting parameter	Description
Pmax	Can prevent high airway pressure caused by patient
Vt	The gas volume the patient inspires or expires each time during resting breathing.
O_2%	The volume percentage of oxygen in the mixed gas delivered to the patie nt.
Tinsp	Inspiratory time.
Texp	Expiratory time

PEEP	Positive end-expiratory pressure.
Setting parameter	**Description**
Plow	Plow is the low pressure level at which the patient can breathe spontaneously.
Phigh	Phigh is the high pressure level at which the patient can spontaneously breathe and is an absolute value.
Pinsp	It is a relative value of the pressure, relative to PEEP.
Psupp	Pressure support level in pressure control mode. It is a relative value relative to PEEP or Plow.
Tslope	Controls pressure rise slope in pressure mode.
Tpause(%)	Percent of gas delivery pause time in inspiratory time within the inspiratory phase.
Rate	The number of mechanically controlled breaths delivered to the patient in one minute.
Thigh	Thigh is the time that the ventilator will hold the high pressure level.
Tlow	Tlow is the time that the ventilator will hold the low pressure level.
Tinsp	Inspiration Time in one breathing cycle.
Trigger	Pressure trigger and flow trigger included. When the trigger level is detected, the ventilator starts to enter the inspiratory phase.
Exp%	Inspiratory termination level. The ventilator is switched to the expiratory phase when the inspiratory flow drops to peak flow*Exp％.
Apnea ventilation	Turn on or turn off apnea ventilation function.
Apnea Rate	Breathing frequency set in apnea ventilation mode.
Apnea Vt	It is delivered tidal volume in apnea ventilation when volume mode is selected for apnea ventilation.
Apnea Tinsp	Inspiration time set in apnea ventilation mode.
Sigh	Turn on or turn off sigh function.
Interval	It is the setting value of number of cycles of every group of sigh ventilation.
Delta Vt	It is intermittent vt augmentation, added during the sigh cycle.
Delta Pinsp	It is intermittent pinsp augmentation, added during the sigh cycle.
Disable ATRC	Turn on or turn off ATRC function.
ET Tube	Initiate ATRC function for ET tube.
Trach Tube	Initiate ATRC function for Trach tube.
Tube I.D.	It refers to the diameter of tracheal or ET tube.
Compliance compensate Com	Turn on or turn off compliance compensate function.

Exp.Speed	It is the expiratory compliance compensate speed.

Monitored parameter	**Description**
Ppeak	The maximum pressure value in one breathing cycle.
Pplat	The airway pressure during inspiratory pause.
Pmean	The mean pressure value in one breathing cycle.
PEEP	Positive end-expiratory pressure.
Vti	The inspired tidal volume in one cycle.
Vte	The expired tidal volume in one cycle.
Vte spon	The spontaneous expired tidal volume in one cycle.
VTe mand	The mandatory expired tidal volume in one cycle.
VTi spon	The spontaneous inspired tidal volume in one cycle.
VTi mand	The mandatory inspired tidal volume in one cycle.
Vt Leak	The tidal volume leak in one cycle.
MVe	The accumulated expired tidal volume in one minute.
Mvi	The accumulated inspired tidal volume in one minute.
MVe spon	The accumulated spontaneous expired tidal volume in one minute.
MVi mand	The accumulated mandatory inspired tidal volume in one minute.
MVi spon	The accumulated inspired tidal volume in one minute.
Rtotal	The accumulated number of breaths in one minute.
RRspon	The accumulated number of spontaneous breaths in one minute.
I:E	The ratio between the inspiratory and expiratory time.
Tinsp	Inspiration Time in one breathing cycle.
Texp	Expiratory Time in one breathing cycle.
Rlung	Static compliance - easiness of patient's lungs being filled during mechanically assisted breathing. It is calculated in case of breathing paused and inspiration hold.
Cdynamic	Dynamic compliance - easiness of patient's lungs being filled during mechanically assisted breathing. It is calculated during the inspiratory phase.

RSBI	Rapid shallow breathing index - quotient between fspn and TVe spn (measured in liters).
Ptracheal	Pressure tracheal.
Poutput	Pressure output.
Pambieat	Pressure ambieat.
FiO2	The percentage of oxygen in the patient's inspired gas.
FiO2 Cal	Oxygen concentration calculation shows values
FiO2 measu	Oxygen concentration monitoring actual value
EtCO2	The concentration of CO_2 measured at the end of expiration.
FiCO2	The concentration of CO_2 measured at the end of Inspiration.
awRR	Patients with respiratory rate
PIF	Inspiratory flow.
PEF	Expiration flow.
P0.1	The occlusion pressure drop in the first 100 ms when the patient starts spontaneous breathing.

6.9 Enter Standby Status

Press the [**Standby**] key. Standby status commences after your confirmation.

⚠WARNING

- **To prevent possible patient injury due to lack of ventilatory support, secure alternative ventilation for the patient before entering the Standby status. You must confirm that no patient is attached before entering Standby status.**
- **To prevent possible patient injury or damage to breathing circuit from overheated gas, turn off the humidifier before entering the Standby status.**

6.10 Turn the System off

Press the  key in Standby or non-standby status, pop-up prompt window select OK, 5s countdown end, the system automatically shut down.

FOR YOUR NOTES

Chapter 7 CO_2 Monitoring

7.1 Summary

The carbon dioxide monitor are used during respiratory Ventilator therapy, for patient gas monitoring, used in adults, children, babies.

CO2 module using the principle of gas having absorption characteristics with infrared to measure the gas concentration.All the gases that can be measured by the module can absorb the infrared and each gas has it's own absorption characteristics.The gas sent to a sampling room ,infrared filter select a particular band infrared thread the gas.If measure with several gases, then it will have a number of infrared filter.In a given volume,the higher the gas concentration,the more infrared absorbed,the less the transmission volume of infrared that thread the gas. Through measuring the transmission volume of infrared can calculate the gas concentration.

CO2 module only monitor the gas concentration of CO2. Also divided into Main stream （IRMACO2）and Side stream(ISA CO2).

NOTE

- **For guarantee the safty of the patient, when operate this Ventilator you need to monitor the anesthetic and CO2.If the anesthetic system doesn't configure anesthetic gas module or (and) CO2 module, please use the module that having anesthetic gas or (and) CO2 monior function which comply with relevant standard requirements to ensure the anesthetic system can realize the monitoring of anesthetic gas and CO2 in the meatime.**
- **Rise to 10kPa periodic pressure doesn't affect the performance of gas monitor.**

7.2 Monitoring ways

7.2.1 Main stream

IRMA main stream CO2 module is install it's probe to the airway adapter, then insert the airway adapter to the connection port between endotracheal tube and breathing circuit Y-shaped tube, the module through the two sides window of the IRMA airway adapter to read the respiratory gas measurement value.The two sides windows of airway adapter use the special design and material, can prevent performance degradation due to water vapor.

NOTE

- **Main stream IRMA module can only be used by trained or authorized medical staff.**
- **IRMA module can not be used in flammable anesthetic gas environment.**
- **IRMA modulebanned for MRI environment.**
- **To avoid cross-infection, do not reuse disposable IRMA airway adapter.**
- **The used disposable airway adapter should be disposed according to local medical waste disposal regulations.**
- **If IRMA airway adapter occurs water droplets / condensation, replace the adapter.**

- **Use only with IRMA monitor supporting MASIMO airway adapter.**
- **After IRMA adult / child model airway adapter access to circuit will increase 6mL of dead space, and therefore prohibited for infants.**
- **Do not use IRMA infant airway adapter for adults, otherwise it will lead to excessive flow resistance.**
- **To avoid the patient's secretions clogging the adapter window caused operational errors, do not put IRMA airway adapter between the endotracheal tube and elbows.**
- **Ensure IRMA module is placed in the vertical direction and the status LED upward.**

- **To avoid effect the light propagation of airway adapter windows, do not use airway adapter andquantitative spray or spray together.**

- **Ensure IRMA module used in electromagnetic environment that this specification defined, in case of to be affected by mobile or portable communication devices.**
- **IRMA module is only designed as an auxiliary method to patient assessment. Always with other vital signs and symptoms assessed with the use of equipment.Please use it together with other vital signs and symptoms assessed equipment.**
- **Do not stretch IRMA module probe cable.**

7.2.2 Side stream

ISA side stream CO2 module is through the sampling tube to collect a small quantity of mixed gas from the endotracheal tube of breathing circuit, which is transferred to the sampling gas input port of the monitors, the module will measure and analysis the sample gas.Nomoline sampling tube has a special impermeable area regardless of the direction, the impermeable area with a hydrophobic bacterial filter and made of special polymer. Impermeable area can remove the condensate that produced by sampling gas or removal inhaled water, serve to prevent cross-contamination caused by moisture intruded into the monitor. The design of sampling tube ensures sampling air flow continuous unimpeded, and therefore the response time of measure the gas is very short.

NOTE

- **Side stream ISA module can only be used by trained or authorized medical staff.**
- **ISA module can not be used in flammable anesthetic gas environment.**
- **Use only with ISA module supporting MASIMO sampling tube.**
- **To reduce the risk of bridling or entangleding the patient, be sure to carefully straighten out the sampling tube.**

- **To avoid cross-infection, do not reuse disposable sampling tube.**
- **The used disposable sampling tube should be disposed according to local medical waste disposal regulations.**
- **Do not through Nomoline sampling tube apply negative pressure (such as using a syringe) to remove condensate.**
- **Do not grab sampling tube to lift the ISA module or system components, or it may make off with the ISA module or system components, resulting in ISA module or system components fall on the patient.**
- **To avoid the ISA module fall on the patient, please ensure it has been fixed when using.**
- **After ISA adult / child model sampling tube access to circuit will increase the patient's dead space, and therefore prohibited for infants.**
- **Do not use ISA infant sampling tube for adults, otherwise it will lead to excessive flow resistance.**
- **If the collection of gas sample need to provide gas for breathing, always use bacteria filter in the exhaust side.**
- **Ensure ISA module used in electromagnetic environment that this specification defined, in case of to be affected by mobile or portable communication devices.**
- **ISA monitor or system uses high-frequency electro-surgical devices in the vicinity may cause interference, and led to incorrect measurements.**
- **ISA monitor banned for MRI environment.**
- **To avoid bacterial filter clogging, do not use ISA monitor and quantitative spray or spray together.**
- **Check if the sample gas flow rate for given patient type is too high.**
- **If the screen prompts Nomoline blockage information or the input port of ISA sampling tube is beginning to show red flash, replace the sampling tube.**
- **Do not make any changes to the ISA module, If it has been changed, please do appropriate tests and inspections to ensure long-term safe operation.**
- **Do not use ISA module external natural cooling function.**
- **If the patient circuit's positive or negative pressure is too large,which may affect the sample flow.**
- **If the discharge suction pressure is too large, it may affect the sample flow.**
- **Exhaust gases should be discharged into the drainage system.**
- **ISA module is only designed as an auxiliary method to patient assessment. Please use it together with other vital signs and symptoms assessed equipment.**
- **Do not stretch ISA monitor probe cable.**
- **To avoid the damage to ISA monitor, should be ensure it has been fixed installed.**

7.2.3 Set CO2

In standby state,select【Menu】->【Factory setting】->enter the required password->【Module Type Setup】.

7.3 Mainstream CO2 module

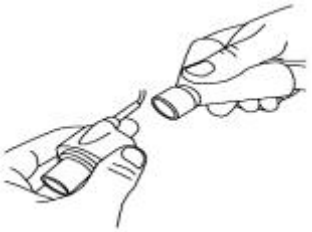
7.3.1 Installation

1. Make sure the ventilator is turned off, connect the communication port of IRMA monitor

with the module interface cable on the backboard of the ventilator;

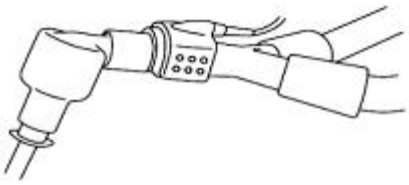
2. Install IRMA probe to the airway adapter,the probe buttoned means installed correctly;

3. Connect the 15mm male adapter of the airway adapter to the connection port of the patient Y-shaped tube of breathing circuit;



4. Connect the 15mm female adapter of the airway adapter to the patient's endotracheal tube;

Also can connect HME(heat and Moisture Exchanger) between the patient's endotracheal tube and IRMA probe. Can protect the airway adapter from affected by secreta and water vapor through put the HME in front of the probe, so there is no need to replace the adapter. In addition, by installing the exchanger, can place IRMA probe at will.



1. Unless use HMEto protect IRMA probe， ensure when place the IRMA probe , the status LED is always upward.

2. Press the start key to start the system, in the beginning the LED on probe flashes, probably about 10 seconds later turn to normally green.

3. AG module defaults to standby mode, when connected AG module,the screen will display 【AG is sleeping】.
4. Click【Menu】hot key->【System Setup】->【CO2 module】; 【Operating Mode】select 【Measure】,the screen display【AG is starting】.
5. After finish the preheat the module into full precision measurement state.

NOTE

- **IRMA probe is not designed to be used in contact with the patient;**
- **When connected the IRMA probe to the patient circuit, IRMA probe must avoid direct contact with the patient's body;**
- **No matter for any reason need to use the IRMA probe to contact with the patient's body directly, must use an insulating material between the IRMA probe and body.**

7.3.2 Checking before using

Before connecting the breathing circuit of IRMA Airway adapter to the patient, be sure to perform the following operations:

1. Ensure that the you have finished all related operations in Chapter "7.3.1 Installation" ;
2. Connect the airway adapter to patient circuit, should observe the gas readings and waveforms display on ventilator interface;
3. After installed the IRMA probe on the IRMA airway adapter, do tightness check for the patient circuit.

7.3.3 Affectingfactors of monitoring

Factors affecting the monitoring accuracy of mainstream gas monitor to, including：

- Quantitative effects of humidity or condensation；
- Quantitative effects of atmospheric pressure；
- Interfering gases or water vapor；
- Other interference sources.

7.3.4 Monitor calibration

In the following situations Main stream Anesthetic gas module（IRMA AX+）、Main stream CO2 module（IRMA CO2）should be calibrated to zero:

- Everytime after start IRMA probr or change IRMA aiwway adapter；
- Display the gas concentration appear an offset or accuracy error.

IRMAzero calibration operation as follows:

1. IRMA　monitor to atmospheric, see step 1)~step 2) in Chapter "7.3.1 installation"；
2. Press the system switch button to start the system.The LED on IRMA probe from flash to normally green , need wait about 30s in order to wait the probe pre-heat；
3. Select【Menu】->【System setup】->【CO2 module】，press【Start Zero Cal.】button，the screen will display【AG is zeroing】，in the meantime IRMA probe LEDflash display，lasts about 5s，and【Start】button turn to【Stop】 button；after finish checking，【Start】button turn to the original one，in the meantime prompt the test result, if the test passed,prompt：【PASS】；if failed，prompt：【Failure】。
4. If zero calibration failed, please try again after change airway adapter.

NOTE

- **Incorrect IRMA probe zero calibration will cause false gas reading；**
- **After finish IRMA probe ZERO calibration should always check before using.**
- **When do IRMA probe zero calibration should ensure it doesn't connect with the patient；**
- **Before or during do IRMA probe zero calibration，should pay special attention to avoid airway adapter close to airway adapter,exist air in the IRMA airway adapter is very important for zero calibrating successfully；**
- **When standard zero calibration failed, if prompt calibration failed after re-calibration,please contct with our after-sales service department.**

7.3.5 Module LED status information

LED on mainstream gas module offers a variety of instructions in order to reflect the current state

in time：

Display mode	Statements
Green light no twinkle	System OK
Green light twinkle	Calibrating
Blue light no twinkle	Exist anesthetic gas
Red light no twinkle	Sensor error
Red light twinkle	Check the adapter
Note1：Only apply to IRMA AX+ main stream anesthetic gas module.	

7.3.6 Module cleanliness

Allow to clean the probe. Before cleaning should take down the airway adapter,then use the damp cloth that soaked in the highest concentration of 70% of medical alcohol to clean the probe,at last, with a dry lint-free cloth to dry it.

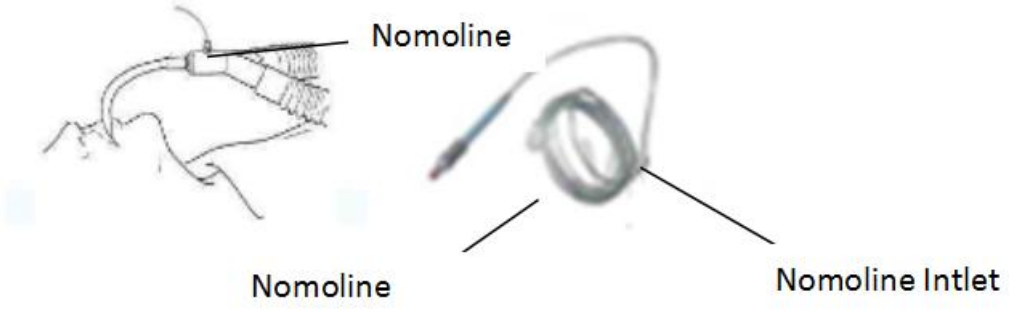
NOTE

- **When do IRMA probe zero calibration should ensure it doesn't connect with the patient；**
- **Before or during do IRMA probe zero calibration，should pay special attention to avoid airway adapter close to airway adapter,exist air in the IRMA airway adapter is very important for zero calibrating successfully；**
- **When standard zero calibration failed, if prompt calibration failed after re-calibration, please contct with our after-sales service department.**

7.4 Sidestream CO2 module

7.4.1 Installation

1. Make sure the ventilator is turned off, connect the communication port of IRMA monitor with the module interface cable on the backboard of the ventilator;
2. Connect Nomolinesampling tube output port to the air inlet port of ISA monitor ；
3. ISA monitor air outlet port ， use soft tube connect to AGSS system，discharge the exhaust gas together with AGSS;
4. Connect Nomoline gas inlet port of sampling tube to the sampling port of the patient's breathing circuit；



5. Press the system switch button,start the system;
6. After LED flash on ISAmonitor flashed sereval seconds turn to normally on means mearuring state.
7. Sidestream module defaults to standby mode, when connected sidestream module,the screen will display【AG is sleeping】。
8. Click【Menu】->【System Setup】->【Gas Module】: select【Measure】,the screen display 【AG is starting】.

7.4.2 Checking before using

Before connecting Nomoline sampling tube to the mask of the patient,please do the following checking:

1. Ensure that the you have finished all related operations in Chapter "7.4.1 Installation";
2. Exhale to the sampling tube to check if the monitoring interface of the ventilator has display valid CO2 waveform and value;
3. Use your fingertip to block off the sampling tube,last 10 seconds,should observed on the anesthetic operation interface display"* Please check the sampling tube", in the meantime the red LED light on the monitor flash;
4. In appropriate situation, to check the patient breathing circuit and sealing of the connection of the sampling tube;
5. After finish above steps, can connect the Nomoline sampling tube to the patients' mask or Y shaped connector.

NOTE

- **To prevent contaminate operating room, make sure the sidestream gas outlet through the soft tube connected to the AGSS system.Discharge the exhaust together with AGSS.**
- **The leak of sample gas will cause the measurement accuracy beyond specification; internal exhaust is not smooth, it may cause the monitor can not working properly. Therefore, we must ensure the correct connection.**

7.4.3 Affecting factors of monitoring

Effects of atmospheric pressure

Use the percentage of the volume as the unit to reporte the gas concentration, at this time the measurement results are not affected by atmospheric pressure. Concentration is defined as follows：

%gas=Partial pressure of gas component/Total pressure of gas mixture*100.

The total pressure of the mixed gas using the cup pressure sensor of ISA gas analyzer tomeasure.

When the test result using partial pressure indicated that it is related with the current atmospheric pressure , need to be calculated based on the actual atmospheric that the analyzer sent, the following formula:

CO2（mmHg）=CO2 concentration×pressure from the ISA (kPa) ×(750/100).

For example：5.0Vol%Co2(101.3kPa)，according to the above method transfer：
0.05×101.3×750/100=38 mmHg.

Effects of moisture

The partial pressure and the volume percentage of CO2、Nitrous oxide、O2 and Anesthetic depend on water vapor content.Calibrate theO2 measurement will display 20.8Vol% at the actual ambient temperature and humidity level, but not the actual partial pressure. 20.8Vol% O2 corresponding to the actual O2 concentration in the room (water concentration 0.7Vol%) (e.g., at 101.3kPa, corresponding to 25 ℃ and 23% RH). When measuring CO2, Nitrous oxide and O2(for example, all gas measured by the infrared pool) will always show the actual partial pressure in current humidity level.

In patient’s alveolar, water vapor in respiratory gas at body temperature achieved saturated (BTPS).

After collected and put the breathing gas to the sampling tube,before the gas enter ISA sidestream monitor,it’s temperature turn to close to ambient temperature.When Nomoline sampling tube remove all condensed water，the moisture will not enter ISA sidestream monitor.The relative humidity of the collected gas is about 95%.

If you need Co2 value under BTPS, the formula as follow：

EtCO2(BTPS)= EtCO2*(1-(3.8/pamb))

Of which：EtCO2=from ISA delivered EtCO2 value[Vol%]

pamb=from ISA delivered atmospheric pressure [kPa]

3.8= typical partial pressure between the patient circuit and the water vapor of condensed water of ISA [kPa]

EtCO2(BTPS)= EtCO2 value[Vol%] under BTPS

Assumed to have been calibrated the O2 using the room air in 0.7Vol% H2O humidity level.

7.4.4 Module calibration

ISA marginalia gas analyzer with automatic zero calibration function, no need the user to operate. Switch the gas sampling from the breathing circuit to ambient air will calibrate to zero automaticlly. Every 24 hours to perform an automatic zero calibrate, ISA CO2 module calibration takes less than 3s, ISA AX + monitor calibration time less than 10s.

NOTE

- **Exist air in the ISA module is very important for zero calibrating successfully, so need to ensure it's ventilated environment is good; before and after zero calibration,avoid breathing in it's vicinity.**
- **ISA modules adopt stable design, and has been done a permanent calibration when leave factory, so no need for routine calibration. When appear a large measurement bias or need the annual calibration, please contact our after-sales service department for professional calibration.**

7.4.5 Module LED status information

LED on sidestream gas module offers a variety of instructions in order to reflect the current state in time：

Display mode	Statements
Green light no twinkle	System OK
Green light twinkle	Calibrating
Blue light no twinkle	Exist anesthetic gas
Red light no twinkle	Sensor error
Red light twinkle	Check the sampling pipe

7.4.6 Module cleanliness

Allow do regularly cleaning for the monitor. To avoid dust or cleaning liquid through LEGI interface enter the monitor, during the cleaning process should always make sure Nomoline sampling tube is connected with the monitor. When cleaning the monitor, first use the damp cloth that soaked in the highest concentration of 70% of medical alcohol to wipe clean the probe, at last, with a dry lint-free cloth to dry it.

NOTE

- **Do not soak the ISA module in liquid or disinfect it;**
- **Nomoline sampling tube it's not a sterile component;**
- **Please do not do high-temperature high-pressure sterilization to the ISA module(including the sampling tube), otherwise it will damage the components.**

7.5 Compensation

If this Ventilator need to configure mainstream CO2 module（IRMA CO2）, or sidestream CO2 module（ISA CO2）, need to do N2O and O2 compensation set to ensure the accuracy of CO2 monitoring.Operation see "5.14.3 O2 Compen " and "5.14.4 N2O Compen " instructions.

NOTE

- **If equipped IRMA CO2 or ISA CO2 module,in the monitored gas exist nitrous oxide or O2, must do compensation settings for nitrous oxide and O2, otherwise it will cause the CO2 monitoring result is not accurate.**

7.6 About Masimo

Masimo holds the following patent relateding products described in this manual:

SE519766; SE519779; SE523461; SE524086. Other patents pending.

Masimo holds the following licensed trademark;

Masimo IRMATM, Masimo ISATM, Masimo XTPTM+, Sigma Multigas TechnologyTM, LEDTM, NomolineTM, IRMA EZ IntegratorTM, and PHASEIN Gas MasterTM are trademarks of Masimo Corportation.

FOR YOUR NOTES

Chapter 8 SpO2 (optional)

8.1 Overview

Blood oxygen saturation (SpO2) is the percentage of oxyhemoglobin (HbO2) capacity bound by oxygen in the blood in the total hemoglobin (Hb) capacity that can be combined, that is, the concentration of oxygen in the blood.

The principle for monitoring the pulse SpO2 is to fix the probe fingerstall on the patient's finger, use the finger as a transparent container for hemoglobin, use 660nm wavelength red light and 880nm near-infrared light as the incident light, maximum output power is 300 mw, measure the light transmission intensity through the tissue bed, and calculate the concentration of hemoglobin and SpO2.

The passing lights depend on a variety of factors, most of which are constant. However, one of these factors, the arterial blood flow, changes with time, as it is pulsating. By measuring the light absorbed during pulsating, it is possible to obtain the arterial blood SpO2. Detection pulsation can give a "plethysmography" wave and pulse rate signal.

The main screen displays "SPO2" value and "plethysmography" wave.

This monitor applies to measure SPO2 of adults (>18 years), pediatric (30 Days to18 years). Contact SPO2 probe to Patient's finger to get "SPO2" value and "plethysmography" wave

SPO2 function of this monitor has been calibrated in factory.

8.2 Safety Information

⚠ Warning

- **Please use SpO2 sensor specified in this Manual, operate in accordance with the Manual, and observe all warnings and precautions.**
- **Before monitoring, check whether the sensor cable is normal. When SPO2 sensor cable is unplugged from the socket, the screen will display [SPO2Sensor OFF] error message, and trigger an audible and visual alarm simultaneously.**
- **If the sensor or sensor packaging has signs of damage, do not use this SPO2 sensor; return it to the manufacturer.**
- **If there is carboxyhemoglobin, methemoglobin or dye diluted chemical, the SPO2 value will have deviation.**
- **When the patient has a tendency to hypoxia, use the oximeter to analyze blood samples in order to fully grasp the patient's condition.**

- **Do not put the sensor on limbs with arterial duct or intravenous tube.**
- **Do not intertwine electrosurgical equipment cable with the sensor cable.**
- **Avoid using the monitor and sensors while using the NMR equipment, in order to avoid severe burns to the patient as a result of induced currents.**
- **During long time continuous monitoring of a patient, check the position of SpO2 sensor once every 2 hours, and move properly when the skin changes or every four hours. Some patients may require more frequent inspection, such as patients with perfusion disorders or sensitive skin, because persistent and prolonged monitoring may increase unpredictable skin changes, such as allergies, redness, blistering or pressure necrosis.**
- **Carefully select SpO2 alarm upper limit. High oxygen level will cause crystal-like fibrous tissue disease to premature children.**

Note

- **Do not put the oxygen probe and blood pressure cuff on the same limb, because blood flow occlusion during blood pressure measurement will affect the SpO2 readings.**
- **This monitor cannot be used to verify the accuracy of SPO2 Probe and SPO2 machine.**

8.3 Monitoring Steps

1. Select the appropriate SpO2 sensor according to the patient.
2. Turn on the monitor, and connect the SpO2 lead wire to the monitor.
3. Clean the measurement site, such as finger with nail polish.
4. Put the SpO2 sensor probe on the patient's body.
5. Select the appropriate alarm settings.
6. Start monitoring.

Note

- **Turn on the monitor, plug in SPO2 probe and connect patient's finger, monitor displays SPO2 wave，【SPO2 Pulse Search】 displayed in the technical alarm area until the monitor measured SPO2 value and pulse rate. 【SPO2 Search Timeout】displayed in the technical alarm area until the monitor measured pulse rate. Check the sensor mounting position, whether the sensor is damaged or sensor type. Reconnect the sensor or use new sensor.**

8.4 Display

SpO2 parameter area is shown in Fig. 8-1.

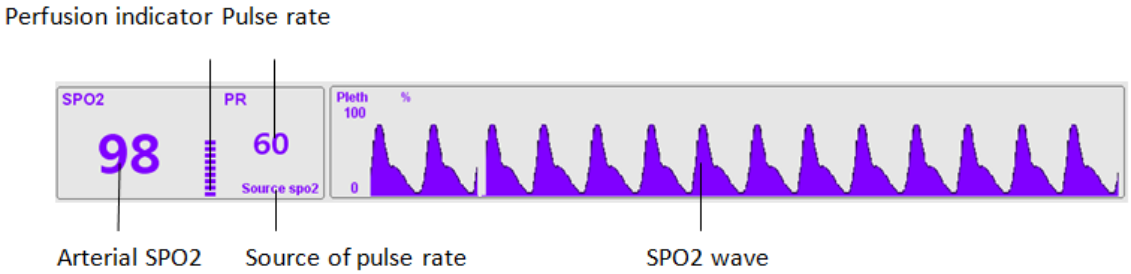


Fig. 8-1 SpO2 Parameter Area

8.5 Setting SpO2

Select SpO2 parameter area or Pleth wave area → [SpO2 Setup] menu, which is shown below. You can set SpO2 through [SpO2 Setup] menu.

Fig. 8-2 [SpO2 Setup] Menu

8.5.1 Setting Wave Speed

- Select [Wave Speed] and set wave speed to [12.5mm/s] or [25mm/s]; the faster speed, the smoother wave.

10.5.1 Setting Wave Mode

- Select [Wave Mode], and set the wave drawing mode
  - [Scan]: Scan mode.
  - [Fill]: Fill mode.

10.5.2 Setting Average Time

SpO2 values displayed on the monitor are the results averaged from the data collected over time. The shorter the average time, the faster the monitor responds when the patient's SpO2 value changes, but the measurement accuracy is lower. Conversely, the longer the average

time, the slower the monitor responds when the patient's SpO2 value changes, but the measurement accuracy is higher. In monitoring critically ill patients, a smaller average time is conducive to timely analysis of the disease.

The setting method follows:

- Select [Avg.Time] to set the average time to [2s], [3s], [4s], [5s], [6s], [7s] or [8s].

8.6 Measuring Influencing Factors

During operation, the following factors can affect the accuracy of SpO2 measurement:

- High-frequency radio wave interference, such as interference generated by the host system or interference from electrosurgery instrument connected to the system.
- Intravenous dye.
- Too frequent movement of the patient.
- External light radiation.
- Sensor is improperly installed or improperly in contact with the patient.
- Sensor temperature (optimum temperature 28 ℃~42 ℃).
- The sensor is placed on limbs with blood pressure cuff, arterial duct or lumen tube.
- Concentration of non-functional hemoglobin such as carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- SpO2 too low.
- Poor perfusion of test site.
- Shock, anemia, hypothermia, and the application of vasoconstrictor drugs may reduce the arterial blood flow to a level that can not be measured.
- The measurement also depends on the absorption of specific wavelengths of light by oxyhemoglobin and reduced hemoglobin. If there is any other substance that absorbs the same wavelength, the measurement may have false or low SPO2 values, such as: carbon hemoglobin, methemoglobin, methylene blue, and indigo carmine.
- SPO2 probe described in Annex is recommended.
- Operating environment limit: Operating temperature range: 5～40℃, Humidity range: 0~80% (non-condensing), Elevation range: -500m~5000m.

8.7 Alarm Setup

In [SpO2 Setup] menu, select [Alarm >>] to enter [Alarm Setup] interface, and set SPO2 alarm switch, alarm level, upper and lower alarm limit.

Chapter 9 Special Functions

9.1 Manual Breath

Select the [**Tools**] key→[**Functions**]→[**Manual Breath**], and the ventilator system delivers a breath to the patient based on the current ventilation mode.

NOTE

- **Manual breath is disabled in Standby status.**
- **Pressing the [Manual Breath] key during inspiratory phase cannot initiate a manual breath.**
- **Manual breath function is disabled in Spn-CPAP mode and is supported when apnea ventilation occurs.**

9.2 Expiration Hold

Expiration Hold means to extend the patient's time of expiratory phase manually and to prevent the patient from inspiration for a certain period of time.

Select the [**Tools**] key→[**Functions**]→[**Exp. Hold**]. Push and hold the [**Exp. Hold**] key. The ventilator starts the Expiration Hold function.Release the [**Exp. Hold**] key. The ventilator terminates the Expiration Hold function. Expiration Hold is active for a maximum of 30 seconds. If the [**Exp. Hold**] key is pushed and held for more than 30 seconds or is released, the ventilator terminates the Expiration Hold function automatically.

NOTE

- **Expiration Hold function is disabled in Spn-CPAP mode and is supported when apnea ventilation occurs.**
- **There is at least one inspiratory phase between two expiration holds.**
- **The system responds to Exp. Hold key pressing operation only in non-standby status.**

9.3 Inspiration Hold

Inspiration Hold means to extend the patient's time of inspiratory phase manually and to prevent the patient from expiration for a certain period of time.

Select the [**Tools**] key→[**Functions**]→[**Insp. Hold**]. Push and hold the [**Insp. Hold**] key. The ventilator starts the Inspiration Hold function.Release the [**Insp. Hold**] key. The ventilator terminates the Inspiration Hold function. Inspiration Hold is active for a maximum of 30 seconds. If the [**Insp. Hold**] key is pushed and held for more than 30 seconds, the ventilator terminates the Inspiration Hold function automatically.

NOTE

- **Inspiration Hold function is disabled in Spn-CPAP mode and is supported when apnea ventilation occurs.**
- **There is at least one expiratory phase between two inspiration holds.**
- **The system responds to Insp. Hold key pressing operation only in non-standby status.**

9.4 Nebulizer

During nebulization, aerosolized medicament is inhaled by the patient for the purpose of therapy.

Press the [**Nebulizer**] key and set the appropriate [**Nebulizer Time**] in the accessed menu. Select [**Ok**] to start nebulization. When nebulization starts, nebulization remaining time is displayed in the system prompt message field.

When the set nebulization time is up or the [**Nebulizer**] key is pressed again, the ventilator terminates nebulization.

NOTE

- **Nebulization may cause fluctuation in the patient's FiO2.**
- **CO2 cannot be measured in the aerosolized medicament environment. CO2 module sampling and monitoring are disabled when the nebulizer is started.**
- **Nebulizer is disabled in Standby status.**
- **When O2 supply type is low-pressure, pressing the [Nebulizer] key will not activate nebulizer, rather display the prompt message [Fail to Start with Low Pressure O2 Supply].**
- **Aerosolized medication may occlude the expiration valve and flow sensor. Please have them checked and cleaned after nebulization.**

9.5 100%O2 (O2 enrichment)

100%O_2 is also called as O_2 enrichment. It means that the oxygen depth is set to 100% ventilation for a certain period of time.

Press the [100%O_2] key and the ventilator starts oxygen enrichment. The indicator light for [100%O_2] key is background color for the green and the remaining oxygen enrichment time is displayed in the prompt message field. Oxygen enrichment is active for maximum two minutes. During oxygen enrichment, the currently set oxygen concentration is displayed in the [**O_2 %**] parameter setup quick key field.

When the 2-minute period of oxygen enrichment is up or the [**100%O_2**] key is pressed again, the ventilator terminates oxygen enrichment.

NOTE

- **When O2 supply type is low-pressure, pressing the [100%O2] key will not activate oxygen enrichment, rather display the prompt message [Fail to Start with Low Pressure O2 Supply].**
- **100%O2 (oxygen enrichment) is disabled in Standby status.**
- **Removing the patient tubing during oxygen enrichment will start suction function. Refer to section 9.6 Suction.**

9.6 P0.1

P0.1 is the occlusion pressure drop within the first 100 ms after a patient starts spontaneous breathing.

1. Select the [**Tools**] key→[**Diagnostics**]→[**P0.1**].
2. Select [**P0.1**] to access the P0.1 measurement window.
3. Select [**Start**]. The system starts P0.1 measurement and prompts [**Measurement Active**].
4. After the measurement is completed, the measurement result is displayed. The ventilator can display the three most recent measurement results.
5. After the measurement is completed, Waveforms and Spirometry screen is frozen automatically.

NOTE

- **During P0.1 measurement, pressing the [Freeze] key does not produce freezing operation.**
- **If no operation is performed on P0.1 measurement window within three minutes, the measurement window exits automatically.**

9.7 O2 Therapy

O_2 therapy is a method to increase O_2 concentration in the airway at normal pressure through simple tube connections. O_2 therapy is a medical measure which can increase O_2 concentration in the alveolar gas and facilitate O_2 diffusion so as to increase PaO_2 and SpO_2 saturation and relieve or correct hypoxia by increasing O_2 concentration in the inspired gas. O_2 therapy is a way for hypoxia prevention or treatment, providing O_2 concentration higher than that in the air.

⚠WARNING

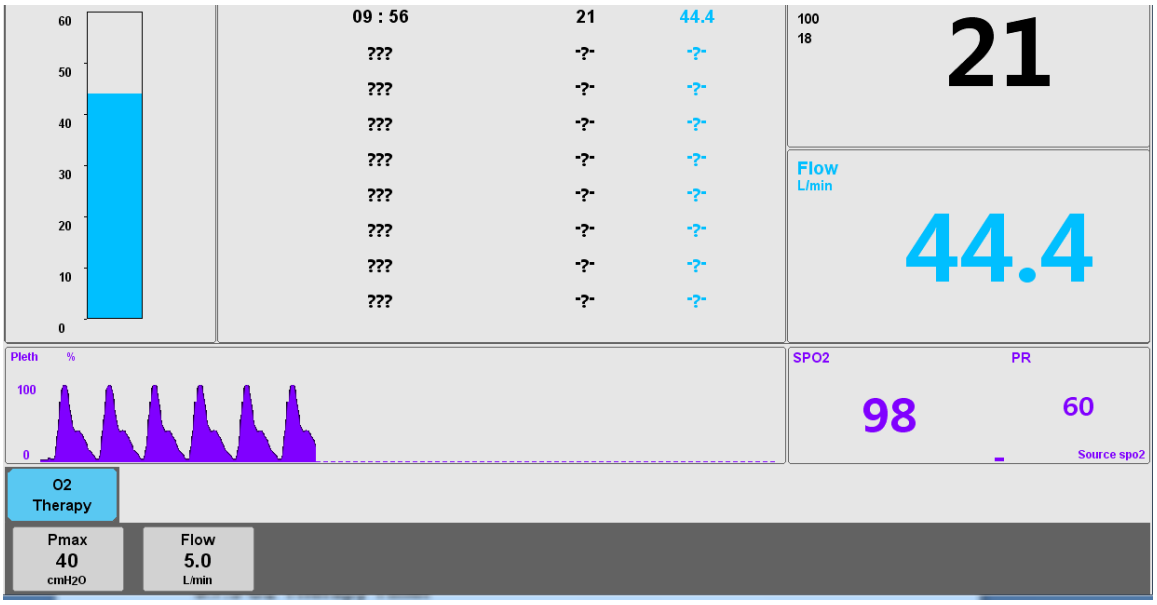
- **Only use oxygen masks for O2 Therapy. Do not use masks for non-invasive ventilation (NIV). The patient may be at risk if unsuitable masks are used.**
- **During O2 therapy, only the O2 concentration FiO2 and O2 flow monitored.**
- **During O2 therapy, all physiological alarms are shielded except O2 concentration physiological alarms.**
- **Airway pressure and expiration-dependent ventilation parameters, such as flow, minute volume, or apnea, are not monitored.**
- **O2 therapy can only be used on patients with spontaneous breathing.**

9.7.1 Switching on O2 Therapy

WARNING

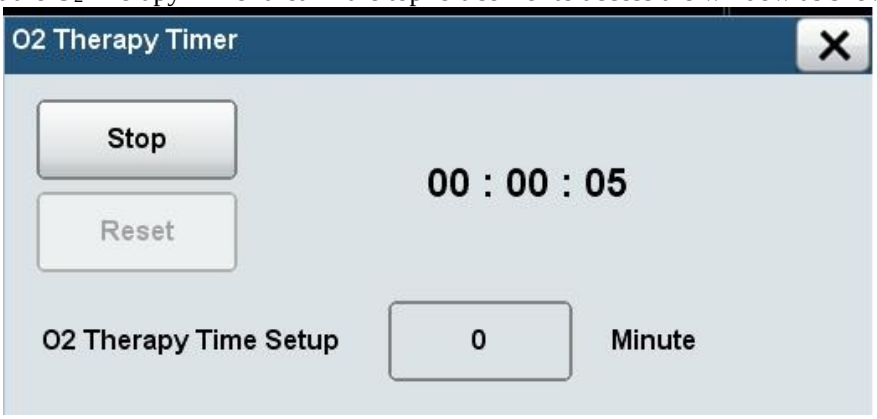
- **The device must only be used under the supervision of qualified medical staff, so that help is immediately available if malfunctions occur or the patient has insufficient spontaneous breathing.**

1. Select the [**Standby**] key to enter Standby status after confirmation.
2. Select [**O_2 Therapy**] in the Standby status to enter O_2 therapy screen.
3. Set [**Flow**]、 [**O_2%**] and [**Pmax**] to appropriate values as required.



9.7.3 O2 Therapy Timer

Select the O_2 Therapy Timer area in the top left corner to access the window as shown below.



Select [**Stop]/ [Start**] to stop or start timing. Select [**Reset**] to reset the displayed time of the timer.

Enter the number of timing minutes in [**O_2 Therapy Time Setup**] to start the timer. When the set time expires, the system gives prompt sound and O_2 supply is not interrupted.

9.7.4 Switching off O_2 Therapy

During O_2 therapy, select the [**Standby**] key to enter Standby status after confirmation, so as to switch off the O_2 therapy function.

Chapter 10 Alarms

10.1 Summary

Alarms, triggered by a vital sign that appears abnormal or by technical problems of the ventilator, are indicated to the user by visual and audible alarm indications.

NOTE
■ **When the ventilator is started, the system detects whether audible alarm tones and alarm lamp function normally. If yes, the alarm lamp flashes red and yellow successively, and the speaker and the buzzer give check tones. If not, do not use the equipment and contact us immediately.** ■ **When multiple alarms of different priorities occur simultaneously, the ventilator selects the alarm of the highest priority and gives visual and audible alarm indications accordingly.**

10.1.1 Alarm type

According to the nature of the alarm, the alarm in ventilator can be divided into physiological alarm, technical alarm and prompt information.

■ Physiological alarm

Physiological alarm is usually due to some physiological parameters of patients exceeds the seted high and low limit range alarm or the patient occurs physiological abnormalities. The physiological alarm information display on the top of the screen of the physiological alarm area.

■ Technical alarm

Technical alarm also known as the system error message, it is to point to some system function can not work normally or the monitoring results in distortion then trigger the alarm which caused by improper operation or system failure normal operation. Technical alarm information display on the top of the screen of the technical alarm area.

■ prompt information

Strictly speaking, prompt information does not belong to the alarm, it is to point to except the Physiological alarm and Technical alarm, the monitor will display some information related to the system state, the information is generally not involved in the patient's vital signs. Generally Prompt information display in the system technology alarm area and parameters area.

10.1.2 Alarm level

According to the severity of the alarm, the physiological alarm of the ventilator can be divided into advanced alarm, secondary alarm and low level alarm.

- **High Priority alarm**

The patient is in critical condition, and may have life risk, should be an immediate rescue.

- **Medium Priority alarm**

Physical signs of patients with abnormal, should take the corresponding measures and treatment.

- **Low Priority alarm**

Physical signs of patients with abnormal,maybe need to take the corresponding measures and treatment.

All technical alarm and some physiological alarm level has been set in ventilator factory, the user can't change it. Some physiological alarm level can be modified.

10.2 Alarm mode

when the alarm occurs，the ventilator use the following auditory or visual alarm prompt the user:

- Light alarm
- Audible alarm
- Alarm information
- Parameter twinkle

Among them, the light alarm, audible alarm and alarm information respectively in different ways to distinguish alarm level.

10.2.1 Light alarm

when the alarm occurs，alarm indicator lights use different colors and twinkle frequency suggest different levels of the alarm.

- High priority alarm：Red、twinkle frequency fast
- Medium priority alarm：Yellow、twinkle frequency slow
- Low Priority alarm：Yellow、Normally on not twinkle

10.2.2 Audible alarm

Audible alarm refers to when the alarm occurs, ventilator adopts different voice characteristics to indicate different levels of the alarm.

- High priority alarm： the speaker gives out rhythmic sound prompt,i.e.the “beep-beep-beep--beep-beep----beep-beep-beep--beep-beep”,of a cycle in about 10s;
- Medium priority alarm： the speaker gives out continuous sound prompt,i.e.the “beep-beep-beep”,of a cycle in about 25s;
- Low Priority alarm: the speaker gives out monosyllabic sound prompt, i.e. the single “beep”, of a cycle in about 35s.

Alarm Sound Pressure Level: within the range of 45dB-85dB, and the higher level of alarm is higher than the lower level of alarm in sound pressure level, namely the Low Priority ≤ Medium Priority ≤ High Priority.

When alarms occur, the ventilator prompt the user by the type of audible alarm and visual alarm below:

- Visual alarm
- Audible alarm
- Alarm information
- Scintillation of parameters

Herein, Visual alarm, audible alarm and alarm information could distinguish the alarm levels by the different means.

10.2.3 Alarm information

Alarm informations are when alarm occurs, the physiological alarm zone or the technical alarm zone of the ventilator display the corresponding alarm information. The system distinguish the levels of the alarm informations by the different ground colors

- High-level alarm： red
- Secondary alarm： yellow
- Low-level alarm： yellow

Distinguish the levels of alarm information by these symbols in front of the alarm information:

- High-levels alarm： !!!
- Secondary alarm： !!
- Low-level alarm： !

10.2.4 Parameters scintillation

When the alarm of parameters which are for monitoring the patients such as monitoring EtCO2, FiCO2, awRR, the parameter value will blink once per second frequency, high limit or lower limit of the parameter will also be the same frequency flashing, indicating that the parameter exceeds the upper limit or a low limit.

10.2.5 Alarm Audio Pause

Press the alarm Audio Pause Button  on the panel under the display, and click for confirmation, until the display shows 120s countdown and sound pause icon  , meaning the alarm sound pause has been successfully set, whereas the suspended audible alarm continues for 120s.

10.2.6 Cancellation of Alarm Audio Pause

When the system is in an alarm sound pause, press the alarm Audio Pause Button  and click for confirmation until the 120s countdown and audio pause icon  disappear, meaning the alarm audio pause has been successfully cancelled, resuming the audible alarm function.

10.3 Flashing Alarm Numeric

If an alarm triggered by an alarm limit violation occurs, the numeric of the measured parameter in alarm will flash at a specified frequency.

10.4 Set Alarm Volume

1) Click [Menu] -> [System setup] - [Others];

2) Alarm Volume: 1 ~ 9 is the lowest volume; 9 is the maximum;

WARNING

- **Do not rely exclusively on the audible alarm system when using the ventilator. Adjustment of alarm volume to a low level may result in a hazard to the patient. Always keep the patient under close surveillance.**

10.5 Set Alarm Limits

⚠CAUTION

- **In case that high pressure alarm limit of 60 cmH2O is not required under clinical condition, setting high pressure alarm limit to 60 cmH2O or less is recommended so as to extend the service life of the turbine and the battery.**

NOTE

- **An alarm is triggered when the parameter value is higher than the high limit or lower than the low limit.**
- **When using the ventilator, always keep an eye on whether the alarm limits of a specific parameter are set to the appropriate values.**

Select [**Alarm Setup**] and then select [**Limits 1**] 、 [**Limits 2**]、[CO2] to set the alarm limits for Ppeak, PEEP, MVe, VTi mand, Rtotal, Tapnea, $EtCO_2$, or FiO_2 (when the ventilator is connected to low-pressure oxygen supply).

10.6 Alarm Tests

10.6.1 Loss of Power

1. Connect the ventilator to AC power and push the  hardkey to switch on.
2. After the system starts up, disconnect the external power supply when the battery is fully charged.
3. Connect a test lung to the ventilator and start normal ventilation.
4. The ventilation time is approximately 3 hours for the ventilator configured with one battery (approximately 6 hours for the ventilator configured with two batteries). The battery capacity is to be depleted. The [**System DOWN. Connect External Power Supply.**] alarm is activated.
5. Reconnect the external power supply.
6. Verify that the alarm resets and the ventilator is again powered by external power supply.

10.6.2 Paw Too High

1. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation.
2. Set Paw high alarm limit to current Peak.
3. Squeeze the test lung hard during inspiration.
4. Verify that the [**Paw Too High**] alarm is activated, the ventilator cycles into expiration, and airway pressure falls to PEEP level.

10.6.3 Paw Too Low

1. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation.
2. Set Paw low alarm limit to current Peak.
3. Squeeze the test lung hard during inspiration.
4. Verify that the [**Paw Too Low**] alarm is activated, the ventilator cycles into expiration, and airway pressure falls to PEEP level.

10.6.4 VTi mand Too Low

1. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation.
2. Set the VTi mand low alarm limit to be greater than the current VTi mand. Verify that the [VTi mand **Too Low**] alarm is activated.

10.6.5 VTi mand Too High

1. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation.
2. Set the VTi mand high alarm limit to be less than the current VTi mand. Verify that the [VTi mand **Too High**] alarm is activated.

10.6.6 MVe Too High

1. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation.
2. Set the MVe high alarm limit to be greater than the current MVe. Verify that the [**MVe Too High**] alarm is activated.

10.6.7 MVe Too Low

1. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation.
2. Set the MV low alarm limit to be greater than the current MV. Verify that the [**MVe Too Low**] alarm is activated.

10.6.8 O2 Supply Failure

1. Connect the ventilator to high-pressure O_2 supply.
2. Switch off the high-pressure O_2 supply. Verify that the [**O_2 Supply Failure**] alarm is activated.

10.6.9 PEEP Too High

1. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation.
2. Set the PEEP high alarm limit to be greater than the current PEEP. Verify that the [PEEP **Too High**] alarm is activated.

10.6.10 PEEP Too Low

1. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation.
2. Set the PEEP low alarm limit to be greater than the current PEEP. Verify that the [PEEP **Too High**] alarm is activated.

10.6.11 Rtotal Too High

1. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation.
2. Set the Rtoatl high alarm limit to be greater than the current Rtotal. Verify that the [Rtotal **Too High**] alarm is activated.

10.6.12 Rtotal Too Low

1. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation.
2. Set the Rtotal low alarm limit to be greater than the current Rtotal. Verify that the [Rtotal **Too High**] alarm is activated.

10.6.13 Airway Obstructed

1. After the ventilator system starts up normally, connect a test lung to the ventilator and set the ventilator to pressure mode to start ventilation.
2. Nip the inspiration tube with hands. Ensure the monitoring value of TVi is lower than 10 mL.
3. Verify that the [**Airway Obstructed?**] alarm is activated after several breathing cycles.
4. Loosen the inspiration tube and verify this alarm is reset automatically.

10.6.14 FiO2 Too High

1. Connect the ventilator to low-pressure O_2 supply.
2. Connect a test lung to the ventilator and start ventilation.

3. Set the FiO_2 high alarm limit to be less than the current O_2 concentration monitored value after ventilation is stable.
4. Verify that the [**FiO_2 Too High**] alarm is activated.

10.6.15 FiO2 Too Low

1. Connect the ventilator to high-pressure O_2 supply.
2. Connect a test lung to the ventilator and start ventilation.
3. Switch off the high-pressure O_2 supply after ventilation is stable.
4. Verify that the [**FiO_2 Too Low**] alarm is activated.

10.6.16 EtCO2 Too High

1. Connect a test lung to the ventilator and start ventilation.
2. Connect the CO_2 test module. Select the [Menu] key → [System setup] → [**CO_2 Module**] to set [Operating Mode] to [Measure].
3. After CO_2 warm-up is completed and the CO_2 module enters operating mode, deliver 3 % to 7 % of CO_2 standard gas to the sampling port of sidestream CO_2 module or the airway adapter of mainstream CO_2 module. Set the $EtCO_2$ high alarm limit to be less than the standard gas concentration.
4. Verify that the [**$EtCO_2$ Too High**] alarm is activated.

10.6.17 EtCO2 Too Low

1. Connect a test lung to the ventilator and start ventilation.
2. Connect the CO2 test module. Select the [Menu] key → [System setup] → [CO2 Module] to set [Operating Mode] to [Measure].
3. After CO2 warm-up is completed and the CO2 module enters operating mode, deliver 3 % to 7 % of CO2 standard gas to the sampling port of sidestream CO2 module or the
4. Airway adapter of mainstream CO2 module. Set the EtCO2 low alarm limit to be greater than the standard gas concentration.
5. Verify that the [EtCO2 Too Low] alarm is activated.

10.6.18 FiCO2 Too High

1. Connect a test lung to the ventilator and start ventilation.
2. Connect the CO2 test module. Select the [Menu] key → [System setup] → [CO2 Module] to set [Operating Mode] to [Measure].
3. After CO2 warm-up is completed and the CO2 module enters operating mode, deliver 3 % to 7 % of CO2 standard gas to the sampling port of sidestream CO2 module or the airway adapter of mainstream CO2 module. Set the FiCO2 high alarm limit to be less than the standard gas concentration.

4. Verify that the [FiO2 Too High] alarm is activated.

10.6.19 awRR Too High

1. Connect a test lung to the ventilator and start ventilation.
2. Connect the CO2 test module. Select the [Menu] key → [System setup] → [CO2 Module] to set [Operating Mode] to [Measure].
3. Set the awRR high alarm limit to be less than the current awRR.
4. Verify that the [awRR Too High] alarm is activated.

10.6.20 awRR Too Low

1. Connect a test lung to the ventilator and start ventilation.
2. Connect the CO2 test module. Select the [Menu] key → [System setup] → [CO2 Module] to set [Operating Mode] to [Measure].
3. Set the awRR low alarm limit to be greater than the current awRR.
4. Verify that the [awRR Too Low] alarm is activated.

10.6.21 SPO2 Too High

1. Connect a test lung to the ventilator and start ventilation.
2. Connect the SPO2 test module. StandBy state.Select the [Menu] → [Factory Setting], input password (112358) → [SPO2 Module] to set SPO2 Type].
3. Set the SPO2 High alarm limit to be less than the current SPO2.
4. Verify that the [SPO2 Too High] alarm is activated.

10.6.22 SPO2 Too Low

1. Connect a test lung to the ventilator and start ventilation.
2. Connect the SPO2 test module. StandBy state.Select the [Menu] → [Factory Setting], input password (112358) → [SPO2 Module] to set SPO2 Type].
3. Set the SPO2 low alarm limit to be greater than the current SPO2.
4. Verify that the [SPO2 Too Low] alarm is activated.

10.6.23 PR Too High

1. Connect a test lung to the ventilator and start ventilation.
2. Connect the SPO2 test module. StandBy state.Select the [Menu] → [Factory Setting], input password (112358) → [SPO2 Module] to set SPO2 Type].
3. Set the PR High alarm limit to be less than the current PR.
4. Verify that the [PR Too High] alarm is activated.

10.6.24 PRToo Low

1. Connect a test lung to the ventilator and start ventilation.
2. Connect the SPO2 test module. StandBy state.Select the [Menu] → [Factory Setting], input password (112358) → [SPO2 Module] to set SPO2 Type].
3. Set the PR low alarm limit to be greater than the current PR.
4. Verify that the [PR Too Low] alarm is activated.

⚠WARNING

- **Do not rely exclusively on the nurse call system for alarm notification. Remember that the most reliable alarm notification combines audible and visual alarm indications with the patient's clinical condition.**
- **Use the specified nurse call cable when connecting with the hospital's nurse call system through the nurse call connection port. Failure to do so may burn the machine and produce electric shock hazard.**
- **Inspect the ventilator alarm signals periodically when using the nurse call function.**

10.7 When an Alarm Occurs

When an alarm occurs, do as follows:

1. Check the patient's condition.
2. Determine the alarming parameter or alarm category.
3. Identify the alarm source.
4. Take proper actions to eliminate the alarm condition.
5. Make sure the alarm condition is corrected.

For details about how to troubleshoot alarms, refer to ***10.12 Alarm information table.***

⚠WARNING

- **To prevent possible patient injury when alarms are active, ensure that the patient receives adequate ventilation. Identify and remove the cause of the alarms. Readjust the alarm limits only when they are inappropriately set for the current conditions.**

⚠CAUTION

- **Contact the Customer Service Department if the alarm persists without obvious cause.**

10.8 Alarm information table

1) Alarm information includes physical and technical alarm information, but some alarm information is not necessarily listed.

2) Column P stands for the default alarm level: H for high, M for medium and L for low.

3) For each alarm message, list all the corresponding countermeasures. Follow the oprations of the countermeasures if the problem persists, contact your service personnel.

10.8.1 Physiological alarm

Physiological Alarm Table

Alarm message	Level	Cause and action
Paw Too High	H	The airway pressure exceeds the set pressure high alarm limit.
		1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the alarm limits. 4. Check the patient tubing for occlusion.
Paw Too Low	H	The airway pressure is lower than the set pressure alarm low limit
		1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the alarm limits. 4. Check breathing pipe leakage or loss. 5. Check breathing pipe leakage or loss. Check the patient tubing for occlusion.
FiO_2 Too High	H	The inspired O_2 concentration is greater than the FiO_2 high alarm limit for at least 30s.
		1. Check the ventilation parameter setup. 2. Check the alarm limits. 3. Check the HEPA filter for occlusion. 4. Calibrate the O_2 sensor.
FiO_2 Too Low	H	The inspired O_2 concentration is less than the FiO_2 low alarm limit for at least 30s or is less than 18 %.
		1. Check the ventilation parameter setup. 2. Check the alarm limits. 3. Check the O_2 supply. 4. Calibrate the O_2 sensor.
TVe Too High	M	The TVe monitored value is greater than TVe high alarm limit for continuous 3 mechanical ventilation cycles.
		1. Check the ventilation parameter setup. 2. Check the alarm limits.

TVe Too Low	M	The TVe monitored value is less than TVe low alarm limit for continuous 3 mechanical ventilation cycles.
		1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the alarm limits. 4. Check the patient tubing for leakage or occlusion. 5. Perform System Check to test the leakage.
MVe Too High	M	MVe is greater than MVe high alarm limit.
		1. Check the ventilation parameter setup. 2. Check the alarm limits.
MVe Too Low	M	MVe is less than MVe low alarm limit.
		1. Check the ventilation parameter setup. 2. Check the alarm limits. 3. Check the patient tubing for leakage or occlusion. 4. Perform System Check to test the leakage.
Apnea	H	The time of failure to detect respiration exceeds Tapnea.
		1. Check the patient. 2. Manual breath. 3. Check apnea time setup. 4. Check if the patient tubing are disconnected.
Apnea Ventilation	H	The time of failure to detect respiration exceeds Tapnea. Start apnea ventilation mode.
		Check apnea ventilation parameter setup.
Rtotal Too High	M	Rtotal is greater than ftotal high alarm limit.
		1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the alarm limits.
Rtotal Too Low	M	Rtotal is less than Rtotal low alarm limit.
		1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the alarm limits.
Apnea Ventilation	H	This alarm is given when apnea ventilation ends. There is no need to process this alarm.
$EtCO_2$ Too High	M	The monitored parameter value exceeds the alarm limit.
		1. Check the patient type. 2. Check the alarm limits.
$EtCO_2$ Too Low	M	The monitored parameter value exceeds the alarm limit.
		1. Check the patient type. 2. Check the alarm limits.
$FiCO_2$ Too High	H	The monitored parameter value exceeds the alarm limit.

		1. Check the patient type. 2. Check the alarm limits.
Apnea CO_2	M	The time of failure to detect respiration by the CO_2 module exceeds Apnea Tinsp.
		1. Check the patient. 2. Check apnea time setup. 3. Check the connections of CO_2 module sampling device.
SPO2 Too High	M	SpO2 value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
SPO2 Too Low	M	
PR Too High	M	SpO2 value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
PR Too Low	M	

10.8.2 Technical alarm

Technical Alarm Table

Alarm message	Level	Cause and action
Battery Low	M	The remaining battery power is lower than a threshold.
		Connect to the external power supply.
The system will shut down	H	Battery power is depleted. The system will shut down in a few minutes.
		Connect to the external power supply immediately.
Battery Disconnect	L	Equipment is not installed the battery
		Please install the battery, so as not to power off the external power supply, battery-powered.
AC Disconnect	L	The device is not connected to an external power supply
		Please access the external power supply.
MERCURY Comm. Malfunction	H	Breathing communication failure.
		Please check if the ventilator communication USB interface cable is loose.
Apnea Ventilation	M	Current mode ventilation patients without inspiratory triggering ability.
		Please check the patient.
Insp. Vt Limit Reached	M	Exhaled air volume exceeds the set tidal volume.
		1. Check the patient. 2. Check the ventilation parameter settings. 3. Check the pressure alarm high limit.
Insp. Flow Trigger	L	Inspiratory flow rate trigger.
		1. Check the patient. 2. Check ventilation settings.

Exp. Flow Trigger	L	Exhalation flow rate trigger. 1. Check the patient. 2. Check ventilation settings.
Pressure Limited	L	In volume mode or pressure mode when ATRC function is enabled, the pressure reaches Paw high alarm limit-5. 1. Check the patient. 2. Check the ventilation parameter setup. 3. Check pressure high alarm limit.
O_2% Too High	H	During O_2 therapy, the O_2 concentration is greater than the O_2% high alarm limit for at least 30s. 1. Check the ventilation parameter setup. 2. Check the alarm limits. 3. Check the O_2 supply. 4. Calibrate the O_2 sensor.
O_2% Too Low	H	During O_2 therapy, the O_2 concentration is less than the O_2% low alarm limit for at least 30s or is less than 18 %. 1. Check the ventilation parameter setup. 2. Check the O_2 supply. 3. Calibrate the O_2 sensor.
PEEP Too High	H	Monitored PEEP exceeds PEEP+5 cmH_2O within any fully mechanical ventilation cycle. 1. Check the ventilation parameter setup. 2. Check the patient tubing for occlusion.
PEEP Too Low	M	Patient's PEEP is less than the setting value to a certain extent. 1. Check the patient tubing for leakage. 2. Perform System Check to test the leakage.
Tube Leak	L	Tube is leaky. 1. Check the patient tubing for leakage. 2. Perform System Check to test the leakage
Hose Disconnected	H	Tube is disconnected. Re-connect the patient tubing.
Paw Senseor Malfunction	H	Pressure sensor failure. 1. Calibrate the pressure sensor. 2. Please contact your designated service representative.
No Available Pressure Sensor	H	There is no reliable pressure sensor. 1. Check that the pressure sensor is in place. 2. Please calibrate the pressure sensor. Please contact your designated service representative.
CO_2 Sampleline Occluded	L	Sampling line is faulty or occluded. 1. Check the sampling line for occlusion. 2. Replace the sampling line. 3. Replace the water trap.
		O2 pressure is low or high-pressure O2 is not connected.

O_2 Supply Failure	H	1. Check connection with O2 supply. 2. Check O2 supply pressure.
CO2 communication stopped	H	CO2 module communication stopped
		1. Check if the module is faulty. 2. While removing the ventilation module, unplug the CO2 module. 3. Please contact your designated service representative.
$EtCO_2$ Overrange	L	Parameter measured values exceed the measurement range (error range is included).
		Perform CO2 module zeroing. Contact your service personnel.
Oxygen sensor is not connected	L	Oxygen sensor is not connected.
		Please connect the oxygen sensor.
Please Replace O_2 Sensor.	M	The O2 sensor is used up.
		Replace the O2 sensor.
Please calibrate O_2 sensor.	L	Calibrate the O2 sensor.
		Calibrate O2 concentration.
SPO2 Comm. Stop	H	SpO2 module failure, or communication failure between the module and the host; please restart the device.
SPO2 Comm. Error	H	
SPO2 No Sensor	L	SpO2 sensor falls off from the patient or monitor, malfunctions, or sensor other than specified in this Manual is used. Check the sensor mounting position, whether the sensor is damaged or sensor type. Reconnect the sensor or use new sensor.
SPO2 Sensor Off	L	

FOR YOUR NOTES

Chapter 11Cleaning and Disinfection

⚠WARNING

- **Obey applicable safety precautions.**
- **Read the material safety data sheet for each cleaning agent.**
- **Read the operation and service instructions for all disinfection equipment.**
- **Wear gloves and safety glasses. A damaged O2 sensor can leak and cause burns (contains potassium hydroxide).**
- **Reuse of undisinfected reusable accessories or components may cause cross-contamination.**
- **To prevent leaks, avoid damaging any component in case of disassembling and reassembling the breathing system. Ensure the correct installation of the system. Make sure of the applicability and correctness of the cleaning and disinfection methods.**
- **Disassemble and reassemble the breathing system as described in this manual. If you need further disassembly and reassembly, contact us. Improper disassembling and reassembling may cause breathing system to leak and compromise normal system use.**
- **Seeping liquid into the control assembly can damage the equipment or cause personal injury. When cleaning the housing, ensure that no liquid flows into the control assemblies and always disconnect the equipment from the AC mains. Reconnect the AC mains after the cleaned parts are fully dry.**
- **To avoid sticky residuals, do not use talc, zinc stearate, calcium carbonate, corn starch, or equivalent materials. These materials can go into the patient's lungs and airways and cause irritation or injury.**

⚠CAUTION

- **To prevent patient exposure to disinfection agents and to prevent premature deterioration of parts, use the cleaning and disinfection methods and agents recommended in this section.**
- **To reduce the risk of electrical shock, disconnect electrical power from the ventilator before cleaning and disinfection.**

NOTE

- **Clean and disinfect the equipment as required before it is put into use for the first time. Refer to this chapter for the cleaning and disinfection methods.**
- **To help prevent damage, refer to the manufacturer's data if you have questions about a cleaning agent.**
- **Do not use organic, halogenated, or petroleum based solvents, anesthetic agents, glass cleaners, acetone, or other harsh cleaning agents.**
- **Do not use abrasive cleaning agents (such as steel wool, silver polish, or cleaner).**
- **Keep all liquids away from electronic parts.**
- **Do not permit liquid to go into the equipment housings.**
- **Only autoclave parts marked 134ºC.**
- **Cleaning solutions must have a pH of 7.0 to 10.5.**

- **After cleaning and disinfection is completed, run System Check before using the equipment. Use the equipment only when System Check is passed.**
- **The expiration valve assembly, inspiration safety valve assembly, and patient hose of the gas pathways through the ventilator can become contaminated with body fluids and expired gases during both NORMAL CONDITION and SINGLE FAULT CONDITION.**

11.1 Methods for Cleaning and Disinfection

Parts marked 134 °C are autoclavable. Recommended temperature is 134° C. By using autoclave to solidify bacterioprotein rapidly, quick and reliable sterilization effect can be achieved.

Different parts of the ventilator can be disinfected by different methods. You need to select the appropriate method to clean and disinfect the parts based on the actual situations to avoid cross-contamination between the ventilator user and the patient.

This table is our recommended cleaning and disinfection methods for the ventilator parts, including use for the first time and use after many times.

Parts	**Recommended frequency**	**Cleaning**		**Disinfection**			
		①	②	A	B	C	D
Ventilator Housing							
Ventilator external surface (including housing, power cord, supply gas hose)	Each patient	①		A or D			
Trolley and support arm	Each patient	①		A or D			
Touch screen	Each patient	①		A or D			
Fan dust filter	Every four weeks/as necessary*	②		**B**			
Main unit air outlet dust filter	Every four weeks/as necessary*	②		**B**			
Air intake dust filter	Every four weeks/as necessary*	②		**B**			
Ventilator inspiration safety valve assembly							
Inspiration safety valve assembly	as necessary*	②		B or C			
Ventilator expiration valve assembly							
Expiration valve membrane (silicone)	Each patient/weekly	②		B or C			
Expiration valve assembly (except membrane)	Each patient/weekly	②		B or C			
Ventilator patient tubing (reusable)							

Patient tubing (including water trap, Y piece, adapter)	Each patient/weekly	②	B or C
Other			
Mainstream CO_2 sensor	Each patient/weekly	Refer to the cleaning and disinfection methods provided by the mainstream CO_2 vendor.	
SPO2 Probe	Each patient/weekly	Refer to the cleaning and disinfection methods provided by theSPO2 vendor.	
Nebulizer	Each patient/weekly	Refer to the cleaning and disinfection methods provided by the nebulizer vendor.	
Humidifier	Each patient/weekly	Refer to the cleaning and disinfection methods provided by the humidifier vendor.	

Cleaning methods（Wipe and Bath Immersion）:

① Wipe: Wipe with a damp cloth immersed in alkalescent detergent (soap water, etc.) or alcohol solution and then wipe off the remaining detergent with a dry lint free cloth.

② Immersion: flush with water first and then immerse it in alkalescent detergent (soap water, etc.) (water temperature 40℃ recommended) for approximately three minutes. Finally clean with water and dry completely.

Disinfection methods:

A: Wipe: wipe with a damp cloth immersed in medium- or high-efficiency detergent and then wipe off the remaining detergent with a dry lint free cloth.

B: Immersion: immerse it in medium- or high-efficiency detergent (alcohol or isopropyl alcohol, etc.) for more than 30 minutes (recommended time). Then clean with water and dry completely.

C: Steam autoclave at 134℃ for 10 to 20 minutes (recommended time).

D: Ultraviolet radiation for 30 to 60 minutes (recommended time).

As necessary*: shorten the cleaning and disinfection intervals if the equipment is used in dusty environment to ensure that the equipment surface is not covered by dust. Clean and disinfect the inspiration safety valve assembly only when the patient's exhaled gas may contaminate the inspiratory limb. For disassembling and installation methods, refer to ***11.2***.

The table below lists the cleaning and disinfecting agents and autoclaving process that may be used on the ventilator.

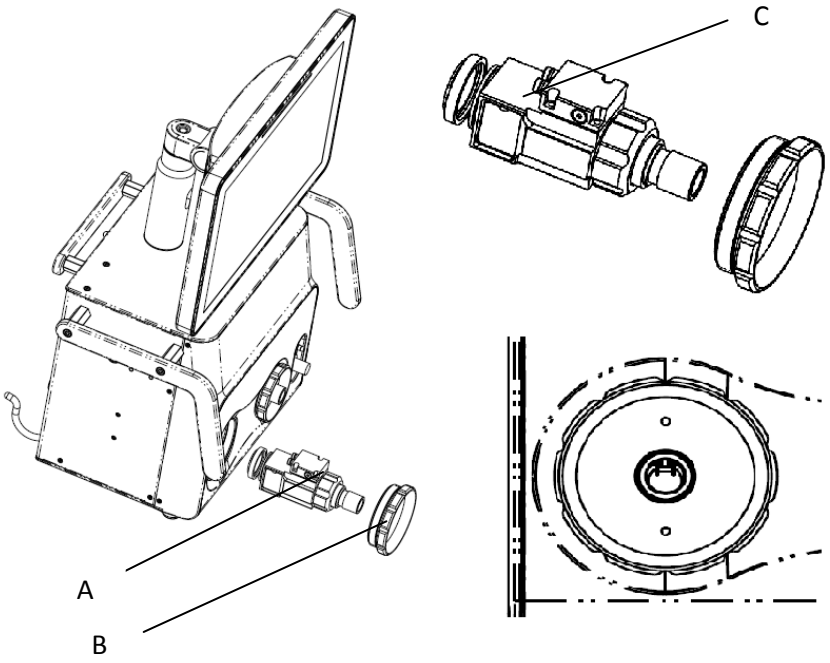
Name	**Type**
Ethanol (75%)	Moderately efficient disinfectant
Isopropanol (70%)	Moderately efficient disinfectant

Glutaraldehyde (2%)	Highly efficient disinfectant
Ortho-Phthalaldehyde disinfectant (such as Cidex®OPA）	Highly efficient disinfectant
Soap water (pH value of 7.0~10.5)	Rinsing agent
Clean water	Rinsing agent
Steam autoclave*	Highly efficient disinfection

Steam autoclave*: The recommended temperature of this disinfection method is 134℃ (273℉).

11.2 Disassemble the Ventilator's Cleanable and Disinfectable Parts

11.2.1 Expiration Valve Assembly and Membrane



A. Expiration valve assembly B. Expiration valve handwheel

C. Expiration valve membrane

■ To disassemble the expiration valve assembly:

1. According to the position rotate the expiration valve handwheel counter-clockwise until unlock. Then pull out the expiration valve assembly horizontally.
2. Remove the expiration valve membrane.

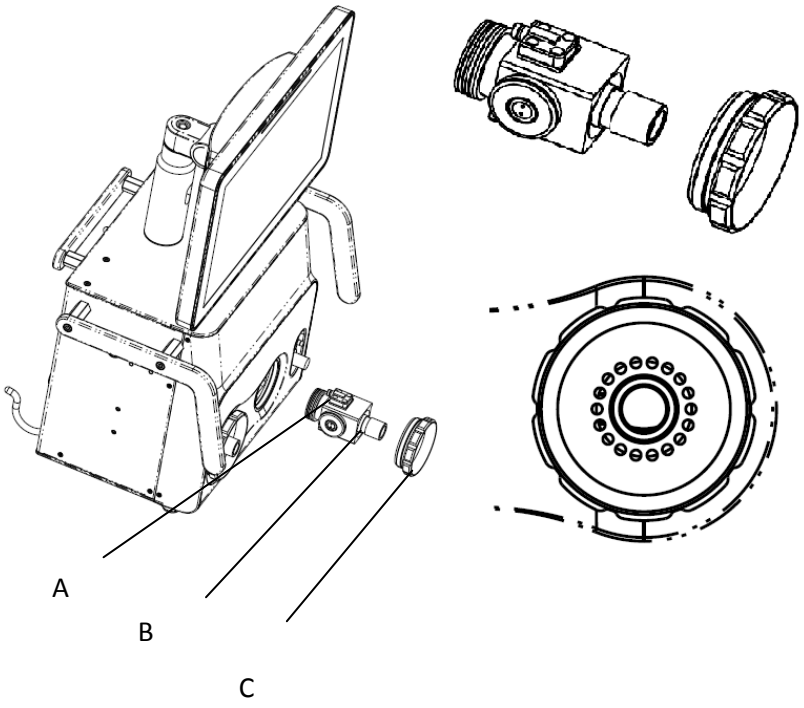
- To install the expiration valve assembly:

1. Install the expiration valve membrane onto the expiration valve assembly.

2. According to  direction of rotation, Then rotate the expiration valve handwheel clockwise (and depress the handwheel in the direction the expiration valve is installed) until the knob to tight.

11.2.2 Inspiration Safety Valve Assembly

11.2.2.1. Inspiration Safety Valve Assembly



A. Sealing ring B. Safety valve assembly C.Safety valve handwheel

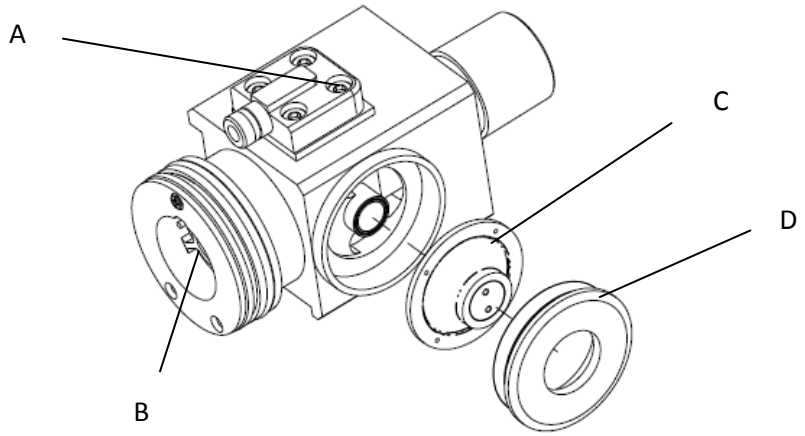
- To disassemble the inspiration safety valve assembly:

Ensure ventilator is in Standby or switched off. According to the  position rotate the expiration valve handwheel counter-clockwise until unlock. Then pull out the inspiration safety valve assembly horizontally. Check if the sealing ring at the end of the inspiration safety valve is disconnected. If it is disconnected, re-install the sealing ring onto the inspiration safety valve.

- To install the inspiration safety valve assembly:

Push the inspiration safety valve assembly into the corresponding connector on the ventilator horizontally to the end. According to direction of rotation, Then rotate the expiration valve handwheel clockwise (and depress the handwheel in the direction the expiration valve is installed) until the knob to tight.

11.2.2.2. Inspiration Safety Valve Membrane



A. Safety valve body B. Membrane fixing knob

C. Safety valve membrane D. Membrane support

E. Groove of safety valve body F. Guides on membrane fixing knob

- To disassemble the inspiration safety valve membrane:

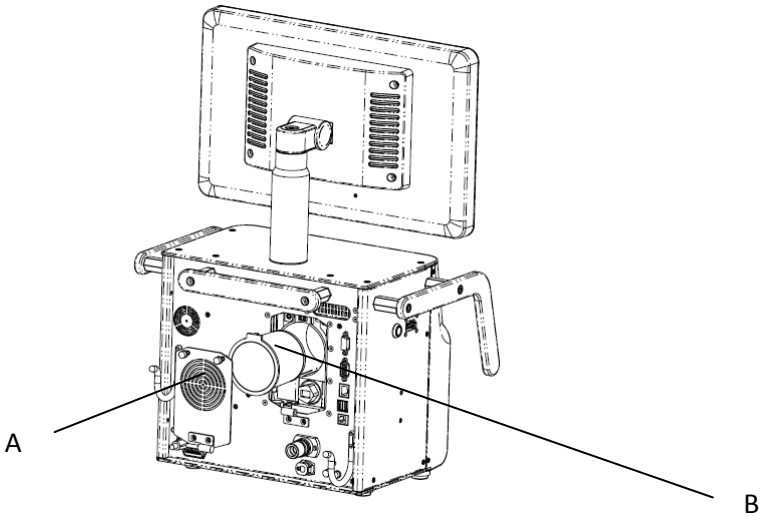
1. Face the membrane fixing knob and rotate the membrane fixing knob counter-clockwise to the end position. When the knob guides reach the grooves of safety valve body, pull out the membrane fixing knob.
2. Remove the safety valve membrane.

- To install the inspiration safety valve membrane:

1. Assemble the safety valve membrane to the membrane fixing knob. The 3 holes on the membrane match the 3 posts on the membrane fixing knob, as shown below. Ensure the metal side of the membrane support can be seen through the hole on the membrane fixing knob.

2. Align the guides on membrane fixing knob with the grooves of safety valve body. Insert the membrane fixing knob, press it tightly and rotate it clockwise to the end position.

11.2.3 High Efficiency Particle Air (HEPA) Filter Assembly and Dust Filter



A. HEPA filter B. Main unit air inlet grille C. Air intake dust filter

■ To disassemble the HEPA filter assembly and air intake dust filter:

1. Pull the two snaps on the main unit air inlet grille to remove the grille.
2. Pull the snap on the HEPA filter to take it out. If it is necessary to remove the air intake dust filter, pinch the dust filter with two fingers and take it out.

■ To install the HEPA filter assembly and air intake dust filter:

1. Align the HEPA filter with the corresponding slot, and push in the direction the HEPA filter is installed.
2. Fasten the snap of the HEPA filter.
3. Check the snap on the HEPA filter and make sure it is fastened in place.
4. Install the main unit air inlet grille.

NOTE

- **Install the specified HEPA filter and air intake dust filter.**

⚠ CAUTION

- **Do not run the ventilator if the ventilator is not equipped with HEPA filter to avoid contaminating the ventilator inspiration port and patient tubing.**

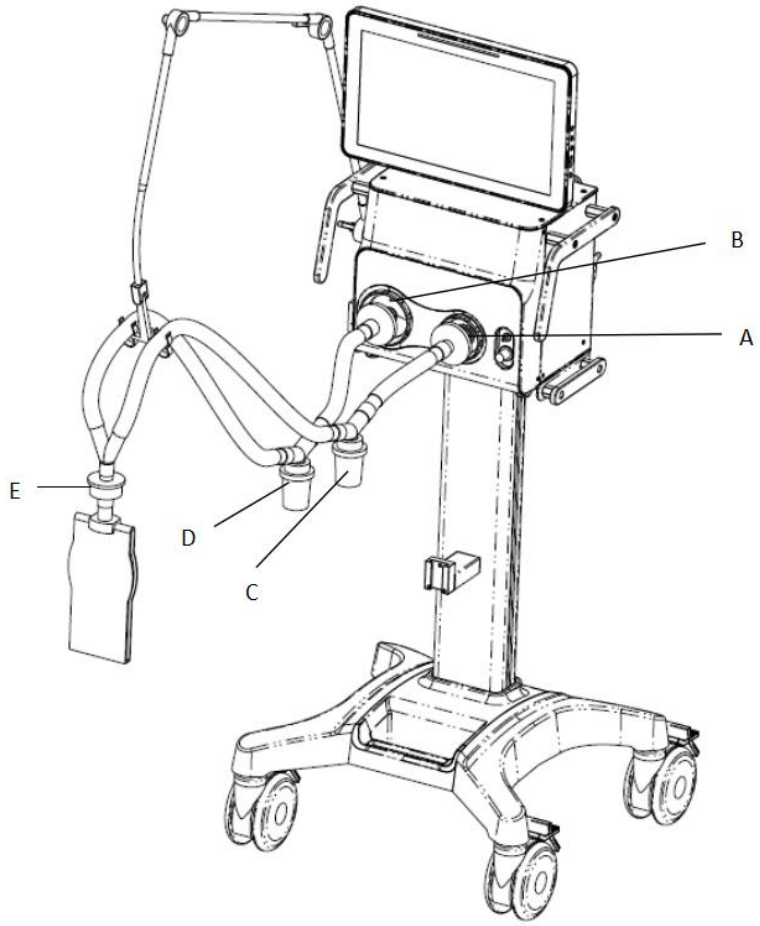
11.2.4 Patient Tubing

⚠ WARNING

- **To minimize the risk of bacterial contamination or physical damage, remove and install the bacterial filter with care.**

⚠ CAUTION

- **When removing the reusable patient tubing, disconnect the tubes from the ventilator connectors instead of pulling the tubes.**



A. Inspiratory filter B. Expiratory filter C. Inspiratory filter

D. Expiratory filter E.Heat&Moisture Exchange(HME)

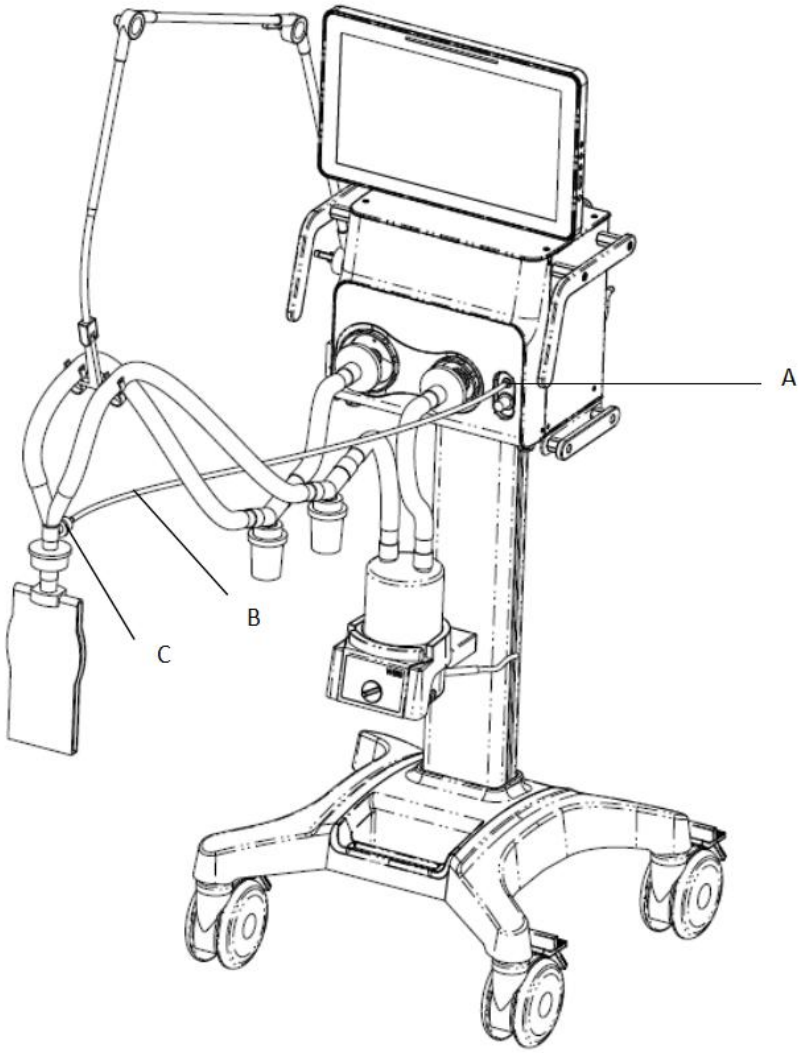
- To disassemble the patient tubing:

  Pull out the patient tubing one by one.

- To install the patient tubing:

1. Mount the filters onto the inspiratory and expiratory ports.
2. Connect the inspiratory filter to the water trap via the tube. Connect the other end of the tube to the Y piece.
3. Connect the expiratory filter to the water trap via the tube. Connect the other end of the tube to the Y piece.
4. Connect the patient side of the Y piece to the HME and then connect the patient to the HME.
5. Place the patient tubing onto the support arm hook.

11.2.5 Nebulizer



A. Nebulizer connector B. Nebulizer tube C. Nebulizer

- To disassemble the pneumatic nebulizer:

1. Pull out the nebulizer tube from the nebulizer connector.
2. Pull out the nebulizer tube from the nebulizer and remove the nebulizer.

- To install the pneumatic nebulizer:

1. Connect one end of the nebulizer tube to the nebulizer connector and the other end to the nebulizer.
2. Install the nebulizer in the inspiratory limb via the tube.

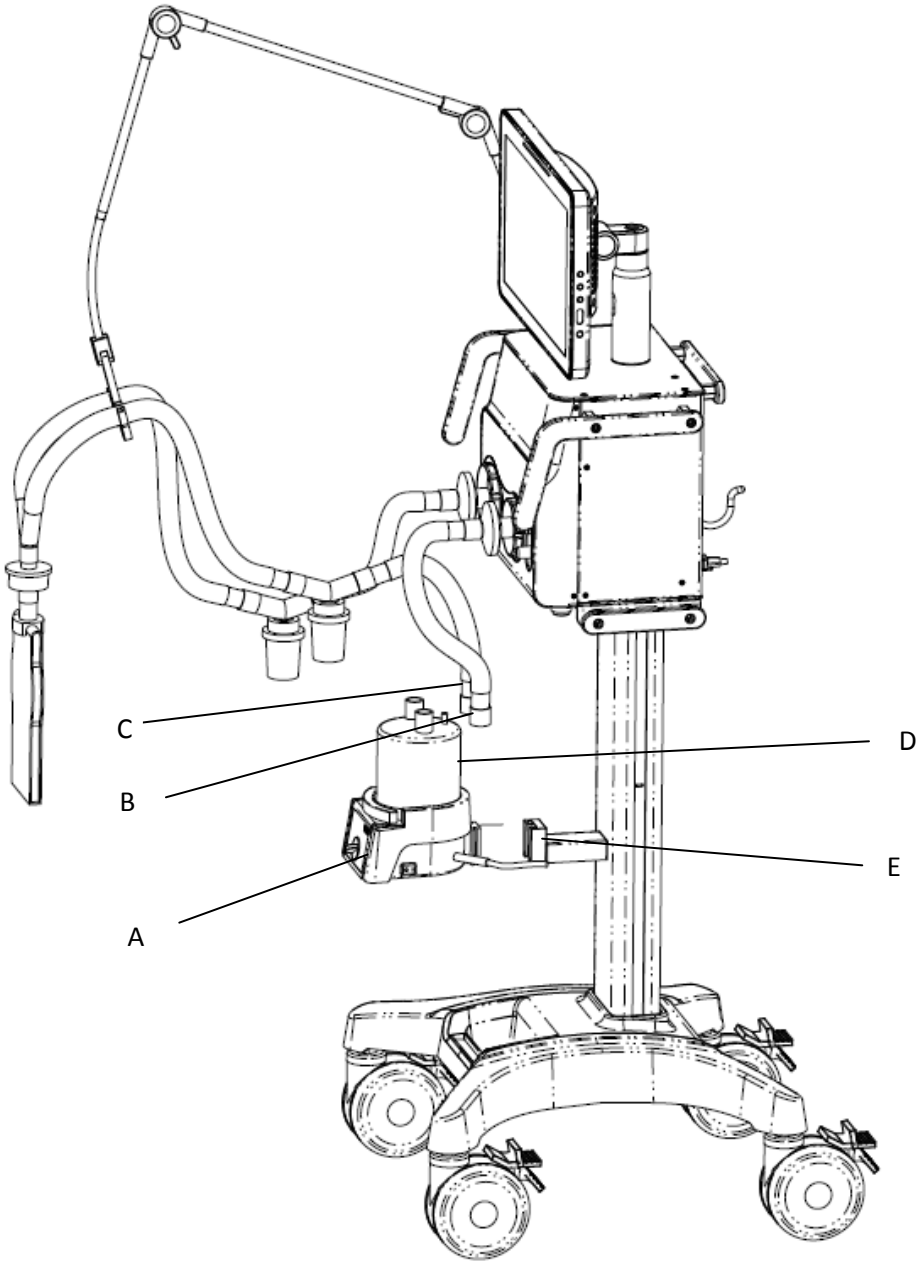
NOTE

- **Install the specified nebulizer. The nebulizer assembly, its installation and disassembling steps described in this section are only for reference.**

11.2.6 Humidifier

NOTE
■ **The humidifier shall comply with the requirements of ISO 8185. The humidifier assembly, its installation and disassembling steps described in this section are only for reference.**

11.2.6.1. Humidifier on the Ventilator



A. Humidifier B. Humidifier mounting plate C. Humidifier bracket slot
D. Screw E. Humidifier inlet F. Humidifier outlet

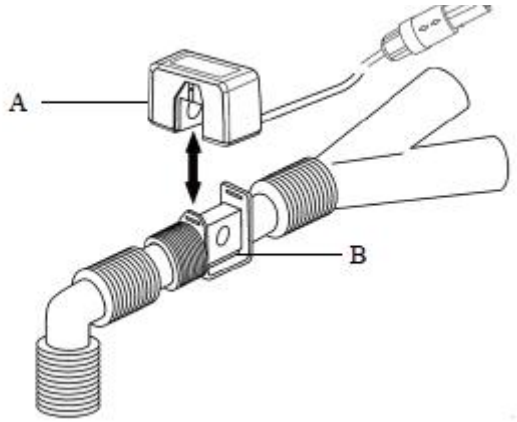
■ To disassemble the humidifier from the ventilator:

1. Disconnect the tubes from the humidifier.
2. Remove the screw.
3. Lift up the humidifier to remove it from the humidifier bracket fixed seat.

■ To install the humidifier onto the ventilator:

1. Align the humidifier mounting plate and the slot, and slide the humidifier in.
2. Tighten the screw.
3. Mount the filters onto the inspiratory and expiratory ports.
4. Connect the inspiratory filter to the humidifier inlet via the tube.
5. Connect the humidifier outlet to the water trap via the tube. Then, connect the water trap to the Y piece via the tube.
6. Connect the expiratory filter to the water trap via the tube. Then, connect the water trap to the Y piece via the tube.
7. Place the patient tubing onto the support arm hook.

11.2.7 Mainstream CO2 Sensor



A. CO2 sensor B. CO2 airway adapter

■ To disassemble the CO_2 sensor:

Pull out the CO_2 sensor vertically.

■ To install the CO_2 sensor:

Fix the CO_2 sensor on the CO_2 airway adapter vertically.

Chapter 12 Maintenance

12.1 Repair Policy

⚠WARNING

- **Obey infection control and safety procedures. Used equipment may contain blood and body fluids.**
- **Movable parts and removable components may present a pinch or a crush hazard. Take care to move or replace system parts and components.**
- **Do not use lubricants that contain oil or grease. They burn or explode in high O2 concentrations.**

Do not use malfunctioning ventilator. Have all repairs and services done by an authorized service representative. Replacement and maintenance of the parts listed in this manual may be undertaken by a competent, trained individual having experience in the repair of devices of this nature.

After repair, test the ventilator to ensure that it is functioning properly, in accordance with the specifications.

NOTE

- **No repair should ever be attempted by anyone not having experience in the repair of devices of this nature.**
- **Replace damaged parts with components manufactured or sold by us. Then test the unit to make sure that it complies with the manufacturer's published specifications.**
- **Contact us for service assistance.**
- **For further information about the product, contact us. We can provide documents about some parts depending on the actual condition.**

12.2 Maintenance Schedule

Interval	Part/accessory	Procedure
Each patient or as necessary	Patient tubing (including mask, inspiratory filter, flow sensor, expiration valve and membrane)	Perform pressure and flow zeroing. Perform System Check. Perform flow sensor calibration (refer to ***12.4***). Replace with disinfected parts or new disposable parts.
As necessary	Inspiration safety valve assembly	When the patient's exhaled gas may contaminate the inspiration safety valve assembly, it is necessary to replace with disinfected inspiration safety valve and membrane (refer to ***11.2.2***).

	Expiration valve	Replace the expiration valve if it is damaged (refer to ***11.2.1***）.
	CO_2 calibration	Calibrate the CO_2 module when the CO_2 measured value has a great deviation.
	Touch screen	Calibrate the touch screen if its function is degraded.
Several times a day or as necessary	Patient tubing	Check the patient tubing and water traps for water build-up. Empty water build-up if there is. Inspect the parts for damage. Replace as necessary.
During cleaning and setup	Ventilator	Inspect the parts for damage. Replace as necessary.
Daily or as necessary	Ventilator	Clean the external surfaces.
	O_2 cell	Calibrate the O_2 cell.
Before each use or after continuous use of two weeks	Entire ventilator	Perform System Check. Check the breathing system resistance and leakage.
Monthly or as necessary	Air intake dust filter and fan dust filter	Check the dust filter for dust build-up. Clean or replace as necessary (refer to ***11.2.4***).
Check every 6 months and replace every two years	Lithium battery	Check the charging and discharging of the lithium battery every 6 months and replace the lithium battery every two years. Contact us for replacement.
Annually or as necessary	Inspiration safety valve membrane	Check the inspiration safety valve membrane. Contact us for replacement if necessary.
Annually, or every 5000 ho urs, or as necessary	O_2 cell	Replace the O_2 sensor if it is damaged (refer to ***3.8***）. [**NOTE**] Oxygen cell life specifications are approximate. The actual cell life depends on operating environment. Operation at higher temperatures or higher oxygen concentrations shortens cell life.
	Air intake HEPA filter	Replace (refer to ***11.2.3***).
	Ventilator	Contact us for preventive maintenance.
	Check valve	Check the check valves, including gas source check valve, spontaneously inspiratory check valve, and expiratory limb check valve. Contact us for replacement if necessary.

	Backup alarm system	Check the alarm duration of backup alarm system (buzzer). If it is too short, contact us.
	Gas source sealing ring	Check the gas source sealing ring. Contact us for replacement if necessary.
	Expiration valve membrane	Check the expiration valve membrane. Contact us for replacement if necessary.
Every 6 years or as necessary	Battery of the clock module	Replace the battery of the clock module. Contact us for replacement.
Every 20,000 hours	Turbine box	Contact us for replacement.

12.3 Pressure and Flow Zeroing

Zero pressure and flow when the monitored pressure or flow value has a great deviation.

Zeroing can be performed in both Standby status and ventilation mode.

Follow these steps to zero pressure and flow:

1. Press the [**Setup**] key. Select [**Calibrate**] and select [**Zero**]. Select [**Start**] to which pressure and flow zeroing correspond on the right side to start Paw and flow zeroing. The [**Sensor Zeroing**] prompt message is displayed.
2. After a successful zeroing, the screen shows [**Sensor Zeroing Completed!**]. Otherwise, the message indicating zeroing failure is displayed. In this case, you need to do the zeroing again.

12.4 Flow Calibration

NOTE

- **Do not perform calibration while the unit is connected to a patient.**
- **Do not perform flow calibration when low-pressure oxygen source is used.**
- **During calibration, do not operate the pneumatic parts. Especially, do not move or press the patient tubing.**
- **Ensure that the system is in Standby status. If not, push the [Standby] key to enter standby screen.**
- **It is recommended not to connect the humidifier to the ventilator before the calibration.**

Calibrate the flow sensor when the measured value has a great deviation from the setting, or when the flow sensor is replaced.

Follow these steps to calibrate flow:

1. Ensure high-pressure oxygen source is connected.
2. Connect the patient tubing and insert the Y piece into the leak test plug to close the breathing circuit.
3. Press the [**Setup**] key. Select [**Calibrate**] and select [**Flow Calibration**]. Select [**Start**] on the right side to start Flow Calibration. The [**Calibrating**] prompt message is

displayed.

4. During the calibration, if you select [**Stop**], the ongoing calibration will stop and the message [**Calibration Stopped! Calibration is unfinished.**] is displayed.
5. After a successful calibration, the screen shows [**Calibration Completed!**]. Otherwise, the message indicating calibration failure is displayed. In this case, you need to do the calibration again.

NOTE

- **In case of calibration failure, check for relevant malfunctioning alarm and then troubleshoot it. If it still fails or great measurement error occurs after troubleshooting, replace the flow sensor and repeat the above operations. If the measurement error is still significant, contact the authorized service personnel.**

12.5 Oxygen Concentration Calibration

NOTE

- **Do not perform oxygen concentration calibration while the unit is connected to a patient.**
- **Do not perform oxygen concentration calibration when low-pressure oxygen source is used.**
- **Ensure that the system is Standby. If not, push the [Standby] key to enter standby screen.**

Calibrate the oxygen concentration when the measured oxygen concentration has a great deviation from the setting, or when the O_2 sensor is replaced.

Follow these steps to calibrate the oxygen concentration:

1. Ensure high-pressure oxygen source is connected.
2. In standby state. Select [**Calibrate**] ->[**O_2 Cal.**]. Select [**Start**] on the right side to start Flow Calibration. The [**Calibrating**] prompt message is displayed.
3. During the calibration, if you select [**Can**cel], out of calibration.
4. After a successful calibration, the screen shows [**Calibration Completed!**]. Otherwise, the message indicating calibration failure is displayed. In this case, you need to do the calibration again.

NOTE

- **In case of calibration failure, check for relevant malfunctioning alarm and then troubleshoot it. Then do the calibration again. In case of repeated calibration failures, replace the O2 sensor and do the calibration again. If it still fails, contact your service**

personnel or us.

- **Handle and dispose of the O2 sensor according to your biohazard policies. Do not incinerate.**
- **Oxygen concentration monitoring does not provide automatic atmospheric pressure compensation. Do oxygen concentration calibration again when atmospheric pressure has changed.**
- **Increasing to periodical pressure of 10 kPa (100 cmH2O) has no effect upon oxygen concentration monitoring accuracy.**
- **O2 cell measures the partial pressure of oxygen. Increase or decrease of pressure (absolute pressure) affects the partial pressure of oxygen. Increase of pressure (absolute pressure) by 10 % causes oxygen concentration to increase by 10 %. Decrease of pressure (absolute pressure) by 10 % causes oxygen concentration to decrease by 10 %. Do oxygen concentration calibration when atmospheric pressure has changed.**

12.6 CO2 Calibration

12.6.1 Sidestream CO2 Module

NOTE

- **Ensure that the system is in Standby. If not, push the [Standby] key to enter standby screen.**

Follow these steps to perform CO_2 calibration:

1. Check the airway and ensure that there are no occlusions or leaks. Ensure that the CO_2 module is already warmed up or started.
2. Select the [**Menu**] key→[**System setup**]→[CO_2 Module]→[Start Zero Cal.].
3. After a successful calibration, the screen shows [**CO_2 % Calibration Completed!**]. Otherwise, the message [**Calibration Failure! Try again!**] is displayed. In this case, you need to do the calibration again.

12.6.2 Mainstream CO2 Module

For a mainstream CO_2 module, manual calibration is not required. The system sends altitude to the mainstream CO_2 module for calibration compensation.

12.7 Touch Screen Calibration

NOTE

- **Ensure that the system is in Standby. If not, push the [Standby] key to enter standby screen.**

1. Press the [**Menu**] key. Select [**System setup**] and select [**Others**]. Select [**Cal.Touchsereen**].

2. The  mark appears in different locations of the screen.

3. Click the central point of  one by one.

4. After the calibration, the button [OK],[Cancel] and [Retry] is displayed. Select [**Ok**] to complete the calibration.

12.8 Battery Maintenance

⚠CAUTION

- **The batteries can only be charged by this ventilator.**

NOTE

- **Use batteries at least once every month to extend their lives. Charge the batteries before they are depleted.**
- **Inspect and replace batteries regularly. Battery life depends on how frequent and how long battery is used. For a properly maintained and stored lithium battery, its life expectancy is approximately 2 years. For more aggressive use models, life expectancy can be shortened. We recommend replacing lithium batteries every 2 years.**
- **In case of battery failure, contact us or have your service personnel replace it. Do not replace the battery without permission.**
- **Check battery performance once every six months. Checking battery performance is also required before ventilator repair is carried out or when battery is doubted to be the source for ventilator failure.**
- **Condition batteries once every time when they have been used for three months or when the battery running time becomes noticeably short.**

The ventilator is designed to operate on battery power whenever power supply becomes interrupted. When the ventilator is connected to the external power source, the batteries are charged regardless of whether the ventilator is currently on or not. In case of power failure, the ventilator will automatically be powered by the internal batteries. When external power source is restored within the specified time, power supply is switched from battery to external power supply automatically to ensure continuous system use.

On-screen battery icon indicates the battery statuses as follows:

-  The battery work normal, the battery is full of electricity.
-  The battery work normal, the green part indicates the electricity of battery.

-  The battery power is low, need to be charged immediately, otherwise the device will automatically shut down.
-  Battery is not installed
-  The battery is normal, in a state of charge.

If the capacity of the internal battery is limited, the alarm [**Battery Low**] will be triggered. In this case, apply external power to the ventilator.

12.8.1 Battery Performance Conditioning

Condition batteries when they are put into use for the first time. A complete battery conditioning cycle is: uninterrupted charging, followed by uninterrupted discharging until the ventilator shuts off, and then uninterrupted charging. Condition batteries regularly to maintain their service lives.

NOTE

- **Condition batteries every time when they have been used for three months or when the battery running time becomes noticeably short.**
- **Over time and with the use of the battery, the actual battery capacity will decrease. For an old battery, the battery full icon does not indicate that the battery capacity or battery running time still meets the requirement specified. When conditioning batteries, replace the battery when its running time becomes noticeably short.**

Follow these steps to condition batteries:

1. Disconnect the patient from the ventilator and shut down the ventilator.
2. Connect the ventilator to the external power source and charge the batteries uninterruptedly for at least 10 hours.
3. Disconnect the external power source. Allow the ventilator to operate on battery power until the ventilator shuts off.
4. Re-connect the ventilator to the external power source and charge the batteries uninterruptedly for at least 10 hours.
5. Battery conditioning is now completed.

12.8.2 Battery Performance Checking

Check battery performance once every six months. Checking battery performance is also required before ventilator repair is carried out or when battery is doubted to be the source for ventilator failure. Battery performance may degrade over time.

Follow these steps to check battery performance:

1. Disconnect the patient from the ventilator and shut down the ventilator.
2. Connect the ventilator to the external power source and charge the batteries uninterruptedly for at least 10 hours.
3. Disconnect the external power source. Allow the ventilator to operate on battery power until the ventilator shuts off.
4. The running time of the battery reflects its performance.

If the running time of the battery is noticeably shorter than that stated in the specifications, replace the battery or contact the service personnel.

NOTE

- **If the running time of the battery is too short after fully charged, the battery may be damaged already or defective.**
- **If obvious signs of damage are detected on the battery or the battery recharging has failed, replace the battery and recycle it properly.**

12.8.3 Battery Storage

During storing batteries, ensure the battery electrodes do not get in touch with metal. In case of long-time storage, place batteries in a cool environment and keep battery power at 40% to 60%.

Placing batteries in a cool environment can delay battery aging. Ideally, batteries should be stored in a cool environment of 15℃ (60℉). Do not store batteries outside the environmental range of -20℃ (-4℉) to +60℃ (140℉).

Remove the batteries from the ventilator if the ventilator is not used for a long time. Failure to do so will over-discharge the batteries and extend the battery charging time noticeably. Fully charge the batteries once every 2 months and keep battery power at 40% to 60%. Fully charge the batteries before use.

NOTE

- **Remove the batteries from the equipment if the equipment is not used for a long time.**
- **Long-time storage of batteries above 38℃ (100℉) greatly shortens the battery life expectancy.**

12.8.4 Battery Recycling

If obvious signs of damage are detected on the battery or the battery recharging is failed, replace the battery and recycle it properly. Dispose of the battery in compliance with the local laws regulating the disposal of such product.

⚠WARNING

- **Do not disassemble batteries, or dispose of them in fire, or short-circuit them. They may ignite, explode and leak, causing personal injury.**

12.9 Electrical Safety Inspection

NOTE

- **Perform electrical safety inspection after servicing or routine maintenance. Before the electrical safety inspection, ensure all the covers, panels, and screws are correctly installed.**
- **The electrical safety inspection should be performed once a year.**

1. Perform protective earth resistance test:

   a. Plug the probes of the analyzer into the protective earth terminal of the AC power cord and the screw.

   b. Test the earth resistance with a current of 25A.

   c. Verify the resistance is less than 0.1ohms (100 mohms).

   d. If the resistance is larger than 0.1ohms (100 mohms) but less than 0.2ohms (200 mohms), disconnect the AC power cord and plug the probe, that was previously plugged in the protective earth terminal of the AC power cord, into the protective earth contact of the power outlet. Repeat steps a to c.

2. Perform the following earth leakage current tests:

- normal polarity
- reverse polarity
- normal polarity with open neu

- tral; and
- reverse polarity with open neutral.

3. Verify the maximum leakage current does not exceed 500 μA (0.5 mA) in the first two tests. While for the last two tests, verify that the maximum leakage current does not exceed 1000 μA (1 mA).

NOTE

- **Ensure the safety analyzer is authorized by certificate organizations (UL, CSA, or AMAI etc.). Follow the instructions of the analyzer manufacturer.**

12.10 Water Build-up in the Flow Sensor

12.10.1 Prevent Water Build-up

The patient's exhaled warm and moist gas is condensed when it flows through the expiratory hose. The condensed water remains on the hose wall and finally enters the water trap. When the patient's exhaled gas arrives at the expiration valve, condensed water may appear at the expiration valve (including the expiratory flow sensor), compromising the measurement accuracy of expiratory flow sensor.

Check the expiration valve for water build-up when abnormal flow waveform or unstable tidal volume fluctuation is detected. If there is water build-up inside the expiration valve, clear it before use.

Check the expiratory water trap for water during the use of the ventilator. If there is water build-up, empty it promptly. Water condensation in the expiration valve can be reduced by using a bacteria filter between the expiratory tube and expiration valve.

12.10.2 Clear Water Build-up

If there is water built up inside the expiration valve, remove the expiration valve and clear the water. Then reinstall the valve for use.

⚠ WARNING

- **Ensure that all breathing system parts are dry every time when the breathing system is cleaned and disinfected.**
- **Check the expiration valve for water build-up when abnormal flow waveform or unstable tidal volume fluctuation is detected. If there is water build-up inside the expiration valve, clear it.**

FOR YOUR NOTES

Chapter 13 Accessories

⚠ WARNING

- **The user shall buy legally launched products for other accessories required to implement the functions of the machine.**
- **Use only accessories specified in this chapter. Using other accessories may cause incorrect measured values or equipment malfunction.**
- **Disposable accessories can not be reused. Reuse may degrade performance or cause cross infection of the next patient.**
- **Check the accessories and their packages for damage. Do not use them if any sign of damage is detected.**
- **Parts which are intended to contact patients must comply with the biocompatibility requirement of ISO10993-1 to prevent any adverse reactions arising from such contact.**
- **Disposal of the accessories shall comply with the applicable waste control regulations.**

NOTE

- **The CO2 module and mask accessory material that contacts the patients has undertaken the bio-compatibility test and is verified to be in compliance with ISO 10993-1.**
- **All the accessories listed are validated for use with this specific ventilator. And the hospital is responsible for ensuring the compatibility of the ventilator and the accessories before use. The incompatible parts can result in degraded performance.**

Replaced accessories list:

Accessory description	Part No.
Corrugated pipe	
Adult corrugated pipe sets(including corrugated pipe、Y-connector,L-connector,filter, manual breathing bag)	040-000105-00
Pediatric corrugated pipe set(including corrugated pipe,Y-connector, L-connector, filter, manual breathing bag)	040-000106-00
Fow sensor	
Breating flow sensor set	040-000140-00
Breathing flow sensor set	040-000141-00
Oxygen sensor	
Oxygen sensor	040-000100-00
CO_2 module accessories	
Mainstream CO_2 module	040-000033-00
Mainstream CO_2 module airway adapter (adult,disposable)	040-000036-00
Mainstream CO_2 module airway adapter(pediatric,disposable)	040-000069-00
Sidestream CO_2 module	040-000034-00
Sidestream CO_2 module nomoline sampling line(disposable)	040-000036-00

Power cable	
Power cable（0A，125V/3m）	040-000101-00
Battery	
Li-ion battery, 4800mAh 11.1V）	022-000002-00
Humidifier kit (including humidifier, water tank, heated patient tubing, etc.)	
Humidifier kit	022-000102-00
Gas supply hose assembly	
Ventilator oxygen hose accessories kit	022-000302-00

*：

The pulse oximeter probes and probe cable extenders listed for this device have been validated and tested for compliance with ISO 80601-2-61.

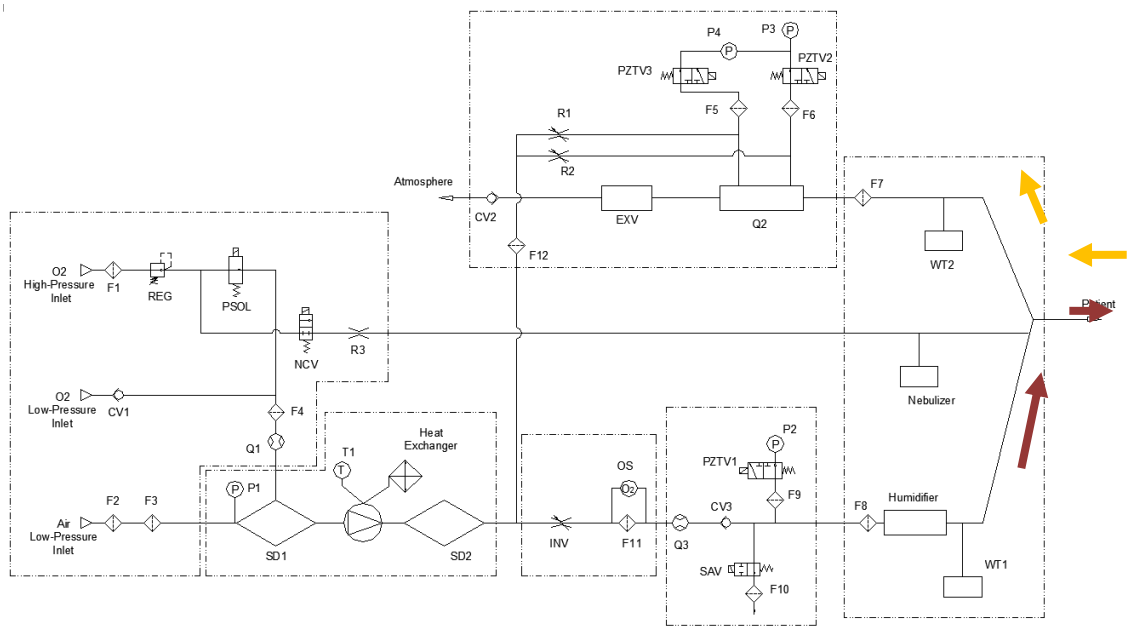
The maximum photic output consumption of the sensor is less than 18 mW.

The information about the wavelength range and maximum photic output consumption can be especially useful to clinicians, for example, clinicians performing photodynamic therapy.

Chapter 14 Theory of Operation

14.1 Pneumatic System

14.1.1 Pneumatic Circuit Diagram



14.1.2 Parts List

Symbol	Description	Symbol	Description
Air Low-Pressure Inlet	Air supply (low pressure)	PZTV1	Zeroing three-way valve
F2	Dust filter (Air)	P2	Inspiratory pressure sensor
F3	HEPA filter (Air)	F9	Inspiratory pressure sensor filter
P1	Vacuum sensor (Air)	Humidifier	Humidifier
O_2 Low-Pressure Inlet	O_2 supply(low pressure)	WT1	Water trap
CV1	Check valve	P1	Patient

O_2 High-Pressure Inlet	O_2 supply(high pressure)	NCV	Nebulizer switch
F1	Filter (O_2)	R3	Nebulizer resistor
REG	Regulator	Nebulizer	Nebulizer
PSOL	Proportional solenoid valve	WT2	Water trap
F4	Filter screen	F8	Bacteria filter (connecting to inspiratory port)
Q1	Flow sensor	Q2	Expiratory flow sensor
SD1	Level 1 mixed noise reduction chamber	F7	Bacteria filter (connecting to patient port)
T1	Temperature sensor	F6	Filter
Blower	Turbine blower	F5	Filter
SD2	Level 2 mixed noise reduction chamber	PZTV2	Zeroing three-way valve
Heat Exchanger	Heat exchanger	PZTV3	Zeroing three-way valve
Insp. valve	Inspiration valve	P4	Expiratory differential pressure sensor
OS	O_2 concentration sensor	P3	Expiratory pressure sensor
F11	Filter screen	F12	Filter
Q3	Flow sensor	R1	Resistor
CV3	Check valve	R2	Resistor
SAV	Safety valve	EXV	Expiration valve
Atmosphere	Atmosphere	CV2	Expiratory check valve

Note: the nebulizer mentioned in this manual shall be the legal product with medical device certificate registered in the People's Republic of China. This requirement applies to nebulizers mentioned in other places than here.

14.1.3 Theory

This product is an electronically driven and electronically controlled ventilator. Oxygen is provided by high- or low-pressure oxygen port. Air is inhaled from the ambient atmosphere due to vacuum produced by the turbine motor. During the inspiratory phase, the inspiration valve opens. Gas with specific O_2 concentration is formed in the upstream of inspiration valve after Air and O_2 are mixed. Such gas becomes gas with specific flow or pressure after passing through the inspiration valve and enters the patient's lungs via inspiratory tube. During the expiratory phase, the inspiration valve is closed while the expiration valve opens. The gas reaches the expiration valve from the lungs via the expiratory tube and is finally discharged out of the human body.

When the turbine works to inhale Air from the ambient atmosphere, Filter (F2) filters dust in the Air. Filter (F3) is an HEPA filter for filtering bacteria. After the machine is used or placed

for a period of time, dust or foreign substance absorbed on the surfaces of the two filters at the Air inlet can occlude the Air inlet when the dust or foreign substance is accumulated to a certain extent. This may cause insufficient Air intake of the machine and compromise the ventilation performance of the machine. Vacuum sensor (P1) at the Air inlet monitors the vacuum at the Air inlet in real-time, effectively judges filter occlusion at the Air inlet, and gives the replacement prompt.

Check valve (CV1) ensures unidirectional flow of low-pressure O_2. Filter (F1) filters foreign substance in the high-pressure O_2 supply. Regulator (REG) regulates and stabilizes the pressure of high-pressure O_2 supply to ensure the stability and repetitiveness of flow outputted by the rear proportional solenoid valve (PSOL).

Filter screen (F4) is placed before the flow sensor to stabilize gas flow for the convenience of sensor measurement. Flow sensor (Q1) is a hot-wire mass flow sensor which does not require calibration.

The gas supply part includes three parallel limbs: high-pressure O_2, low-pressure O_2, and low-pressure Air. The high-pressure O_2 and low-pressure O_2 converge before mixing with Air. High-pressure O_2 and low-pressure O_2 cannot be used at the same time. Flow sensor (Q1) is placed at the common outlet of low-pressure O_2 and high-pressure O_2 to monitor O_2. Room air enters the machine after passing through filter (F2) and HEPA filter (F3).

Turbine blower (Blower) inhales the room air and externally connected O_2 and outputs them to the rear end of the inspiratory limb after compression. The turbine blower module contains two levels of labyrinth, which are located in the upstream and downstream of the turbine blower respectively. Air and O_2 are inhaled by the turbine blower after going through the first level of labyrinth chamber (SD1). The mixed gas of Air and O_2 is then compressed by the turbine blower and enters the second level of labyrinth chamber (SD2). These two levels of labyrinth chamber mix Air and O_2 and reduce noise. The turbine blower motor has a thermal conductive metal piece which conducts heat for heat dissipation via a cooling fan.

The large-diameter inspiration valve (Insp. valve) controls inspiratory pressure or flow. This valve uses voice coil motor as the driving component. In case of power failure, the valve port is automatically sealed via spring preload. When the voice coil motor takes actions, the valve port opens. Different output flows or pressures are acquired by exerting different control currents to the voice coil motor.

The outlet of large-diameter inspiration valve is connected to flow sensor (Q2) which monitors the flow in the inspiratory limb. Flow sensor (Q2) is a hot-wire mass flow sensor which does not require calibration. O_2 sensor (OS) monitors O_2 volume percentage concentration in the inspiratory limb.

Check valve (CV3) prevents patient's expired gas from polluting the components in the upstream of this valve under the single fault condition of expiratory limb being occluded.

Safety valve (SAV) ensures that the pressure in the inspiratory limb is kept within the safe range and provides flow to the spontaneous inspiratory channel when the system is powered down. It is controlled by electromagnet. When the ventilator is in normal working state, the electromagnet is powered on and the safety valve is in closed state. When the pressure in the inspiratory limb exceeds the system setting pressure, the electromagnet is powered down and the safety valve is opened to release excess pressure. When the system is powered down, the electromagnet is in power-down state and the safety valve is opened by default. The patient inhales the external gas through the spontaneous inspiratory channel.

The expiration valve assembly integrates the expiration valve (EXV) and flow sensor (Q2). Q2 is a diaphragm differential pressure flow sensor. It monitors the front and rear pressure and Flow Calibration processes for calibration via the differential pressure sensor P4. PE is an expiratory pressure sensor which monitors the airway pressure. F6, F5 and F12 are filters which protect the upstream components from being polluted by the patient's expired gas. R1and R2 are resistors which flush weak flow introduced to the expiration valve from the gas source, preventing water vapour condensation from occluding the pressure measurement tubes. CV2 is a check valve which prevents gas from flowing in the reverse direction.

F7 and F8 are bacteria filters. They are connected to the inspiration port and patient port when they are used by the ventilator. The nebulizer is pneumatic. The drive gas is introduced into the nebulizer via the nebulizer connector on the front panel; and the liquid medicine is nebulized, enters the inspiratory tube, and reaches the patient's lungs. The pneumatic nebulizer can be connected only when the machine is connected with high-pressure O2.

FOR YOUR NOTES

Chapter 15 Product Specifications

The ventilator is already integrated with expiratory volume monitor, pressure measurement device, and pressure release device. It is equipped with alarm system, O_2 monitor and CO_2 monitor, where:

- The expiratory volume monitor, pressure measurement device, and pressure release device comply with ISO 80601-2-12.
- The alarm system complies with IEC 60601-1-8.
- The O_2 monitor complies with ISO 80601-2-55.
- The CO_2 monitor complies with ISO 80601-2-55.
- The gas supply hose assembly complies with ISO 5359.

15.1 Environmental Specifications

Main unit			
Item	**Temperature (℃)**	**Relative humidity (non-condensing)**	**Barometric pressure (kPa)**
Operating	5 to 40	10 to 95 %	62 to 106*
Storage and transport	–20 to +60 (O_2 sensor: –20 to +50)	10 to 95 %	50 to 106

The ventilator performance satisfies the specifications at barometric pressure 80 kPa to 106 kPa. The inspiration pressure of the ventilator can reach 60 cmH2O at barometric pressure 62 kPa to 80 kPa.

15.2 Safety Specifications

Type of protection against electric shock	Class I equipment with internal electrical power supply.
Degree of protection against electric shock	BF, defibrillation-proof
Operating mode	Continuous
Degree of protection against hazards of explosion	Ordinary equipment, without protection against explosion; not for use with flammable anaesthetics.

Degree of protection against harmful ingress of water	Degrees of protection provided by enclosures(IP Code)—IP21 Protection Index according the EN 60529 standard: 2: Protected against solid foreign objects of 12.5 mm diameter and greater 1: Protected against vertically falling water drops
Electrical connections between the equipment and the patient	Non-electrical connections
Equipment type	Mobile

15.3 Power Requirements

External AC power supply	
Input voltage	100 to 240 V
Input frequency	50/60 Hz
Input Power	2A
Fuse	T10AH/250 V
Internal battery	
Number of batteries	One or two
Battery type	Lithium-ion battery
Rated battery voltage	14.8 VDC
Battery capacity	5200 mAh for a single battery
Overcurrent protection	10 ±5 %A
Time to shutdown	10±5 % min at least (powered by new fully-charged batteries after the first low battery alarm)
Battery run time	180 min (powered by one new fully-charged battery in standard working condition); 360 min (powered by two new fully-charged batteries in standard working condition).

The standard work condition is:

- Ventilation mode : PC-ACV ;
- Pmax: 30cmH_2O;
- Pinsp : 10 cmH_2O;
- PEEP:5cmH_2O
- Rate :10 bpm ;

- Tinsp : 2 s ;
- Tslope:1.0s;
- Trigger:0.5L/min;
- O2% : 21 Vol.% ;
- R: 20 cmH2O/L/s ;
- C: 20 ml/cmH2O ;
- Gas supply nominal work pressure : 400±100 kPa.

15.4 Physical Specifications

System noise	
System noise	A-weighted sound pressure level (L_{pA}) ≤47 dB(A) A-weighted sound power level (L_{WA}) ≤55dB (A)
Main unit	
Dimensions	1390mm×537mm×495mm (height×width×depth) (including the ventilator cart) 576mm×404mm×284 mm (height×width×depth) (excluding the ventilator cart)
Weight	Approximately 30 kg (including the ventilator cart) Approximately 10 kg (excluding the ventilator cart)
Caster	
Caster	4 casters. All casters have brakes.
Display	
Type	TFT LCD
Size	15.6"
Resolution	1366 x 768 pixels
Brightness	Adjustable
Touch screen	Available, anti-glare.
LED indicator	
Alarm LED	One (yellow and red. When high and medium priority alarms occur simultaneously, it flashes red only).
External power LED	One (green; lit when the external power supply is connected).
Battery LED	One (green; lit when batteries are installed and external power supply is connected; flashing when powered by batteries; extinguished when no batteries are installed or external power supply is not connected.)
Operating status LED	One, namely, power switch key background light (green; lit when powered on and extinguished when powered off).

Audio indicator	
Speaker	Gives off alarm tones and key tones; supports multi-level tone modulation. The alarm tones comply with the requirements of IEC60601-1-8.
Buzzer	Gives off auxiliary audio alarm in case of speaker malfunction.
Connector	
Network connector	A connector which supports connection with a PC to perform software upgrade and connection with external medical and information device.
RS-232 connector	Connects to the external calibration device for calibrating pressure. An external medical device can be connected via this connector to communicate with the ventilator.
USB connector	Exports captured screen, conducts ventilator software upgrade, configuration information export and history data (such as patient data, alarm log, calibration table) export, configuration transfer between machines of the same type via USB device.
VGA connector	Outputs VGA video signals with the same contents to the primary display and connects to the external display (supporting display with resolution of 1366*768).

15.5 Pneumatic System Specifications

NOTE

- **All gas volume, flow and leakage specification are expressed at STPD except those associated with the VBS which are expressed at BTPS.**

High-pressure oxygen inlet	
Gas type	O_2
Pressure range	280 to 600 kPa
Rated flow requirement	No less than 120 L/min (STPD)
Connector	NIST or DISS
Fresh gas	Fresh gas is called after supplied Air and O_2 are mixed.
Low-pressure oxygen inlet	
Pressure range	Less than 100 kPa
Maximum flow	15 L/min(STPD)
Connector	CPC quick connector

Inspiration module	
Peak flow in case of single	≥210 L/min(BTPS)
Pneumatic medicament nebulizer connector	Synchronous with inspiration at 6 to 9 L/min flow
Safety valve release pressure	<125 cmH_2O
Inspiratory outlet (To patient port)	Coaxial 22 mm/15 mm conical connector
Expiration module	
Expiratory outlet (From patient port)	Coaxial 22 mm/15 mm conical connector
System compliance and resistance	
Compliance	Adult disposable circuit (including inspiration safety valve, adult disposable patient tubing, water trap, expiration valve): ≤4 mL/cmH_2O; Adult reusable circuit (including inspiration safety valve, adult reusable patient tubing, water trap, expiration valve, Y piece): ≤2 mL/cmH_2O; Pediatric disposable circuit (including inspiration safety valve, pediatric disposable patient tubing, water trap, expiration valve):≤2 mL/cmH_2O; Pediatric reusable circuit (including inspiration safety valve, pediatric reusable patient tubing, water trap, expiration valve, Y piece): ≤2 mL/cmH_2O; Infant reusable circuit (including inspiration safety valve, infant reusable patient tubing, water trap, expiration valve, Y piece): ≤1 mL/cmH_2O.
Inspiratory resistance	Not greater than 6 cm H_2O at 60 L/min flow (adult reusable patient tubing) Not greater than 6 cmH_2O at 30 L/min flow (pediatric reusable patient tubing) Not greater than 6 cmH_2O at 5 L/min flow (infant reusable patient tubing)
Expiratory resistance	Not greater than 6 cmH_2O at 60 L/min flow (adult reusable patient tubing) Not greater than 6 cmH_2O at 30 L/min flow (pediatric reusable patient tubing) Not greater than 6 cmH_2O at 5 L/min flow (infant reusable patient tubing)
Bacterial filter	Resistance: < 2 cmH_2O at 60 L/min Particle size: Captures particles of 0.3 mm (micron) with > 99.99% efficiency Dead space: < 80 mL

Leakage	
Leakage	Not greater than 200 mL/min@50 cmH_2O (adult tubes) Not greater than 100 mL/min@40 cmH_2O (pediatric tubes) Not greater than 50 mL/min@20 cmH_2O (infant tubes)

15.6 Ventilator Specifications

Ventilation mode	**VC-ACV、PC-ACV、PVC-ACV、VC-SIMV、PC-SIMV、PVC-SIMV、PC-Dual PAP、PC-APRV、CPAP/PSV、CPAP-AG**		
Controlled parameters			
Parameter	Range	Unit	Accuracy
VT in (VC-ACV,PVC-ACV,VC-SIMV,PVC-SIMV,CPAP-AG)	Neo:5 to 200 Ped:20 to 400 Adu:100 to 2000	mL	VT≦50:±(2 mL + 15% of setting) 50<VT≦100:±(3 mL + 15% of setting) VT>100:± (20 mL + 15% of setting)
Pinsp	(PEEP+5) to 90	mbar	±(2 + 5% of setting)
Phigh in PC-Dual PAP	(Plow+5) to 90	mbar	±(2 + 5% of setting)
Plow in PC-Dual PAP	0 to 40	mbar	±(2 + 5% of setting)
Psupp	0 to 80	mbar	±(2 + 5% of setting)
PEEP	0 to 40	mbar	±(2 + 5% of setting)
FiO2	21 to 100	Vol.%	±(2.5 + 2.5% of setting) Minimum to maximum, how long will it take to stabilize (usually 1 to 2 minutes)
Rate	1 to 100	bpm	±(1+5% of setting)
Texp	0.3 to 12.0	s	±(5% of setting)
Tpause	OFF,5 to 60	%	±(10% of setting)
Thigh in PC-Dual PAP	0.2 to 12.0	s	±(5% of setting)
Tlow in PC-Dual PAP	0.3 to 12.0	s	±(5% of setting)
Trigger	Pressure：OFF, -1 to -10cmH_2O	mbar	±2 cmH2O，or ±(10% of setting)
	Flow：OFF,1 to 15L/min	L/min	±1 L/min，or ±(10% of setting)
Tslope	0.00 to 2.00	s	±(0.2+10% of setting)
Exp%	OFF,5 to 90	%	±(0.5+10% of setting)
Controlled parameters (O_2 Therapy)			
Continuous Flow	2.0 to 50.0	L/min	±(2 L/min+10 % of setting) (BTPS)
O_2 Concentration	21 to 100	%	±(3 Vol.% +1 % of setting)
Hight			
Adu	120 to 250	cm	/
Ped	60 to 136	cm	/
Neo	20 to 80	cm	/
Parameter monitoring accuracy			
Parameter	Range	Unit	Accuracy
Ppeak	-5 to +105	mbar	± (2 + 4% of actual)

Pmean	-5 to +105	mbar	± (2 + 4% of actual)
Pplat	-5 to +105	mbar	± (2 + 4% of actual)
PEEP	0 to 40	mbar	± (2 + 4% of actual)
Ptracheal	-10 to 110	mbar	± (5 + 10% of actual)
Poutput	-10 to 110	mbar	± (5 + 10% of actual)
Pambient	0 to 3000	mbar	± (5 + 10% of actual)
P0.1	-105 to 5	mbar	± (1 or 25% of reading)
VTe mand	0 to 2500	mL	VTe mand≦100:± (2 + 15% of actual) VTe mand>100:± (4 + 15% of actual)
VTe spon	0 to 2500	mL	VTi mand≦100:± (2 + 15% of actual) VTe mand>100:± (4 + 15% of actual)
VTi mand	0 to 2500	mL	VTi mand≦100:± (2 + 15% of actual) VTe mand>100:± (4 + 15% of actual)
VTi spon	0 to 2500	mL	VTi spon≦100:± (2 + 15% of actual) VTi spon>100:± (4 + 15% of actual)
MVe	0 to 100	L/min	± (0.2 + 10% of actual)
MVe spon	0 to 100	L/min	± (0.2 + 10% of actual)
MVi mand	0 to 100	L/min	± (0.2 + 10% of actual)
MVi spon	0 to 100	L/min	± (0.2 + 10% of actual)
Tinsp	0 to 100	s	± (0.05 + 5% of actual)
Texp	0 to 100	s	± (0.05 + 5% of actual)
I:E		/	±50 ms or ±6%, whichever is greater
PIF	0 to 200	L/min	± (2 + 15% of actual)
PEF	-200 to 0	L/min	± (2 + 15% of actual)
Rtotal	0 to 250	bpm	± (5 or 10% of actual)
RR spon	0 to 250	bpm	± (5 or 10% of actual)
FiO2 Cal	21 to 100	Vol.%	± (2.5 + 2.5% of actual)
FiO2 Measu	21 to 90	Vol.%	When TV=500ml, f=10 bpm, I:E=1:2, ≤50s; When TV=150ml, f=20 bpm, I:E=1:2, ≤80s; When TV=30ml, f=30 bpm, I:E=1:2, ≤120s
Rlung	0 to 300	mbar/（L/s）	1.0 mbar/（L/s）~20 mbar/（L/s）: ±10 mbar/（L/s） 2.20 mbar/（L/s）~300 mbar/（L/s）: ±(50% of actual)
Cdynamic	0 to 100	mL/mbar	± (5 + 20% of actual)
RSBI	0 to 10000	bpm/min/L	± (10 or 25% of reading)
PTP	0 to 10	mbar*s	± (0.1 or 25% of reading)

Alarm Settings

Parameter		**Setting range**	**Step length**	Remarks
Paw	High limit	0 to 98	1mbar	The upper limit is

	Low limit	-4 to 97	1mbar	greater than the lower limit.
PEEP	High limit	1 to 40	1mbar	
	Low limit	0 to 39	1mbar	
MVe	High limit	Adu:0.2 to 100.0 Ped:0.2 to 60.0 Neo:0.2 to 40.0	0.1L/min	
	Low limit	Adu:0.1 to 99.9 Ped:0.1 to 59.9 Neo:0.1 to 39.9	0.1L/min	
VTi mand	High limit	Adu:5 to 5000 Ped:5 to 1000 Neo:5 to 500	1mL	
	Low limit	Adu:0 to 4999 Ped:0 to 999 Neo:0 to 499	1mL	
Rtotal	High limit	1 to 150	1bpm	
	Low limit	0 to 149	1bpm	
FiO2	High limit	19 to 100	1vol.%	
	Low limit	18 to 99	1vol.%	
Tapnea	High limit	15 to 60	1s	/

15.7 Special Functions

Function	Specification
Inspiration Hold	Push and hold the Insp. Hold key to activate this function. Inspiration Hold is active for a maximum of 30s.
Expiration Hold	Push and hold the Exp. Hold key to activate this function. Expiration Hold is active for a maximum of 30s.
100%O_2	100%O_2 is delivered for a fixed 2 min.
Nebulizer	Supports jet nebulizer; Supports to set nebulizer time ranging from 1 to 60 min.
Manual Breath	One breath is delivered in the expiratory stage. Manual breath is not responded if one breath is delivered in the inspiratory stage or when the expiratory stage is not finished.
P0.1	The pressure drop in the first 100 ms when the patient starts spontaneous breathing.
ATRC	ATRC stands for the function of automatic tube resistance compensation. By selecting appropriate endotracheal (ET) tube or tracheostomy (Trach) tube of different diameters for the user, the ventilator can adjust gas delivery pressure automatically.
Sigh	The sigh function is used to open collapsed areas of the lung or to keep the lung open. The sigh function can be activated in all ventilation modes except CPAP/PSV, DuoLevel, and APRV. Each time after the sigh function is activated, ventilation is controlled based on the user-set sigh ventilation cycles and the set value of △int.PEEP. PEEP of the sigh ventilation cycle increases △int.PEEP level. After that, sigh is automatically switched off until next sigh time interval.
Screen Locking	Prevents ventilator settings and values displayed from being changed due to inadvertent key clicking.
O_2 Therapy	Continuous flow application with adjustable O_2 concentration and flow for patients with independent breathing and using oxygen masks.

15.8 CO2 Module Specifications

<table>
<tr><td>standard</td><td colspan="4">ISO 80601-2-55</td></tr>
<tr><td>type</td><td colspan="4">Plug and play</td></tr>
<tr><td>Measurement model</td><td colspan="4">sidestream（Masimo ISA CO2）, mainstream（Masimo IRMA CO2）</td></tr>
<tr><td>Preheating time</td><td colspan="4">sidestream：<10s(Concentrations reported and full accuracy)
mainstream ： <30s</td></tr>
<tr><td>Total response time</td><td colspan="4">sidestream：<3s(sampling pipe length:2m)
mainstream ： ≤3s</td></tr>
<tr><td>Pressure risetime</td><td colspan="4">sidestream（50mL/min flow speed）：CO2：≤200ms
mainstream （10L/min flow speed）：CO2：≤90ms</td></tr>
<tr><td>Sampling flow</td><td colspan="4">sidestream：50±10mL/min</td></tr>
<tr><td>Monitoring gas</td><td colspan="4">CO2</td></tr>
<tr><td>Compensation</td><td colspan="4">Sidestream: aotumatic compensation for pressure and temperature</td></tr>
<tr><td>Calibration</td><td colspan="4">sidestream：no need to operate calibration. Automatically zero when starts.
mainstream ： no need to operate calibration, to zeroing when replace the airway adapter.</td></tr>
<tr><td rowspan="3">Measurement scope and accuracy （ standard conditions）</td><td>gas</td><td>scope</td><td>accuracy</td><td>resolution</td></tr>
<tr><td>CO2</td><td>0～13Vol%</td><td>±(0.43Vol%+8% of the reading)</td><td>0.1Vol%</td></tr>
<tr><td colspan="4">The above accuracy is applied for the dry gas in 22℃±5℃， 1013±40hPa</td></tr>
<tr><td rowspan="3">Measurement accuracy （ all conditions）</td><td>gas</td><td colspan="3">accuracy</td></tr>
<tr><td>CO2</td><td colspan="3">±(0.3vol%+4% of the reading)</td></tr>
<tr><td colspan="4">Accuracy specification is valid under the specified temperature and humidity. not including the following“interference gas and water vapor affection”</td></tr>
<tr><td>Accuracy drifting</td><td colspan="4">sidestream：meet the accuracy requirements within 24 hours
mainstream ： meet the accuracy requirements within 24 hours</td></tr>
<tr><td>Breath detection</td><td colspan="4">Sidestream, mainstream: Adaptive threshold, minimum 1 vol% change in CO2 concentration.</td></tr>
<tr><td>Respiration rate</td><td colspan="4">Sidestream: 0 to 150±1 breaths/min
Mainmun: 0 -150 bpm. The respiration rate is displayed after three breaths and the</td></tr>
</table>

	average value is updated every breath.
Airway adapter	disposableadult/pediatric： under 6mL is invalid pressure is lower than 0.3cmH2O
Power input	Only in the 4.5～5.5VDC, voltage fluctuation. Otherwise may lead to incorrect measurments or monitor damaged.
Size and weight	sidestream：33X78X49mm，130g（with cable） mainstream ：38X37X34mm，<25g（without cable）

Interference gas and the water vapor		
Gas or water vapour	Gas concentration	CO2
N204)	60vol%	-2)
Halothane4)	4vol%	-1)
Isoflurane, Sevoflurane, Enflurane4)	5vol%	+8% of the reading3)
Desflurance4)	15vol%	+12% of the reading3)
He4)	50vol%	-6% of the reading3)
Xe4)	80vol%	-10% of the reading3)
Quantitive spray4)	Not applied6)	
Ethyl Alcohol4)	0.3vol%	-1)
Isopropanol4)	0.5vol%	-1)
Acetone4)	1vol%	-1)
Methane4)	3vol%	-1)
NO[5])	0.02vol%	-1)
CO[5])	1vol%	-1)
O_2[5])	100vol%	-1&2)

Note 1：in the above "measurement range and accuracy（all conditions）"including the negligible interference and influence.

Note 2：in the above "measurement range and accuracy（all conditions）"including the negligibleinterference and influence when set the N2O/O2 concentration.

Note 3：The interference of the gas concentration is as：50vol% He usually decreases 6% readingofthe CO2, which means that if the measurment including the 5.0vol% CO2 and 50vol% He, the acutual measured CO2 concentration is（1-0.06）X5.0vol%=4.7vol% CO2；

Note 4：in confirmity with the standard of ISO 80601-2-55,

Note 5：in confirmity with the standard of ISO 80601-2-55,

Note 6：IRMA CO2(not for quantitive spray)；ISA CO2(quantitive spray) .

Alarm upper and lower limit setting		
Alarm speification	Setting range	resolution
FiCO2 alarm upper limit	0.0～19.7 %(V/V)	0.1 %(V/V)
EtCO2 alarm lower limit	（ lower limit+0.1）～19.7 %(V/V)	0.1 %(V/V)

EtCO2 alarm upper limit	0.0～（ upper limit-0.1）%(V/V)	0.1 %(V/V)
awRR alarm upper limit	（ lower limit+1）～120	1bpm
awRR alarm lower limit	0～（ upper limit-1）	1bpm

15.9 O2 Sensor Specifications

Oxygen sensor	
Oxygen Sensor Model	PSR-11-77-CT4
Measuring Range	0-100% O2
Signal Output (1)	9-13 mV
Response Time 90%	T90 = 6 Seconds
Accuracy Full Scale (2) (3)	± 2%
Accuracy Over Operating Range (4)	± 5%
Drift % Signal/Month (2) (5)	< 1%
Linearity (2)	± 2%
Recommended Flow Rate	0.1–10 lpm
Orientation (5)	Sensing Facing down or horizontal
Temperature Coefficient	Compensated
Operating Range	0 to 45° C
Humidity Non-Condensing	0-99% RH
Expected Life (1)	60 months
Storage Temperature (6)	0 to 40°C
Storage Recommendation (1) (7)	< 6 months
Warranty ex-factory (8)	14 months

Specifications validated during design and in the pursuit of improvement are subject along with prices to change without notice.

1. In air (20.9% oxygen) at 25 ºC and 1 atm.
2. At constant temperature, pressure and humidity. < 1% vol. O2 when calibrated at 100%.
3. For optimum performance at elevated oxygen levels calibrate with 100% oxygen.
4. From the signal output value established above, and, once the sensor reaches equilibrium (approximately 1 hour) following step change of 15 ℃ or more.
5. For optimum performance , mount sensor with sensing surface pointing down or horizontal
6. Sensors may be stored at -10 to 55 ℃ on an intermittent basis only up to one week, such as during transportation.
7. To encourage use before expiration of warranty

8. Under normal operating conditions for medical oxygen delivery equipment the sensors are warranted to be free of defects in materials and workmanship for the period specified period above provided the sensor is properly installed and operated. The sole remedy for a sensors determined to be defective by Analytical Industries Inc. is limited to replacing the defective sensors. Analytical Industries Inc. shall not be liable for buyer's negligence, misapplication, alteration, abuse or accident.

15.10 SpO2 Specifications (optional)

Standards compliant	ISO 80601-2-61	
Display range	0%~100%	
SpO2 display resolution	1%	
SpO2 checking accuracy	2% (70%~100%); not define when lower than 70%	
SpO2 alarm preset limits	Upper alarm limit	1%~100%
	Lower alarm limit	0%~99%
SpO2 alarm preset accuracy	±1%	
SpO2 alerting signal generates a delay	No delay	
SpO2 value refresh period	1s/time	
SpO2 value refresh delay	＜ 10s	
Average period	Low sensitivity	7～8s
	Intermediate sensitivity	4～6s
	Advanced sensitivity	2～3s
Alarm condition delay period	Low sensitivity	＜8s
	Intermediate sensitivity	＜6s
	Advanced sensitivity	＜3s
Alarm sign generates delay period	0s	
PR		
Measuring range	30~254bpm	
Resolution	1%	
Accuracy	±2% or ±2bpm	

15.11 Factory Defaults

This chapter lists the most important factory default settings which are not user-adjustable. When necessary, you can restore the factory default settings.

15.11.1 Ventilation Mode

Ventilation mode	Parameter	Defaults setting		
		Adu	Ped	Neo
VC-ACV	Pmax	100mbar	40mbar	40mbar
	PEEP	3mbar	3mbar	3mbar
	Vt	536mL	150mL	150mL
	Tinsp	2.0s	1.0s	0.6s
	Rate	20bpm	20bpm	30bpm
	Tpause	OFF	OFF	OFF
	Trigger	2.0L/min	1.0L/min	0.2L/min
	Sigh	OFF	OFF	OFF
	ATC	Disable ATC	Disable ATC	Disable ATC
	Compliance Compensate	OFF	OFF	OFF
	Exp.Speed	Medium	Medium	Medium
PC-ACV	Pmax	100mbar	40mbar	40mbar
	PEEP	3mbar	3mbar	3mbar
	Pinsp	15mbar	15mbar	15mbar
	Tinsp	2.0s	1.0s	0.6s
	Rate	20bpm	20bpm	30bpm
	Tslope	50%	50%	50%
	Trigger	2.0L/min	1.0L/min	OFF
	Sigh	OFF	OFF	OFF
	ATC	Disable ATC	Disable ATC	Disable ATC
	Compliance Compensate	OFF	OFF	OFF
	Exp.Speed	Medium	Medium	Medium
PVC-ACV	Pmax	100mbar	40mbar	40mbar
	PEEP	3mbar	3mbar	3mbar
	Pinsp	15mbar	15mbar	15mbar
	Tinsp	2.0s	1.0s	0.6s
	Rate	20bpm	20bpm	30bpm
	Tslope	50%	50%	50%
	Trigger	2.0L/min	1.0L/min	OFF
	Sigh	OFF	OFF	OFF
	ATC	Disable ATC	Disable ATC	Disable ATC
	Compliance Compensate	OFF	OFF	OFF

	Exp.Speed	Medium	Medium	Medium
VC-SIMV	Pmax	100mbar	40mbar	0.2L/min
	PEEP	3mbar	3mbar	40mbar
	Psupp	0mbar	0mbar	3mbar
	Vt	536mL	150mL	0mbar
	Tinsp	2.0s	1.0s	150mL
	Rate	20bpm	20bpm	0.6s
	Trigger	2.0L/min	1.0L/min	30bpm
	Exp%	20%	20%	0.2L/min
	Tpause	OFF	OFF	20%
	Sigh	OFF	OFF	OFF
	ATC	Disable ATC	Disable ATC	Disable ATC
	Compliance Compensate	OFF	OFF	OFF
	Exp.Speed	Medium	Medium	Medium
PC-SIMV	Pmax	100mbar	40mbar	OFF
	PEEP	3mbar	3mbar	40mbar
	Psupp	0mbar	0mbar	3mbar
	Pinsp	15mbar	15mbar	0mbar
	Tinsp	2.0s	1.0s	15mbar
	Rate	20bpm	20bpm	0.6s
	Tslope	50%	50%	30bpm
	Trigger	2.0L/min	1.0L/min	50%
	Exp%	20%	20%	0.2L/min
	Sigh	OFF	OFF	OFF
	ATC	Disable ATC	Disable ATC	Disable ATC
	Compliance Compensate	OFF	OFF	OFF
	Exp.Speed	Medium	Medium	Medium
PVC-SIMV	Pmax			
	PEEP			
	Psupp			
	Vt			
	Tinsp			
	Rate			
	Trigger			
	Exp%			
	Sigh	OFF	OFF	OFF
	ATC	Disable ATC	Disable ATC	Disable ATC
	Compliance Compensate	OFF	OFF	OFF
	Exp.Speed	Medium	Medium	Medium
PC-Dual PAP	Pmax	100mbar	40mbar	20%
	Phigh	15mbar	15mbar	40mbar
	Thigh	2.0s	1.0s	15mbar
	Plow	3mbar	3mabr	0.6s
	Tlow	4.0s	2.0s	1.4s
	Psupp	0mbar	0mbar	0mbar
	Tslope	50%	50%	50%
	Trigger	2.0L/min	1.0L/min	0.2L/min
	Exp%	20%	20%	20%

	Apnea went	OFF	OFF	OFF
	Sigh	OFF	OFF	OFF
	ATC	Disable ATC	Disable ATC	Disable ATC
	Compliance Compensate	OFF	OFF	OFF
	Exp.Speed	Medium	Medium	Medium
PC-APRY	Pmax	100mbar	40mbar	40mbar
	PEEP	3mbar	3mbar	3mbar
	Pinsp	15mbar	15mbar	15mbar
	Tinsp	8.0s	4.0s	2.8s
	Texp	4.0s	2.0s	1.4s
	Tslope	50%	50%	50%
	Apnea went	OFF	OFF	OFF
	Sigh	OFF	OFF	OFF
	ATC	Disable ATC	Disable ATC	Disable ATC
	Compliance Compensate	OFF	OFF	OFF
	Exp.Speed	Medium	Medium	Medium
Spn-CPAP	Pmax	100mbar	40mbar	40mbar
	PEEP	3mbar	3mbar	3mbar
	Psupp	0mbar	0mbar	0mbar
	Apnea went	OFF	OFF	OFF
	ATC	Disable ATC	Disable ATC	Disable ATC
	Compliance Compensate	OFF	OFF	OFF
	Exp.Speed	Medium	Medium	Medium
Alarm parameter				
		Adu	Ped	Neo
Paw	High Limit	50mbar	40mbar	40mbar
	Low Limit	10mbar	8mbar	8mbar
PEEP	High Limit	10mbar	10mbar	10mbar
	Low Limit	3mbar	2mbar	1mbar
MVe	High Limit	50.0L/min	20.0L/min	10.0L/min
	Low Limit	5.0L/min	3.0L/min	2.0L/min
VTi mand	High Limit	1000mL	400mL	100mL
	Low Limit	300mL	50mL	20mL
Rtotal	High Limit	60bpm	60bpm	60bpm
	Low Limit	10bpm	20bpm	30bpm
FiO2	High Limit	100Vol.%	100Vol.%	100Vol.%
	Low Limit	18Vol.%	18Vol.%	18Vol.%
窒息	High Limit	15s	10s	5s

15.11.2 Wave Color

Setting	Factory default setting
Pressure wave	Pink
Volume wave	Cyan
Flow wave	Orange
CO_2 wave	Yellow
SPO2 wave	Pink

15.11.3 Setup

Setting	Factory default setting
Layout	Normal
Setting Pattern	Day
Paw unit	cmH_2O
Pressure unit	MPa
Wave mode	Fill
Time-date format	YYYY-MM-DD
Time-time format	24 h
Alarm delay	4s
Alarm Vol	5
BackLight	6

15.11.4 CO2 Module

CO_2 module	Factory default setting		
	Adu	Ped	Neo
Operating Mode	Measure	Measure	Measure
CO_2 Unit	mmHg	mmHg	mmHg
O_2 Compen	Low	Low	Low
N_2O Compen	off	off	off
Apnea Delay	20s	20s	20s

15.11.5 History Data

Trend log	Factory default setting
Graphic trend-interval	1s
Tabular trend-interval	1 s
Alarm log-level	All

15.11.6 Therapy

O_2 Therapy	Factory default setting		
	Adu	Ped	Neo
O_2%	21 %	21 %	21 %
Flow	5.0 L/min	3.0 L/min	2.0L/min
Pmax	40cmH_2O	30cmH_2O	20cmH_2O

15.12 EMC and Radio Regulatory Compliance

15.12.1 EMC

Crius V6 ventilator is in compliance with IEC 60601-1-2 for EMC.

The essential performance verified during the immunity testing comprise of TVi control accuracy, TVi monitoring accuracy, CO_2 monitoring accuracy, O_2 control accuracy, O_2 monitoring accuracy, PEEP control accuracy and PEEP monitoring accuracy.

NOTE

- **Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the equipment.**
- **The ventilator or its components should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the ventilator or its components should be observed to verify normal operation in the configuration in**

which it will be used.

- **The ventilator needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.**
- **Other devices may interfere with this equipment even though they meet the requirements of CISPR.**
- **When the input signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.**
- **Use of portable or mobile communications devices can degrade the performance of the equipment.**

Guidance and manufacture's declaration - electromagnetic emissions		
The Crius V6 ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the Crius V6 ventilator should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Crius V6 ventilator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Crius V6 ventilator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration - electromagnetic immunity			
The Crius V6 ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the Crius V6 ventilator should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment- guidance**

Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines (>3 m)	±2 kV for power supply lines ±1 kV for input/output lines (>3 m)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) fo5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of Crius V6 ventilator requires continued operation during power mains interruptions, it is recommended that Crius V6 ventilator should be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC. mains voltage prior to application of the test level.			

Guidance and Manufacturer's declaration - electromagnetic immunity
The Crius V6 ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the Crius V6 ventilator should assure that it is used in such an environment as described below.

IMMUNITY test	IEC60601TEST LEVEL	Compliance level	Electromagnetic environment - guidance
Conduced RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz (for RGM performance) 3 Vrms 150 kHz to 80 MHz Outside ISM bands[a] (for Ventilator performance) 10 Vrms 150 kHz to 80 MHz In ISM bands[a] (for Ventilator performance)	3 Vrms 3 Vrms 10Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Crius V6 ventilator, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. **Recommended separation distances** $d = 1.2\sqrt{P}$
Radiated RF IEC61000-4-3	3V/m 80 MHz～2.5 GHz (for RGM, SpO_2 performance) 10 V/m 80 MHz～2.5 GHz (for Ventilator performance)	3 Vrms 10 V/m	$d = 1.2\sqrt{P}$ 80 MHz～800 MHz $d = 2.3\sqrt{P}$ 800 MHz～2.5 GHz Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [c], should be less than the compliance level in

			each frequency range [d].
			Interference may occur in the vicinity of equipment marked with the following symbol:  .

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. The ISM (Industrial, Scientific and Medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

b. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range of 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Crius V6 ventilator is used exceeds the applicable RF compliance level above, the Crius V6 ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Crius V6 ventilator.

d. Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the Crius V6 ventilator

The Crius V6 ventilator is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the Crius V6 ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Crius V6 ventilator as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of the transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range of 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix A Toxic or harmful substances or elements

Part name		PB	Hg	Cd	Cr(VI)	PBB	PBDE
Machine casing	Ventilator casing	○	○	○	○	○	○
	key	○	○	○	○	○	○
	facing	○	○	○	○	○	○
	label	○	○	○	○	○	○
Trolley and support arm	Trolley	○	○	○	○	○	○
	Support arm	○	○	○	○	○	○
Display	Display screen	X	X	X	X	X	X
	Host machine additions	○	○	○	○	○	○
Mainframe	Internal connection	○	○	○	○	○	○
	PCBA	○	○	○	○	○	○
Packaging	Packing material	X	X	○	○	X	X
Commonly used	Adapting piece	○	○	○	X	○	○
	Power line	○	○	○	○	○	○
	Weasand	○	○	○	○	○	○
Battery	Lithium battery	X	X	X	X	X	X
Accessory	Exhalation valve	○	○	○	○	○	○
	Air hose assembly	○	○	○	○	○	○
	Oxygen sensor	X	○	○	○	○	○
	CO2 accessory	X	○	○	○	○	○
Remark	○：It means that the content of the toxic and harmful substance in all homogeneous materials of the component is below the limit specified in SJ/ t11363-2006. X： Indicates that the content of the toxic and hazardous substance in at least one homogeneous material of the component exceeds the limit specified in SJ/ t11363-2006.						

Northern Meditec Limited

Address： Floor 4, Block C, Gold Power Industry Park, julongshan, Grand industrial Zone, Pingshan New District, Shenzhen (518118), P.R. China

Post Code：518118

Tel.：+ 86 755 29970566

Fax.：+86 755 23010273

E-mail：info@northernmeditec.com

Website：www.northernmeditec.com